

**DIMINISHED CAPACITY: CAN THE FDA ASSURE
THE SAFETY AND SECURITY OF THE NATION'S
FOOD SUPPLY?**

HEARINGS
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND
INVESTIGATIONS
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED TENTH CONGRESS
FIRST SESSION

APRIL 24, JULY 17, 2007

Serial No. 110-33 Part A



Printed for the use of the Committee on Energy and Commerce
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**DIMINISHED CAPACITY: CAN THE FDA ASSURE THE SAFETY AND SECURITY OF THE
NATION'S FOOD SUPPLY**

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² Ibid.

DIMINISHED CAPACITY: CAN THE FDA ASSURE THE SAFETY AND SECURITY OF THE NATION'S FOOD SUPPLY—PART I

TUESDAY, APRIL 24, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 9:30 a.m., in room 2123, Rayburn House Office Building, Hon. Bart Stupak (chairman) presiding.

Present: Representatives DeGette, Melancon, Waxman, Green, Doyle, Schakowsky, Inslee, Dingell, Whitfield, Walden, Ferguson, Murphy, Burgess and Barton.

Staff present: John Sopko, David Nelson, John Arlington, Keith Barstow, Kyle Chapman, Alan Slobodin, Peter Spencer, Krista Carpenter, and Matthew Johnson.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. This hearing will come to order.

Today we have a hearing on Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply. Each Member will be recognized for 5 minutes for their opening statement.

This is the first of two hearings the subcommittee is holding on the issue of whether the FDA can assure the safety and security of the Nation's food supply. In today's hearing, we will hear from three people with firsthand experience in dealing with the terrible illness that food poisoning can induce. Next month, we will hear from the FDA, which has the main responsibility for ensuring the safety of our fruits, vegetables, produce and other food sources from all around the globe.

I am grateful for our first three witnesses and their families for their heart-wrenching testimony. I know it will be difficult for you to describe your experiences. But each of you give *E. coli*, Salmonella and noroviruses a human face, so Americans can understand and see the health hazard to all of us when the Federal agency in charge does fewer inspections, as more and more food is imported into this country.

Michael and Elizabeth Armstrong are here with their children, Isabella, age 5, and Ashley, age 2, both of whom became critically ill from eating spinach. Worse, the nightmare is not over for them,

as Ashley will probably need a kidney transplant as a result of severe kidney damage.

Mr. and Mrs. Armstrong, you and your children have endured much; and we wish you all the best for your family now and in the future.

We also have Ms. Terri Marshall, whose mother-in-law, Mora Lou Marshall, has been hospitalized since January 2 of this year after eating peanut butter, a source of protein recommended by her health care provider. Unfortunately, the Peter Pan peanut butter she ate was contaminated with salmonella.

Our third witness is Mr. Gary Pruden, with his son, Sean. The Pruden family was on a Thanksgiving trip when they stopped at Taco Bell; and, unbeknownst to them, the meal included lettuce contaminated with *E. coli*. Sean wound up in the hospital as a result.

The terrible food poisoning that continues to plague these families is a small part of a growing problem. The 2006 outbreak of *E. coli* in spinach that sickened the Armstrong children was the twentieth outbreak of *E. coli* in fresh produce from the Salinas Valley in California since 1995 and second one in the past year. In the spinach episode, three people died and at least 102 were hospitalized. Another 70 people were hospitalized due to salmonella in peanut butter.

What has the FDA done to prevent food-borne illnesses? It appears the FDA has decided to centralize food safety decisions made here in Washington, DC, cut back on field inspections and hope that the food producers and manufacturers will self-police their industry based on voluntary guidelines.

Natural Selections' president will testify how his company just began to test all lots of leafy green produce. The result has been startling. Natural selections has found 35 lots of spinach with *E. coli* contamination. Is this the extent of *E. coli* in natural selection spinach? Or is it the tip of the iceberg? What about its other produce? What do other producers find? Do other producers even test? If Salinas Valley seems to have repeated outbreaks, what has the FDA done to protect our food coming from this valley?

Not all the companies appearing this morning have been as forthcoming as Natural Selections. In the case of salmonella poisoning in Peter Pan peanut butter, the actions of ConAgra are cause for concern. Our investigation shows that ConAgra found salmonella in their peanut butter in 2004 but did not report it to the FDA, even when the FDA in 2005 requested ConAgra's records. Perhaps if the FDA had been more aggressive in learning what happened at ConAgra or if the FDA had subpoena power, the latter salmonella poisonings could have been detected, prevented or maybe even limited.

Finally, we will also hear testimony from two companies involved in the recent outbreak of pet food contamination. In this case, wheat gluten imported from China by ChemNutra was contaminated with melamine, an industrial chemical that should not be anywhere near food of any kind. Menu Foods used the contaminated wheat gluten in producing wet cat and dog food. When reports of sick and dying cats and dogs began to mount, Menu notified the FDA; and now approximately 100 brands of pet food, in-

volving more than 5,000 varieties, have been pulled from our store shelves.

Over the past few days, there have been additional reports of contaminated rice protein concentrate and corn gluten, used in pet food. All of the wheat gluten, corn gluten and rice protein were imported from companies in China. There is concern that some of the rice gluten has been fed to hogs, thereby raising the possibility of melamine contamination in food destined for human consumption.

Food-borne illnesses and pet food contamination demonstrates serious flaws in our food safety network. With more and more of our food, fruits, produce and vegetables being imported, there appears to be less and less Government inspection or oversight and no enforceable safety and health standards.

Imported fruit from China and other countries does not have to comply with U.S. health and safety standards. Last week, China refused to permit FDA inspectors access to the plants that supplied the suspected contaminated wheat gluten to ChemNutra.

The safety of the food Americans put on their table every night is more than just a trade issue. It is more than just a public health issue. Food safety has the potential of becoming a national security risk, a national security threat. I urge my colleagues to consider the pet food incident as a wake-up call. The poor pets that died remind me of the canaries brought into the underground mines to warn miners of imminent danger.

The canary is at our door. I hope these hearings will help alert the American people, Congress and the administration to the seriousness of this issue. If it is not taken seriously, these kinds of poisonings can and will happen again. Food poisonings will happen to you, to me to our children and to our pets. The American people expect and deserve better from its Government.

With that, I yield back the balance of my time and next turn to the gentleman from Kentucky, Mr. Whitfield, the ranking member of the Oversight and Investigations Subcommittee.

Mr. Whitfield, 5 minutes sir.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. WHITFIELD. Well, Mr. Chairman, thank you very much. I am certainly delighted that we are holding this hearing today on this important topic.

I notice that the Centers for Disease Control has said that food causes may have accounted for as many as 5,000 deaths and 325,000 hospitalizations each year. We know that the FDA cannot force a disclosure, cannot force a recall or even a plant closure except in cases of extreme circumstances; and I think that this will be the beginning of a series of hearings in which we are going to take a closer look at food safety. I know that back in the 1970s food safety took up one-half of the budget of FDA, and today it is my understanding that it is one-fourth.

Now we recognize that sometimes productivity and technology developments make it unnecessary to spend as much money, but that is an issue that we also want to look at. I know the FDA will

be testifying, I suppose, maybe in May; and certainly it is an issue that we want to look at very closely.

Today, I want to also thank the Armstrong family for being here and conveying to this subcommittee their personal experiences in this issue; and Ms. Terri Marshall, we appreciate her being here, as well as the Pruden family. And we will have two other panels of witnesses in addition to that, including representatives from ConAgra and some of the food companies.

Today, we will also be focusing on the *E. coli* outbreak in the Salinas Valley which, as the chairman mentioned earlier, caused three deaths and 102 hospitalizations. We also will be looking at the salmonella outbreak in peanut butter primarily out of the ConAgra plant. I can't remember now if it is out of Georgia or Tennessee. I think that plants has now been closed, but there were 425 people affected with illness in 44 States as a result of that outbreak.

And then all of us are very much concerned about increased imports into this country into our food supply, and it was particularly disturbing that the Chinese Government or officials would not even allow FDA to inspect the plant where the wheat gluten was processed.

I know that in today's paper it says that the Chinese will allow a U.S. pet food inquiry, so we will have access to their plant. And that is something that we must demand, that we have access. Because when they are—if they—and I don't mean to be finger-pointing here, and we want to be sure that we have our facts correct, but if they are adding melamine, an industrial product, to wheat gluten and other glutens for the purpose of increasing protein content, then that is something that is quite serious and we have got to take steps to deal with that. We know that the U.S. does not have a lot of enforcement action related to imported food items.

So I think all of these issues are vitally important to the American people, and I want to thank the chairman for instigating this hearing, and we look forward to the testimony from all the witnesses.

Mr. STUPAK. I thank you, Mr. Whitfield.
Next for opening statement, Ms. DeGette.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you very much, Mr. Chairman. This is an important topic, and I commend you for holding this hearing and continuing your push on rigorous oversight.

Food safety is an issue that we don't have to think about very much in the wealthiest country on the planet because we take safe food for granted. But here is something else that we take for granted in this country, that our Nation's corporations and public officials are always acting in the best interest of our citizens. Sadly, that is not always the case, as we have seen in this latest string of incidents.

Spinach, peanut butter, pet food, normal, ordinary, everyday items that make us think twice about our daily business. As I see these two girls here with the spinach, I think about how Moms like

me—I also have two girls—are always trying to improve our children’s diets by feeding them things like spinach, which we think will be good for them. But then we read the recent headlines and we know that calls into question everything that we thought we knew.

Today, we are going to hear these heart-wrenching stories. And I want to take the opportunity to thank these families for having come today, because your stories are what give perspective to what we do here in Congress every single day. And although your testimony is difficult to give—not nearly as difficult as your daily lives—it will help shed light on exactly what happened, how it affects real families, and the real need to make sure it doesn’t happen again. Your courage will not go unnoticed; and, hopefully, your message won’t either.

Mr. Chairman, we need real reform for our food safety laws. Some will argue that the recent *E. coli* in spinach, the salmonella in peanut butter and the contaminated pet food are isolated incidents. But I don’t see the latest string of incidents as aberrations. It has become a systemic problem, and it calls for systemic solutions.

I have been arguing for years that our Nation’s food safety laws are broken. For the last three Congresses, I have introduced legislation that would tighten up our Nation’s food safety regulations; and for that entire time I could not get a single hearing on these issues. That is why this hearing is even more important, Mr. Chairman.

One of my bills would give the FDA and the USDA mandatory recall authority in event of an outbreak. It absolutely shocks people when I explain to them that during an outbreak in food-borne illness—like the ones we will hear about today—the Federal Government’s hands are tied when it comes to recalls. We must rely on the industry to voluntarily recall their products.

We will learn today that the companies involved eventually did issue recalls. But I would argue—and I am sure the families here today would—it was far too little, far too late. During the foot dragging, more people got sick. And I think what we need is real Government oversight and Federal food safety laws that have real teeth in them. We need a mandatory recall bill.

Another bill I have been working on for years is the bill to require unitary reporting systems for meat and poultry so that contaminated lots can be traced through and we can identify where it came from. These concepts could be examined for other food products as well.

We also need to reform the system before there is an outbreak. The last Congress starved our food protection agencies for funding. The FDA has become more and more reliant on industry to police itself. Inspections are going down as imports are going up. And, unfortunately, the latest string of incidents seems to indicate the problem is getting worse and not better.

We need to continue our oversight. We need to make progress. And I think these hearings will have an impact. Just yesterday, for example, the committee received a letter from ConAgra Foods detailing positive changes to company safety reporting at least as a result of this committee’s investigation.

Sometimes people ask me, why do you have O&I hearings? This letter from ConAgra is a good reason. Something almost always changes just the day before we have these hearings.

But Congress needs to act as well. I hope this latest unprecedented series of outbreaks will give us the political will we need to begin to reform the broken laws so that we can regain some semblance of order though this country's food safety.

Again, thank you to the witnesses for appearing today. My thoughts and prayers are with you as you move forward in this difficult process.

And I yield back, Mr. Chairman.

Mr. STUPAK. I thank the gentlelady for yielding back.

Just note you mention the legislative history, and you go back to the act of 1997 introduced by Frank Pallone of this committee. Mr. Brown is now a Senator. The following year, 1998, Mr. Dingell, Mr. Brown, myself, Mr. Pallone, yourself, Ms. DeGette, Mr. Waxman, who is here, others on this side of the panel here, have been pushing for food safety food inspections. We even proposed a user fee. We could never even get a hearing on it. New Congress. There will be changes.

Next, I go to Mr. Walden from Oregon. Mr. Walden, please, for 5 minutes.

Mr. WALDEN. Mr. Chairman, I am looking forward to hearing from our witnesses today. I am going to yield on my opening statement and reserve the balance of my time for further questions.

Mr. STUPAK. Next, Mr. Waxman from California for an opening statement, please.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman Stupak, for holding this hearing.

As you mentioned, many have tried to change the way the food safety issues have been handled. We couldn't even get a hearing. I found over the years that interest in food safety questions waxes and wanes. After a crisis, everybody wants to know about it and do something about it. But, too often, a few minor changes are made, the system is tweaked one way or the other, and the commitment to meaningful change disappears.

I am hopeful that this Congress will end this cycle. We are at a critical moment for food safety. The FDA system for overseeing the safety of our food is all but broken. Outbreaks in fresh produce have doubled since 1998, we inspect only a tiny fraction of the food we import, and our food supply is deeply vulnerable to attack. As a result, over 300,000 people are hospitalized each year; and 5,000 die due to food-borne illnesses.

Well, in addition to the human costs, there are economic costs. Recent outbreak of *E. coli* traced back to spinach caused tens of millions of dollars in financial harm; and these costs, of course, are magnified by the fact that we can't then export our food to the rest of the world without ensuring its safety.

We need to do more than tweak the system in a piecemeal fashion. We need to examine the system as a whole to determine the

proper solutions. There are looming questions about overlapping authorities and wasted resources that we need to explore.

There are some things we ought to do about FDA. There are three fundamental problems in FDA's oversight of food safety: inadequate resources, inadequate standards and inadequate enforcement. FDA's own budget analysis estimated a decline of \$135 million for food safety activities from just 2003 to 2006 due to inflation and increased responsibilities, about a 24 percent budget cut. This, of course, has led to a decline in staffing levels; and we now find that these inspections are not adequately addressing even the most critical problems. FDA records show that the agency inspected the ConAgra peanut butter plant during the period of apparent contamination, meaning that contaminated product was sold before, during and after an FDA inspection.

Second, FDA must set clear, enforceable standards for food production, especially for fresh produce. These standards would address the primary sources of danger, such as soil contamination, unclean water, inadequate worker sanitation. Although FDA has issued a number of voluntary standards, it is clear that what we have seen in this year's, past year's, outbreaks, this voluntary approach does not work.

It is not often that industry groups stand side by side with the Government and call for the same thing, stand side by side with consumers calling for the same thing: FDA issuing enforceable standards. FDA has the authority to do this now, and I hope they will act.

And, third, FDA must enforce its own standards. In spite of repeated outbreaks, warning letters from FDA's food division have dropped by 45 percent under the Bush administration. FDA can and must do better. Each outbreak and each food recall has chipped away at the confidence that the American public has so long held in the safety of our food supply. We owe it to the consumers, food manufacturers to ensure that this confidence is restored.

It will take getting FDA the increased resources and authority it needs to do its job, and I am hopeful it will do what it takes to address this very grave situation. I look forward, Mr. Chairman, to working with you and our colleagues to get the job done.

I yield back the balance of my time.

Mr. STUPAK. Mr. Green for opening statement, please.

Mr. GREEN. Thank you, Mr. Chairman.

I would like to ask my full opening statement be placed into the record.

Mr. STUPAK. Without objection, so ordered.

**OPENING STATEMENT OF HON. GENE GREEN, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. GREEN. The FDA's effectiveness on this issue is seriously questioned by recent high-profile contaminations of the food supply both for humans and pets, and I appreciate our subcommittee's interest.

According to the Centers for Disease Control, approximately 76 million Americans are affected by food-borne illnesses each year. More than any segment of our food supply, the contamination of produce is responsible for these food-borne illnesses. The appear-

ance of *E. coli* in bagged spinach the most recent high-profile, with three deaths and 206 illnesses, 102 hospitalizations, resulting from this outbreak. The outbreak of *E. coli* and spinach offers a textbook case from which to examine the regulatory framework ensuring the safety of our food supply.

Unfortunately, this case has only underscored the gaps. The system is fragmented, at best, and needs new tools at its disposal. The Government Accountability Office agrees and dubbed the country's food supply program is high risk. I will repeat that. The GAO, who all of us depend on their research, agrees and dubbed our country's food supply is high risk. I don't think the average American would believe that. But when you have the Government Accountability Office saying it, then something needs to be done.

The bulk of our food safety falls under the jurisdiction of the FDA, which continues to be responsible for regulating approximately 80 percent of our Nation's food supply. And after reading yesterday's Washington Post, which reported FDA had known for years about contamination problems in both spinach and peanut butter, I would like to have the FDA before us today to explain themselves; and our chairman assures us they will. FDA will appear at later hearings. So I look forward to hearing the FDA's perspective.

There is no question the food supply gets short shrift at FDA. They have an enormous job and too little funding and too little authority. Its ability to recall food products is extremely limited, especially dependent on food manufacturers to voluntarily remove food from supermarket shelves. Too often, FDA actions occur so late that shelf life of the food product has already expired.

This is inexcusable; and, Mr. Chairman, as a member of the Health Subcommittee, I hope we will take a serious look at expanding FDA authority in this area. And since you mentioned the Chair of our Health Subcommittee is Frank Pallone, who introduced those earlier bills on the FDA, hopefully our subcommittee will go forward.

The common denominator among the cases of spinach, peanut butter and pet food contamination is lack of appropriate testing. What we can and should do is have the appropriate testing mechanism in place to ensure that contaminated food is pulled and does not make it to our supermarket shelves and into the homes of our public.

Like my colleagues, I want to thank all of our panel for being here today but particularly our first panel of witnesses, who are here to relate how the food safety issue affected them in their daily lives.

I yield back my time.

Mr. STUPAK. I thank the gentleman for yielding back.

Next, we will turn to ranking member of the full committee, Mr. Barton of Texas.

**OPENING STATEMENT OF HON. JOE BARTON, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. BARTON. Thank you, Mr. Chairman. I am pleased to join you and Mr. Whitfield and Mr. Dingell in this investigation in the safety and security of our food supply.

We began the investigation last October into FDA's food security projects and whether these efforts were leveraged to prevent or detect outbreaks such as *E. coli* and spinach. We did gain some records and information from that inquiry that should be helpful in this investigation.

This is really a preliminary hearing, since we are still gathering information and interviewing experts and fact witnesses. The FDA and other witnesses will be appearing in a hearing on this subject in a few weeks. I appreciate your interest in moving quickly in this investigation.

Since we only have partial information at this time, I don't think we are in quite as good a position as I would like to be to question some of today's witnesses or to assess fully the accuracy and completeness of the answers to some of the questions that we are prepared to ask. Given such limitations—and also since this subcommittee has always tried to be fair—I hope we don't rush to conclusions on some of the matters based on this hearing by itself.

There is one ongoing matter in which I am prepared to comment, and that is the reluctance of the Chinese Government to cooperate in assisting the FDA in investigation of tainted pet food which is manufactured in China.

Over the past few weeks, pet food manufacturers have recalled millions of cans pouches and bags of food after finding their products have been contaminated and have caused serious illnesses and in some cases even deaths in animals that had eaten these pet foods. The FDA has traced the problem to an industrial ingredient called melamine in samples of wheat gluten that was imported from a Chinese firm. In high-enough doses, this substance is believed to be toxic.

A few days ago, it was detected in rice protein concentrate used in some pet food. FDA is also investigating whether tainted pet food containing this poisoning has been fed to hogs, possibly bound for the human food market.

Melamine is used to make plastics and is not edible. In light of that fact, the FDA is investigating whether it was intentionally added to the wheat gluten or other ingredients to produce the protein content in order to make the bulk products more valuable.

For the last 2 weeks, the FDA has been attempting to get visas from China so that its inspectors could join Chinese inspectors at the company listed as the manufacturer of the suspect wheat gluten. China rejected FDA's first request and only yesterday approved the second one.

China's foot dragging in the public health incident is totally unacceptable. Building a great wall of bureaucracy between our experts and their problem isn't going to make the problem disappear. American consumers who buy these products have the right to know that they are safe, and that is why other nations routinely cooperate with the United States in food safety investigations, including giving USDA, FDA inspectors access to their manufacturing facilities.

The suspicion of intentional contamination is eerily similar to past incidences in China.

A dozen years ago, 89 children in Haiti died after taking cough medicine made with—believe it or not—antifreeze that was traced

back to China. The world never got an answer from the Chinese on how this crime occurred.

In an investigation started in 1998, when I was chairman of this same subcommittee, we found that 155 U.S. citizens were sickened by impure gentamicin sulfate made by a Chinese firm. We never got a definitive answer on how this unapproved, impure drug ingredient got into that particular product. Significantly counterfeit animal drug ingredients have been linked to the same Chinese firm before it moved to the human drug side.

As in the counterfeit drug cases in this pet food investigation, we are confronted with numerous discrepancies. The Chinese firm listed as the manufacturer of the wheat gluten for food in the U.S. import record told Chinese Government it was exporting its product not for food purposes but industrial purposes. There is also a question whether the Chinese firm is in fact the actual manufacturer. Those questions can only be answered with confidence if the FDA is allowed into China to do the inspection themselves.

My message and I think the message of this subcommittee on a bipartisan basis to the Chinese Government is pretty straightforward: Cooperate, stop these shenanigans.

I want to thank you, Mr. Chairman, for your cooperation and your leadership on this issue. I want to welcome all of our witnesses today, and I want to thank the families who have suffered and come here to share their unfortunate experiences.

With that, I yield back.

Mr. STUPAK. I thank the gentleman.

Next, we will hear from Ms. Schakowsky from Illinois. Five-minute opening statement, please.

OPENING STATEMENT OF HON. JAN SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Thank you, Mr. Chairman, for holding today's hearing on food safety. Not only is this a serious public health issue but it is also a matter of national security to which we should give our utmost attention.

I want to especially thank the families that are here, the Armstrongs and Marshalls and Prudens for coming and a special welcome to Isabella and Ashley and Sean for being here today.

I am going to cut straight to the chase. I think that in order to get a handle on the problem we have to follow the recommendation of the Government accountability office and consolidate Federal food safety programs.

In February of this year, the GAO deemed Federal oversight of food safety as high risk to the economy and public health safety. So I support such legislation as the Safety Food Act sponsored by Representative DeLauro, which would consolidate all the food safety agencies—we spread it around to too many places—and establish the food safety administration that would bring it all together.

The FSA would be responsible for the creation, administration and enforcement of our food safety laws which is currently lacking.

When the news of the *E. coli* contamination of spinach broke out last year, Representatives DeLauro, DeGette and I called on Chairman Barton to hold a hearing on this bill which has been referred

to in our committee. I am very glad that under your leadership, Chairman Stupak, we are discussing the issue today.

I also want to add my support to Mr. Waxman's call for increased oversight right now by the FDA.

We also have to start holding food, including pet food, conglomerates accountable now. For instance, ConAgra's corporate policy tries to keep the lid on what they are up to. Employees are told to never volunteer information and never give more information than necessary and are even told to hide product codes from the on-the-ground inspectors.

This vital information that could alert the FDA and consumers to whether a questionable facility is being used to process food or whether a questionable supplier is providing ingredient is—it is vital, and a failure to share this information keeps us in the dark about what they are doing to the food that makes it to our kitchen tables.

I wish I could say I was amazed at the incidence of corporate shenanigans that has been noted in the press and will be revealed at this hearing today, though I have seen it all before. When I was a very young mother—it is about 37 years ago—I fought another effort of food producers to keep us in the dark about the age of our food. Some of you are old enough to remember that everything was coded at that at that time—in 1969, 1970—and a group of young mothers got together and said we want to know how old your food was. And believe you me it was a battle to get manufacturers and retailers to begin to freshness date their food. Now, of course, those dates are ubiquitous.

I also think we need to look further into the lack of inspection of ingredients to food products that are being imported into the United States from countries like China.

Because I am short of time, I would like to submit for the record the AP article, "U.S. Food Safety Strained by Imports."

This article details how food products are not a priority for the FDA inspections, even as the import of ingredients has increased by 73 percent over the last 5 years. If someone wanted to attack the United States through its food supply, we have a frighteningly easy way for them to do it. It is time that we act to ensure that our food supply is safe.

Thank you, Mr. Chairman; and I yield back.

Mr. STUPAK. I thank the gentlewoman.

Next, we will hear from gentleman from Texas, Mr. Burgess.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Thank you, Mr. Chairman. Thank you for holding this hearing today.

America has the safest, least expensive and most abundant food supply of any country in the world. In the past, whenever I went to the market to buy food for my family, I never stopped and wondered is it going to be safe to eat? Is it going to make anyone at home sick? The security of our food supply in my mind has really never been in question.

I still believe that our food supply is generally safe and secure, but the recent outbreaks of both *E. coli* and salmonella have caught the country's and this committee's attention.

Today, we will hear troubling stories from the Armstrong family, the Pruden family and the Marshall family. I thank you all for being here today and putting a human face on what has been an astonishing tragedy in this country. I am deeply sorry for the pain that you have all been through, and I sincerely appreciate your willingness to come to Congress to tell your story.

Thank you.

In addition to the food safety issue, I am pleased that this committee is also investigating the recent pet food recalls. Like many of my constituents back home in Texas, I have been struck by the contamination of pet food and the fact that thousands of beloved animals have died. The fact that companies mixed a form of plastic with wheat gluten to manipulate the protein levels in the food is not only wrong, it is criminal.

As we have all learned during the aftermath of Hurricane Katrina, Americans view their pets as members of the family; and to put a pet's life in danger just to increase the profit line is completely unacceptable.

While I realize that we have only begun our investigation into this matter this practice must be stopped. Earlier this month, I sent a letter to both Chairman Stupak and Ranking Member Whitfield requesting that we allocate an adequate amount of time on this issue; and I thank the leadership of this committee for doing so.

I think it is important to remember that there are still many questions that need to be answered, and today is merely the beginning of the investigation into these troubling circumstances. I do welcome the companies here to tell their side of the story and what they have done and are doing and will do to remedy the situation and see that it never happens again. But we all know that nothing in the world is ever 100 percent safe. However, I look forward to hearing what the companies view as their role and responsibility in this situation.

Many of us in Congress may have a different opinion, but I think we can all agree that innocent people, innocent animals, should not have to die because of a mistake, negligence or especially criminally intent on another's behalf. I look forward to this investigation and learning what needs to be done so that this does not happen again.

Thank you, Mr. Chairman, for your indulgence; and I will yield back my time.

Mr. STUPAK. I thank the gentleman.

Next, turn to the chairman of the full committee, Mr. Dingell, for an opening statement, please, sir.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Mr. Chairman, thank you; and I thank you for conducting this hearing. I also commend you for the vigor with which you are proceeding. This is an important hearing on the threats to

public health from contaminated food products and, very frankly, from the inadequacies of the Food and Drug Administration, their budget, the number of personnel that they have and their competence to carry out their responsibilities.

Every American has reason to worry about pathogens in our food supply. They sicken 73 million Americans, and they kill 5,000 of us each year. It is important that we learn of this. Death and illness could have been prevented by diligence and properly funded regulatory agencies, primarily the Food and Drug Administration. And this is not limited to foods, nor to cosmetics but also to pharmaceuticals.

I want to begin by thanking our first panel of witnesses, the courageous and patriotic Americans who have come here at their own expense to recount the personal tragedies that have befallen them and their families.

I also want to commend my colleagues, Mr. Pallone and Mr. Inslee, for their assistance in these matters.

Now these are not easy matters for our witnesses to discuss. Two of our witnesses, Elizabeth Armstrong and Gary Pruden, will speak of the *E. coli* poisoning that caused grave harm and in one case is still causing grievous harm to their children because all of these kids ate their vegetables.

The children who are victims of food contaminations, Isabella, Ashley and Sean, are also with us today. Terri Marshall will speak of the terrible infection that her aging mother-in-law has suffered from salmonella-contaminated peanut butter. These tragedies represent serious problems in our food supply that should and must be addressed.

We will also hear today from two of the companies that sold tainted products. And we will hear from two witnesses that give us even more concern, because the source and breadth of the contaminated wheat, rice and possibly corn products that found its way into pet foods suggests an even more dangerous breakdown in the regulatory system that is supposed to protect Americans. These protein products are pervasive. They are used in all manner of human food.

The principal seller of the tainted pet food, Menu Foods, tells us that only the highest grade of wheat gluten was ordered for their pet products. So these important proteins that are imported by the ton could easily wind up in our pantries, our restaurants, or snack food vending machines.

Regardless of whether they are wheat, rice or corn based proteins, they share two important characteristics: First, they were contaminated deliberately. I will repeat that. They were contaminated deliberately. Second, they came from our trading partners in China. So far, the evidence suggests that the deliberate contamination was for greed and not as a trial run for terrorist purposes.

But we certainly could look forward to some serious consequences where it to be the other way around.

The chemical melamine, the component that poisoned the pet food, fraudulently elevates the measurement of protein in the gluten, thus increasing its market value. While it matters not to the victims whether they are poisoned for profit or for politics, we must be particularly concerned that these profiteers have drawn a road

map to holes in our regulatory scheme, with serious consequences to our people.

I recall an episode involving tainted canned mushrooms from China a few years ago. At that time, the FDA shut down all imports of mushrooms from China until FDA inspectors went there and approved each and every plant.

We will expect that similar efforts and similar consequences will obtain as a result of the hearings of this committee today.

Up to yesterday, China would not let our inspectors into the contaminated wheat gluten factories. In fact, they wouldn't even tell us where the plants were located, much less to whom they ship.

The response of this administration was simply to shut off imports only from the trading company that shipped the poisoned product. Chinese wheat gluten continues to pour into this country.

Relying on imperfect testing at the ports, the agency gambles with the health of Americans so as not to disturb the trading profits of the Chinese.

I will note that the failure of this Government to properly fund the Food and Drug Administration and see to it that they have the adequate resources to address their important responsibilities is a national scandal and has been a concern to this committee for a number of years.

In a couple weeks, we will note that we will hold a second day of hearings. At that time, we will have the FDA here to account for their imperfect stewardship of their public health, and we will expect them to tell us not only about that but what resources they have to address these problems and what resources they need to see to it that they can carry out their proper and very important mission.

I have watched the Food and Drug Administration chase too many imports with too few resources for too many years. Whether the life-threatening product is a counterfeit drug or tainted food, the FDA lacks enough properly trained, properly motivated personnel to do an increasingly difficult job, particularly at the ports of entry of imported foods.

Good people in the field continually report how disillusioned they have become with the management of FDA. Some are resigning. Some are being driven out. A curious pattern of closure of facilities of FDA at our ports now goes on and still threatens our food supply and our other health-related products in a very serious way.

The FDA field management will be before us, as I mentioned, in a couple of weeks. They have some serious accounting to do regarding the game of roulette they are playing with the lives of Americans, and perhaps they will tell us about how they are being denied the adequate resources to carry out their proper responsibilities in protecting the American people.

Thank you, Mr. Chairman.

Mr. STUPAK. I thank the chairman.

Mrs. Blackburn for opening statement please.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman; and I want to thank you for holding the hearing. I want to thank our witnesses for their willingness to come before us.

The food safety issue, as you have heard, is a high-priority issue from a public health standpoint as well as from a national security issue. And you don't have to be a scientist. You simply have to be a concerned citizen or a parent to know that a very real threat exists when a terrorist could easily put some type of toxic chemical into some product that is moving through the food chain and that could go about causing a lot of damage before it is detected.

Since September 11, our national sense of vulnerability has steadily risen; and we have been warned time and again of the vulnerability of our food and water supplies. We are now also facing up to a less publicized but potentially devastating threat, terrorism directed at the Nation's food and agricultural infrastructure; and I think it is something that we have to face up to and recognize that it is there. It is a threat that is very real. Derelict poisoning and deliberate poisoning to any of our food items will undermine confidence in the supplies. It would wreak havoc on the agricultural sector of this Nation's economy, which accounts for about a sixth of our GDP.

Americans are consuming increasing amounts of imported food and drink, and the demand among U.S. makers for overseas ingredients is constantly increasing. However, according to the FDA, it only has enough inspectors to check about 1 percent of the 8.9 million imported food shipments that come into the country each year. One percent is all that gets checked. So we do have to realize this means we have an increased vulnerability, and it leads to some questions that we will be asking through this hearing and through some others.

Is the FDA too large and too bureaucratic to respond? Has it not made it a priority to respond? And in a post 9/11 world have they chosen not to shift their priorities?

Not everything is a matter of money. Many things are a matter of priority and taking the time to restructure to meet the challenges that are before you. Is the FDA capable of restructuring so that they have the ability to address these concerns? Or do they choose to turn a blind eye and a deaf ear to the concerns that we have?

Do we need to apply the standards that we seek for imported foods and drugs? Does this need to be applied to reimportation of drugs if we allow reimported drugs into this country?

What is the expected level of corporate, bureaucratic and personal responsibility? How do we make certain we don't see a new group of class action lawsuits?

We must seek greater accountability in these questions and in our Nation's food and drug supply, and we must expect that all imports that are coming into this country are going to meet our U.S. safety standards. They are rigorous, but we intend for them to be met.

According to the GAO, our food supply is generally considered to be safe. We realize that there are vulnerabilities. We look forward to working with the FDA to address these questions.

And I yield back the balance of my time.

Mr. STUPAK. I thank the gentlelady for yielding.

Mr. Inslee from Washington. Opening statement please.

OPENING STATEMENT OF HON. JAY INSLEE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Mr. INSLEE. Thank you to my colleagues. I want to thank the witnesses, who are involved in an act of courage today. We very much appreciate their stepping forward in a difficult situation.

I want to note our previous experience with meat. We had in the State of Washington an *E. coli* outbreak. A local establishment became the subject of national news and national debate on how to clean up the meat industry, and we were engaged in that in an effort to clean up that industry.

We have had substantial progress. It was not without controversy, it was not without debate, it was not without effort, but we will note today the cases we are involved in today do not involve the meat industry because there has been substantial progress made. And that involved mandatory requirements, hazard point reductions, a whole slew of efforts; and we need to have this same thing now in another part of the industry.

I want to note as well a constituent of mine, Bill Marner, who has worked very hard on eradicating food-borne illnesses; and he was part of the success in the meat industry. I am going to make his statement a part of my opening statement.

It is clear to me and I think many of my colleagues that we need to have some much more rigorous food safety standards, and I want to note four things that I will be introducing legislation I believe with some of my colleagues on in the near future.

First, we have got to have standards that are binding. Voluntary guidance is clearly a recipe for failure and injury and even death in our food safety standards.

Quoting the 2007 March guidance from FDA, it says, "the use of the word 'should' in agency guidance means that something is suggested or recommended but not required."

We are not requiring food safety. We need to require food safety, not make nice, gentle suggestions in this context. It is not an accident that this is the twentieth time in a single decade that we have had leafy green vegetables involved in damages coming out of one single county in this country. That is inexcusable. We have got to have requirements for Americans, not simply suggestions.

Second, we have got to establish hazard point identification programs, as we have done in the meat industry to great success. When we have adopted protocols like that we have found great improvement in food safety. We have to have the hazard point identification protocols used in this other industry.

Third, we need to treat *E. coli* and salmonella as adulterants, with accompanying criminal and civil penalties. It is a step forward recognizing the severity of damages that we will hear about today. It is only common sense to do that.

And, fourth, and this is perhaps the most obvious, we have to have mandatory recall authority. To not have mandatory recall authority in the context of these types of severe damages simply beggars belief that we don't have a mechanism in that regard.

Now, as in the meat industry, there may be opposition to some of these suggestions. But I think that we should keep in mind we are going to hear some of the personal tragedies today involved in this.

But the industry itself has a stake in the ability to stop loss of confidence in these tremendous products. The spinach outbreak has cost the industry somewhere between \$37 million and \$74 million already.

There is an economic motivation as well as a personal one for us to have a food safety system that gives Americans confidence in the industry. They do not have that today. There is some meaningful things we can do that we know are going to be economically productive. We should take them.

I look forward to our testimony. Thank you.

Mr. STUPAK. I thank the gentleman.

Next, Mr. Murphy from Pennsylvania, opening statement.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. Thank you very much.

I just wanted to thank you for holding this hearing. It is so important in light of how much illness and how many deaths have occurred with a number of problems with food safety.

But I am reminded of, as part of the time when I was on the Government Reform Committee, of some of the problems that also occurred with some of the waste, just redundancy and lack of coordination between the FDA and USDA. And I recall this. There was 12 different agencies that administered as many as 35 laws in regard with the Federal food safety program. But it was always odd to me that no single agency had oversight over everything. Because of this fragmented system, the USDA inspects open-faced meat sandwiches and frozen pepperoni pizzas, while the FDA inspects closed-faced sandwiches and cheese pizzas.

Somehow in this we have to find ways of more efficient use of Government money as we go through this. I know there is not enough inspectors. I know that is part of what we should be hearing about today to find out what we need to do to improve this system. But in context of all as we go through witnesses today I hope a part of what we hear in improving the system is to make the system far more efficient in ways that we can eliminate the redundancy that is unnecessary, improve the efficiency, where we can let us know what we need in terms of increasing funding for more employees to do these inspections. And, above all, we will stand up for the safety of the American public.

Mr. Chairman, I commend you for continuing to push this issue. Thank you, and I yield back.

Mr. STUPAK. Thank the gentleman for yielding back.

That concludes the opening statements of the members of the subcommittee. I would like to note that all members of the sub-

committee on both sides of the aisle have been here. Not all have chosen to give an opening statement, but they have all been here. That is the importance of this issue.

There has been questions about the FDA. We will have FDA in the next few weeks. We thought it would be wise to use this first hearing just to lay out the scope of the problem but also to try to help the FDA in its effort to try to get into China, and I think our efforts by holding these hearings put pressure on. Now the FDA will be able to get into China. So when they come to testify in the next couple of weeks we will give a broader hearing and more in depth of what the problems are that we face, not only in access to foreign markets when you have to inspect something like food safety.

So the purpose behind oversight and investigation is not only to investigate but also to use our oversight role to get Government agencies and others and corporations to change their behavior. And, once again, through bipartisan work on this committee, I think that has happened here.

So let's call up our first panel to come forward.

Our first panel we have Michael and Elizabeth Armstrong with their children, Isabella and Ashley; Mr. Gary Pruden and his son, Sean; and Ms. Terri Marshall.

Would you please come forward, please.

It is the policy of this subcommittee to take all testimony under oath. Please be advised that the witnesses have the right under the rules of the House to be advised by counsel during their testimony. Do any of you wish to be represented by counsel? Ms. Armstrong? Mr. Armstrong? Ms. Marshall? Mr. Pruden?

[Witnesses sworn.]

Thank you. You may be seated.

Let the record reflect that the witnesses replied in the affirmative. They are now under oath.

We will hear an opening statement on behalf of the Armstrongs; and Ms. Armstrong or Mr. Armstrong, who would like to give the opening statement?

STATEMENT OF MICHAEL ARMSTRONG

Mr. ARMSTRONG. So our experience is actually with both girls. Isabella got sick after eating a salad of spinach. She was sick for 5 days with vomiting and diarrhea. And that was pretty bad. That was pretty rough. About the same time that she started clearing up, Ashley had a fever; and she started with the same symptoms. So we thought it was the same, and we thought she would get over it.

Two days later, it wasn't getting better. It was getting worse. We called her pediatrician, and we went into the hospital. They said an IV will do the trick, and she will be feeling better.

About 24 hours later, she was again even worse than before. In fact, she was in the hospital bed banging against the walls almost like a caged animal. She was inconsolable, trying to pull the IV out of her arm.

At that point, we realized that there was something much more wrong with her.

At that point, her pediatrician got a consult from an expert and really at the—because Elizabeth brought it up. She said, have you tested for *E. coli* or any other bacteria along those lines? And that is when she got the consult. And the expert said, oh, that is HUS, hemolytic uremic syndrome.

Let me tell you why that came to her mind. Two years ago, my cousin, who had a 2-year-old son, was a missionary in Rumania; and his son actually had HUS from *E. coli*. They weren't able to get him back into the States for medical care anytime, and he died.

To me, that really gives you a different backdrop here in that the United States and Rumania, really, when it comes to food safety, it is not much different.

So, anyway, at that point we went into a special children's hospital; and she was diagnosed there officially with HUS.

The next week, when we were in intensive care, it was pretty rough. We really didn't know if she was going to make it. The doctors couldn't really tell, of course. They were as optimistic as they could be at the time. She was on dialysis. She required blood transfusions. Her kidneys had shut down. She had pancreatitis. She had brain swelling. It is a really nasty syndrome.

She was in intensive care for 3 weeks on dialysis; and at that point she was well enough to move to the regular ward where she was attached to, of course, an IV and what we call an octopus, which was several bags of a fluid for dialysis. She was there for about another 4 weeks, roughly. At that point, we were able to go home—on dialysis still.

She is now off the dialysis but requires five medications a day, and we have to give her a shot once a week, and it is quite likely she will need a kidney transplant in the next several years.

But she does pretty well. She does real well.

Anything you want to tell them?

Mrs. ARMSTRONG. [Shakes head.]

[The prepared statement of Mr. and Mrs. Armstrong follows:]

TESTIMONY OF MICHAEL AND ELIZABETH ARMSTRONG

ASHLEY'S STORY

Sunday, August 27, 2006 I went to Marsh, as usual, and purchased a bag of Dole spinach, like I always did. We had it for dinner that night as a raw salad with our spaghetti and meatballs. Both Isabella, my 5 year old, and Ashley, who was 2, and I had the spinach. We always worked very hard to make sure our girls ate healthy. This generally meant lots of fruits and vegetables and very little sugar.

By Saturday, September 2, 2006, Isabella had come down with Colitis from the spinach. Of course at this point, we just thought she had a viral diarrhea. She had the diarrhea for almost a week when I finally took her to the doctor. It was on Friday, Sept 8, 2006, and the doctor just said that it was a viral diarrhea and there was nothing that she could do about it. She just said to keep her hydrated, and to let the doctor know if she had blood in her stool.

Isabella started feeling better the next day, and we thought we were in the clear. Then, about mid-day on Saturday, September, 9 Ashley started having diarrhea. We just thought she caught the same bug that Isa did, and just kept giving her fluids and keeping an eye on her. She was pretty lethargic that day. She would drink fluids, but was not really interested in food (which is a shocker for anyone who knew her!). The next day, Sunday, she seemed to feel a little bit more like herself. She ate a little more, and she was more interested in playing. We even went to my sister's wedding shower, where she played with all of her cousins and seemed to us like she had got the bug out of her system. By Monday, however, she was feeling much worse. She was very lethargic, slept a lot and did not want anything to eat and very little to drink. She still had diarrhea. We went out and got haircuts for

the girls that afternoon, but she definitely was not feeling like herself. At this point she was more lethargic again and wasn't interested in playing.

By Tuesday, September 12, 2006, she was getting worse and I knew something was really wrong. During one of the nearly a dozen diaper changes in a day we were doing at this point, I noticed she had some blood in her stool. I remembered what Isa's doctor had told me and I called and scheduled a sick appointment for Ashley that day. We met with the doctor and she still felt that it was viral diarrhea and nothing to worry about, but because I had brought the diaper with me, they tested it to see if it was in fact blood. The doctor felt that Ashley looked dehydrated and wanted me to go to their other office in Castleton to get a blood draw to find out for sure. I took Ashley to the other office, where the nurse there drew her blood samples and sent them to the lab for analysis. I then took Ashley back home to wait for the results.

About an hour later I got a call from my doctor telling me that Ashley was in fact dehydrated and wanted me to take her to Community North hospital. They told me not to worry, that they would just admit her to get an IV in her and they would monitor her hydration levels and we would probably be out of there that same night. So, on Tuesday, September 12, 2006, we checked into Community North and they hooked her up to an IV to re-hydrate her.

Right after checking in and getting her into her room, the nurses had to come in and hook up the IV and all of the wires to monitor her with. Also, because of the diarrhea in her diapers, the nurses could not tell if she was producing any urine so they inserted a catheter into Ashley to monitor this, as well. So, always having been a healthy baby, this was Ashley's first introduction to the world of pain and needles. She was such a trooper, but how sad to be grateful that God had blessed you with a cooperative child. How sad that at the tender age of 2, Ashley was about to learn that she just had to become resigned to being poked, prodded and generally tortured to get her better. She always had been a good, healthy eater and was plump with health. Seeing her lying in that hospital bed, she was so unnaturally skinny and sickly, it was so sad.

It is now late afternoon on Tuesday and Ashley is still having countless diapers with diarrhea, not producing any urine, and now she has started vomiting. At first the vomiting was bile, yellow in color. But as the night progressed and it got into Wednesday, the vomiting started to get darker and darker green. Our Dr did stop by later that afternoon to see how she was responding. I asked her what else we should be doing because this did not seem to be helping. I also asked her if she had tested for *E coli*. I remember she looked at me strangely for asking, and I don't remember now exactly what she said, but I think the answer was yes.

By Wednesday, September 13, 2006, the vomit was almost black, she could barely even sit up by herself, she still was having diarrhea, and that was when I had finally had enough. The IV was not making her better, her vomiting was getting worse, she was not producing any urine, and to me she looked like she was getting puffy. I had not seen my doctor since yesterday and I grabbed a nurse and told her to call her immediately. I told the nurse all of these things and told her she needed to get my doctor in to see me, now. About 15 minutes later the nurse came back into the room and told me that my doctor had ordered that Ashley have some labs run on her. So, the nurses came in drew a few tubes of blood and sent them to the lab. I don't remember how long we waited, watching poor little Ashley cry and lie in her bed, but I remember how small and helpless I felt. We did not know why at the time, but Ashley was inconsolable. She did not want to be held or even looked at! This just broke our hearts, because as a parent, you always want to comfort and take away the pain of your baby, and also because this was so out of character for little Ash. She always wanted to be held, especially when she was sick. To see her screaming and banging around in the crib like a caged animal was more than we could stand. When she was happy and healthy, people often asked us, "is she always like that?" referring to how smiley and friendly she seemed.

When the nurse came back to tell us about the lab results, I knew something was wrong. She came in and told us that our Doctor was conferring with someone at Riley and would call us as soon as she was done. The nurse did not offer any other explanation, but did say that our Dr would call shortly. When our Dr did call, I spoke with her first. I don't remember all that she said, but I remember her asking if I was still there. I could not speak because I was choking back tears. She told me that Ashley's blood tests showed that her kidneys were shutting down. This was why she was not producing urine and why she was getting puffy. Her pancreas was also not working properly, which was causing the vomiting. I remember her telling me that as she was talking with this specialist at Riley, she remembered me asking her about *E coli*, and she brought that up with him. Apparently it was that question that made our situation crystal clear to what was happening to our baby. She men-

tioned something about HUS, but she said the specialist at Riley could explain it better once we got down there. I still do not know how our Dr got in touch with the person at Riley that she did, but I thank God for His hand in that today. The specialist she spoke with knew exactly what was causing Ashley's kidneys to shut down. As our Dr tried to explain to us what was going on, my brain shut down. All I could think about was that she said "dialysis" and not knowing exactly what that meant at the time and how scary it sounded. It was also scary when she said that the Lifeline ambulance from Riley was en route to take Ashley down there and that our Dr was transferring our care over to this specialist.

I thank God that she knew enough to call Riley. I thank God that she got a hold of the specialist at Riley who knew about this rare disease. I thank God that He made me ask about *E. coli*. And I thank God that He made me take Ashley into our pediatrician's office that day to ask about the blood in her stool.

It was Wednesday, September 13, 2006, at about 4:30 pm when the ambulance arrived at Community North to take Ashley down to Riley. Three paramedics came into the room with this special gurney just for children and began unhooking her from her hospital bed and transferring her to the gurney. She looked so small lying there. We were told that we could not ride in the ambulance with her, so we just had to stand there while they wheeled our baby away. She was very brave and went quietly with the strangers as they wheeled her into the ambulance and took the trip down to Riley.

We followed the ambulance in our car. It was a very quiet ride for my husband and I, each of us lost in our own thoughts. Each of us was trying to be brave and tried not to breakdown as we worried about what was wrong with our baby. We did a lot of praying, that was for sure.

When we got to Riley, we went straight to the ER where Ashley was. They were transferring her from the gurney to her new bed. They had to hook up all of the monitors all over again in her new bed, and then they had to insert a new catheter. I had to hold my baby down while they shoved the plastic tubing into her bladder again. I could do nothing to help relieve the pain and discomfort that they were causing. She just looked up at me and was probably wondering why her mommy was letting them hurt her like this.

At this time, Michael had to leave to go home because Isabella was at home with my mother. He could not wait any longer for the specialist, but I assured him that I would put Michael on speaker phone when the Dr did arrive.

The renal doctor on call, the one who spoke with our pediatrician, came in to talk to us (me in person, and Michael on the phone) about what was going on with Ashley. This was the beginning of our education about HUS and all of its ramifications. He described how in a small percentage of children, *E. coli* can cause Hemolytic Uremic Syndrome (HUS). He described all of the various implications it can cause in the body, from the brain, pancreas, kidneys, liver, etc. He explained that HUS can cause swelling in the brain resulting in mood changes, which was what was causing Ashley to be so inconsolable and angry. HUS was also affecting Ashley's pancreas, which was causing the vomiting, and obviously her kidneys, which were shutting down. He explained everything that could happen, even death. The main problem with HUS, he said, was that there was nothing that doctors could do to prevent it or to treat it once a child had it. The only thing that we could do was watch what it affected and then treat the symptoms. So, for now, all we could do was wait and see if her kidneys continued to shut down, and if so, we would need to put her on dialysis.

After he left and gave us time to digest, my husband and I were just speechless. We were terrified and did not know if our daughter was going to make it through the night. We prayed, called relatives, and then I settled in for a sleepless night in ER, and Michael to spend a scary night at home with Isabella and all of her questions. (Unbeknownst to us, this was to be our first of many of such long nights.) One thing I remember vividly is Michael telling me that as he was putting Isabella to bed that night she asked him, "Daddy, is Ashley going to die?" He answered her with tears in his eyes that, "No, God is going to keep Ashley safe."

The next day, Thursday, September 14, it was decided that Ashley's kidneys were not improving and that we were going to need to put her on dialysis to keep her alive. The type of dialysis that they preferred for HUS kids was peritoneal dialysis, in which a catheter is inserted into the peritoneal cavity. She was taken in for surgery, where they implanted the catheter, as well as a central line for her IV and her blood draws. Surgery took an hour, and all we could do was pace the floor and hope that she would come out of anesthesia ok. We had never before had to deal with anything like this in our life.

They called us to recovery after her surgery and a parent should never have to see their child lying semiconscious in a hospital cage, I mean crib. We were told that

Ashley would be transferred up to the PICU as soon as a bed opened up. We waited for 5 hours in recovery. Luckily, I guess, Ashley was so sick that she just slept through this whole ordeal. Michael and I were not so lucky. We had to stand by her bedside waiting.

They finally came in and announced that a room had opened up, so Ashley was wheeled into her new home-away-from-home; a tiny hospital room that could barely hold her hospital crib, a reclining chair for us to sleep in and all of her dialysis and medical machinery. It is hard to write all of the emotions and fears that we were feeling through all of this. It was just surreal.

When we first got to the PICU, because Ashley's problems stemmed from *E coli*, she was in isolation. That meant that anyone coming in and out of her room had to put on a gown, mask, and gloves. For an entire week, we had to make sure that she and the rest of the hospital was safe from any possible *E coli* contamination. Luckily, since we were living in the room with her, we did not have to wear the gloves, but all of our relatives did not get to have any skin on skin contact with Ash the first week. This was very tough on Grandparents who wanted to hold their little granddaughter's hand.

Another thing I remember vividly was that Ash was hooked up to so many wires, plus the IV, plus her dialysis line. I could not hold my child. I went for more than 2 weeks without being able to hold or comfort or rock my baby girl. This was the first time in the two years since we had her that I did not rock her to sleep. And then when I was able to pick her up, it was with all of those things attached to her and I could barely move away from her bed. But it was worth it just to be able to hold her and feel her little head rest on my shoulder.

The next 6 weeks were somewhat of a blur. It is hard to explain to someone who has never lived through something like this how time just seems to stop. In the first few days and weeks we watched Ashley go from being swollen with excess fluid, to too much fluid being removed and she looked like a skeleton. I remember how Michael would not even let me mention how skinny she looked and how sunken her eyes were because we were just so terrified of what that might mean. Our lives were consumed by nurses coming in every 2 hours to check vitals and draw tubes of blood. Every time Ashley would move in her crib, she would set off her monitor alarms, so we never got any sleep.

Ashley was on 24 hour dialysis while in the PICU. There was no doubt from any of our doctors that Ashley had HUS, but because there was nothing else to do but wait and see if her body got better, one of her specialists decided to run all of the blood tests he could think of to see if maybe he could find some other cause for her kidney failure. We think he wanted it to be something else that was treatable instead of just waiting and seeing. All of the tests came back negative. This was definitely HUS, and we would just have to see what would happen. They told us that most kids with HUS have their kidneys come back in a few weeks. They told us that they could not estimate when Ashley's would come back, but they did tell us that the longer she remained on dialysis, the more worried they became about permanent kidney failure. Again, nothing to do but watch and pray that her kidney function would return.

Our lives revolved around blood test results, and seeing how much, if any, urine she produced. We prayed for pee. Any tenth of an ounce was celebrated. It was maybe a month in before we even saw that much. But, finally, Ashley's kidneys did start to pick back up again. They slowly weaned her off of 24 hour dialysis by going from 6 exchanges with 4 hour dwells, to 4 times a day, the fluid dwelling for 6 hours.

At some point Ashley's kidneys started picking up a little more to the point where she could be off of the dialysis machine, and she was put on to a manual form of dialysis. This was with a contraption called the "octopus" because this is exactly what it looked like. All of Ashley's dialysis bags for the day, or a few days, were placed on this huge IV pole, and she would then be manually filled and drained every 4 hours. This was another challenge we had to learn to deal with. The good part was that she was now "mobile". The bad part meant that if we wanted to take her for a wagon ride, we had to drag her IV pole and this dialysis pole along, too. This was not a one-man job. That meant that the only time Ash could go for a "walk" was when both of us were there to help. But this was still a blessing. For the first time in over a month, Ashley was able to get out of her hospital room. This was the highlight of her day and ours.

Finally we got to the point where her exchanges were stretching out longer and longer, we could take walks for longer periods of time. I remember the first day that we actually got to take her outside for the first time in over a month. When it just got too cold and we had to come back in, I remember how I thought her little heart

would break having to go back into her hospital crib. A 2 year old should never have to be confined to a cage.

And have I mentioned all of the medications this poor little child had to endure? Because kidneys touch every function of the body, and because hers were not working, they were not doing a lot of their jobs correctly, like being able to clear potassium, or other critical jobs. So, Ash had to take terrible tasting medicines, and still does. We would have to hold her down while we squeezed this black ooze into her little mouth. I don't remember what that medicine was for, but it was awful. There will be more about current medications later.

When we got to the point where she could be on the 4 exchanges a day, they transferred us to the regular pediatric unit. At first we were excited about getting out of the PICU, and avoiding the every 2 hour check-ups by the nurses. We quickly learned how wonderful we had, in fact, had it. Going to the regular floor meant sharing a room. We had the horrifying experience of living in a Jerry Springer episode. Our roommate was an eight year old girl, who was actually very sweet. Unfortunately, she had a mother and a sister who were not so considerate.

Our girls have always gone to bed early, and then awoke very early. Ashley would go to bed about 6:30 or 7 p.m., and then she would wake up about 6 a.m.. Surprisingly we were even able to keep to a close proximity to this schedule in the hospital up until now. But now, we were living with extremely rude people who were not only awake until after 11:00 p.m. every night, but they also had countless visitors and were very loud. Poor little Ashley would finally just pass out at night because she was so exhausted. And of course, we never got any sleep because of them.

We lived through weeks of that hell. Finally another room opened up and we were able to move, but again, it was still a shared room, and their schedules were always different than ours.

Again, if you have never had a seriously ill child, it is hard to understand the strain that living in a hospital puts on you. You are, of course, worried sick about whether or not your child will make it through it all, let alone be normal again. But, there is also the strain of not getting any sleep. They do provide one chair that extends to be a "bed", but it is hard to sleep on it, especially when nurses come in every 2 hours, and her monitor alarms go off every hour or so. Then there is the minor detail of showers. I will say that Riley has the Ronald McDonald house, which was definitely a blessing. They had shower facilities that parents could use, so we did enjoy that.

And through all of this we had to balance the fact that we were also the parents of a 4-year old, who was not old enough to understand where her Mommy and Daddy were and why they had essentially abandoned her with her Grandparents. For the 2 months that we lived in the hospital, our 4-year old lived without us. We missed her so much, but the hospital was no place for her, plus she could not understand what was going on with her sister. We only got to see Isabella for a couple of hours each week. It was heartbreaking to have to say good bye to her each time she left again. I have it burned into my memory the sight of her staring out of the backseat window driving off with tears in her eyes. There is no way of knowing what affect all of this had on her. I do know that we are still dealing with the after effects of all of this. She still needs constant reassurance when we are leaving her that we will in fact be coming back. She is much clingier, and does not want us to leave her side.

Another aspect that we had to deal with was the fact that both Michael and I had full time jobs. There was no question that one of us would always be in the room with Ashley, so it was extremely difficult to balance it all. We had our computers with us, and we were able to work a little bit while Ashley was sleeping, but in the end both of our boss's had had enough. The biggest issue this has all had with respect to our careers, is that we are both relatively young and had plans to advance our careers. Now, this is not so easy.

When Ashley's dialysis got the point of 4 exchanges a day, her Doctor's felt comfortable with us going home. Michael and I went through several weeks of dialysis training at the hospital. We had to learn about care for the catheter exit site and how to give her shots several times a week (she requires shots of epogen because her kidneys do not properly control the production of new red blood cells). We also learned how to monitor her blood pressure.

But we were finally able to go home and get our family back together. Once at home, we were able to figure out our new schedule. Dialysis exchanges were done 3 times a day, blood pressure was checked twice a day, her daily medications were spaced out throughout the day and shots were on Monday, Wednesday and Friday. We also had to drive down to Riley every week for Renal Clinic. There we would have to have Ashley's blood drawn and see the dialysis nurses and the renal specialist.

Home dialysis came with several new worries. There was the constant fear of cleanliness and making sure our home was as germ free as possible, especially during exchanges. Then there was the new one of her blood pressure. Peritoneal dialysis uses fluid in the peritoneal cavity to filter out things that the kidneys normally would handle. A side effect of this is that the fluid can also be absorbed into the body. When there is too much fluid in the body, then blood pressure increases. We had one week where here bp spiked to 170 and we were right back at Riley for a weekend. That weekend we learned a lot about blood pressure and blood pressure medication. After that episode we spent a lot of time considering if Ashley seemed puffy and what dialysis solution we should use.

We were constantly struggling with maintaining her blood pressure with being on dialysis. We were also struggling with seeing a different renal specialist every week at clinic, depending on who was on call. We finally called Dr Andreoli, one of her specialists, and requested we meet with her specifically since she was the expert in this area. We told her of our frustrations with clinic and the lack of consistent care we were receiving because each doctor had a different idea of what we should do with Ashley's treatment. We discussed the problems we were having keeping Ashley's blood pressure in check with the dialysis. Dr Andreoli felt that maybe it was time to consider coming off of dialysis, since it seemed to be doing more harm than good with respect to her blood pressure. She said that we would just need to do more labs on Ashley every week as we started to wean her off to make sure her Creatinine could remain stable.

So, we began taking Ashley for blood draws twice a week to monitor her levels while we reduced the number of exchanges and then stopped them all together. (Let me tell you, trying to hold your child down while they stick a needle into her arm to draw out blood is an extremely painful task to ask of any parent and child.) So, even though her Creatinine levels are 3 times the normal limit for a child her age, Dr Andreoli said that did not need to remain on dialysis. She told us that the percentage of her kidneys that were working would learn to take over for the damaged parts. She told us that this would eventually wear her kidneys out and she will need a transplant, but she hopes that it won't be for many more years.

Ashley was on dialysis until the end of December. Even though she is off of dialysis, she will still be on medication the rest of her life. We also have to take her for blood draws every week to monitor her potassium and other levels. We have found that another side effect of kidney failure is a very strict dietary restriction of potassium, as well as other minerals. Her potassium levels are too high, so we have to monitor everything that she eats and drinks and she has to take a very disgusting, thick medication twice a day to remove the excess in her body since her kidneys cannot do it for her. So, our once healthy eater is now on an extremely strict diet that she, and for fairness to her, all of us are now on. Because her kidneys are not functioning properly, we have to maintain an extremely strict, potassium-limited diet. And potassium is in everything, literally. We just have to find foods that have less potassium than others. So, bananas are out, period. Avocados and chocolate are out. (Remember, this is a 2 year old we are restricting this from). What else? All leafy greens, melons, potatoes of any kind, dairy, yogurt, nuts, peanut butter, tomatoes and tomato sauce, and pizza to name a few. (Notice that most of these foods are a small child's favorites).

So every day, at the time this was written, Ashley takes four different medications orally everyday, and then we have to give her a shot every week. I am sorry, but parents should never have to hold down a 2-year old and force them to drink nasty, thick medications that make them gag and want to throw up. Nor should a parent ever have to hold a child down to stick a needle in their back side to deliver the necessary medications to make up for something their little body should just produce naturally. And as I mentioned before, we take her for blood draws every week, as well.

Ashley's condition seems stable now. The problem, and the constant cloud that is always over our heads, is that we don't know for how long. A kidney transplant WILL be required. That is a question of when, and not if. Michael and I spend a lot of time wondering how normal of a life Ashley will be able to lead.

IT is hard to put down in words all of the fears that go through our heads on a daily basis now. We worry about Ashley and her future. We worry about when her kidneys are going to stop working for good, and if she will ever be able to get married and have children of her own one day. Our doctor has told us that the stress of puberty and pregnancy are serious concerns for Ashley.

We worry about if she will grow normally. Because her kidneys do not function properly, her growth will always be an issue. We worry about numerous other complications and conditions that are brought about by renal failure. For instance, her PTH levels have been off lately, which is a measure that her Parathyroid gland not

working correctly. Her carbon dioxide levels have also been off, which means that something with the lungs "talking" to the kidneys aren't working right either. The kidneys touch every part of the body, so we now have constant fear and worry in our lives that we never expected to have.

We worry about what life is going to be like as she grows up and goes to school. We will always have to pack her a lunch now because she cannot eat most normal school foods. How is she going to feel while all of her other friends are eating pizza, and she just has to sit back and watch. We worry about how she will ever be able to play such sports as basketball, or even softball, because can we really afford for her to get hit and possibly damage one of her kidneys?

We were a family that enjoyed cooking and eating new foods. We like to try new flavors and dishes. That part of our lives is over. Ashley just cannot have most foods. We also like to travel and had planned to take the girls to many places. We wanted them to experience other cultures. At this point, I don't see that kind of travel happening.

Like we mentioned earlier, our careers have no been put on hold. Michael had begun a serious search that should have resulted in a big career move. This effort has had to be put on hold indefinitely. Michael and I will always have to weigh the pros and cons of moving jobs due to Ashley's now pre-existing medical conditions and that effect it will have on our insurance policies. We will always have to weigh job location and whether or not we will be able to have a renal specialist in the area. All career advancement plans have been put on hold.

We also talk about how we can try and get our lives back on track. A baby sitter for a night is not a luxury we are really able to enjoy. We are hopeful that this will be possible in the future, but her medications and general condition make this difficult. We cannot just use a neighborhood babysitter, because of Ashley's specialized care she now requires. Vacations are now are harder because we cannot be too far away from home in case something should happen while we are gone.

The only thing that we can do is focus on living day to day. Unfortunately, giving multiple medications and shots, and worrying about results of Ashley's blood tests are just a part of life now. We are hopeful that medical research will make things better in her future. We just pray that Ashley's kidneys can hold out for a few more years.

Mr. STUPAK. Your full statement is part of the record. It was a lengthy one, and I know everybody on the committee enjoyed the opportunity to read it. If you would like to have more time, you still have more time left, sir.

I am sure members will have questions, but thank you and thank you for being here.

Ms. Terri Marshall, if you would, please, for an opening statement.

STATEMENT OF TERRI MARSHALL

Ms. MARSHALL. The purpose of my testimony here today is to tell the story of what happened to my mother-in-law, Mora Lou Marshall, after she ate Peter Pan peanut butter contaminated with the Tennessee strain of salmonella. Our story is simple, and yet it is also very complex. It seems as though our lives are segmented into two time periods. There was life before Peter Pan peanut butter, and now we have life after Peter Pan peanut butter.

First I will briefly describe our lives before the peanut butter. My 85-year old mother-in-law moved in with our family in November 2006. At that time, Mora Lou was able to do very basic things like make her bed, shower, dress on her own, prepare her own breakfast. She read the newspaper. She loved flipping through magazines. She went to the beauty shop once a week, looked forward to that and was also able to ride in a car to go to the doctor or dentist for her appointments. She also enjoyed walking through the yard, coming to the table for dinner or even going out for meals or treats.

It was not unusual for Mora Lou to help with light household duties for which I was very thankful. She lived in my home; light dusting, folding clothes and loading the dishwasher. She kept in touch with her Little Rock friends and family by visiting with them on the phone or reading cards and letters.

Mora Lou kept a jar of Peter Pan Plus peanut butter by her bedside all the time. On her night stand in the room, she had it there as a supplemental way to increase her nutrition, with a spoon right there handy so she could have it. She would eat a spoonful or two several times a day or night just to supplement her nutrition. The reality is the very food she thought would improve her health began to ravage her body.

And on January 2, we entered our life after Peter Pan peanut butter. Mora Lou had severe vomiting, diarrhea and pain. We actually had to call an ambulance to transport her to the hospital because she was so weak we could not get her into the car. She couldn't stand. And that was the last time she was at home.

We first heard the news of the Peter Pan recall in February. I believe it was February 14. And my husband went to the nursing home where Mora Lou, his mother, had been living to check her Peter Pan. You see, she was back in the hospital at that time, so he had to go to the nursing home where we had to put her to check her peanut butter. And, yes, our worse fears were realized because the numbers did match the recall.

And then another fear struck us because we knew she had been eating this contaminated peanut butter while in the hospital and at the nursing home. And I'm sure a lot of the medical staff that were there attending to her could attest to her many requests throughout the day, "please get me another spoon so I can eat some more of my peanut butter."

The next week, a representative from the local office of the Department of Health in our parish called with the news that Mora Lou's lab report from January 3 testified positive for salmonella Tennessee. It was then the pieces to the puzzle began to fall into place. Mora Lou was on a vicious cycle of salmonella poisoning up until the recall, which was the middle of February.

We are now in a more advanced stage of life after Peter Pan. It seems Mora Lou has literally lost her life without even physically dying. She has been either in the hospital or the nursing home since January 2 with that hospital ambulance ride. She cannot walk, get out of bed, use the bathroom, shower, read the newspaper, look through her magazines, talk on the telephone, ride in a car. All those aspects of her former life are gone. Her nutrition is now supplied from a feeding tube. She can't swallow even those pureed foods that they give you or even drink water without aspirating most of the time. And I talked to my husband yesterday. She's back at the nursing home from the hospital. She tried to eat food yesterday, and she cannot keep it down. So more than likely they're going to increase her stomach nutrition.

The testimony I've given today is a very brief overview of what our family has experienced this year. We will forever be changed on how we purchase, prepare and trust whether the food we are buying is safe for us to eat. I will never eat peanut butter again. I hate to say that because I love it. And I won't feed it to any of

my family. It would take more time than I'm allowed in this forum to fully explain our challenges so I will close with this final comment.

The topic for this hearing is Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply? And I would change it to relate personally to our own experience to read: Mora Lou's Complete Incapacity: Can Anyone Prevent it from Happening to Someone Else? Thank you.

[The prepared statement of Ms. Marshall follows:]

TESTIMONY OF TERRI MARSHALL

The purpose of my testimony here today is to tell the story of what happened to my mother-in-law, Mora Lou Marshall, after she ate Peter Pan peanut butter contaminated with the Tennessee strain of Salmonella.

Our story is a simple one, yet it is also very complex. It seems as though our lives are now segmented into two time periods: life before the peanut butter and life after the peanut butter.

First, I will briefly describe our lives before the peanut butter. My 85 year old mother-in-law moved in with our family in November 2006. At that time, Mora Lou was able to do very basic things like make her bed, shower and dress on her own, prepare her breakfast, read the newspaper, or flip through magazines. She went to the beauty shop once a week, and was able to ride in the car to go to the doctor or dentist for her appointments.

She also enjoyed walking through the yard, coming to the table for dinner, or even going out for a meal as a treat. It was not unusual for Mora Lou to help with light household duties like dusting, folding clothes, and loading the dishwasher. She kept in touch with her Little Rock friends and family by visiting with them on the phone, or reading their many cards and letters.

Mora Lou kept a jar of Peter Pan Plus peanut butter on the nightstand in her room. She would eat a spoonful or two several times during the day or night to supplement her nutrition. The reality is the very food she thought would improve her health began to ravage her body.

On January 2, 2007, we entered our life after the peanut butter. Mora Lou had severe vomiting, diarrhea and pain. We called an ambulance to transport her to the hospital because she was so weak we could not get her in the car. That was the last time she was at home.

We first heard the news of the Peter Pan recall in mid-February. My husband went to the nursing home where Mora Lou had been living to check her peanut butter. And yes, our worst fears were realized because the numbers matched the recall. And then another fear struck us. We knew she had been eating the contaminated peanut butter while in the hospital and at the nursing home.

The next week a representative from the local office of the Department of Health called with the news that Mora Lou's lab report from January 3, 2007, tested positive for Salmonella Tennessee. It was then the pieces to the puzzle began to fall into place. Mora Lou was on a vicious cycle of salmonella poisoning up until the recall.

We are now in a more advanced stage of life after Peter Pan. It seems Mora Lou has literally lost her life without physically dying. She has been either hospitalized or in the nursing home since January 2, 2007. She cannot walk, get out of bed, use the bathroom, shower, read the newspaper, or talk on the telephone. All aspects of her former life are gone. Her nutrition is now supplied from a feeding tube. She cannot swallow even pureed foods or water without aspirating most of the time.

The testimony I have given today is a very brief overview of what our entire family has experienced this year. We will forever be changed in how we purchase, prepare and trust whether the food we are buying is safe for us to eat.

It would take more time than I am allowed in this forum to fully explain our challenges, so I will close with one final comment.

The topic for this hearing is "Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?" If I could change it to relate to our personal experience, it would read: "Mora Lou's Complete Incapacity: Can anyone prevent it from happening to someone else?"

Thank you.

Mr. STUPAK. Thank you, Ms. Marshall. And your full statement is part of the record. We appreciate your summary of it.

Mr. Gary Pruden and Sean.

Mr. Pruden, you're going to give the testimony.

Mr. GARY PRUDEN. Yes, I am.

Mr. STUPAK. OK. You're recognized, sir, for 5 minutes.

STATEMENT OF GARY PRUDEN

Mr. GARY PRUDEN. Thank you, Mr. Chairman.

I have the written statement that has been submitted. I will not go through that in detail, but I would like to highlight four points from this testimony to the committee this morning.

First of all, my son Sean is 11, and he contracted *E. coli* from eating at a Taco Bell in Brenigsville, PA, before the Thanksgiving break.

The first point I want to make is that it is very difficult to diagnose this in its early stage. The *E. coli* takes about 4 days to incubate in the human body before it takes effect. In exactly the 4 days after he ate, the symptoms began.

But the problem is, as a parent, you don't know what is going on. The child is vomiting. The child has diarrhea. And we are not doctors, we are parents, and we just don't know. And meanwhile, during this time, the sickness is developing even further.

I want to just make a quick point. Representative DeGette, you made a good point when you mentioned that we often want our kids to eat their vegetables. Well, at this particular Taco Bell, I have 2 younger kids who are very picky eaters, and my wife had to brush off all the lettuce and all that for them. I must say, it is one time I am glad that we capitulated to their needs. But Sean didn't; he ate lettuce, and he was infected.

For about a week or 2 weeks, Sean was very sick with diarrhea and vomiting, and occasionally it would get better, but it always resurfaced. And our family doctor, who we visited twice, simply saw this as a virus of some sort and gave him some shots of Fenegrin and such and really didn't know what the diagnosis was.

It got to the point where we had to take him to the emergency room. And that was prompted when the news reports of *E. coli* broke out at Taco Bell. We simply connected the dots and assumed that this was what he had. And those particular symptoms of course were the diarrhea and the vomiting. It also includes, your urine is very brown. I know that because my mother-in-law is a nurse and called us and asked about that when she heard of these news breaks. So we assumed at that point he had contracted it.

He was rushed to the Penn State Hershey Medical Center in Hershey, PA, by an ambulance, admitted and stayed there for roughly I believe 5 days. There is no treatment for *E. coli*. I have learned this. It is simply a matter of waiting it out. And you either can have dialysis and of course blood transfusions. Fortunately, in our case, Sean missed dialysis by about 4 hours. The blood work simply got better. But he was certainly in a very, very bad state in a hospital bed for 4 or 5 days, and we simply didn't know what the outcome would be. Fortunately, he did recover, although we are not certain what the long-term effects are at this point.

I would like to also point out in my testimony the effect this has on the family. This whole experience was very exhausting to myself and my wife. As a businessman, and it was very busy, I had to

take time away from my business. And certainly my wife was physically and emotionally exhausted as well. There was one point in the emergency room when Sean looked at my mother, and she was in tears because she simply had the guilt of not knowing and what should she have done. He looked at her and said: Are you OK, mom? And I thought that was a very striking moment for both of them.

Finally, I just want to make a few quick comments which is, in my testimony, regarding public oversight, and I will read directly from my testimony this morning.

A key element of successful commerce and trade is trust. We trust that the accountant hired to do our taxes is following the laws in preparing the tax return. And we trust that pilots are adequately trained to fly a commercial jet. And we trust that our auto mechanic is going to return our cars in safe conditions. That is also extended to the trust and food that we order or buy from a grocery store; that it is edible, and it is safe. Without this trust, commerce can't work. And where failure occurs oversight is required.

We are fortunate that Sean has recovered and is back to a normal life of school activities, baseball, friends and constant activities. It is my hope that this testimony this morning will help compel action to provide better controls and oversight of our Government officials and agencies responsible for public food safety. As consumers and citizens, we should expect and demand this. Thank you for allowing me to testify before you this morning.

[The prepared statement of Mr. Pruden follows:]

**United States House of Representatives
House Energy and Commerce Committee
The Hon. John D. Dingell (MI) - Chairman
Washington, DC**

**Subcommittee on Oversight and Investigation
Public Hearing: "Diminished Capacity: Can the FDA Assure the Safety and
Security of Our Nation's Food Supply"**

**Gary and MaryAnn Pruden
425 Lori Ann Court
Lebanon PA 17042**

**Victim Impact Testimony
Tuesday, April 24th 2007**

Summary Points:

- **Difficulty in diagnosing food borne illnesses**
 - **Symptom's and treatment of E-Coli**
 - **Effect on Family**
 - **Public Trust and Oversight**
-

**Victim Impact Testimony
Gary and MaryAnn Pruden
Tuesday, April 24th 2007**

**To: Distinguished Representatives -- Subcommittee on Oversight and
Investigations of the Committee on Energy and Commerce**

Thank you for allowing my son and me to participate in this hearing.

My name is Gary Pruden. I am the father of Sean Pruden who is here with me this morning. I would like to outline for you the sequence of events that led to a serious sickness my son endured after eating contaminated food at a Taco Bell restaurant and the subsequent impact this has had on Sean as well as our family.

On Wednesday, November 22nd, 2006, my wife MaryAnn, along with me and our three children, Sean (11), Emily (8) and Matthew (6) stopped at a Taco Bell restaurant in Brenigsville PA on our way to Upstate New York to spend time with family for the Thanksgiving holiday. The meal was finished quickly and we were back on the road to the Hudson NY area.

On Sunday morning, November 26th, we prepared to leave to go back to our home in Pennsylvania after attending mass at the local Catholic Church. Sean had indicated that he did not feel well and complained of stomach cramping and nausea and could not attend mass. We thought that he may have simply been over-tired but did note that he appeared very lethargic and unresponsive. It was unusual for Sean to miss Sunday mass. As an altar boy and an active member of our Church and school, missing mass for Sean was a serious episode. We assumed that he had a stomach bug of some sort and would probably be okay in another day or so.

The next morning Sean was feeling a little better but still had some stomach cramping. He attended school on Tuesday (there was no school on Monday) but was still not feeling 100%. Tuesday night he started waking up with frequent diarrhea and missed school the rest of the week. On Friday, December 1st my wife took Sean to our family doctor who concluded that he had a virus and ordered a bland diet. By Sunday December 3rd, Sean was feeling somewhat better and the diarrhea was less frequent. However the next morning, (December 4th) Sean's condition

dramatically worsened as he began vomiting frequently. My wife took Sean back to the family doctor on Tuesday, December 5th as our concern began to grow that he was becoming increasingly dehydrated. The Doctor examined him again and still concluded that it must be a virus. Sean was given a shot to control the vomiting. That evening, Sean's grandmother called and asked if we had eaten at a Taco Bell. She had heard some news reports of an E-coli outbreak in NJ and NY related to food eaten at the restaurant chain, and as a retired nurse familiar with the effects of e-coli, she was concerned about the symptom's her grandson was displaying, particularly the color of Sean's urine which was noticeably brown. My wife began to be suspicious thinking back to our trip to Upstate NY and our short stop to the Taco Bell in Brenigsville PA. We decided to take Sean to the local emergency room that night around 8:00 pm as Sean's condition continued to worsen. I stayed at home with our two other children anxiously awaiting word from my wife.

At the emergency room, the triage nurse took one look at Sean and had him stay within eyesight of her until she could get him admitted. She knew he was very sick just by looking at him and that his condition was deteriorating quickly. Finally he was examined by the ER Doctor and blood

was drawn and other tests were taken. He was placed on an I.V. When the test results came back, the Dr. explained that Sean was very sick and that his kidneys were shutting down. He wasn't sure of how to treat this and decided immediately to transfer him to a pediatric nephrology specialist at the Penn State Hershey Medical Center in Hershey PA about a half hour away. Sean was transferred via ambulance to the Hershey Medical Center at about 4:00 a.m. Wednesday morning where he was admitted to the Intermediate Care Unit.

Once admitted to the hospital, Sean had all kinds of tests and exams. When Dr. Wassner, the pediatric nephrology specialist, came in to see us he explained that Sean had acute hemolytic uremic syndrome (referred to as H.U.S.). H.U.S. is basically the body's reaction to being overloaded by toxins often following an E-coli infection. It was determined that Sean's kidneys were only about 20% operational and he was extremely anemic due to red blood cell destruction. There was very little that could be done at that point except to keep Sean in the hospital while waiting to see if his kidneys would recover. Blood transfusions and dialysis were likely and it would be a long road to recovery. If the kidneys did not recover, he would need a transplant. The average hospital stay for H.U.S. patients is

between 4 and 6 weeks. It was December 6th and Dr. Wassner warned that it could be a long road. At that point, we were hoping that Sean would be well enough to get a day pass to at least be home for part of Christmas. We tried to keep other thoughts out of our minds.

Sean was hooked up to an I.V. as well as a heart / blood pressure / oxygen monitor during his hospital stay. He had blood drawn on a regular schedule day and night. He was too sick to do anything and seemed very distant and helpless. Thursday, Sean had to be scheduled for dialysis the following morning to give his kidneys a break. He wasn't allowed to eat or drink after 10pm that evening. This proved to be very difficult as Sean was very thirsty due to being dehydrated after five days of not keeping any food or liquid down. Amazingly on Friday morning Sean's bloodwork showed signs of kidney stabilization and dialysis was postponed for a possible Saturday treatment. If his tests showed improvement on Saturday, there was a chance he could come home that day. Once again, it was a long night without being able to drink anything, but we were hopeful about the next day. On Saturday his labs showed stabilization and the dialysis was canceled but his red blood cell count had continued to deteriorate and a blood transfusion was necessary. He would have to remain in the hospital

at least one more night. After the transfusion Sean did feel somewhat better. By Sunday afternoon, his blood count had stabilized and his kidney function had increased to 50% so he was allowed to come home. Follow up care was scheduled with both a pediatrician and his nephrologist. Sean's doctors and nurses were amazed by his quick recovery considering the severity of his condition when he was admitted.

Sean has continued to improve and as of his last nephrology appointment in March, he was not required to return unless complications develop. He is to continue to have his blood pressure monitored yearly for at least the next five years. It is imperative that Sean always indicate on his medical records that he had H.U.S.

The local hospital where the initial tests were taken confirmed that Sean had tested positive for the E-coli virus. E-coli has about a four day incubation period in the human body before the painful effects begin to surface. We had eaten at the Taco Bell restaurant on a Wednesday, and by Sunday morning, the symptoms began. There was no question in my mind, with all the news reports of the breakout in the NY and NJ areas that this was the cause of Sean's illness.

This incident has most definitely affected our family. My wife often lamented how helpless she felt watching Sean lay in the hospital so sick. We were aware that he could actually die from H.U.S. and this was too much to handle. My wife would later comment of the guilt that she felt for not getting him to the emergency room sooner. During the long stay in the emergency room with Sean, she recalled being upset and in tears while they waited. Sean, as sick as he was, looked at his mother and asked if she was alright (emphasis added). There are many other poignant moments that are too lengthy to include in this testimony.

Since this entire episode, we have been very reluctant to eat out anywhere. I used to think that food poisoning was a problem of undercooked meat. But now, I am more concerned about non cooked food (ie, salad, fruit, etc.) at any restaurant or even our local grocery store.

A key element of successful commerce and trade is trust. We trust that the accountant hired to do our taxes is following the laws in preparing a tax return. We trust that pilots are adequately trained to fly commercial jets. We trust that the auto mechanic is competent and will return our car in

better and safer condition. And we trust that the food we order at a public restaurant is edible and safe. Without this assumption of trust, commerce cannot work. And where failure occurs, oversight is required.

We are fortunate that Sean has recovered and is back to a normal life of school activities, baseball, friends and constant activities. We are fortunate that he is young and resilient but others may not be as lucky. It is my hope that this testimony here this morning will help compel action to provide better controls and oversight of our government officials and agencies responsible for public food safety. As consumers and citizens, we should expect and demand this.

Thank you for allowing me to testify before you this morning.

St. Joan's student beats serious illness



Sean Pruden, a sixth-grade student at St. Joan of Arc in Hershey, was hospitalized at Penn State Milton S. Hershey Medical Center with e-coli recently, but has since made quite a recovery.

Pruden makes rapid recovery from e-coli

A Christmas miracle came early for the Pruden family this year.

Sean Pruden, a sixth-grade student at St. Joan of Arc School, became seriously ill with e.coli and was hospitalized at Penn State Hershey Medical Center. He was sick with stomach flu symptoms before the diagnosis was made that he in fact had the sometimes deadly e.coli.

His kidneys were not functioning properly and his blood counts were so low that doctors said he could be hospitalized for at

More PRUDEN on page 3

PRUDEN

Continued from page 1

least four weeks. When his friends at school heard the news, the entire school stopped and prayed together for him. The children made cards, signs and wrote songs for Sean. A prayer chain was started and St. Joan's families collectively prayed for the sick boy.

Sean's parents, Gary and MaryAnn Pruden, recently moved from Kansas to the area with their three children, all of whom attend St. Joan's School. They were overwhelmed with the outpouring of love and prayers from the school and parish of St. Joan of Arc. What was looking like a Christmas season in the hospital with their son, turned out to be a Christmas filled with miracles.

Sean started an astounding recovery. He read the cards from his classmates over and over and was humbled by the prayers and concern shown to him. His parents believe that the prayers made the difference in his recovery. Sean was scheduled for dialysis for his kidneys but the next morning his numbers improved to the point where it was not needed. His doctors were amazed and said he was getting better.

"The doctors said that Sean's rapid recovery cannot be due to

SISTER EILEEN MCGOWAN:

"The doctors said that Sean's rapid recovery cannot be due to their treatment alone. What Sean did in 2-4 days generally takes 2-4 weeks. The power of prayer just cannot be overestimated."

ST. JOAN'S
PRINCIPAL

their treatment alone," Sister Eileen McGowan, St. Joan's principal, said. "What Sean did in 2-4 days generally takes 2-4 weeks. The power of prayer just cannot be overestimated. Being in a Catholic school enables us to pray for those in need, together as a community. It's a wonderful blessing that we could pray for Sean."

Sean recently returned to school and continues to be prayed for. He is weak but very happy to be back with his friends. He and his family want to thank everyone for their prayers and love and wish their new family at St. Joan of Arc a very Merry Christmas.

the superintendent's office short-

Mr. STUPAK. Thank you, Mr. Pruden.

Sean, did you want to add anything.

Mr. SEAN PRUDEN. Nope.

Mr. STUPAK. OK. Playing baseball, Jose Reyes, 14 homers and hit another one last night; is that pretty good?

Mr. SEAN PRUDEN. Yes, very good.

Mr. STUPAK. We begin with questions.

Mrs. Armstrong or Mr. Armstrong, whoever purchased the spinach. I have one here. It is not spinach, but it is the spring mix. And it says right on here that it is field fresh and ready to eat. Did you ever think that someone would test it to make sure that it was good before it went from the field to your dinner table?

Mrs. ARMSTRONG. Well, I felt that if they said that it is ready to eat, then I assumed that it was safe and that they have done everything in their power to make it so. I trusted that it was safe.

Mr. STUPAK. Mr. Armstrong.

Mr. ARMSTRONG. In fact, the bag we purchased said it was triple washed and ready to eat.

Mr. STUPAK. OK. Did you know what triple washed meant? And you're right, it does say on here—this one here says completely washed.

Mr. ARMSTRONG. I think it means nothing actually.

Mrs. ARMSTRONG. Now we know it means nothing.

Mr. STUPAK. Now you know. Hindsight.

Mr. ARMSTRONG. Right.

Mr. STUPAK. Let me ask this question. In your full written testimony you talked quite a bit about how your life has significantly changed and how Ashley's life will significantly be changed. There are many foods now she cannot eat. And the whole family's diet has changed, such as chocolate, pizza, other foods kids normally eat at home and at school. Could you talk a little bit about how this has changed your eating habits? Not just for fear of being sick, but how has this illness caused the whole family diet to be off and what's your future like as a young growing person?

Mrs. ARMSTRONG. We always enjoyed eating very healthy. We loved fresh fruits and vegetables. Now we can't eat them, one, because of Ashley's illness. We have to watch the high potassium content. But also we just don't trust that they are safe any more. There have been no changes made to the way things are processed or packaged. So there are no guarantees that the food we're eating is safe. So we just have no faith that it is safe, so we just choose not to eat it.

Mr. STUPAK. Let me start with Mr. Pruden, Ms. Marshall and then we'll go back to the Armstrongs.

We have Members of Congress here. We are investigating this thing. We will have FDA here in a couple of weeks. What would you like us as policymakers, what's the one thing you would like to leave with us as policymakers that we should be doing here on food safety, pet safety, because the next panel has some pet foods, an incident we have had? This is just from this one valley alone the 20th outbreak in the last 10 years.

Mr. GARY PRUDEN. I would say in many of the opening remarks, you hit on what is really key. And that is the needed consistent oversight and kind of manage that with the funding that is also

available. But it seems that these outbreaks occur, and there are a lot of press releases on them, and people get all up in arms, and it drops. And then 6 months later, a year later, it is going to happen again. I am here to tell you it will happen again. You will see it in news reports in a couple weeks maybe, who knows. I think that I would personally like to see more consistent oversight and more coordination between departments.

I would also add that is required at the State and county level as well. I did not see a lot of coordination with the health departments in the State of Pennsylvania on this. There was some big operation in Montgomery County and in Lehigh County where our outbreak was. I didn't see coordination. So I think that is the key, is coordination and consistency.

Mr. STUPAK. Ms. Marshall.

Ms. MARSHALL. I think one of the things that concerned our family is that the January 3 lab report from the hospital said salmonella. I don't think at that point it said Tennessee, that it was attached to that. We never heard the words salmonella at all until February 23 when the Department of Health called my house and inquired as to whether my mother-in-law was better. And I said, well, in fact, she's still in the hospital. And they wanted to know if anybody in the family was sick. And I still was a bit confused. And I said, why are you asking these questions? And she said, your mother-in-law has been diagnosed or the lab report says salmonella Tennessee. And that was our first time to know. That was some 9, 10 days after the recall that we heard that word. Had we heard salmonella, not even with the attached Tennessee word with it, the first week in January, we would have started a method of isolation to see what food had she eaten that the rest of the family had not eaten. It would have been so easy because she is the only one in our house that ate Peter Pan Plus peanut butter. I would have immediately pulled it. She would not have continued to eat it in the hospital for those periods of the weeks following up until the recall in the middle of February.

So I guess to answer your question, if there was a way that anyone who tested for salmonella, that it had to be reported somewhere on either a local, State or national level so that then, obviously, we didn't get the information from our hospital, but it would be a requirement that just that word itself triggered something that would then say, this is a problem, we need to figure out what is contaminated in that Marshall family home that needs to be pulled. And we could have taken appropriate action. We didn't pull it until ConAgra and Peter Pan came out and said, pull it. We would have pulled it a lot sooner. So I don't know what could be done to actually make that happen.

Mr. STUPAK. Notice, then, is what you're concerned with?

Ms. MARSHALL. Exactly. More immediate notice when that salmonella test comes up on a report.

Mr. STUPAK. Mr. Armstrong.

Mr. ARMSTRONG. You can see, these are my little girls. And I am their dad, obviously. And it is my job to protect them and my job to make sure they get a good education; they learn right from wrong and that I teach them everything I can. But the one thing I found out is that I can't protect them from spinach. Only you

guys can. You can protect them. I can't. And I don't know what the right answer is, but I know what the wrong answer is. And that is to keep doing what we are doing when it is not working.

Mr. STUPAK. Thanks. You mentioned your cousin, the unfortunate loss of your cousin from the same thing, HUS. If that would never have happened, do you think you would have triggered this thought of *E. coli* in Ashley's illness?

Mr. ARMSTRONG. I don't think so. Who knows what would have happened there. I don't think it would have been as positive an outcome if we hadn't thought of it.

Mr. STUPAK. Thank you. And thank you for sharing your story with us.

Mr. Whitfield for questions please.

Mr. WHITFIELD. Thank you, Mr. Chairman. We appreciate the testimony of all three families very much today. One of the questions that I would like to ask, in this process, and I would just ask all of you, did you ever have any discussion with or contact with the Centers for Disease Control or the Food and Drug Administration or local health authorities? Now, I think, Ms. Marshall, you said you had local health authorities contact you?

Ms. MARSHALL. Yes. Late. It was February 23. The reason I remember that, it is my son's birthday. And that was the afternoon that the call came. Again, I said I was confused because I really didn't know what the purpose of the call was. And she was mainly calling to inquire was anyone else in the house sick. And of course, the sickness from my mother-in-law had been going on since January 2.

Mr. WHITFIELD. And they called because they had received the medical reports?

Ms. MARSHALL. That's correct. They had a lab report. I guess something from the Centers for Disease Control. But I have not heard from anyone on a national level, no.

Mr. WHITFIELD. Mr. Pruden, what about your family?

Mr. GARY PRUDEN. I reached out to the county health department where this outbreak occurred and was compelled to do that only from basically the news reports of this outbreak with Taco Bell in the northeast, particularly in New Jersey and eastern Pennsylvania. So I did reach out to them and explained to them, it seems to make sense that this is a connection. And I don't know that I saw the proper follow-up.

Mr. WHITFIELD. But your mother-in-law is a nurse; is that correct?

Mr. GARY PRUDEN. That's correct.

Mr. WHITFIELD. And she told you that Taco Bell—

Mr. GARY PRUDEN. That's correct. She heard it on the news, and she said, I think at that time, she said, check his urine, and if it is brown and you got all the symptoms, you better get him to the hospital.

Mr. WHITFIELD. Mr. And Mrs. Armstrong, it is my understanding that it took quite a while for them to really diagnose the problem with your girls; is that correct?

Mrs. ARMSTRONG. It took a while for them to figure out where the kidney failure was coming from. The blood tests—

Can you talk?

Mr. ARMSTRONG. It took quite a while. Like I said, it took several days to actually diagnose HUS. And after that, it took several days to figure out what the source might have been. We didn't know it was spinach. Kind of went through the list of the past fast foods and et cetera. But it took probably another week before we started zeroing in on the spinach.

Mr. WHITFIELD. But this occurred in August of 2006. And I am assuming this Isabella seems to be doing relatively well. And Ashley is the one that is still having some significant issues; is that correct?

Mr. ARMSTRONG. That is correct.

Mr. WHITFIELD. And so she is—how often do you take her to the doctor now?

Mrs. ARMSTRONG. Right now it is every 6 weeks. We have extensive blood work that has to be done.

Mr. WHITFIELD. Well, thank you all very much for taking time to be with us today, and we genuinely appreciate your testimony.

Mr. STUPAK. Ms. DeGette for questions.

Ms. DEGETTE. Thank you very much, Mr. Chairman.

I think that Ashley and Isabella are both candidates for future congressional careers, they are so personable.

And Sean, I think that you are going to be doing all the high tech for some company. So listening to this today, it seems like we have issues with the reporting on both ends. Listening to all of your personal stories, here you have an 85-year old mother-in-law who seems to be declining physically, which happens with 85 years old. Here you have three young children who have what appear to be viruses which kids get all the time. And it is really hard for parents to detect. And it is also hard for parents to figure out, or children, any families, to figure out, is your family contaminated? I was thinking about the spinach. And in fact, I don't buy the prewashed lettuce. I only buy the prewashed spinach because it says "triple washed" because I hate to wash spinach. And so you just don't know as a parent. And you can't be expected to be a diagnostician to find some kind of advanced condition. So this is the thing. Right now, staff tells me, for an outbreak of *E. coli*, for example, to be detected, what has to happen is the doctor has to order a stool sample to go to the lab, which then goes to the county health department, which then goes to the Centers for Disease Control in Atlanta. And about one out of every 20 or 30 of those are actually reported. And so the first thing is we have no mandatory reporting by the food processors to the FDA that there's some problem. So if ConAgra, for example, with this peanut butter had found salmonella in that peanut butter, there's no requirement that they have to report that to someone.

Ms. Marshall, I would assume you would agree with me that it would be a good idea if that would happen.

Ms. MARSHALL. If I had known prior to her illness that that salmonella was a problem in that brand of peanut butter, it would have been a huge red flag that that was what was making her sick. And possibly we could have prevented her from being totally disabled now.

Ms. DEGETTE. Right. And then the second thing that happened, when the FDA investigators actually showed up at ConAgra,

ConAgra refused to give them their records, which that sounds really outrageous, too, to me. You are nodding, Ms. Marshall.

Ms. MARSHALL. Well, one thing that is interesting to us, my husband requested medical records for the hospital stay in January. And he picked them up. And it was just a short stack, which I thought was a little interesting because she had been there so long. And I said, flip through there and find the report that says salmonella. It wasn't there. And he called the hospital, medical records, and they said, oh, well, here it is right here. So I don't know if that has anything to do with anything, but it just was odd that out of that whole stack of papers the very piece of paper we wanted to see that we had been told by the local health department was there was not there. We did eventually get a copy of it.

Ms. DEGETTE. Well, and this is the last question I want to ask all of you. And I want to start with you, Mr. Pruden. We seem to be relying—you said and actually everybody said, you put two and two together when you saw the news accounts of the Taco Bell recall. We seem to be sort of relying on parents or kids, relatives' deductive reasoning, looking at news accounts and figuring out, oh, that is what is wrong with my kid. If you hadn't known about those news accounts, do you think that Sean's problem would have been clearly diagnosed the way it was?

Mr. GARY PRUDEN. I don't think it would have. I think eventually we would have continued to go back to our family doctor. But again, his diagnosis was, it is a virus. I think it is simply common sense. At some point, you have to connect the dots. And I am afraid that sometimes you get caught up with some of the bureaucratic activity with either the State or Federal level, and it doesn't seem to go anywhere.

Ms. DEGETTE. A better reporting system, as you said in your testimony, would clearly help families to put two and two together without just having to rely vaguely on media accounts.

Mr. GARY PRUDEN. Correct. A coordinating reporting strategy.

Ms. DEGETTE. Ms. Marshall, do you agree with that?

Ms. MARSHALL. I do agree. In our case, it would have made the difference of whether she is going to live or die.

Ms. DEGETTE. What about you, Mr. And Mrs. Armstrong?

Mr. ARMSTRONG. I would agree with that. In fact, we ended up tracing the SKU number ourselves from our receipt all the way back through the distribution chain. And we did that all ourselves.

Ms. DEGETTE. Maybe we will give you some high level job at the FDA. Thank you very much for your testimony.

Mr. STUPAK. Thank you, Ms. DeGette.

Mr. Burgess for questions.

Mr. BURGESS. Thank you, Mr. Chairman. I don't know that I have a lot to add over what has already been asked, except my children are now in their 30s, and I would just like to know how you get girls age 5 and 2 to eat spinach. I never had much success.

Just because of my interest in clinical matters, what did they say to you was the reason for the delay in onset in your younger daughter, in Ashley's case, with the symptoms that she eventually came down with? There was a 5-day delay between Isabella's symptoms and Ashley's symptoms?

Mrs. ARMSTRONG. We were told that *E. coli* can take up to 2 weeks to start showing effects on the body.

Mr. BURGESS. But their time of exposure would have been identical, both eating at the same meal?

Mrs. ARMSTRONG. Yes. It could have been maybe that her immune system was stronger at first. I have no idea.

Mr. BURGESS. Of course the witnesses in front of us today show us the particular vulnerability. It is not the same bug necessarily in every case, but individuals who are very young and individuals who are very old are the most susceptible to these problems.

Ms. Marshall, following your testimony, which State was your mother in? Of the 50 States, what State?

Ms. MARSHALL. She was in Louisiana. She had moved in with us.

Mr. BURGESS. I confess to you, I don't know. I know from years of practicing in Texas, there are a number of illnesses that are reportable conditions. And there is contact information and verification it goes through. Generally those are illnesses that are transmitted sexually. I don't know whether in your case it would have made a difference had the State had a reporting mechanism in place. Your story is the fact that she was continually fed the product that was causing the problem; I'll just tell you from a practitioner's standpoint, I can't imagine anything worse. It is tough enough when everybody else in the community has viral gastroenteritis, and the child with toxigenic *E. coli* comes in. Here in Washington, before I got here, the anthrax outbreak where the information was not disseminated quickly enough and the emergency room doctor missed the diagnosis on a gentleman from the Post Office who eventually died of that disease. And those are tragic terrible occurrences. But as bad as those are, they don't even compare with setting the jar of peanut butter by the hospital bed and continuing to spoon the poison into the mouth of the patient you are trying to get better.

Ms. MARSHALL. It was horrible. When my husband went to the nursing home to pull her jars, one was almost completely eaten, and one was not opened. And the reason that she was not there to see him pick up her peanut butter from the nursing home, she had to be taken back to the hospital. They had found her unresponsive in her room.

Mr. BURGESS. And were those products themselves tested in the confirmation that the salmonella was present in those?

Ms. MARSHALL. They were not. That was prior to the call from the Department of Health. So we did what they said to do in the media, take your peanut butter back to the grocery store where you bought it. And we did have them—we had to sign a receipt that we returned it. But because the Centers for Disease Control had a report that said salmonella Tennessee, she is one of the 400 that has been identified as having that. But, no, we did not have the product. We did what the media told us to do. We trusted what we were hearing in the news; take it back, throw it away. If you want to throw it away, here's how to do it. Because we never connected that that is why she was sick, didn't think it was an issue.

Mr. BURGESS. Well, this is of course a process that continues to improve. Mr. Inslee mentioned the difficulties that occurred with *E. coli* and ground beef back in 1992 and 1993, and those were tragic

occurrences. Different handling of the product now has resulted. We don't hear of those cases any longer. And I suspect there will be some further improvements. There of course was the story with the strawberries out of Mexico, and I don't remember the year, 1995 or 1996, with cryptosporidium on them. The microbes that perplex us as humans, there is no end to their creativity in the ways that they find their way into our environment. I think the ongoing work of this committee, to ensure that when problems are developed, and perhaps even preventing some problems that might occur in the future, has to be our goal.

But as I said in my opening statement, we are never going to live in a world that is 100 percent safe. And it is incumbent upon all of us to be vigilant. That is why I really appreciate you guys sharing your stories with us today, because by doing so, you are going to alert families across the country of things that might not have come up in the course of their normal conversations at home.

Thank you, Mr. Chairman. I yield back.

Mr. STUPAK. Next. Ms. Schakowsky for 5 minutes for questions.

Ms. SCHAKOWSKY. Thank you. I agree with Dr. Burgess that we are never going to make the world completely safe. But a friend of mine, Nancy Donley's son, died in 1993 from that ground beef *E. coli* presence and created an organization at that time, Safe Tables Our Priority, STOP, and the idea was that there are actually things that we can do. And you have pointed up some things today I think that beg for addressing. Ms. DeGette talked about mandatory recalls. At the time, Nancy Donley was talking about not voluntary recalls, but voluntary recalls. And she was working with our Senator, Dick Durbin from Illinois, on creating a central food safety agency that would consolidate all of the different parts. So we don't have to worry, well, meat, is it under USDA or is it under the FDA or Interior Department, all these different agencies? And the timeliness of the reporting is definitely an issue.

But I also want to tell you that ConAgra, who made the Peter Pan peanut butter, has actually—and we have the documents, our staff has done a good job—has instructed in their manual, instructed employees, quote, to answer only to direct questions—this is for FDA inspectors—only to direct questions. Never volunteer information or elaborate on answers beyond basic questions. And it says, quote, as a rule of thumb, it can be stated that the inspector will generally request to see more than is authorized by law.

And then a really troubling procedure, which I intend to ask them about later, it states, I am quoting from their own reporting, FDA inspectors are generally not, capitalized and underlined, entitled to the following: If the inspector insists on any of the following and he is not claiming to be acting under the authority of the Bioterrorism Act, ask that he direct a written request to the corporate office in Irvine.

And what are those things? Codes, which I know you had to work a long time to try to discover. It says: However, we do supply copies of all our codes to FDA regional officers, and inspectors should be referred to their regional office to obtain a copy. Records: This includes quality control records, examination records, warehouse records, production records, consumer complaint records, plant locations, distribution center locations, product formulae,

product specifications, photographs, except State inspections in California, Wisconsin, names of suppliers. I am going to ask them if that is a correct reading of their instructions, but it sure sounds to me like there is an effort to hide information from those who would get it. I just wondered if you had any comments or any other suggestions of obvious holes that made your loved ones, made you, Sean, ill?

Mr. GARY PRUDEN. It is easy in hindsight to look back and try to find those holes. I don't know what could have been done to prevent this. Again, I go back to the fact that you have a situation that to the average American citizen looks pretty suspicious. I have an outbreak in a county here. I have one here, and he happened to be at a Taco Bell in a county right next to it, but none of those Taco Bells were shut down. And it was confirmed that he had it. I don't know that—

Ms. SCHAKOWSKY. Because it was in the neighboring county?

Mr. GARY PRUDEN. Yes, I believe that to be the case. I don't know that for sure. But, again, when I explained the circumstances to the county health department I said, you realize you got these in Montgomery County, which is just south of Lehigh County and over in New Jersey?

Ms. SCHAKOWSKY. And you didn't have to report it, right?

Mr. GARY PRUDEN. No. That is the point, I did not have to but felt compelled to do that.

Ms. SCHAKOWSKY. Well, I just think this has been such valuable testimony, and I really want to thank you and wish all of you the best. I know that there are ongoing issues that you are going to have to deal with. And I am so sorry about your mother-in-law, which sounds like this is not necessarily reversible. So I thank you very much, all of you.

Mr. STUPAK. I thank the gentlelady.

Mr. Burgess and also Ms. Schakowsky brought up the meat situation. Last year we had a situation on the Floor that actually went to a vote where the FDA has allowed manufacturers to put carbon monoxide into meat to extend the shelf life and to make it look fresher and redder so consumers would buy it, because that is what we base our appearance upon. It looks like a nice fresh looking piece of meat. But you extend the shelf life which then runs the threat of greater exposure to *E. coli* if not properly taken care of. So the FDA seems to be going backwards allowing more things that are questionable on a market shelf longer with things like carbon monoxide. Unfortunately, we ran an amendment to try to stop that from happening, and we lost on sort of a party line vote.

So there has been a lot going on in food safety and that is why your testimony is so important to bring this home to us.

Mrs. Blackburn for questions please.

Mrs. BLACKBURN. Thank you, Mr. Chairman. I am going to be very brief because our witnesses have been so incredibly patient, and we do appreciate so much of what they have had to say. I know last October I think it was, we sent a letter to the FDA to begin a conversation looking at the safety and with concerns about the safety of our Nation's food supply. I think that this points out when we need to do it. It also points out a couple of other things

that, Mr. Chairman, I hope that we will continue to consider as we move forward in our work.

Number 1 is the lack of a reporting process for consumers and also for the industry. We don't have a standardized process that we follow or expected steps that we would follow.

The other is for consumer education and awareness. And this is something last fall that we talked about some as we looked at food safety and the expectations of that.

So to our witnesses, I thank you for your patience and your willingness to be with us this morning. We hope that everyone will see a recovery and that there will be no long-term or ill effects. And again, we thank you for your testimony. And with that, I am going to yield back so that we can continue with our hearing.

Mr. STUPAK. Thank you.

Mr. Inslee for questions please, 5 minutes.

Mr. INSLEE. Mr. Armstrong, I just want to tell you, as one father to another, we discovered a new thing today, that the one thing about *E. coli*, it could lead to irresistible cuteness, too, I can tell you that. That is the one bright side of this whole thing.

The way I look at this, and I think, Mr. Armstrong, you said with great eloquence, essentially Congress is *in loco parentis*. We have got to be the parents in a sense for our kids in our food steps. And I appreciate you saying it that way.

I will be working on a bill that its thrust is to prevent the contamination from starting in the first place. We've talked a lot about notification after the contamination gets out there which are important things. But I want to be focusing on preventing the contamination from getting into the food chain in the first instance. I think you may have heard me talking about it; there are four things we need. We need to make sure these things are enforceable standards, not just wish lists to make sure this contamination does not occur. We've got to make sure the industry adopts what the meat industry did, which is to identify the hazard points and then reduce and eliminate them. We have got to prevent this adulteration and make sure we have civil and criminal penalties for it. Fourth, we have to have mandatory recall authority.

Now, this won't surprise you that sometimes when you propose things like this the industry doesn't like to kind of, quote, be told what to do. But I think these are some reasonable proposals. And I just would invite your comment about what you think we ought to, if the industry resists this, what should we tell them. What would be your response to their assertion that if this costs them some money, that these are things they shouldn't be required to do?

Mr. GARY PRUDEN. I certainly understand that that would be a natural reaction from industry. Though I think that in the long-term, any business is better served by partnering in situations like this to prevent situations up front before they happen. Public companies or private companies have much more responsibility today than just broad profits and growth. It is a more broad range. There are a lot of tentacles. And I think there has to be some education and awareness to many companies that you are better served in the public by working with agencies to prevent up front these things from happening. There can be a lot of good out of that. And

yes it is costly, but certainly the public image of your company will be enhanced for the long term.

Mr. INSLEE. Mr. Armstrong, did you want to add something?

Mr. ARMSTRONG. Yes. Actually, prevention I think has got to be the No. 1 priority. I think we heard here today a lot about information, however, after the fact. After the fact, I think, is important because the measurement of what is going on, the information getting out, in my opinion is a very strong argument for prevention. Because if the truth is in fact told, if information is available, I don't know how these industries can be profitable if nobody is going to buy their product. If the information was available, I don't think anybody would buy their product.

Mr. INSLEE. I want to give you confidence. I think something will come of your efforts today. I have seen that in the meat industry, where people stood up and were counted and really helped clean up that industry. And I know you have been working with Mr. Marler, who has worked with the meat industry to adopt some of these measures that reduce the incidence of people being poisoned like this. I just want to you give you some confidence that your coming here today, I hope, will result in some good things. We have seen it in meat. Now we need to extend it further. So thanks for your work. Take care.

Mr. STUPAK. Mr. Armstrong, if I may, you said you tracked your package all the way back; right, your spinach?

Mr. ARMSTRONG. Right.

Mr. STUPAK. And it was Dole brand; right?

Mr. ARMSTRONG. Yes.

Mr. STUPAK. I'm taking a look at this one here that we purchased in this area last night. And again, this is spring mix. But it says on the back, distributed Salinas, CA, product of USA and Mexico, processed in USA. Now, did you track yours back to Salinas Valley, your spinach?

Mr. ARMSTRONG. What we did is we tracked our spinach back to the same SKU number. And that batch had been tested positive for *E. coli*. So I think it was from Salinas Valley, but that is how we were able to trace it back.

Mr. STUPAK. Salinas Valley is California, and you live where?

Mr. ARMSTRONG. Indianapolis, Indiana.

Mr. STUPAK. Mr. Pruden, did anyone ever tell you where the lettuce came from, which part of the country or world?

Mr. GARY PRUDEN. No. It was only from news reports, it probably came from southern California through a distributor.

Mr. STUPAK. And that was purchased in Pennsylvania?

Mr. GARY PRUDEN. Correct.

Mr. STUPAK. And the best you know from news reports, it came from California?

Mr. GARY PRUDEN. That's correct.

Mr. STUPAK. Of course, Ms. Marshall, we know yours came from Georgia?

Ms. MARSHALL. That's correct.

Mr. STUPAK. Any other members have any further questions before we let this panel go?

On behalf of the full committee, and members have been in and out because we meet with constituents, we have other hearings. Ac-

tually there is a Telecommunications Internet Subcommittee hearing I am supposed to be at, but this hearing is a little bit more important, so Members are back and forth. But we appreciate your testimony. Your full statements are part of our record. Thank you again for putting a human face on this illness that Americans face each and every day. Thank you for being here. We will dismiss this panel.

Mr. STUPAK. Our second panel, if they would come forward, please, is Dr. Anthony DeCarlo of Red Bank Veterinary Hospital, and also Ms. Lisa Shames, acting director of the Natural Resources Environment at the Government Accountability Office, GAO.

It is a policy of this subcommittee to take all testimony under oath. Please be advised that witnesses have the right under rules of the House to be advised by counsel during their testimony.

Dr. DeCarlo and Ms. Shames, do you have counsel with you today for today's testimony? You both indicate not. I would ask you to please rise, raise your right hand and take the oath.

[Witnesses sworn.]

Let the record reflect witnesses replied in the affirmative. You are now under oath. We will now have a 5-minute opening statements.

Ms. Shames, please

STATEMENT OF LISA SHAMES, ACTING DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Ms. SHAMES. Members of the subcommittee, I am pleased to be here today as part of your oversight of the safety and security of the Nation's food supply. Let me state at the outset that while the food supply is generally considered to be safe, the recent outbreaks of *E. coli* in spinach, salmonella in peanut butter, along with the contamination in pet food underscores the risks posed by accidental food contamination.

Each year, as we've already heard, the Centers for Disease Control and Prevention reports that about 76 million people contract a foodborne illness; 325,000 people require hospitalization; and 5,000 people die. As the experiences we heard shared this morning, it gives us a personal face to these Government statistics.

This morning I would like to focus on two key points. First, GAO designated food safety on its high-risk list because of the Federal Government's inconsistent oversight, ineffective coordination and inefficient use of resources. The Federal Government's oversight is fragmented; 15 agencies collectively administer over 30 laws related to food safety. Further, the Federal Government's resources spent on food inspections do not align with the risks of food contamination. For example, FDA is responsible for regulating about 80 percent of the food supply, but accounts for about 20 percent of food inspection resources; whereas USDA, the Department of Agriculture, is responsible for regulating about 20 percent of the food supply but receives the majority of food inspection resources.

To address this fragmentation, we are calling for a fundamental reexamination of the Federal oversight of food safety. To this end, we have recommended comprehensive uniform and risk-based legislation, a blue-ribbon panel to study alternative organizational

structures and a reconvened Council on Food Safety to facilitate a Government wide approach.

Second, limitations in Federal agency's recall programs heighten the risk that unsafe food will reach consumers. Food recalls are voluntary. And both FDA and USDA do not have authority to issue a mandatory recall order. The exception is FDA's authority to require a recall for infant formula. In contrast other Federal agencies, such as the Consumer Product Safety Commission and the National Highway Traffic Safety Administration, have authority to require a company to notify the agency when it has distributed a potentially unsafe product, to order a recall, to establish recall requirements and to impose monetary penalties if a company does not cooperate.

Even within the context of their limited recall authority, we reported in October 2004 that FDA and USDA could have done a better job in carrying out their food recall programs. Specifically, at that time, USDA and FDA did not know how promptly and completely companies were carrying out the recalls. It did not promptly verify that recalls had reached all segments of the distribution chain and used procedures such as press releases and Web postings that may not have been effective. According to agency officials, USDA and FDA are taking actions to address some of our recommendations. We have not yet reviewed these actions to determine if they are adequate.

In addition, we have proposed that Congress enact legislation that would require companies to alert USDA or FDA when they discover they have distributed potentially unsafe food and give both agencies mandatory food recall authority.

In summary, the recent food contamination outbreaks underscore the need to transform the Federal oversight of food safety. Today's hearing appropriately focuses on FDA's capacity. In the long run, the Federal oversight of food safety needs to be approached on a Government-wide basis. GAO's high risk designation in concert with congressional hearings such as today's can bring needed attention to address the weaknesses caused by the current fragmented system and restore public confidence in the Government's ability to ensure the integrity of the food supply. Mr. Chairman, this concludes my prepared statement. I would be pleased to answer any questions that you or members of the subcommittee may have.

[The prepared statement of Ms. Shames follows:]

United States Government Accountability Office

GAO

Testimony
Before the Subcommittee on Oversight
and Investigations, Committee on Energy
and Commerce, House of Representatives

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FEDERAL OVERSIGHT OF FOOD SAFETY

High-Risk Designation Can Bring Attention to Limitations in the Government's Food Recall Programs

Statement of Lisa Shames, Acting Director
Natural Resources and Environment



GAO-07-785T

April 24, 2007

FEDERAL OVERSIGHT OF FOOD SAFETY

High-Risk Designation Can Bring Needed Attention to Limitations in the Government's Food Recall Programs



Highlights of GAO-07-785T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

Each year, about 76 million people contract a foodborne illness in the United States; about 325,000 require hospitalization; and about 5,000 die. The outbreaks of *E. coli* in spinach and *Salmonella* in peanut butter, along with contamination in pet food, have highlighted the risks posed by accidental food contamination. The attacks of September 11, 2001, heightened awareness that the food supply could also be vulnerable to deliberate contamination. This testimony focuses on the (1) role that GAO's high-risk series can play in raising the priority and visibility of the need to transform federal oversight of food safety, (2) fragmented nature of federal oversight of food safety, and (3) limitations in federal food recall programs.

What GAO Recommends

While many of GAO's recommendations to promote the safety of the nation's food supply have been acted upon, others have not yet been addressed. For example, GAO recommended that the executive branch reconvene the President's Council on Food Safety to facilitate interagency coordination. GAO also proposed that Congress enact comprehensive, uniform, and risk-based food safety legislation; analyze alternative organizational food safety structures; and consider legislation giving agencies authority to order food recalls.

www.gao.gov/cgi-bin/getrpt?GAO-07-785T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Lisa Shames at (202) 512-3841 or Shamesl@gao.gov.

What GAO Found

GAO's High-Risk Series is intended to raise the priority and visibility of government programs that are in need of broad-based transformation to achieve greater economy, efficiency, effectiveness, accountability, and sustainability. These reports also help Congress and the executive branch carry out their responsibilities while improving the government's performance and enhancing its accountability for the benefit of the American people. In January 2007, as part of our regular update of this series for each new Congress, GAO designated the federal oversight of food safety as a high-risk area for the first time.

We designated federal oversight of food safety as a high-risk area because of the need to transform this system to reduce risks to public health as well as the economy. While this nation enjoys a plentiful and varied food supply that is generally considered to be safe, the federal oversight of food safety is fragmented, with 15 agencies collectively administering at least 30 laws related to food safety. The two primary agencies are the U.S. Department of Agriculture (USDA), which is responsible for the safety of meat, poultry, and processed egg products, and the Food and Drug Administration (FDA), which is responsible for virtually all other food. We have identified examples where the federal government's resources and enforcement activities can better align with the risks of food contamination. For example, the majority of federal expenditures for food safety inspection were directed toward USDA's programs for ensuring the safety of meat, poultry, and egg products; however, USDA is responsible for regulating only about 20 percent of the food supply. In contrast, FDA, which is responsible for regulating about 80 percent of the food supply, accounted for only about 24 percent of expenditures.

Among the reasons we designated federal oversight of food safety as a high-risk area is that limitations in the federal government's food recalls heighten the risk that unsafe food will remain in the food supply and ultimately be consumed. Food recalls are voluntary, and federal agencies responsible for food safety have no authority to compel companies to carry out recalls—with the exception of FDA's authority to require a recall for infant formula. USDA and FDA provided guidance for companies to carry out voluntary recalls. We have reported that USDA and FDA could do a better job carrying out their food recall programs so they can quickly remove potentially unsafe food from the marketplace. At the time of our review, these agencies did not know how promptly and completely companies were carrying out recalls, did not promptly verify that recalls had reached all segments of the distribution chain, and used procedures that may not have been effective to alert consumers to a recall.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the designation of federal oversight of food safety as a high-risk area in the January 2007 update to our High-Risk Series and, specifically, the limitations in the government's food recall programs. Let me state at the outset that this nation enjoys a plentiful and varied food supply that is generally considered to be safe. However, each year, about 76 million people contract a foodborne illness in the United States; about 325,000 require hospitalization; and about 5,000 die, according to the Centers for Disease Control and Prevention. Further, as the population grows older and more vulnerable to foodborne illness, food safety will become increasingly important. The recent outbreaks of *E. coli* in spinach and *Salmonella* in peanut butter, for example, along with contamination in pet food, have highlighted the risks posed by accidental food contamination.

Ensuring the safety of the nation's food supply is even more urgent since the terrorist attacks of September 11, 2001 heightened awareness of agriculture's vulnerabilities to terrorism, such as the deliberate contamination of food or the introduction of disease to livestock, poultry, and crops. Agriculture, as the largest industry and employer in the United States, generates more than \$1 trillion in economic activity annually, or about 13 percent of the gross domestic product. An introduction of a highly infectious foreign animal disease, such as avian influenza or foot-and-mouth disease, would cause severe economic disruption, including substantial losses from halted agricultural exports, which exceeded \$68 billion in fiscal year 2006.

We added the federal oversight of food safety to our list of high-risk programs needing urgent attention and transformation to ensure that our federal government functions in the most economical, efficient, and effective manner possible.¹ As we have repeatedly reported, our fragmented food safety system has resulted in inconsistent oversight, ineffective coordination, and inefficient use of resources. With 15 agencies collectively administering at least 30 laws related to food safety, the patchwork nature of the federal food safety oversight system calls into question whether the federal government can more efficiently and effectively protect our nation's food supply. In addition, food recalls are voluntary, and the U.S. Department of Agriculture (USDA) and the Food

¹GAO, *High-Risk Series: An Update*, GAO-07-310 (Washington, D.C.: January 2007).

and Drug Administration (FDA), which have primary responsibility for food safety, have no authority to compel companies to carry out most recalls, except for FDA's authority to require a recall for infant formula. Instead, USDA and FDA provide guidance for companies to carry out voluntary recalls. We have reported that USDA and FDA could do a better job in carrying out their food recall programs so they can quickly remove potentially unsafe food from the market place.²

Because of your responsibility for oversight of federal agencies, I will focus on three key points: (1) the role of GAO's High-Risk Series in raising the priority and visibility of the need to transform federal oversight of food safety, (2) the fragmented nature of federal oversight of food safety, and (3) limitations in federal food recall programs. My testimony is based on published GAO products that were developed in accordance with generally accepted government auditing standards.

GAO's High-Risk Series Raises the Priority and Visibility of the Need to Transform Federal Oversight of Food Safety

We designated the federal oversight of food safety as a high-risk area to raise the priority and visibility of the need to transform this system. Overall, our High-Risk Series has identified and helped resolve serious government weaknesses in areas that involve substantial resources and provide critical services to the public. Since we began reporting on high-risk areas, the government has taken high-risk problems seriously and has made long-needed progress toward correcting them.

In designating federal oversight of food safety as high risk, we considered whether it had national significance or a management function that was key to performance and accountability. Further, we considered qualitative factors, such as whether food safety

- involved public health or safety, service delivery, national security, national defense, economic growth, or privacy or citizens' rights; or
- could result in significantly impaired service, program failure, injury or loss of life, or significantly reduced economy, efficiency, or effectiveness.

²GAO, *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*, GAO-05-51 (Washington, D.C.: Oct. 6, 2004).

Clearly, these factors weighed heavily into our deliberations to place the federal oversight of food safety on our high-risk list. For example, food contamination, such as the recent *E. coli* outbreaks, can have a detrimental impact on public health and the local economy. According to FDA, the outbreak resulted in 205 confirmed illnesses and three deaths. In addition, industry representatives estimate losses from the recent California spinach *E. coli* outbreak to range from \$37 million to \$74 million.

To address the weaknesses in federal oversight of food safety, executive agencies can start by implementing our recommendations intended to improve the problems we previously identified. Further, continued congressional oversight, including today's hearing, and additional legislative action will be key to achieving progress, particularly in addressing challenges in the broad-based transformation needed to promote the safety and integrity of the nation's food supply.

Fragmented Federal Oversight of Food Safety Led to High-Risk Designation

The fragmented nature of the federal food oversight system calls into question whether the government can plan more strategically to inspect food production processes, identify and react more quickly to outbreaks of contaminated food, and focus on promoting the safety and integrity of the nation's food supply. While 15 agencies collectively administer at least 30 laws related to food safety, two agencies have primary responsibility—USDA, which is responsible for the safety of meat, poultry, and processed egg products, and FDA, which is responsible for virtually all other foods.

The food safety system is further complicated by the subtle differences in food products that dictate which agency regulates a product. For example, which agency is responsible for ensuring the safety of frozen pizzas depends on whether or not meat is used as a topping. USDA inspects manufacturers of frozen pepperoni pizza, while FDA inspects manufacturers of frozen cheese pizza. In other instances, how a packaged ham and cheese sandwich is regulated depends on how the sandwich is presented. USDA inspects manufacturers of packaged open-face meat or poultry sandwiches (e.g., those with one slice of bread), but FDA inspects manufacturers of packaged closed-face meat or poultry sandwiches (e.g., those with two slices of bread).

We have identified examples where the federal government's resources and enforcement activities can better align with the risks of food contamination. For example, the majority of federal expenditures for food safety inspection have been directed toward USDA's programs for

ensuring the safety of meat, poultry, and egg products; however, USDA is responsible for regulating only about 20 percent of the food supply. In contrast, FDA, which is responsible for regulating about 80 percent of the food supply, accounted for only about 24 percent of expenditures. Also, under current law, thousands of USDA inspectors maintain continuous inspection at slaughter facilities and examine all slaughtered meat and poultry carcasses. They also visit each processing facility at least once during each operating day. For foods under FDA's jurisdiction, however, federal law does not mandate the frequency of inspections.³ FDA has jurisdiction over the food products involved in the recent food contamination outbreaks I mentioned today.

The federal regulatory system for food safety, like many other federal programs and policies, evolved piecemeal, typically in response to particular health threats or economic crises. During the past 30 years, we have detailed problems with the current federal food safety system and reported that the system has caused inconsistent oversight, ineffective coordination, and inefficient use of resources. We have cited the need to integrate this fragmented system as a significant challenge for the 21st century, to be addressed in light of the nation's current deficit and growing structural fiscal imbalance.⁴

To help decisionmakers update programs to meet present and future challenges within current and expected resource levels, we framed illustrative questions for them to consider. While these questions can apply to other areas needing broad-based transformation, we specifically cited the myriad of food safety programs managed across several federal agencies. Among these questions are the following:

- How can agencies partner or integrate their activities in new ways, especially with each other, on crosscutting issues, share accountability for crosscutting outcomes, and evaluate their individual and organizational contributions to these outcomes?
- How can agencies more strategically manage their portfolio of tools and adopt more innovative methods to contribute to the achievement

³GAO, *Overseeing the U.S. Food Supply: Steps Should be Taken to Reduce Overlapping Inspections and Related Activities*, GAO-05-549T (Washington, D.C.: May 17, 2004).

⁴GAO, *21st Century Challenges: Reexamining the Base of the Federal Government*, GAO-05-325SP (Washington, D.C.: February 2005).

of national outcomes?

Integration can create synergy and economies of scale and can provide more focused and efficient efforts to protect the nation's food supply. Further, to respond to the nation's pressing fiscal challenges, agencies may have to explore new ways to achieve their missions.

Many of our recommendations to agencies to promote the safety and integrity of the nation's food supply have been acted upon. For example, we recommended that FDA adopt a risk-based approach to overseeing states' shellfish safety programs.⁵ In response to our recommendation, FDA designed a risk-based approach to reviewing the states' shellfish safety programs and incorporated it into their fiscal year 2003 to 2005 compliance program, which FDA's shellfish specialists use to evaluate state programs.

Nevertheless, as we discuss in the 2007 High-Risk Series, a fundamental reexamination of the federal food safety system is warranted. Taken as a whole, our work indicates that Congress and the executive branch can and should create the environment needed to look across the activities of individual programs within specific agencies and toward the goals that the federal government is trying to achieve. Others have also called for fundamental changes to the federal food safety system overall. In 1998, the National Academy of Sciences concluded that the system is not well equipped to meet emerging challenges.⁶

Going forward, to build a sustained focus on the safety and the integrity of the nation's food supply, Congress and the executive branch can integrate various expectations for food safety with congressional oversight and through agencies' strategic planning processes. The development of a governmentwide performance plan that is mission-based, is results-oriented, and provides a cross-agency perspective offers a framework to help ensure agencies' goals are complementary and mutually reinforcing. Further, this plan can help decisionmakers balance trade-offs and compare performance when resource allocation and restructuring decisions are made.

⁵GAO, *Food Safety: Federal Oversight of Shellfish Safety Needs Improvement*, GAO-01-702 (Washington, D.C.: July 9, 2001).

⁶Institute of Medicine, *Ensuring Safe Food from Production to Consumption*, Washington, D.C.: National Academy Press, 1998.

We have recommended, among other things, that Congress enact comprehensive, uniform, and risk-based food safety legislation and commission the National Academy of Sciences or a blue ribbon panel to conduct a detailed analysis of alternative organizational food safety structures.⁷ Members of this subcommittee and others have introduced food safety legislation, none of which has been enacted thus far. We also recommended that the executive branch reconvene the President's Council on Food Safety to facilitate interagency coordination on food safety regulation and programs. According to documents on the council's Web site, the current administration has not reconvened the council. These actions can begin to address the fragmentation in the federal oversight of food safety.

Limitations in Federal Agencies' Recall Programs Heighten the Risk that Unsafe Food Will Reach Consumers

Among the reasons we designated federal oversight of food safety as a high-risk area is that limitations in the federal government's food recalls heighten the risk that unsafe food will remain in the food supply and ultimately be consumed. Food recalls are largely voluntary, and federal agencies responsible for food safety have no authority to compel companies to carry out recalls in these cases, with the exception of FDA's authority to require a recall for infant formula. Specifically, USDA does not have authority to issue a mandatory recall order for meat, poultry, and processed egg products. Similarly, FDA, which is responsible for virtually all other foods, does not have recall authority beyond infant formula.

Government agencies that regulate the safety of other products, such as toys and automobile tires, have recall authority not available to USDA and FDA for food and have had to use their authority to ensure that recalls were conducted when companies did not cooperate. These agencies have the authority to

- require a company to notify the agency when it has distributed a potentially unsafe product,
- order a recall,
- establish recall requirements, and

⁷GAO, *Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food*, GAO-02-471 (Washington, D.C.: Oct. 10, 2001).

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- impose monetary penalties if a company does not cooperate.

For example, manufacturers of many consumer goods are generally required to notify the Consumer Product Safety Commission within 24 hours of obtaining information that suggests a product could create a substantial risk of injury. The commission has the authority to impose monetary penalties of up to \$1.825 million if a company does not inform the commission promptly about an unsafe product. Furthermore, the National Highway Traffic Safety Administration has the authority to establish recall requirements to require companies to directly notify the purchasers of vehicles with defects and to remedy the defects. Likewise, FDA has authority to order recalls of unsafe biological products and medical devices—and it has used this authority in the past. In addition, FDA can impose penalties of up to \$100,000 per day on companies that do not recall unsafe biological products, such as vaccines.⁸

Even in the context of their limited recall authority, we reported in October 2004 that USDA and FDA could do a better job in carrying out their food recall programs so they could quickly remove potentially unsafe food from the marketplace.⁹ Specifically:

- USDA and FDA did not know how promptly and completely companies were carrying out recalls. The agencies were not using their data systems to effectively monitor and manage their recall programs. They did not track important dates to calculate how long companies take to carry out recalls and the percentage of food that is recovered. Furthermore, managers did not receive routine reports on the progress of ongoing recalls to target program resources. Moreover, neither agency's guidance provided time frames for how quickly companies should initiate and carry out recalls. Consequently, companies may have had less impetus to notify downstream customers and remove potentially unsafe food from the marketplace.
- USDA and FDA did not promptly verify that recalls had reached all segments of the distribution chain, yet monitoring the effectiveness of a company's recall actions is the agencies' primary role in a food recall. For the 10 USDA recalls in 2003 we examined in depth, USDA staff

⁸The statute requires that this be adjusted annually for inflation. We have not adjusted the \$100,000 figure for inflation.

⁹GAO-05-51.

averaged 38 days to complete verification checks, and for the 10 FDA recalls we examined in depth, FDA staff averaged 31 days. These time frames exceeded the expected shelf life for some perishable foods that were recalled, such as fresh ground beef and fresh-cut bagged lettuce.

- The procedures USDA and FDA used to alert consumers to a recall—press releases and Web postings—may not have been effective. According to consumer groups and others, relatively few consumers may see that information. They identified additional methods to notify the public, such as posting recall notices in grocery stores and directly notifying consumers using “shoppers’ club” information.

We have proposed that Congress consider legislation that would require companies to alert USDA or FDA when they discover they have distributed potentially unsafe food and that would give both agencies mandatory food recall authority. Congress has not enacted legislation granting agencies general mandatory recall authority. We have also recommended that USDA and FDA better track and manage food recalls, achieve more prompt and complete recalls, and determine if additional ways are needed to alert consumers about recalled food that they may have in their homes. According to agency officials, USDA and FDA are taking actions to address some of our recommendations. Specifically, they are currently updating their recall data systems. In addition, USDA amended a directive in order to improve its recall effectiveness checks and how it communicates information about recalls. FDA is also conducting a quality management review of its food recall system with a goal of providing a documented, uniform, and streamlined recall process. We have not reviewed these actions to determine if they adequately address our recommendations.

The recent outbreaks of *E. coli* in spinach and *Salmonella* in peanut butter, along with outbreaks of contaminated pet food, underscore the need of a broad-based transformation of the federal oversight of food safety to achieve greater economy, efficiency, effectiveness, accountability, and sustainability. GAO’s high-risk designation raises the priority and visibility of this necessary transformation and thus can bring needed attention to address the weaknesses caused by a fragmented system. Among the reasons we designated the federal oversight of food safety as a high-risk area is that USDA and FDA have limited recall authority. Even within this limited authority, we found that these agencies could have done better in carrying out their food recall programs. Positively, agency officials are taking actions intended to improve their

food recall programs. However, we have not reviewed these actions to determine if they adequately address our recommendations.

Mr. Chairman, this concludes my prepared statement. I would be pleased to respond to any questions that you or other Members of the Subcommittee may have.

**Contact and Staff
Acknowledgments**

Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. For further information about this testimony, please contact Lisa Shames, Acting Director, Natural Resources and Environment at (202) 512-3841 or ShamesL@gao.gov. Key contributors to this statement were José Alfredo Gómez, Bart Fischer, Terrance N. Horner, Alison O'Neill, Beverly Peterson, and Rebecca Yurman.

Mr. STUPAK. Thank you. And thank you for your testimony.
Dr. DeCarlo.

**STATEMENT OF ANTHONY DECARLO, D.V.M., RED BANK
VETERINARY HOSPITAL, TINTON FALLS, NJ**

Dr. DECARLO. Thank you, Mr. Chairman, and members of the subcommittee. And also thank you to Congressman Pallone, whose statement I have read, for an informed and heartfelt plea for better controls in reporting mechanisms when it comes to the health and safety of our pets. I consider it an honor to be here and appear and give testimony before this esteemed subcommittee.

On April 5, Congressman Pallone visited Red Bank Veterinary Hospital to gather facts about how our hospital was dealing with suspected cases of contamination. Now he's working on his own legislation in the Health Subcommittee he chairs on ways to improve Federal regulatory oversight, including the establishment of a central registry to expedite the Government's response on any future situations.

I don't feel that I can speak with authority on proving regulatory oversight because I'm not clear that there is a lack of oversight and is indeed the reason for the problem based on when the problem was first known to us.

What we need as veterinarians is a better mechanism in place to track unusual occurrences, be able to get information to an appropriate centralized reporting agency and then back out to the veterinary community in a timely manner.

Congressman Pallone has done an excellent job of distilling a large body of information into an accurate and concise statement. As a result of this consolidation of information, I'll be speaking this morning about an improved means of gathering and disseminating information from the veterinary perspective.

There are many sites where veterinarians gather information regarding this recall, from the American Veterinary Medical Association to State veterinary medical associations and to the pet food manufacturers themselves and the media. While each of these organizations did a fine job of relating their real time information to their Web sites, the veterinary community does not have readily available resources to add to and retrieve this information in a focused timely manner.

Many veterinary practices have only enough staff to meet the existing needs of that practice and its normal volume of cases. What happened in a situation such as this one is that many veterinarians were alerted by the breaking story on television long before they were alerted via e-mail or phone call from their clients, colleagues or other vendors. Having a central reporting agency and a way for that agency to quickly disseminate the information would be a key factor in heading off similar problems in the future.

A possible solution to this problem would be a program utilizing a network of sentinel veterinary hospitals and institutions across the country as a way to quickly get information to a central agency and get feedback in a likewise timely manner. It would be the agency's responsibility to educate the sentinel hospitals on how to interact with the give-and-take information. It would be the responsibility of the sentinel hospitals to educate their staff as to how

to work internally on organizing and reporting to the agency. The sentinel hospitals would be reporting on a regular basis in the ideal situation, thereby establishing a surveillance baseline to predict and forecast potential crises. This would allow the agency to report back to the sentinel hospitals the proper diagnostics to engage in how to deal with these results. This is not really the agency's responsibility reporting to all veterinarians when a crisis occurs. If you continue to build on the existing infrastructure and prove the ebb and flow of information to a central reporting agency, we as veterinarians will have better ability to work with the Government at all levels, to aid in the surveillance and reporting of potential animal health related situations. Thank you.

[The prepared statement of Dr. DeCarlo follows:]

STATEMENT OF ANTHONY DECARLO, D.V.M.

Thank you Mr. Chairman and members of the subcommittee, and thank you to Congressman Pallone (whose statement I've read) for an informative and heartfelt plea for better controls and reporting mechanisms when it comes to the health and safety of our pets. I consider it an honor to appear and give testimony before this esteemed Subcommittee.

On April 5, Congressman Pallone visited Red Bank Veterinary Hospital to gather facts about how our hospital was dealing with suspected cases of contamination. Now he is working on his own legislation in the health care subcommittee he chairs on ways to improve Federal regulatory oversight, including the establishment of a central registry to expedite the Government's response to any future such situations.

I don't feel that I can speak with authority on improving regulatory oversight because I'm not clear that a lack of oversight is indeed the reason for this problem to have existed and grown. What we need as veterinarians is to have a better mechanism in place to track unusual occurrences, be able to get information to an appropriate centralized reporting agency and then back out to the veterinary community in a timely manner.

Congressman Pallone has done an excellent job of distilling a large body of information into an accurate and concise statement; as a result of this consolidation of information, I will be speaking this morning about an improved means of gathering and disseminating information from the veterinary perspective.

There are many sites where veterinarians gathered information regarding this recall, from the American Veterinary Medical Association, to the State Veterinary Medical Associations, to the Pet Food Manufacturers, to the media and more. While each of these organizations did a fine job of relating their real-time information to their Web sites, the veterinary community does not have readily available resources to add to and retrieve this information in a focused and timely manner.

Many veterinary practices have only enough staff to meet the existing needs of that practice and its normal volume of cases. What happened in a situation such as this one is that many veterinarians were alerted by the breaking story on television long before they were alerted via email or phone call from their clients, colleagues or vendors.

Having a central reporting agency and a way for that agency to quickly disseminate the information would be a key factor in heading off a similar problem in the future. A possible solution to this problem would be a program utilizing a network of sentinel veterinary hospitals across the country as a way to quickly get information to a central agency and to get feedback in a likewise timely manner.

It would be the agency's responsibility to educate the sentinel hospitals on how to interact with the give and take of information. It would be the responsibility of the sentinel hospital to educate their staff as to how to work internally on organizing and reporting to the agency.

The sentinel hospitals would be reporting on a regular basis to the appropriate agency, thereby establishing a surveillance baseline to predict and forecast potential crisis.

This will allow the agency to report back to the sentinel hospital the proper diagnostics to engage and how to deal with the results.

This does not relieve the agency of the responsibility of reporting to all veterinarians when a crisis occurs.

If we can continue to build on the existing infrastructure and improve the ebb and flow of information to a central reporting agency, we as veterinarians will have a better ability to work with the government, at all levels, to aid in the surveillance and reporting of potential animal health related issues.

Mr. STUPAK. Thank you. And thank you both for your testimony.

Doctor, if I may. There have been reports in news media of thousands of cats and dogs falling ill and dying due to the contaminated pet food. Is there any good way to get an estimate on that number?

Dr. DECARLO. We've tried. There has been so much reporting to multiple places it's hard to get a real number. There's some generalizations that can be made. It appears, of those animals that we feel comfortable were a result of this problem, probably less than two-tenths. It ranges from 1 percent to less than three-tenths of a percent of those animals.

Mr. STUPAK. Let me ask you this. The Michigan Veterinary Medical Association reports that, as of April 16, there were 155 suspected cases of pet illnesses caused by contaminated foods, with 52 deaths. In Oregon, as of April 24, the State veterinarian reports 106 suspected cases of illness and 38 deaths. Now, applying those numbers across the entire United States, that would imply probably about 6,500 ill dogs and cats, and 2,250 deaths. Would that seem consistent with what you've been able to gather?

Dr. DECARLO. No, the percentages have been all over the place, and that is the problem. Because we are a small profession, and that is an important part of the statistics, and who reports where is a very selective group of people.

We have seen situations where the mortality rate was less than 1 percent and as high as 10 percent and even higher. We have also seen numbers of the percent of animals who we think were affected range from three-tenths of a percent to 10 percent of the entire volume of a specific institution or hospital.

That is why, after having done this investigation myself, there really needs to be an organized and focused place for veterinarians to report any kind of situation to you so you would have these facts and very accurate facts.

Mr. STUPAK. So even based your investigation you really can't today give us any kind of an estimate as to how many dogs and cats died, how many became ill, even a best guesstimate?

Dr. DECARLO. I think the range of—well, there is two different questions there, those who have had died and those are affected. I think the affected numbers vary more, because, again—

Mr. STUPAK. Greater than 6,500.

Dr. DECARLO. Right, I think that is probably going to be more than that that have been affected. I think the problem with that situation is it was only recently that there are ways to confirm whether or not it was affected, and that is where I am going with this.

Second, the fatality rates from some universities as well has been extremely low. In some cases, like I said, less than 1 percent of those cases that are affected and as high as 10 or 15 percent.

The statistics that you just mentioned are extremely on the high side from the data we have gathered. Our own particular situation—which is a very large hospital—it has been about 1 percent

of the affected cases, mostly cats. That has been consistent, the majority had been cats, and the minority had been dogs.

Mr. STUPAK. Have you seen melamine poisoning in dogs or cats in the past? Have you seen this type of poisoning?

Dr. DECARLO. Nobody has looked, so you can't answer that question. I don't know.

Mr. STUPAK. OK, thanks.

Ms. SHAMES, you indicate that the food supply is relatively safe. Yet we have had 20 different outbreaks in Salinas Valley in the last 10 years. How do you determine safe? Volume? Outbreaks? Deaths? Illness? How do you determine it? Because we lose about 5,000 people a year to food poisoning. So where does it become safe and nonsafe? What is the tipping point?

Ms. SHAMES. We say it is generally regarded as safe or considered safe based on the numbers that CDC report.

Now, granted, any single death or hospitalization or sickness is one too many. But, nevertheless, compared to other countries' food safety systems, we have to say that, for the most part, we have a safe system.

Nevertheless, if you—as you pointed out, the number of incidences have been identified, and I think the problem becomes more and more complex as our food supply becomes more and more globalized. We have heard about some of the complicated networks here among retailers and distributors and producers, and I think it is a problem that we have to recognize as something that will be increasing in light of the demographics of this population.

Mr. STUPAK. We saw today we had three young children here who were sick. Now nobody ever would have put it together that they had food poisoning but for either press reports or their parents. I would imagine with young children and even I am sure with older adults it is, oh, a viral infection, and it will pass, and they had food poisoning. Maybe not to the point where they may need a kidney transplant, but a lot of it is underreported.

Ms. SHAMES. Yes, you are absolutely right. That is the case. For many people, you may go out for dinner, feel a little queasy a little later and in a day or two you are feeling OK. Others may not recover quite as quickly. Go to see their physician, their physician may or may not go on to report or diagnose it. So you are correct. So the tendency is to underreport these incidences.

Mr. STUPAK. In preparation for this hearing, many of us were surprised to learn about, other than baby formula, the FDA has no right to recall any product. But it seems like we recall toys and tires and everything else in this country. Is this a safety concern that they do not have recall authority on food, the FDA? Did the GAO find that?

Ms. SHAMES. We believe it does heighten risk that there will be increased sickness and increased death.

What the other Federal agencies have told us, such as the Consumer Product Safety Commission, the National Highway Traffic and Safety Administration, that, for the most part, companies do cooperate. In other words, they do have a business incentive to try to ameliorate or fix the problem. Nevertheless, they have told us that they have had to exercise their recall authorities in certain cases.

Mr. STUPAK. Also, with that business interest, as we saw with the first panel, they had talked about lack of notice; no one telling them; if we would have known, we would have done it quicker. Somebody has to take the bull by the horns and either recall or put out a warning or something that has the authority to back it up.

Ms. SHAMES. Right. For example, the Consumer Product Safety Commission requires that within 24 hours, if a company suspects that one of the products is unsafe, it needs to report it to that agency.

Mr. STUPAK. Within 24 hours of notice.

Ms. SHAMES. Yes.

Mr. STUPAK. For questioning, Mr. Whitfield.

Mr. WHITFIELD. Thank you, Chairman Stupak; and thank you all for being with us this morning.

Ms. Shames, you were with the GAO, and recently you all came out with your high-risk report on Federal oversight of food supply. Now was that a report that was requested by a Member of Congress or Senate or what is the difference in a high-risk report and a non-high-risk report?

Ms. SHAMES. GAO has been preparing its high-risk series since the early 1990s, and we prepare it for each new Congress as a way of providing them information of what we think are the most pressing issues that Congress should address.

The high-risk series has evolved over the years. At its outset, it was looking primarily at issues of fraud, waste and abuse. And that is why you would see, for example, the Department of Defense contracting as an issue there.

But over the years we have recognized and the list has evolved so that we are looking at Government systems, and that is why we thought that food safety—based on identified criteria that we have issued to Federal agencies, we felt that food safety was an area that merited the high-risk designation.

Mr. WHITFIELD. OK, and how many high-risk designations did you all prepare for this Congress?

Ms. SHAMES. There are close to 30 high-risk issues.

Mr. WHITFIELD. So this food safety is high up on your list of problem areas?

Ms. SHAMES. It is a Federal issue. We consider it to be of topmost importance.

Mr. WHITFIELD. I was a little bit shocked that you had indicated that FDA is responsible for 80 percent of the food supply and USDA is responsible for 20 percent, but USDA receives 80 percent of the funding and FDA receives 20 percent of the funding.

Ms. SHAMES. Yes.

Mr. WHITFIELD. Now would there be any rational explanation for that kind of disparity?

Ms. SHAMES. The Federal food safety system has evolved over the years. It has been piecemeal, as has been observed by many people already. It tends to react to a crisis and then attention subsides. So it really is a patchwork, and that is why we say that it is the fragmentation that really is the source of many of the problems.

Mr. WHITFIELD. Because you have 15 organizations and 30 separate laws, correct?

Ms. SHAMES. Yes. Yes.

Mr. WHITFIELD. But the FDA is responsible for the entire food supply, with the exception of meat, poultry and processed eggs, is that correct?

Ms. SHAMES. That's correct.

Mr. WHITFIELD. And yet they only receive 20 percent of the funding.

Ms. SHAMES. Twenty percent of the funding, that's right, for inspection activities, that's right; and that is the bulk of the Federal expenditures.

Mr. WHITFIELD. Now Chairman Stupak had mentioned, and we saw that earlier, that there are mandatory recalls available to the Federal Government for tires, for toys, for whatever, but there is no mandatory recall available for food. What are the arguments against mandatory recall for food?

Ms. SHAMES. USDA and FDA could, if they needed to, seize products if they deemed them to be contaminated; and they could detain those products for up to 20 days. After that time period, there would need to be some sort of court injunction to say that the food needs to be condemned.

Mr. WHITFIELD. But in the salmonella Peter Pan peanut butter case, if ConAgra had not recalled that peanut butter voluntarily, the Federal Government could not have recalled it?

Ms. SHAMES. No. Could not have the mandatory. The recall authority is strictly voluntary. It would have been up to the companies to disclose that this was happening.

Mr. WHITFIELD. Dr. DeCarlo, I know that FDA, for example, has a regulation that says if any animal has one of like 12 different chemicals or medicines in its carcass it cannot be used for human consumption, and you may not be aware of that, but I am aware of that.

Dr. DECARLO. Yes.

Mr. WHITFIELD. But yet USDA is the agency that is required to enforce that regulation. So FDA makes the regulation, USDA enforces the regulation, and it is my understanding, from analysis, that USDA really does not have a very good mechanism in place to detect those particular chemicals in those animals used for human consumption.

But if a pig, for example, is down on a farm and digests melamine and then ends up being slaughtered for human consumption, is that anything that would really concern you? Or is that so remote that it is really not something we need to be concerned about?

Dr. DECARLO. It certainly would concern me.

Again, I think the problem is how do we deal with that? I think, again, our biggest—our biggest problem is really getting information. And I think the multiple agencies out there makes it confusing for us on what to do and how to do it. It has only been recently that we have been notified that there are two places in the country that will test for this in the urine to help make a diagnosis. That took a long time coming. It was available.

So, not to disregard your statement, I still think all these things are of concern. We just need a system that gets you the information quickly as well as you getting the information. The less agencies

involved—I am not a politician, so I don't know how it all works, but simplicity works most efficiently. So that really is a concern.

Mr. WHITFIELD. Thank you very much.

Mr. STUPAK. Ms. DeGette for questions, please.

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. DeCarlo, I think you hit on something. Simplicity is always good. And one of the things that we are concerned about is, with food safety, is that we have—and this isn't really a pet food issue, but with food for humans we have 15 agencies administering 30 laws, as Ms. Shames said in her paper, and so that is what we are trying to figure out.

Ms. Shames, one idea that I have had for some time—and I have been working with Congresswoman Rosa DeLauro about this—is the idea of having one agency sort of in charge of meat and other types of food. Because you have this weird situation which we have talked about in this committee before, like pizzas, and you raised this in your paper, where if you have a cheese pizza, then the FDA has jurisdiction over that. But if you have a pepperoni pizza, then that is the USDA, right?

Ms. SHAMES. That is correct.

Ms. DEGETTE. And those agencies have very different regulatory schemes, correct?

Ms. SHAMES. Correct.

Ms. DEGETTE. Can you describe for a minute about how those two pizzas would be regulated in a different way?

Ms. SHAMES. Yes, I can. USDA, for example, is required by statute to have continuous presence in a processing facility. So, in other words, every carcass needs to be looked at every day.

In FDA, that is not the case. There is no statutory requirement in terms of its oversight or inspection to the food; and, for that reason, FDA inspects the food as frequently as it can.

Ms. DEGETTE. I guess maybe there was, in the long-past history, some sense maybe because meat could be more potential to be contaminated than cheese or something like that.

Ms. SHAMES. That is possible. In truth, our diets have changed; and we are consuming less meat. We are eating more seafood. We are eating more fresh produce. So we need to make sure that the regulatory structure meets consumers' needs.

Ms. DEGETTE. Right. And this is one thing when you were talking about the mandatory recalls of some of the other agencies, and I have been talking about that this morning, mandatory. If you had mandatory recalls, then it would seem to me that as with these—I am wondering what the Consumer Product Safety Commission and others have said to you. If you had mandatory food recalls, it would seem that would give more incentives for the industry to get ahead of the curve. What would your view be on that?

Ms. SHAMES. That is what these other agencies told us, is that generally with that authority they know that businesses are likely to cooperate. But, nonetheless, there have been instances where they have had to rely on this mandatory recall authority.

Ms. DEGETTE. So if you had the mandatory recall authority, they would probably be more forthcoming with their—from a PR standpoint—to get ahead of the curve to announce a recall.

Ms. SHAMES. That is certainly how these other agencies feel.

Ms. DEGETTE. I am wondering—the staff told me for the last panel that, right now, the food safety reporting is if a health care provider finds something in the stool, say, with these young girls who were on our last panel, then they report it to the County Health Department, who then reports it to the CDC, and then somehow some eager reporter gets ahold of it, it becomes publicized. Is there some more efficient way to, A, report and, B, to publicize recalls or outbreaks of diseases?

Ms. SHAMES. It is certainly worth asking FDA how it breaks down or identifies if there is some sort of food contamination.

What we did find out in our October, 2004, report is that what FDA had posted in terms of once it started to suspect that there was outbreak, that consumer groups told us that the information could have been more effective, and you have heard some of the concerns from the last panel.

One thing that we were hearing is that they wanted more specificity, and I think FDA heard and certainly is following through on that one recommendation. For example, when we were preparing for this hearing, we found that FDA has a pilot in terms of the way it disseminates information for an outbreak, and they are now including a photograph of the product that is suspected or has been confirmed to be contaminated.

Ms. DEGETTE. And are they doing anything with targeting where the outbreak is to be sure that they give the notifications to those geographic areas?

Ms. SHAMES. They post it in a blanket e-mail or a Web site, so they have not targeted that way. Agency officials told us that they don't have the authority even to identify the place of retail where a certain product may have come from.

Ms. DEGETTE. That would be problematic.

Thank you very much.

Mr. STUPAK. Mr. Walden from Oregon, questions, please.

Mr. WALDEN. Thank you very much, Mr. Chairman; and since I didn't get an opening statement do I get my extra 3 minutes?

Mr. STUPAK. We will let you go a little bit.

Mr. WALDEN. I thought that is the rule.

Mr. STUPAK. We usually announce that at the beginning of the hearings. Go ahead.

Mr. WALDEN. First of all, I want to go to Ms. Shames.

I hear a lot from my constituents regarding the lack of inspection of imported foods, and I think this latest incident with the wheat coming from—wheat gluten coming in from China wholly elevates that issue. One of the things we are told is there are chemicals and things allowed to be used in foreign countries that are prohibited for use here. First of all, that is the case?

Ms. SHAMES. We haven't looked at that specifically.

What FDA does have the authority to do, though, is to have certain equivalency agreements with countries that import food to this country. We were looking specifically at seafood a couple of years ago and reported that FDA had not had any of those agreements for imported seafood.

Mr. WALDEN. Was there not an outbreak a year or two ago involving—I think it was salmonella, it may have been *E. coli*, on melons? It was the outside of melons, and it turned out there was

human waste perhaps being used as fertilizer in a foreign country and that the people—the melons then were imported here and people got sick.

Ms. SHAMES. I am not familiar with that particular instance, but that was certainly one of the hypotheses for the outbreak of the *E. coli* contamination for the spinach.

Mr. WALDEN. And did that turn out to be the case?

Ms. SHAMES. CDC and California State Health Department is saying that it is from the runoff of wild animals and contaminating the water; and the water runoff was what then caused the pathogens in the spinach.

Mr. WALDEN. From wild animals?

Ms. SHAMES. Yes.

Mr. WALDEN. Interesting.

The bag of lettuce here that the chairman raised up, and it talks about how this is multiple washed, or at least one of them was three times washed, and this is completely washed. Can you wash lettuce or spinach and get rid of the *E. coli* pathogen?

Ms. SHAMES. That is a good question, and certainly the more rinsing it helps. I couldn't tell you exactly how many times the food would have to be rinsed. Generally, those foods with the thinner skins such as grapes, strawberries tend to infiltrate the pulp of the food. Melons, for example, it is a little safer.

Mr. WALDEN. If you would at some point take a look at this issue of inspections of imported foods especially relative to chemicals being used in foreign countries on producing foodstuffs that our providers, our agencies have said those aren't safe to use, I would sure like to know the answer to that at some point. If you could get a written answer for the record, that would be helpful, to the extent you can.

Mr. WHITFIELD. Dr. DeCarlo, I appreciate your testimony today.

Last fall, I toured a facility out in Oregon called the Banfield Pet Hospital that you may be familiar with.

Dr. DECARLO. Yes.

Mr. WALDEN. Veterinarians of most of the pet companies, I think. We went through their new facility that included a computer room where I believe the storage capacity was something like three terabytes of computer storage, and they track everything related to the animals that come in. They look at what the symptoms are, then what the diagnosis is, and they follow it through, and they have review panels.

In fact, when the gentleman was done showing me the facility, I said, gee, that would be great for human health care. I wonder if we could get there. But it strikes me that there are some databases such as that that might be available. Would accessing some partnership with organizations like that that have that those pool of data, would that help us in identifying these problems quicker?

Dr. DECARLO. Yes. However, what I would say to you about that in what I am proposing the selection of databases need to come from several areas. Because what we have in our profession, our general practice is, which is what Banfield is, we have specialty practices which consist of specialists. Then we have universities, and I would not eliminate shelters. Because I am approaching this

from all possibilities, both infectious disease, toxins, all those things I think we need to do that.

So the tendency for these different places to make their diagnosis are based on different criteria. So, for example, there may be one faction of the profession that may to some degree—I don't mean this in an inaccurate way—may tend to over-diagnose, others may under-diagnose because of training preferences and that kind of thing. And you also have to deal with volume of each one of these places versus—and you—unfortunately, you also have to look at locations as well.

But to your point, I think what is important to note if we go this route and choose hospitals and information, they do have to have sophisticated IT; and not all hospitals will have not only the computer equipment but also staffing. Veterinary hospitals, for the most part, 70 percent of our profession are small hospitals. They are working to the max already.

So that is why I think the selection process with who you would choose should be a group effort and really span the different types of veterinary practice out there.

Mr. WALDEN. Isn't it also true that some diseases that pop up in animals could be a link to a future human problem? For example, the bird flu, I understand, affects cats. And to the extent you would see a spike in cat illness related to the bird flu might be a precursor or at least an indicator that we might have a potential human outbreak.

Dr. DECARLO. Yes. This model is not new. There is a county in New Jersey that is testing this out. They are educating us. They are looking at more from a terrorist point of view and how it would present in animals. That is where the Sentinel Group idea came up.

The mistakes—I shouldn't say mistakes, but the things that became obvious to us was that we had to choose the right place that could get the information back to these agencies and also some degree of funding as well. But there is no question for our profession we need a single place to send all this information to. Because it can predict problems ahead of time. But, more importantly, I think rules and laws are great and no matter how you make it things are still going to fall through the cracks. So when this happens that information highway has to be simple.

Mr. WALDEN. I would conclude, and I thank the chairman for his generous allocation of time here, but as we look at how to coordinate agencies, we did that with Homeland Security, and that didn't necessarily solve the every problem related to the Nation's security. We need to continue a vigilant effort in terms of what is working and what is not.

So I appreciate your testimony and that of the other witnesses. So thank you, Mr. Chairman.

Mr. STUPAK. Homeland Security, they are part of this whole food inspection aspect now, too. So it seemed like we added another agency involved in and made it more splintered, our inspection process.

Ms. SHAMES. Yes, the Department of Homeland Security is the designated Federal agency to address any agra terrorism.

Mr. WHITFIELD. Mr. Chairman, I appreciate your giving Mr. Walden the opportunity to go a minute and 54 seconds over, but I just want to just clarify. I know when he gave his opening statement—he did not give his opening statement and he said that, because of that, that he would get an additional 3 minutes. And I was just curious, is that still the rules of our committee or what is our situation?

Mr. STUPAK. Rules of our committee does not address it. As you also know, many times we will go 10 minutes for a round. I think before each hearing we should probably sit down, you and I, and discuss it and get it down. And that is why I was more than happy to let Mr. Walden do it, because I did appreciate his waiving his opening statement. As a general rule, we try and move it along.

Any more questions, Mr. Walden?

I think we are next with Mr. Inslee.

Mr. INSLEE. I yield a couple minutes to Mr. Walden, if he needs any more.

Mr. WALDEN. No.

Mr. INSLEE. Thank you.

I was reading some reports about some potential melamine contamination of wheat gluten, and there was some suggestion that this actually was in wheat gluten originally that was actually food grade that would have been eligible for use in human consumption that, by luck—and I don't want to be disparaging our animals—but, by luck, was not in human consumption but was eligible for it.

Is there any light any of you can shed on that situation at the moment?

Ms. SHAMES. I can't speak specifically to that, to the melamine, except that it just underscores how the Federal oversight of food safety needs to be considered from a Government-wide perspective. Because we do have these interconnections with ingredients that may get into either pet food or possibly animal feed which then is ingested by hogs that may get into the food chain. It is something that needs to be addressed on a system-wide basis.

Mr. INSLEE. So coming back to this recall issue, to me it has always been stunning to me that the Government doesn't have recall authority for food. We have it for cars and various other consumer products but not the stuff we actually put into our bodies. That has never made a lot of sense to me, and it has worked I think fairly well in some of our industry.

Could you talk about, as far as in a recall scenario, what mandatory reporting—what would trigger mandatory reporting to an agency of a problem that the industry has recognized or experienced? And could you describe at all how you consider recall authority has worked in other industrial applications?

Ms. SHAMES. Well, we are looking at other countries and their food safety systems, and certainly one of the issues would be to see how they address recall. I can tell that you the Canadian food system does have mandatory recall, and it is something that they feel that at times they need to exercise.

I think in terms of the specifics for either USDA or FDA, it is worth looking at what other agencies have and certainly to see if it is appropriate in the food instance. For example, 24 hours may

be the right number, it may be too long, it may be too soon for certain outbreaks, and what we need to do is just study and to see what makes sense, given these circumstances.

Mr. INSLEE. Thank you.

Mr. STUPAK. Does the gentleman yield back?

Mr. INSLEE. Yes, I would yield.

Mr. STUPAK. OK, Mr. Burgess for questions, please, 5 minutes.

Mr. BURGESS. Thank you.

Dr. DeCarlo, help me with something, if you would. When we first heard about the pet food problem, the original compound that was pinpointed was eminoptrin folic acid antagonist; and now we hear it is melamine, which is, I guess, a plastic polymer. What is the reason that eminoptrin first came to the news media's attention as the culprit in this?

Dr. DECARLO. I am probably not the right person to ask that question. I think you probably have your information from the same sources that I do.

Mr. BURGESS. CNN.

Dr. DECARLO. CNN. And, actually, there were many, many sites to get information from and some conflicting, so I don't have any factual information that would be helpful to that question. So I apologize.

Mr. BURGESS. We are now pretty certain in our assumption that it is melamine that is causing this?

Dr. DECARLO. Yes, I think from what I can read on the medical side that it certainly has affected cats more than dogs; and there is many reasons for that. One may be because of the foods they are eating but also because cats don't process toxins as well. They have a different system for that. There are—people feel that sometimes it doesn't explain the symptoms as well, but I think the majority of the literature is pretty comfortable with that association at this point.

Mr. BURGESS. Do we know the concentrations of this compound that they are detecting in the wheat gluten?

Dr. DECARLO. No, but that would be a great thing for us to know about.

Mr. BURGESS. Do we have an idea from previous laboratory analysis what is the LD 50 of melamine for cats and dogs?

Dr. DECARLO. I think that probably exists, but I don't know the answer to that.

Mr. BURGESS. Do you guys routinely suspect a food-borne illness when checking into outbreaks of disease in domesticated pets?

Dr. DECARLO. I think we do. It is probably a little bit easier with animals because they tend to eat a lot of things so that is high on our list of differentials, especially in this situation. Even though cats have high incidences of renal disease, usually it is chronic renal disease in older cats. So to cure renal disease one of the first things we look for is a toxin, because it is so unusual to see acute renal disease in young cats. But in our profession, since it is a common thing, food ingestion of toxins is the first thing we ask because it is in the nature of the cases we see.

Mr. BURGESS. When this outbreak first started, was there—there was no difference between animals that were completely indoor

animals versus outdoor animals. You mentioned that dogs and cats do eat a lot of things out in the environment.

Dr. DECARLO. I can't answer that. No one has looked at that indoor versus outside.

Mr. BURGESS. If I could, Ms. Shames, let me ask you, you referenced in some of your remarks that you have looked at the United States food supply in comparison with other countries, similar demographics, similar population, and said the United States' food supply on the whole is safe. Did I understand that correctly?

Ms. SHAMES. Yes.

Mr. BURGESS. In that course of doing that part of your analysis, I guess one of the things that troubles me in reading your report, and it has already been referenced, you have different agencies looking at a pizza, depending on what the topping is, and you have a different agency looking at a sandwich, if it is an open-face sandwich versus a complete sandwich. Is there any country this has a more streamlined approach to the problem at hand? You reference that we have kind of grown up with a patchwork of regulations. Is there a model out there that suggests a better way to do this?

Ms. SHAMES. We actually have an ongoing engagement to look at the other countries. Similar to ours, they started out as being fragmented. It was—they would describe it, too, as something that evolved piecemeal. They did go for a more consolidated approach.

Now we are looking further at what they mean by consolidated. Some of them actually did go as far as merging all of their agencies into one single food agency. Others merely reduced the number of agencies. But we are now, at the request of Congresswoman DeLauro and Senator Durbin, looking at what actually are the positive consequences of these countries' reorganizations of their countries' food safety systems.

Mr. BURGESS. And certainly I think the committee would appreciate that follow-on information as well.

You referenced in food safety you depend upon industries involved for a voluntary recall. Has there ever been a situation where a company or manufacturer has refused to issue a recall when asked to do so by the appropriate agency?

Ms. SHAMES. Neither FDA nor USDA ever told us that there was a company that refused.

Mr. BURGESS. Has there been a pattern of foot dragging and not complying as quickly as the USDA or FDA normally would like?

Ms. SHAMES. What we know from the other agencies that do have this mandatory recall authority is that it is something that—it is a tool that they have in their belt. It is something they don't use on a routine basis. Nevertheless, they have felt that they have had to use it in given instances. And similarly, for FDA and USDA, we feel it is a case where—to give them the same sort of authority and tools that the other Federal agencies have.

Mr. BURGESS. But has anyone in either other agency ever said to you, boy, if we only had the ability to do a recall, to mandate a recall, this would never have happened? Have we ever gotten a situation like that?

Ms. SHAMES. No.

Mr. BURGESS. Thank you, Mr. Chairman. I yield back my time.

Mr. STUPAK. I thank the gentleman. Mrs. Blackburn for questioning, please.

Mrs. BLACKBURN. Mr. Chairman, just three quick questions.

Do you think the Federal Government needs the authority to mandate recalls?

Ms. SHAMES. We have recommended that for both USDA and FDA.

Mrs. BLACKBURN. So you would support that and you would see that as a positive thing to mandate?

Ms. SHAMES. Yes.

Mrs. BLACKBURN. OK, one of the things that seems to—and you have talked a good bit about the piecemeal approach and the fragmentation, but it also seems when you look at the FDA and USDA, we also have the medical community over here that is not accessing this information, even the CDC I think one of our earlier witnesses mentioned, there seemed to be a lack of communication there. So I feel like not only do we have a two-tiered problem with the FDA and the USDA but being certain that we move this over for the medical community and the public at large.

So as you go looking at the other countries, I think what we would like to have is not only the thoughts on this but looking at what would be the best recommendations, the best practices, that you would have for the agencies in streamlining their approach and making certain that the food supply systems are safer but also what the recommendations would be for the medical community to access this, our hospitals, our trauma care centers, et cetera, and then the public notification system on situations like this.

What we heard from our first panel was they did the legwork themselves and that they got into this and realized there was no orderly process for reporting or for discovery. I think we would appreciate having your top recommendations for that, and you may have something right now that you would like to add for the record.

Ms. SHAMES. Nothing that I can add for the record for specific recommendations, but surely, as we start to design this engagement, we will be looking at the pressing issues that this country is facing.

One thing that the high-risk list does is that we report then on the progress that agencies have made in terms of addressing these high-risk issues. Certainly we can learn from other countries' experiences, and we will try to integrate as much information as possible from what we have learned overseas.

Mrs. BLACKBURN. OK, when you are looking at other countries with our food supply, are we safer than or as safe as other countries and have our incidences of death and illness increased or decreased over the past decade?

Ms. SHAMES. We haven't looked at the data longitudinally in terms of what their safety is. In fact, even CDC is trying to get behind the numbers that they have been publishing for the number of deaths, hospitalizations and illnesses. So it is something that the data reliability is very important and we would be looking for to see how complete and accurate and consistent the reporting system is.

Mrs. BLACKBURN. I think we would like that qualified data once you have it and can say this is how we stack up in relation to other countries.

One quick other question, mandatory recall, would it have made a difference in either the peanut butter or the spinach situation we have heard about this morning?

Ms. SHAMES. Applying it to these specific instances, we haven't looked specifically for the peanut butter or the spinach. Just generally speaking, we feel that this authority is something that has the potential of expediting the recall. We found that when FDA and USDA did carry out their voluntary recall programs, oftentimes by the time the food was removed from the shelf it had expired from the shelf life. And this is especially important for fresh produce.

Mrs. BLACKBURN. Thank you. I yield back.

Mr. STUPAK. Any further members have any further questions of this panel?

Hearing none, I will excuse this panel and thank you again for your testimony.

Mr. BURGESS. Mr. Chairman, if I can follow up on that last point, I would agree that in the case of the *E. coli* contamination of the spinach I don't know of the mandatory recall because of the time involved would have made a difference. But on the peanut butter situation, where they continued to feed the patient the product in the hospital, in the nursing home, that one does bother me. If there had been a recall issued in January, that process might have been stopped.

I am not smart enough to say it would have made a difference in the clinical outcome, but as somebody who has a background in health care I would have liked to have known that and stopped feeding the patient the product many months before it was actually discontinued.

Ms. SHAMES. We did look at some of the recalls of FDA, and, clearly, for canned foods—in fact, we looked at a recall for canned soup and because the shelf life of that canned soup is a couple of years the recall was more thorough and more complete. It was less complete when you looked at ground meat, for example, that has a shelf life of a couple of weeks and surely the same thing for fresh produce. So it does get problematic the more fresh the produce or food happens to be.

Mr. STUPAK. Also, wouldn't there be a benefit if you used recall to help physicians and help diagnose situations such as we had with young children where they think it might be a viral infection where in fact you can focus in more clearly on another possibility? That is where I would see a recall would also help.

Mr. BURGESS. There is. Syndromic surveillance would play a greater role, and that ties into the whole health IT argument debate we have back and forth on the ability to get information to emergency rooms and practitioners in a timely basis. That is what we saw here with anthrax.

Mr. STUPAK. It was amazing. In each one of the cases—the first panel, they learned it from the news media or it was Mr. Pruden's sister or sister-in-law who was a nurse that said check for the brown urine in order to check the problem, to diagnose the problem. Otherwise, we would still be treating a viral infection.

Thank you. Anything further from any members? Thank you again to this panel.

We will call up the third and final panel.

Our third panel consists of Mr. Charles Sweat, president of Natural Selections Foods; Mr. David Colo, senior vice president of manufacturing at ConAgra Foods; Mr. Paul Henderson, CEO at Menu Foods Income Fund; and Mr. Stephen Miller, CEO at ChemNutra.

It is the policy of this subcommittee to take all testimony under oath. Please be advised witnesses have the right under the rules of the House to be advised by counsel during testimony. Do any of you gentlemen wish to be represented by counsel? Mr. Henderson? Mr. Sweat.

Mr. SWEAT. Yes.

Mr. STUPAK. Would you identify your counsel for the record please?

Mr. SWEAT. Marty Schenker.

Mr. STUPAK. Mr. Colo?

Mr. COLO. No.

Mr. STUPAK. And Mr. Miller, sir, do you have counsel present with you?

Mr. MILLER. Yes.

Mr. STUPAK. Would you identify your counsel for the record?

Mr. MILLER. Mr. Marc Ullman.

Mr. STUPAK. Next, as you know, we do take testimony under oath, so I am going to have you ask you all to please rise and raise your right hand.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect all four witnesses answered in the affirmative. They are under oath.

We will begin with the opening statements, 5-minute opening statement. Mr. Henderson, please, if you begin with your 5 minutes, please, opening statement, sir.

STATEMENT OF PAUL K. HENDERSON, PRESIDENT AND CHIEF EXECUTIVE OFFICER, MENU FOODS

Mr. HENDERSON. My name is Paul Henderson, and I am the president and chief executive officer of Menu Foods. The subcommittee invited me today to discuss issues of food security and, in particular, the recent terrible situation involving pet food manufactured with contaminated Chinese wheat gluten supplied by ChemNutra to several pet food manufacturers, including Menu Foods.

Let me begin by noting that I am a pet owner and many of our employees are pet owners. My dog eats food manufactured by Menu Foods. I understand and my employees understand the loss felt by pet owners as a result of the pet food made with contaminated ingredients. All of us at Menu Foods deeply sympathize with pet owners.

Who is Menu Foods? Menu Foods has three manufacturing plants in the United States, employing more than 800 workers here; and the majority of our assets and sales are in this country. Menu is recognized in the pet food industry as a quality manufacturer. This might seem a little odd in light of the recent recall

product, but, as I sit here today, I can't think of a more accurate description of my company.

How can I say that? Well, for starters, just look at our customers, particularly the national brands for which we manufacture. They are the market leaders, and quality pet food is what they are all about. Each had a choice in who would manufacture for them and each turned to Menu.

In reality, it wasn't that easy. For many, we first had to demonstrate an ability to manufacture at a level of quality at least as good as their own. These branded pet food companies sent their inspectors to our plants and satisfied themselves as to our abilities and our quality.

Sometimes they identified a procedure that was standard within their plants and required us to adopt the same procedure in order to secure their business. By doing so, they contributed to our own improvement efforts, with the result that, today, we are one of the highest-quality operations in the United States.

But we don't stop there. All of our facilities are routinely audited by outside experts. Many of our branded customers conduct annual audits of the menu plans manufactured for them.

In addition, we are inspected by the USDA's Animal and Plant Health Inspection Service, the Canadian Food Inspection Agency, the European Food Safety Inspection Service, the American Institute of Baking, and Menu's Pennsauken plant was inspected by the FDA in 2006. In over 35 years of business, Menu has never had a food safety related product recall until the tragic events involving the contaminated wheat gluten.

A lot of speculation has taken place concerning Menu's activities leading up to that recall. Much of that speculation has been inaccurate, and we are pleased to correct that record. A detailed timeline was provided with my written remarks, so I will not repeat that here. Instead, let me summarize the situation by describing what it is and what it is not. First, what it is not.

This is not a situation caused by unclean facilities, poor manufacturing problems or similar problems. Our facilities are first rate. Our sanitation and manufacturing processes are state of the art. This is not a situation where lax inspection of Menu allowed a problem to occur. We have rigorous internal and external inspections. Inspections of our plants would not have prevented the melamine contamination of the wheat gluten.

This is also not a case of reacting improperly to the situation facing us. We took appropriate actions based on the information available at the time.

Let me put this situation into context. In 2006, Menu sold approximately 3.2 million containers of pet food per day. In contrast to this number, at the time we decided to initiate the recall, we had a handful of reports from consumers, three consumer reports passed along by a customer and reports from a taste test facility.

None of these problems conclusively pointed to our food as the cause of the problems. At the same time, Menu had conducted tests of all industry recognized causes of renal failure, and these tests had revealed no problems at all with our pet food. In fact, it took the FDA, prestigious research organizations and commercial lab-

oratories several weeks of hard work to identify melamine in ChemNutra wheat gluten as the source of the problem.

However, in the face of the circumstantial information, we put the interests of pets and pet owners first and notified the FDA and began a voluntary precautionary recall.

We have cooperated in every way with the FDA's investigations and the efforts to identify the source of the problem.

Now let's consider what this is, or at least what it appears to be.

What this appears to be is a deliberate case of contamination of wheat gluten in order to pass off substandard product. Melamine was previously unreported as a contaminant in wheat gluten. Melamine is high in nitrogen, which is significant, because the industry's standard test for protein content for wheat gluten is based on a quantity of nitrogen. Melamine would make wheat gluten appear to have a higher protein content than was actually the case.

For a seller who knows how the industry testing methods work, this would allow them to cheat buyers; and if it were not for the previously unknown toxicity of melamine in cats and dogs, the scam would have worked.

It appears likely that the public, Menu and other pet food manufacturers were the victims of a fraud.

Menu has taken several steps to address the situation, including testing wheat gluten and other vegetable proteins for melamine, increasing our screening process of new suppliers, and discontinuing all business relationships with ChemNutra.

We are also working with Congress, the FDA and the Pet Food Institute and other interested parties in their investigations and in formulating additional measures for preventing similar occurrences in the future.

Thank you.

Mr. STUPAK. Thank you.

[The prepared statement of Mr. Henderson follows:]

TESTIMONY OF PAUL K. HENDERSON

I am Paul Henderson, CEO of Menu Foods Income Fund. The subcommittee invited me today to discuss issues of food security and in particular the recent terrible situation involving pet food manufactured with contaminated Chinese wheat gluten supplied by ChemNutra Inc. to several pet food manufacturers, including Menu Foods.

Let me begin by noting that I am a pet owner, and many of our employees are pet owners. My dog eats food manufactured by Menu Foods. I understand, and our employees understand, the loss felt by pet owners as a result of pet food made with contaminated ingredients. We deeply sympathize with these pet owners. However, we cannot turn back the clock, so now we must analyze what happened and how it happened and consider the steps that the pet food industry and Government agencies should take to try to prevent things like this from happening in the future.

Much has been said and written about these recent events, and a lot of it has been inaccurate. I appreciate the invitation to appear before the Subcommittee today to explain what actually occurred and to share my thoughts on the future of food safety in the pet food industry.

BACKGROUND OF MENU FOODS

Menu Foods is the leading North American private-label/contract manufacturer of wet pet food products sold by supermarket retailers, mass merchandisers, pet specialty retailers and other retail and wholesale outlets. Menu Foods was formed in 1971 and went public in 2002, trading on the Toronto Stock Exchange.

Menu Foods was founded in Canada, but our U.S. operations are much larger than our Canadian operations. We have three manufacturing plants in the United

States, which are located in Emporia, Kansas; Pennsauken, New Jersey and North Sioux City, South Dakota. Menu Foods employs more 700 workers in the United States, and the majority of our sales are in this country.

Menu is recognized in our industry as a quality leader. We are known as the manufacturer of choice in the private-label pet food industry by retailers that value quality in their products. In over 35 years of business, Menu had never had a food safety-related product recall until the recent tragic events involving the contaminated wheat gluten. Menu produced over 1.1 billion containers of pet food last year, so this is quite a record, and we were very proud of it. We hope we can restore our reputation, and we are working hard to do so.

MENU FOODS—PRODUCTS

Menu Foods manufactures two basic types of wet pet food: “loaf” products, which have a pate-like consistency, and “formed” products where formed, precooked pieces are put into the product. The formed products include “cuts & gravy,” which resembles stew, and products that include flakes or slices. Menu Foods does not manufacture dry pet food.

The contaminated wheat gluten supplied by ChemNutra caused us to recall some of our products (primarily cuts & gravy products) manufactured at three plants from November 8, 2006 through March 6, 2007.

Wheat gluten is a natural vegetable protein extracted from wheat grains or flour and is a by-product of wheat starch. Only about 20 percent of the wheat gluten used by human food and pet food manufacturers in the US is produced in the US. Most of the wheat gluten is imported from Europe or Asia. Our United States plants buy wheat gluten from several suppliers around the globe. Wheat gluten is used by some pet food manufacturers, including Menu, as an ingredient in formed meat products. It is a source of protein and also has unique properties that help to hold together the chunks of meat. Wheat gluten is also used by manufacturers of human food products, mostly for baking.

THE PROBLEM: CHEMNUTRA’S SALE OF CONTAMINATED WHEAT GLUTEN

Wheat gluten has been in short supply, and in 2006 we decided we needed to add an additional source for this important ingredient. In November 2006, Menu Foods bought wheat gluten from ChemNutra for the first time. ChemNutra is a U.S. company, based in Las Vegas, that is an established supplier of ingredients to food, feed and pharma companies throughout the country. Although this was our first purchase of wheat gluten from ChemNutra, we had purchased other ingredients from ChemNutra in the past.

As part of our program to ensure high-quality ingredients, Menu Foods provided ChemNutra with a Material Specification stating Menu Food’s requirements for wheat gluten. The Material Specification provided detailed instructions and requirements, including but not limited to: material source, material description, physical requirements, chemical requirements, rejection criteria, packaging/shipping/storage requirements, microbiological standards, grind/particle size standards, water storage standards, ingredient manufacturing requirements, labeling requirements, and key performance/functionality requirements. The Material Specification expressly prohibited foreign material contamination. Each shipment of wheat gluten Menu Foods received from ChemNutra was accompanied by a Certificate of Analysis representing that the wheat gluten complied with Menu Foods’ Material Specification.

Our Material Specifications adhere to the standards of the Codex Alimentarius, which is a collection of internationally recognized standards for food developed under the aegis of the United Nations Food and Agriculture Organization and World Health Organization. There is no FDA standard for human grade wheat gluten, but Menu intends that all wheat gluten we use should be suitable for use in human foods.

ChemNutra promised Menu Foods that it could deliver high-quality wheat gluten that satisfied the requirements set forth in the Material Specification. Menu Foods relied on ChemNutra’s promises. Unfortunately, we now know that ChemNutra provided Menu Foods and other pet food manufacturers with a product that was contaminated with melamine. Needless to say, following this incident, we no longer do business with ChemNutra.

MENU ACTED AGGRESSIVELY TO IDENTIFY AND ADDRESS THE PROBLEM

A lot of speculation has taken place concerning Menu Foods’ activities leading up to the recall. Statements have been made in the media and in public forums and even by some of the participants in the supply chain of the contaminated wheat glu-

ten. Much of the speculation and some of these statements have been inaccurate. A summary of the major events leading up to the recall appears below:

February 22, February 28, and March 5, 2007

The first complaints Menu received that we now believe were related to the contaminated wheat gluten were on February 22 and 28. On those dates, Menu received calls from customers on our consumer response line (a toll-free number on the label or pouch of many of the private-label products we produce). Each call reported the illness of a cat. As part of Menu's follow-up, we contacted the veterinarians who treated the cats. The treating veterinarians indicated that both cats had access to various contaminants and could have gotten into something they should not have, such as antifreeze.¹

These cats were also noted as having been strays at some point in their lives. A third call (about March 5) was received from a consumer reporting a cat death. Menu Foods did not receive information from a veterinarian with this report.

Tuesday, March 6, 2007 . 1 On March 6 and 7, Menu learned of two additional cases of cat illness. Neither of these reports have resulted in cat deaths to Menu's knowledge.

A company Menu Foods retained to perform routine, quarterly palatability studies/taste tests reported that cats involved in one of the studies became sick and died.²

The panel consisted of 20 cats. Three had died (two of the three were euthanized), and six were sick. All of the cats were 10 years old or older. The animals were being simultaneously fed a product manufactured by Menu Foods and products manufactured by other companies. The cats had been involved in taste tests for another pet food company the previous week. The company performing the palatability studies told Menu Foods that it also notified the "other company" of the health issues. Because the cats were exposed to several kinds of food, the source of the problem was unknown. There were at least six possibilities:

- Menu's food used in this taste test.
- The competitor's food against which Menu was conducting the taste test.
- The food of the company that used this same panel of cats for a taste test before Menu's taste test.
- The competitor's food against which the previous company was feeding.
- A hazard within the testing facility.
- An animal illness of an infectious nature.

The company performing the palatability studies reported no problems with a second panel of twenty cats who were eating the same variety of food as the first panel. Both foods had been produced by Menu at the same time, leading Menu to believe that its food was not the source of the problem.

Although Menu Foods did not then believe that its food was the source of the problem, out of an abundance of caution we stepped up our investigation. Our records showed that wheat gluten from ChemNutra was one of several ingredients common to the foods consumed in the cat illnesses and deaths referenced above and the product used in the palatability studies. As a precautionary measure, Menu Foods stopped using wheat gluten from ChemNutra.

Friday, March 9, 2007. The company that performed the palatability studies reported that four additional cats (also of an advanced age) from the first palatability study were euthanized and nine were sick. The company also reported that two cats in the second study of twenty cats were euthanized, one of which was over 16 years old. Like the first study, the cats in the second study had eaten several products.

By this time, Menu Foods' investigative team had traced the raw materials common to the reported incidents and identified wheat gluten, plasma, glycine, taurine, digest, caramel color and salt. Laboratories commissioned by Menu Foods to perform tests began testing the products consumed by the animals in the palatability studies and consumer complaints to try to identify any problems. At Menu's direction, they began tests for minerals, heavy metals, antifreeze, vitamin—D, fluorine and mold

¹ Many pets die every day, and some die from antifreeze poisoning. Euromonitor International reports that there are approximately 82.2 million cats in the United States. Using an estimated life expectancy of 18 years, this would mean that approximately 12,500 cats die every day in the United States. Dr. Ron Hines, a veterinarian, estimates that 10,000 dogs and cats die of antifreeze poisoning each year in the United States.

² Pet food manufacturers, including Menu, regularly perform taste tests where food manufactured by one company is compared to food from another company. Since cats and dogs cannot tell us which food they like better, the only way to tell whether we are making a product the animals like is to feed it to them. These tests are not intended in any way to injure or endanger the participating animals, and Menu's tests are conducted in facilities that meet accepted standards for humane treatment of the animals.

toxins, and for commercial sterility. These tests take several days to complete, but when we received the results, they showed nothing wrong.

Meijer, a grocery store chain in the Midwest, relayed that a customer reported pet health problems. Menu Foods began trying to get in touch with the customer to determine what product was involved so it could be tested.

Monday, March 12, 2007. The company that performed the palatability studies reported that independent tests conducted on the pet foods used in these studies (for heavy metals, antifreeze, pesticides and insecticides) were negative. Menu Foods requested its own pesticide/insecticide tests.

Menu continued to try to reach the consumer involved in the report from Meijer.

Tuesday, March 13, 2007. Menu Foods received results from the tests conducted at Cornell University on the product used in the palatability studies. Cornell University did not find any pesticides, insecticides or toxins. Menu requested that Cornell test for heavy metal and mycotoxin in samples of wheat gluten.

The Iams Company contacted Menu to report renal issues in cats that consumed Iams flaked salmon. Iams explained that it had received telephone calls from three consumers: one involved death of a cat for renal failure, one involved vomiting within fifteen minutes of consumption, and one cat refused to eat the food.

Wednesday, March 14, 2007. Menu reached the consumer involved in the report from Meijer's and learned that the animal consumed product manufactured in October 2006—before Menu Foods began receiving wheat gluten from ChemNutra. The consumer agreed to send Menu the remaining food for testing. The consumer did not know the cause of death. After the recall was announced, Menu received the food from this customer. Testing showed that it did not contain melamine.

Menu and Iams shared with each other the information that each had obtained to that point.

Menu received the results of tests performed on the ChemNutra wheat gluten for antifreeze, which were negative. Menu decided to begin testing for intentionally added toxins.

Cornell University tested the product involved in the palatability studies for intentionally added toxins, but the tests came out negative. Menu continued to perform a broader series of tests on the wheat gluten from ChemNutra.

The company that performed the palatability studies forwarded tissue samples from a deceased animal to Cornell University to perform tests in an attempt to discover whether a toxin killed the animal.

At 8:30 p.m., Iams told Menu Foods that it intended to recall cat food manufactured by Menu Foods in Emporia, Kansas from December 17, 2006 through March 14, 2007.

Thursday, March 15, 2007. On the morning of March 15, 2007, Menu Foods received a call from the owner of five indoor dogs. She reported feeding her dogs Menu-produced product. Thereafter, one of her dogs had died of renal failure, and the other four were ill. Shortly thereafter, Menu was notified by a testing facility that several dogs involved in a taste test had experienced a drop in food consumption similar to the cats in the taste tests described above and were ill and vomiting. These were the first reports of which Menu was aware of dogs being adversely affected by pet food manufactured by Menu.

On the afternoon of March 15, 2007, Menu Foods notified the FDA of its decision to recall products manufactured with wheat gluten obtained from ChemNutra from December 3, 2006 through March 6, 2007. The recall included both dog and cat food. Menu Foods announced the recall the following morning. We chose December 3, 2006 as the start of the recall because the food in the first consumer complaint was produced during that week. Although we did not know whether the recalled product contained a contaminant or what the contaminant was, we recalled products produced with the ChemNutra wheat gluten while we and others continued to investigate the source of the problem.

MENU FOODS RESPONDS BY VOLUNTARILY RECALLING POTENTIALLY AFFECTED PRODUCT

Some people have suggested that Menu acted too slowly and should have contacted the FDA sooner. On the contrary, we acted quickly and took appropriate steps under the circumstances.

Let me put this situation in context. Menu produces over 1.1 billion containers of pet food each year—nearly 100 million containers each month. As of March 15, 2007, Menu had directly received six reports from consumers of possible problems with its pet food—many of which appeared to be something other than pet food, in several cases confirmed by opinions of the animals' veterinarians. One of Menu's customers, Iams, had received, and eventually passed on to Menu, three complaints

involving animal health issues. Both Menu and Iams had received complaints of a refusal to eat the food, which often happens when an owner changes to a different food or for other reasons completely unrelated to food quality. And the taste testing facility reported several deaths and illnesses, but nothing that indicated it was caused by Menu's food. Menu had conducted tests for all industry-recognized causes of problems with pet food, and these tests revealed no problems. In fact, it took the FDA, prestigious research organizations and several commercial laboratories many more days to identify melamine in ChemNutra wheat gluten as the source of the problem.

Based on this information, any pet food manufacturer could well have decided to continue to try to find the problem, but not to contact the FDA or begin a product recall. Indeed, based on what was known at the time, there might well have turned out to be no problem with the food, and announcing a recall could have only resulted in an unnecessary panic among pet owners. And, the only indication we had of any issues with dog food was only hours old and as yet completely uninvestigated. However, Menu placed the interests of pets and pet owners first, so, like our good customer Iams, we decided that, notwithstanding the lack of scientific evidence, we should notify the FDA and begin a voluntary, precautionary recall.

On March 16, 2007, Menu Foods voluntarily recalled pet food manufactured with wheat gluten obtained from ChemNutra, Inc. from December 3, 2006 through March 6, 2007. The FDA initiated an investigation of Menu Foods' formed meat products that same day. Menu Foods gave the FDA its full cooperation and continues to cooperate fully with the FDA.

On March 24, 2007, in order to expedite the recall and satisfy concerns by the FDA, Menu Foods initiated a market withdrawal that included all production dates of the impacted products during the recall period. This change made it easier for retailers to get the identified products off their shelves and reduced the risk that a store clerk would mistakenly leave a recalled product on the shelf because he or she misread the date code on the product.

On Friday, March 30, the FDA announced that researchers at Cornell University located melamine in the finished product that was the subject of the recall. Researchers also located melamine in samples of wheat gluten Menu Foods purchased from ChemNutra, Inc., which has stated that it imported the wheat gluten from Xuzhou Anying Biologic Technology Development Co. Ltd. (Xuzhou Anying) in China. Melamine was not found in wheat gluten Menu Foods obtained from other suppliers. Melamine is a chemical contaminant, not a microbial contaminant. According to the FDA, it is "very unusual" to find melamine in wheat gluten.

On April 3, 2007, ChemNutra issued a press release announcing a recall of all wheat gluten it imported from Xuzhou Anying. ChemNutra admitted that melamine "should absolutely not have been in wheat gluten." Four other pet food manufacturers obtained contaminated wheat gluten from ChemNutra and initiated recalls: Hill's Pet Nutrition, Del Monte Pet Products, Nestle Purina PetCare Company, and Sunshine Mills Company.

On April 5 and April 10, Menu Foods expanded its recall to additional products manufactured with ChemNutra wheat gluten. On April 5, Menu Foods expanded the recall to include products manufactured with ChemNutra wheat gluten from the first date of manufacture (November 8, 2006) through December 2, 2006. (The previous recall included the period spanning from December 3, 2006 through March 6, 2007.) At the time of the initial recall on March 16, 2007, Menu Foods was not aware of any complaints or reports of health problems relating to food manufactured from November 8th to December 2.

On April 10, 2007, Menu Foods expanded the recall to include certain products manufactured at its plant in Canada after discovering through the ongoing investigation that the Canadian plant received a quarter of a load of the contaminated wheat gluten from the Menu Foods plant in Emporia, Kansas. The wheat gluten that was transferred between plants was subsequently used in production at the Streetsville plant during December 2006 and January 2007.

Menu Foods is no longer purchasing any ingredients from ChemNutra and has taken steps to assure that none of the products that contain wheat gluten from ChemNutra are sold. The FDA is blocking all imports of wheat gluten from Xuzhou Anying.

Menu's investigation has revealed a possible motive for the presence of melamine in ChemNutra's wheat gluten. Menu Foods' Material Specification for wheat gluten contains a chemical requirement that the wheat gluten contain no less than 75 percent protein. This is a typical specification for wheat gluten for both human and ani-

mal food. In the human food and pet food industry, protein levels are customarily estimated by determining the quantity of nitrogen in a product.³

Melamine has a high concentration of nitrogen and, as a result, the inclusion of melamine into the wheat gluten would make substandard wheat gluten appear to meet industry standards for protein content.

MENU IS DEDICATED TO PROVIDING SAFE, HIGH-QUALITY PRODUCTS TO ITS
CUSTOMERS

The foundation of Menu's business is providing quality, nutritious food for pets. We have been doing so for over 35 years. The safety of our products and the confidence of pet owners and our customers are our highest priorities.

Menu Foods monitors for spoilage and has thorough quality control procedures. As is common industry practice, Menu Foods tests the wheat gluten it uses for vomitoxin caused by mold growth. This mold toxin is the only contaminant in recent history that has been associated with a pet food recall involving wheat used in dry pet food. Menu tests every load of wheat gluten it receives for vomitoxin using an approved test performed by trained personnel. Menu Foods did not detect melamine during its quality assurance testing because accepted screening procedures do not detect melamine. Melamine is not something that had ever been heard of before in connection with wheat gluten. To our knowledge, no pet food or human food manufacturer tested wheat gluten for melamine prior to this incident.

Some people have noted that Menu's Emporia plant had not been inspected by the FDA. That is true, but not surprising given Menu's excellent performance record and reputation and the FDA's limited resources. However, additional plant inspections would not have prevented the problem in this instance—contaminated wheat gluten purchased from ChemNutra.

Moreover, Menu's plants are subject to significant internal and external inspection and review. Menu has its own quality control systems, which have been reviewed and approved by our customers, including global companies with substantial experience in quality control. In addition to Menu's internal systems, all of our facilities are routinely audited by outside experts. Menu engages the American Institute of Baking to audit food safety and sanitation. These inspections are conducted at least annually, and Menu has consistently scored in the "excellent" and "superior" range. Menu Foods' United States plants are inspected annually by the United States Department of Agriculture Animal and Plant Health Inspection Service (APHIS). Menu Foods' plant in Canada is inspected annually by the Canadian equivalent to APHIS, the Canadian Food Inspection Agency (CFIA). Menu Foods is also inspected by the European Food Safety Inspection Service, which is widely respected for HACCP (Hazard Analysis and Critical Control Point) and food safety concerns. Menu's Pennsauken plant has been inspected by the FDA. Finally, Menu is inspected by multiple global pet food producers with known high quality standards as a condition of manufacturing pet food for them.

To ensure that we are producing the highest quality products, we have taken the following additional steps in response to the situation:

- First, like other pet food manufacturers, we have stopped purchasing wheat gluten from ChemNutra. In fact, we have stopped buying any ingredient from ChemNutra.
- We now test wheat gluten for melamine. Consistent with our desire for continuous quality improvement, we have extended melamine testing to rice protein and corn gluten meal.
- We will conduct additional tests of wheat gluten and other ingredients in the future to make it more difficult for a supplier to sell us substandard product.
- We will implement more rigorous testing and supervision for new suppliers.
- We continue to monitor developments in the industry and will update these measures as necessary to ensure the continued safety of our products.
- We are an active member of the Pet Food Institute and an active participant in its review of pet food safety issues. We will implement recommendations of the PFI review as appropriate for our business.
- We will work with the FDA and other regulatory authorities and Congress to develop additional measures to protect against future occurrences of this type.

³ In testing, crude protein is used as a key indicator of usable amino acids available in the pet food as a source of nutrition. The amount of usable amino acids in the pet food is estimated by determining the quantity of nitrogen in the product and multiplying that figure by an accepted constant.

Finally, we have filed suit against ChemNutra. ChemNutra sold us contaminated wheat gluten that did not meet our specifications and did not conform to the promises of quality that ChemNutra made to us. ChemNutra's actions have caused tremendous injury to the public and to Menu.

SUGGESTIONS FOR IMPROVING FOOD SAFETY PROTECTIONS

Before concluding, let me share some thoughts on improvements that governments might make in the food safety protection system, based on Menu's experience and my observations of the system as a whole.

First, we should recognize the extent to which opening global markets for U.S. products has also opened the U.S. market to foreign products, which, as in Menu's case, are not always in compliance with accepted standards. It is difficult for manufacturers to inspect each supplier. The Government, on the other hand, is in a better position to inspect and certify foreign suppliers of food products or ingredients in order for them to be permitted to sell their products into the U.S. Menu's plants and processes are inspected and approved for compliance with European standards and regulations as a condition of being able to export our products to Europe. These inspections are performed by APHIS in the U.S. and CFIA in Canada under an arrangement with the EU, no doubt because of the confidence the EU has in APHIS and CFIA. Perhaps, in order to sell their products in the U.S., foreign suppliers should be required to submit to inspection and certification by a U.S. agency or some other party accredited by the U.S. Government.

Second, Government agencies could increase their inspections of imported products at the border. These inspections might not have identified the contamination in the wheat gluten from ChemNutra, because melamine was not recognized as a potential contaminant at the time, but we think in many cases problems could be detected at the border. Of course, now that we know about melamine, Government agencies can also test for it at the border, and perhaps prevent future incidents involving that substance.

Third, Government agencies might increase plant inspections in the U.S. We do not believe this would have prevented the melamine problem, but there may be other more conventional hazards that might be detected through on-site inspection.

We believe that the focus of inspections outside the U.S. might be based on the principle of reciprocity. Trading partners that have equivalent regulation to the U.S. might be allowed to import products based on inspection and certification by local authorities in which the U.S. Government has confidence. Suppliers in other countries might be inspected directly by U.S. agencies. Plant inspections in the U.S. might be conducted on the basis of the risks of the business being conducted at the plant. For example, good manufacturing processes, sanitation practices and inspections are important controls in meat processing plants, because of the risks associated with uncooked meat. By contrast, in human and pet food operations where products are heat treated to sterilize them, the risks are different and may warrant a different approach.

Fourth, because understanding relevant risks is so important, Government could invest in development of better risk assessment processes. For example, central to the current pet food recall is the procedure that uses nitrogen testing to estimate protein content. It is possible that someone may have used melamine, which is rich in nitrogen, to pass off inferior product. The nitrogen test was not designed to deter cheaters but rather to estimate protein. What other rapid tests are used throughout the food chain to estimate quality? Is there a risk that these tests can be abused, as appears to have been the case with wheat gluten? If so, could mechanisms or processes be developed to identify and address that risk?

Finally, Government might research or fund research of new technologies for fast, accurate and affordable detection of contaminants in food ingredients. One of the difficulties in the investigation of the wheat gluten situation was that there was no established protocol for testing for melamine. So, the researchers first had to develop a testing method before they could even check for its presence. Even more valuable might be a method for rapid, accurate and cost-effective determination of the presence of any contaminant in an ingredient or in finished product.

Sometimes even well respected manufacturers, like Menu, suffer problems caused by others. We are working with the FDA and with our customers to resume our business of providing nutritious, high-quality pet food for animals throughout North America. We take pride in our products, and we also take responsibility for them. We intend to do everything in our power to make things right for our customers and to prevent this type of situation from ever occurring again.

Mr. STUPAK. And Mr. Sweat for 5 minutes, please, sir.

**STATEMENT OF CHARLES SWEAT, PRESIDENT, NATURAL
SELECTION FOODS**

Mr. SWEAT. Mr. Chairman and members of the committee, thank you for allowing Natural Selection Foods the opportunity to be a part of the important discussion about food safety in this country. We are pleased to cooperate with the subcommittee's investigation in this hearing.

My name is Charlie Sweat, and I am the president of the company.

Before proceeding, I want to say that everyone in our company remains deeply saddened by the human toll that this outbreak has wrought. We are a company founded on the commitment to providing the healthiest food possible, and to learn that food processed by us could have brought anything other than good health was devastating.

On September 14, we received a call from the FDA and the California Department of Health Services that there was an outbreak of *E. coli* 0157:H7 linked to our fresh spinach. We were shocked to learn that some of our products might be involved. Within 24 hours, at the suggestion of the investigators, we voluntarily recalled all products containing spinach under all brands that were packaged in our facility.

Recently, the FDA and CDHS released a joint report on this incident. The report clearly states that no specific transmission vehicle has been identified, but the report's findings point to what we believed from the beginning: The contamination appears to have been somehow linked to the natural environment in which the spinach was grown. Samples matching the outbreak strain were found on a cattle ranch just under a mile from where the spinach was grown but never on the spinach field it self.

Prior to the outbreak, Natural Selection Foods' protocols met or exceeded industry best practices, including the FDA's suggested Good Agricultural Practices and even the FDA's very recently issued Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables. We also followed Good Manufacturing Practices as outlined in the Code of Federal Regulations which are verified by daily audits.

Further, we participate in the USDA's Qualified Through Verification program, a voluntary program of unannounced inspections for fresh-cut processors. Participation in QTV requires that our facilities are inspection ready every day, a demand far more rigorous than what is called for by programs whose inspection schedules are known in advance.

Our experience strengthens our resolve to challenge the thinking about food safety in produce and develop new protocols that significantly heighten the safety of our products. Our efforts in this regard started almost immediately. While simultaneously working with the FDA and CDHS investigators and coordinating our recall, we worked tirelessly with some leading scientists in the country to completely reinvent what state-of-the-art food safety means in fresh produce.

Dr. Samadpour of IEH Laboratories, one of the country's top food safety scientists, has worked extensively in the beef industry in im-

proving safety protocols and reducing outbreaks associated with beef. He has become a valuable consultant to our operations.

In addition, we have established a food safety advisory panel consisting of some of the premier food safety scientists in the country from different academies, including University of Georgia, Rutgers and U.C. Davis.

Within 2 weeks of the recall, we had launched an unprecedented program of pathogen-specific testing in all of our raw, leafy greens. We lab-test—independent third-party lab—all salad greens arriving at our facility for potentially illness-causing *E. coli* and salmonella. All greens are held until the test are completed, and only those greens that show no presence of these pathogens are released for processing.

In February 2007, we launched a finished product testing program as a final hurdle of food safety, following the same protocols as our raw product test and hold program. We believe this kind of testing is a key safety measure for produce that will be consumed raw, since cooking is the only proven kill step for *E. coli*.

We have also signed on to California's new Leafy Green Handler Marketing Agreement. Companies that have signed on have agreed to purchase only from those growers who have accepted the Good Agricultural Practices. This is a good first step for our industry.

But the GAP metrics, in their current form, are not enough. Much more needs to be done, and we will continue to encourage development of standards to provide the strongest food safety program. We welcome regulation in this arena but also believe strongly that, with or without regulation, it is incumbent upon the individual companies and our industry as a whole to act to improve food safety. Private industry can and should move faster than the regulatory process. We have demonstrated that at Natural Selection Foods.

Everyone at Natural Selection Foods cares deeply about this outbreak and its victims and is committed to solving this vexing problem. We have faced many challenges in our 23 years, but none as great or as important as this.

Again, we appreciate the opportunity you have given us to be part of this important discussion. Thank you.

Mr. STUPAK. I thank you for your testimony.

[The prepared statement of Mr. Sweat follows:]

**Testimony of Charles Sweat
Natural Selection Foods**



Mr. Chairman and members of the committee, thank you for allowing Natural Selection Foods the opportunity to be a part of the important discussion about food safety in this country. We are pleased to cooperate with the subcommittee's investigation and this hearing. My name is Charlie Sweat and I am President of the company.

Before proceeding, I want to say that everyone in our company remains deeply saddened by the human toll the outbreak has wrought. We are a company founded on a commitment to providing the healthiest food possible. To learn that food processed by us could have brought anything other than good health was devastating.

Natural Selection Foods, based in San Juan Bautista, CA, was formed in 1995 when the founders of popular organic produce brand Earthbound Farm (founded in 1984) partnered with 3rd-generation family farmers Mission Ranches. In 1999, Tanimura & Antle, another longtime family-run farming company, became a 1/3 partner in the company.

On September 14th, we received a call from the Food and Drug Administration (FDA) and California Department of Health Services (CDHS) that there was an outbreak of *E. coli* linked to fresh spinach. (For purposes of this hearing, when I say *E. coli*, I mean



O157:H7 unless otherwise noted.) We were shocked to learn that some of our products might be involved. Within 24 hours, at the suggestion of the investigators, we voluntarily recalled all products containing spinach under all brands packaged in our facilities, based on patient recollection. Five days later, lab tests would confirm the presence of matching *E. coli* in a bag of non-organic spinach that we packaged.

Our company's long-standing policy has been to provide open access to government regulators and investigators. Once we were provided with manufacturing codes from bags of spinach in which the outbreak strain was found, we were able, within hours, to trace back to the ranches that provided that spinach. Throughout the investigation, we have been cooperative, available, and open, working round the clock with the FDA and CDHS investigators to assist and support their work. Investigators had access to our staff, our facility and our records. From day one, we have been as eager as anyone could be to understand where the problem originated and how this could have happened.

Recently the FDA and CDHS released a joint report on the incident. The report clearly states that no specific transmission vehicle has been identified, but the report's findings point to what we believed from the beginning: the contamination appears to have been somehow linked to the natural environment in which the spinach was grown. Samples



matching the outbreak strain were found on a cattle ranch, just under a mile from where the spinach was grown, but never on the spinach field itself.

Prior to the outbreak, Natural Selection Foods' protocols met or exceeded industry best-practices, including FDA suggested *Good Agricultural Practices* and even the FDA's very-recently issued *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*. We follow *Good Manufacturing Practices* (GMP) as outlined in the Code of Federal Regulations which are verified by daily audits. Further, we participate in the USDA's *Qualified through Verification* program — a voluntary program of unannounced inspections for fresh-cut processors that verifies the strict *Hazard Analysis Critical Control Point* (HACCP) program we follow in our facilities. Participation in QTV requires that our facilities are inspection-ready every day — a demand far more rigorous than what is called for by programs whose inspection schedules are known in advance.

In addition, as we constantly strive to improve food safety on every front, we have worked in research and development for more than three years to perfect a laser sorter that identifies and removes foreign objects in our product stream (such as roots, twigs, rocks). This industry leading, cutting edge technology had recently been installed in our



facility. Following the laser sorting, the greens are thoroughly washed in agitating chilled, chlorinated water and every package is passed through a metal detector.

Our experience strengthens our resolve to challenge the thinking about food safety in produce and develop new protocols that significantly heighten the safety of our products. Our efforts in this regard started almost immediately. While simultaneously working collaboratively with FDA and CDHS investigators and coordinating our recall, we've worked tirelessly with some of the top scientists in the country to completely reinvent what state-of-the-art food safety means in fresh produce.

We've also worked with independent researchers who had been dealing aggressively and successfully with the problems of E. coli in food. Dr. Mansour Samadpour of IEH Laboratories, one of the country's top food safety scientists, has worked extensively with the beef industry in improving safety protocols and reducing outbreaks associated with beef; he has become a valuable consultant to our operations. In addition, we have established a food safety advisory panel consisting of some of the premier food safety scientists in the country, including top academics from the University of Georgia, Rutgers, and U.C. Davis. They are working with us in the development and implementation of the strongest food safety, integrity, and quality measures possible,



exceeding anything in place today and setting a new standard for the fresh-cut produce industry.

Within two weeks of the recall, we had launched an unprecedented program of pathogen-specific testing in all of our raw, leafy greens. We lab-test all salad greens arriving at our facility for potentially illness-causing *E. coli* and *salmonella*. All greens are held until the tests are completed and only those greens that show no presence of these pathogens are released for processing.

In February, we launched a finished product testing program as a final hurdle, following the same protocol as our raw product test and hold program. We believe that this kind of testing is a key safety measure for produce that will be consumed raw, since cooking is the only proven kill step for *E. coli*.

Natural Selection Foods has also signed on to the California Department of Food & Agriculture's (CDFA) new *Leafy Green Handler Marketing Agreement*. The intent of this agreement is to verify and certify that signatories are following industry guidelines for leafy greens production, using a USDA-designed inspection program in use around the country for other commodities, and CDFA inspectors. Companies who have signed on agree to purchase leafy greens only from growers who follow the accepted set of *Good*



Agricultural Practices (GAPs). This is a good, first step for our industry, demonstrating that as an industry we are committed to improving food safety.

However, the GAP Metrics accepted by the Leafy Greens Marketing Agreement Board, in their current form, are not enough. Much more needs to be done and we will continue to work actively within the industry and with regulators to encourage the development of standards that provide the strongest level of food safety possible. We welcome regulation in this arena, but also believe strongly that with or without regulation, it is incumbent upon the individual companies and our industry as a whole to act to improve food safety. Private industry can and should move faster than the regulatory process. We have demonstrated that at Natural Selection Foods.

Everyone at Natural Selections Foods cares deeply about this outbreak and its victims and is committed to solving this vexing problem. We have faced many challenges in our 23 years, but none as great or important as this. As terrible as the outbreak's effects have been for many, we believe that good can be extracted from it – that as a country and as an industry we must share a renewed focus on food safety and an unrelenting commitment to find solutions to this difficult problem.



Again, we appreciate the opportunity you have given us to be a part of this important discussion today.

Mr. Colo, please, for 5 minutes for your opening statement.

**STATEMENT OF DAVID COLO, SENIOR VICE PRESIDENT,
OPERATIONS, CONAGRA FOODS, INCORPORATED**

Mr. COLO. Good morning, Mr. Chairman and members of the committee. My name is Dave Colo. I am the senior vice president of operations for ConAgra Foods, Incorporated. Thank you for your invitation to testify today about this important topic, the safety of the Nation's food supply. I want to assure the committee that we are fully aligned with its objective of ensuring that our food supply is among the safest in the world.

I appreciate the opportunity to share with you ConAgra Foods' recent experience related to the finding of salmonella in our peanut butter products.

First and foremost, we are truly sorry for any harm that our peanut butter products may have caused. As head of operations for this company, I can assure you that not only do we take these issues very seriously but we take them personally, as consumer safety and health is our top priority.

There are four main messages that I want to discuss with you today.

First, ConAgra Foods became aware of a potential issue the evening of February 13, 2007. The Food And Drug Administration contacted the company to schedule a call the following day to discuss a statistical study conducted by the Centers for Disease Control that suggested ConAgra's peanut butter products may have been linked to illnesses. The next day, February 14, after we spoke directly with the CDC and learned the basis for their conclusions, the company voluntarily recalled all peanut butter products and closed the Sylvester, GA, facility.

Second, in addition to the recall, the company initiated a full investigation to determine the cause or causes of any potential salmonella in the product. ConAgra Foods worked with the FDA to identify any potential source of contamination.

Based on its investigation, ConAgra Foods believes that moisture inadvertently entered the production process and enabled the growth of low levels of dormant salmonella already likely present in the plant environment from raw peanuts or peanut dust. We believe the moisture was likely the catalyst that temporarily allowed the salmonella to grow inside the facility. We believe the rate of subsequent contamination was low and, as such, was not detected by our finished product testing program, which employed standard industry testing methods.

Third, the Sylvester Georgia facility is the only ConAgra Foods location where peanut butter is manufactured, and this facility has been idle since the recall was initiated on February 14.

The company is committed to addressing the suspected causes of the contamination, and it will implement significant changes in the facility, including installing new, state-of-the-art equipment, technology and design standards throughout the facility. The estimated minimum cost of these facility modifications are 15 to \$20 million.

ConAgra Foods is committed to taking the time necessary for each of these steps, and we estimate that the facility is not likely to reopen until August of this year.

Finally, in addition to our thorough investigation at the Sylvester facility, ConAgra Foods is conducting additional comprehensive inspections of our other manufacturing facilities throughout the company. We have assembled a team composed of internal experts, along with an external specialist in food safety risk, Dr. Mike Doyle, that is in the process of visiting ConAgra's Foods' facilities, contract manufacturers and suppliers.

Taken together, these measures reaffirm our commitment to food safety and quality. The company will continue to work closely with the FDA going forward and appreciates the excellent work of the FDA and CDC throughout this process.

To clarify our interest in effective dialog with the FDA, we have separately provided the committee with a summary of the procedures we will follow to assure rapid FDA access to company information.

Again, we are truly sorry for any harm that our peanut butter products caused. We plan to make all changes necessary to the manufacturing environment to ensure the situation does not occur again. We are committed to the highest possible standards of food safety throughout our operations, and we believe that measures we have outlined today will clearly meet that commitment.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you.

[The prepared statement of Mr. Colo follows:]

TESTIMONY OF DAVID COLO

Mr. Colo will convey the following four main messages in his testimony:

- First, upon learning of a potential of salmonella Tennessee in our peanut butter products, ConAgra Foods took prompt action to protect the public health by ceasing all production and distribution, and voluntarily initiating a recall of all peanut butter in the marketplace manufactured at its Sylvester, GA facility, the only ConAgra facility manufacturing peanut butter.
- Second, the company conducted an in-depth investigation into the potential root cause or causes of the salmonella Tennessee contamination.
- Third, ConAgra will ensure that, before it resumes operations at its Sylvester, GA facility, it will have addressed all the potential sources of salmonella contamination, such that the facility will serve as a model in the industry for the production of safe and quality product.
- And, fourth, ConAgra is taking steps to improve food safety standards for all its food products.

Good morning Mr. Chairman and members of the committee. My name is David Colo, and I am senior vice president of operations for ConAgra Foods, Inc., where I have worked in various positions for the last 5 years. Thank you for your invitation to testify today about this important topic—the safety of the Nation's food supply. I want to assure the Committee that we are fully aligned with its objective of ensuring that our food supply is among the safest in the world.

ConAgra Foods is one of North America's leading packaged food companies, serving grocery retailers, as well as restaurants and other foodservice establishments. Popular ConAgra Foods consumer brands include: Banquet, Chef Boyardee, Egg Beaters, Healthy Choice, Hebrew National, Hunt's, Marie Callender's, Orville Redenbacher's, PAM and many others, including Peter Pan. We operate over 100 manufacturing facilities in 30 States, as well as facilities in several international locations.

I appreciate the opportunity to share with you ConAgra's recent experience related to the finding of salmonella Tennessee in our peanut butter products, including our Peter Pan brand peanut butter. First and foremost, we are truly sorry for any harm that our peanut butter products may have caused, and we intend to resolve any claims arising from the consumption of our peanut butter products as fairly and expeditiously as possible. As the head of operations for this company, I can assure

you that, not only do we take these issues very seriously, but we take them personally because consumer safety has always been our top priority.

There are four main messages that I want to convey to you today. First, within hours of its initial telephone conference with both the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC) regarding this potential issue, ConAgra Foods took prompt action to protect the public health by ceasing all production and distribution, and voluntarily initiating a recall of all peanut butter in the marketplace manufactured at its Sylvester, GA facility, the only ConAgra facility manufacturing peanut butter. Second, the company conducted an in-depth investigation into the potential root cause or causes of the salmonella Tennessee contamination. Third, ConAgra will ensure that, before it resumes operations at its Sylvester, GA facility, it will have addressed all the potential sources of salmonella contamination, such that the facility will serve as a model in the industry for the production of safe and quality product. And, finally, ConAgra is taking steps to improve food safety standards for all its food products. I would add that, since this issue first surfaced in mid-February, we have worked cooperatively with FDA, CDC and the State of Georgia food safety officials. We have also been pleased to cooperate with this committee's investigation. Let me now describe these points in greater detail.

1. ConAgra Foods took prompt action to protect the public health by ceasing all production and distribution, and voluntarily initiating a recall of all peanut butter in the marketplace manufactured at its Sylvester, GA facility, within hours of its first telephone conference with FDA and CDC.

ConAgra first became aware of a potential issue the evening of February 13, 2007, when the FDA contacted the company to schedule a call the following day to discuss an epidemiological study conducted by the CDC that suggested ConAgra's peanut butter products may have been linked to a salmonella illness outbreak. The next day, February 14, after a series of telephone conversations with both the FDA and CDC, the company initiated a voluntary recall from the market of 100 percent of the peanut butter manufactured at our Sylvester, GA facility. The company simultaneously ceased all production and distribution of peanut butter products from that facility. Throughout the process, ConAgra worked closely and cooperated fully with FDA in all aspects of the recall, including in the collective efforts of the company and FDA to inform the public about the scope of the recall.

2. ConAgra Foods conducted an in-depth investigation into the potential root cause(s) of the salmonella Tennessee contamination.

In addition to initiating this prompt and comprehensive recall, the company initiated a full investigation to determine the root cause or causes of any potential salmonella in the product. ConAgra worked with the FDA to identify any potential source of contamination.

On February 22, 8 days after ConAgra first initiated the voluntary recall, it was notified by FDA of State laboratory findings confirming the presence of salmonella in the company's peanut butter products. ConAgra made a public announcement to this effect that same day, and FDA made a similar announcement the following day.

Based on its investigation, ConAgra believes that raw peanuts and peanut dust introduced some low levels of salmonella Tennessee into the plant. The presence of salmonella is not unusual on raw agricultural products like peanuts. It appears that moisture then inadvertently entered the production facility and enabled the growth of low levels of dormant salmonella Tennessee. We believe the moisture was likely the catalyst that temporarily allowed the salmonella Tennessee to grow inside the facility. We further believe the salmonella Tennessee subsequently came into contact with peanut butter prior to packaging. Finally, we believe the rate of subsequent contamination was low and, as such, was not detected by our finished product testing program which employed standard industry testing methods.

3. ConAgra will ensure that, before it resumes operations at its Sylvester, GA facility, it will have addressed all the potential sources of salmonella contamination, such that the facility will serve as a model in the industry for the production of safe and quality product.

The Sylvester, GA plant is the only ConAgra location where peanut butter is manufactured, and this facility has been idle since the recall was initiated on February 14. No Peter Pan peanut butter has been sold by ConAgra to its customers since that date.

ConAgra is continuing to work closely with the FDA to ensure that when operations resume in the Sylvester plant there will be no reoccurrence of this issue. The company is committed to addressing the suspected causes of the contamination, and it will implement significant changes in the plant, including installing new, state-of-the-art machinery, technology and designs throughout the facility. The estimated

minimum cost of these facility modifications is \$15–\$20 million. These costs are in addition to the \$50–\$60 million cost associated with the recall and the significant costs associated with the ongoing loss of sales.

Before resuming operations, the company will obtain an independent review by an expert third-party and seek the concurrence of the FDA as to the adequacy of the measures implemented. ConAgra is committed to taking the time necessary for each of these steps, and we estimate that the facility is not likely to reopen until August. While we are making these upgrades, we will partner with a reputable third-party manufacturer to produce Peter Pan peanut butter to the highest quality standards and to begin shipping product to retailers this summer.

4. ConAgra Foods is taking steps to improve food safety standards for all its food products.

In addition to its thorough investigation at the Sylvester facility, ConAgra is conducting additional comprehensive inspections of its manufacturing facilities throughout the company. We have assembled a team composed of internal experts, along with an external specialist in food safety, that is in the process of visiting ConAgra's plants, contract manufacturers, and suppliers.

To bring additional focus and leadership to developing and implementing programs that continuously improve product safety and design, the company has appointed a recognized and well-respected food safety expert to a company-wide leadership position, vice president for Global Food Safety. This action will bolster our existing, substantial food safety and quality expertise, and will consolidate responsibility for existing and future company-wide oversight of food safety initiatives and systems. The company has hired Paul A. Hall, a leading expert with more than 30 years of experience in microbiology, food safety and food quality, to fill this position. Hall joins ConAgra Foods from Matrix MicroScience, Inc., a leading producer of technology for the rapid concentration, capture and detection of foodborne pathogens, including salmonella. Previously, he held product safety and quality-related positions of increasing responsibility at another major food company.

We are also forming a Food Safety Advisory Committee, composed of leading independent, third-party experts in food safety, which will provide guidance to the company as part of our ongoing work with Government agencies, research institutions, and scientists in the areas of food production and testing. This advisory committee will provide guidance to the company in the areas of food production and testing, and will advise the company in its plan to fund research involving the detection, control and elimination of foodborne pathogens. The committee will be chaired by Dr. Michael Doyle, director of the Center for Food Safety at the University of Georgia and one of the foremost authorities on foodborne pathogens in the world. The company is currently working with Dr. Doyle to identify other members of the committee.

There is nothing more important to ConAgra Foods than the safety, quality, and wholesomeness of our products. Through our work with the Food Safety Advisory Committee, we will be able to leverage their expertise to ensure that we take all reasonable steps to minimize the risk of foodborne illness.

Taken together, these measures reaffirm our commitment to food safety and quality. The company will continue to work closely with the FDA going forward and appreciates the excellent work of the FDA and CDC throughout this process. We also thank our consumers and customers for their understanding, as well as for the role they have played in ensuring public safety by returning and disposing of the recalled product.

Again, we are truly sorry for any harm that our peanut butter products caused and intend to resolve claims arising from consumption of our peanut butter fairly and expeditiously. We plan to make all changes necessary to the manufacturing environment to ensure this situation does not occur again. We are committed to the highest possible standards of food safety throughout our operations and believe the measures we have outlined today will clearly meet that commitment.

Mr. STUPAK. Mr. Miller, please, for your opening statement.

STATEMENT OF STEPHEN MILLER, CHIEF EXECUTIVE OFFICER, CHEMNUTRA, LAS VEGAS, NV

Mr. MILLER. Thank you, Mr. Chairman and members of the committee, for inviting me to testify today on the subject that is clearly important to many in this Nation—to everyone in this Nation, the safety of pet food and the food supply in general.

My name is Steve Miller, and I am chief executive officer for ChemNutra. ChemNutra is a small business, headquartered in Las Vegas, Nevada. I am here today with ChemNutra's FDA attorney, Marc Ullman of Ullman, Shapiro and Ullman.

Before I proceed on behalf of ChemNutra, I want to express our support and condolences for pet owners whose pets have fallen ill or died as the probable result of contaminated pet food as well as pet owners throughout North America who have become fearful about their pets' food following the news of contamination. We also offer our sympathy for the difficulties imposed on the pet food businesses that were negatively impacted by this situation.

ChemNutra imports high-quality nutritional and pharmaceutical ingredients from China to the United States. Those products come from manufacturers either known to us personally or recommended to us by a number of reputable and well-qualified training agents with whom we have had long-standing relationships. Our U.S. customers are manufacturers of pet food and nutritional ingredients who want high quality, the best service and competitive prices.

Until March 8 of this year, ChemNutra had never had an issue or incident with its Chinese manufacturers, all of whom provide certificates of analysis with their products, which is standard operating procedure for U.S. importers. It was on March 8 that ChemNutra first learned that wheat gluten was one of many ingredients Menu Foods was investigating as suspect in cat illnesses. That was nearly 3 weeks, according to Senate testimony, after Menu Foods first learned of possible contamination of pet foods.

On that date, March 8, notwithstanding what we believed to be a remote risk at the time, ChemNutra quarantined and ceased all shipping, sales and marketing of wheat gluten in our possession, from all sources. On March 16, Menu Foods issued its first recall; and in doing so made no mention of wheat gluten. In fact, Menu Foods said at that time it was testing some 20 ingredients, but to date we have not heard a word about those testing results.

Shortly thereafter, on March 19 we received a request from the Food and Drug Administration for all documents relating to wheat gluten, to which we immediately and fully complied. However, it wasn't until March 29 that ChemNutra heard for the first time that the FDA had found melamine in ChemNutra's wheat gluten, without quantification as to how much.

Between March 29 and April 1, I was in China and in communication with the FDA. Upon hearing of the traces of melamine, I spoke with the president of our supplier, XuZhou Anying Biologic Technology Development Company Limited, who said he didn't know there was melamine in their wheat gluten or how that could have happened. He promised to look into it and to this day has not provided us with additional information, despite many follow-up efforts on our part.

On April 2, after receiving further information from the FDA, we issued a formal recall of contaminated wheat gluten. It is important to note that on March 8, when ChemNutra ceased shipments of its wheat gluten, we had only four customers for that product, one of which was Menu Foods. Prior to any scheduled shipment customers—after that date, prior to any scheduled shipment, customers were made aware that our shipments were stopping.

It has been more than a month since this dreadful issue became manifest. Over this period there have been a raft of surmises and suppositions, but few facts. At this point, the only piece of information of which we can be certain is that melamine was contained in shipments of wheat gluten we imported through XuZhou Anying Biologic Technology Development Company Limited.

However, we at ChemNutra strongly suspect, at this point, that XuZhou Anying Biologic Technology Development Company Limited may have added melamine to the wheat gluten as an economic adulteration designed to make inferior wheat gluten appear to have a higher protein content. They can sell it to us at the price we would pay for higher quality product because the melamine, our experts tell us, falsely elevates the results of a nitrogen contents test used to assess protein content. Melamine is not something that we or anyone else, including the FDA, was ever testing for in the past, though of course we are now.

We have recently been told there was a prior history of this same kind of economic adulteration related to a similar agricultural commodity about three decades ago where this commodity was adulterated with urea, another nitrogen intensive additive, which had at the time become inexpensive enough to use economically to fool the protein testing. Subsequently, that commodity has been tested for urea.

I want to thank the committee for this opportunity to tell the ChemNutra story in an unvarnished and factual manner; and I hope that my testimony will help you develop protocols, regulations or laws that will preclude this sort of event from occurring in the future.

Mr. STUPAK. Thank you.

[The prepared statement of Mr. Miller follows:]

STATEMENT OF STEVE MILLER

Thank you, Mr. Chairman and members of the Committee, for inviting me to testify today on a subject that is so clearly important to many in this nation, the safety of pet food and the food supply in general.

My name is Steve Miller and I'm chief executive officer of ChemNutra. ChemNutra is a small business, headquartered in Las Vegas, Nevada. I am here today with ChemNutra's FDA attorney, Marc Ullman of Ullman, Shapiro and Ullman.

Before I proceed, on behalf of ChemNutra I want to express our support and condolences for pet owners whose pets have fallen ill or died as the probable result of contaminated pet food, as well as pet owners throughout North America who have become fearful about their pets' food following news of the contamination. We also offer our empathy for the difficulties imposed on pet food businesses that were negatively impacted by this situation.

We import high-quality nutritional and pharmaceutical chemicals from China to the United States. Those products come from manufacturers either known to us personally or recommended to us by a number of reputable and well-qualified trading agents with whom we have had long-standing relationships. Our US customers are manufacturers of pet food, and nutritional ingredients who want high quality, the best service, and the most competitive prices.

Until March 8 of this year, ChemNutra had never had an issue or incident with its Chinese manufacturers, all of whom provide certificates of analysis of their products, which is standard operating procedure for U.S. importers. It was on March 8 that ChemNutra first learned that wheat gluten was one of many ingredients Menu Foods was investigating as suspect in cat illnesses. That was nearly three weeks, according to Senate testimony, after Menu Foods first learned of possible contamination of pet foods.

On that date, March 8, notwithstanding what we believed to be a remote risk at that time, ChemNutra quarantined and ceased all shipping, sales, and marketing of wheat gluten in our possession, from all sources. On March 16, Menu Foods issued its first recall and in doing so, made no mention of wheat gluten. In fact, Menu Foods said at that time that it is testing some 20 ingredients, but to date, we have not heard a word about those testing results.

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Between March 29 and April 1, I was in China and in communication with the FDA. Upon hearing of the traces of melamine, I spoke with the president of our supplier, XuZhou Anying Biologic Technology Development Co. Ltd, who said he didn't know there was melamine in their wheat gluten or how that could have happened. He promised to look into it and, to this date, has not provided us with additional information despite many follow-up contacts on our part.

On April 2, after receiving further information from the FDA, we issued a formal recall of the contaminated wheat gluten. It's important to note that on March 8, when ChemNutra ceased shipments of its wheat gluten, we had only four customers for that product, one of which was Menu Foods. Prior to any scheduled shipment, customers were made aware that our shipments were stopping.

It has been more than a month since this dreadful issue became manifest. Over this period there have been a raft of surmises and suppositions, but few facts. At this point, the only piece of information of which we can be certain is that melamine was contained in a shipment of wheat gluten we imported through XuZhou Anying Biologic Technology Development Co. Ltd.

However, we at ChemNutra strongly suspect, at this point, that XuZhou Anying Biologic Technology Development Co. Ltd may have added melamine to the wheat gluten as an "economic adulteration"—designed to make inferior wheat gluten appear to have a higher protein content. They can sell it to us at the price we would pay for a higher-quality product because the melamine, our experts tell us, falsely elevates the results of a nitrogen-content test used to assess protein content. Melamine is not something that we or, anyone else, including the FDA was ever testing for in the past, though of course we are now.

We have recently been told that there was a prior history of this same kind of economic adulteration related to a similar agricultural commodity about three decades ago, where this commodity was adulterated with urea, another nitrogen intensive additive, which had at the time become inexpensive enough to economically use to fool the protein testing. Subsequently, that commodity has been—tested for urea.

I want to thank the committee for this opportunity to tell the ChemNutra story in an unvarnished and factual manner and I hope that my testimony today will help you develop protocols, regulations or laws that will preclude this sort of event from occurring in the future.

CHEMNUTRA FREQUENTLY ASKED QUESTIONS

What Is Chemnutra's Responsibility In The Pet Deaths?

- What we know at this point (April 15, 2007) is that the FDA suspects there may be a direct or indirect connection between pet deaths and illnesses and the melamine found in the wheat gluten supplied to ChemNutra by a single Chinese manufacturer, XuZhou Anying Biologic Technology Development Co. Ltd.

- ChemNutra had no idea that melamine was an issue until being notified by the FDA on March 29. In fact, ChemNutra had never heard of melamine before. It's simply not a chemical even on the radar screen for food ingredient suppliers.

- Consistent with industry practices, we require that our suppliers test for protein content, moisture, ash, water absorption rate, particle size and appearance. We examine the Certificate of Analysis provided by our supplier to ensure it has complied. We now know that what we received was not food grade wheat gluten, as we had ordered and what appeared in the shipping documents, but wheat gluten adulterated to appear as food grade when it was in fact not. Food grade wheat gluten is always 75 percent protein content, but that's not what we received. The melamine content made it appear as if it had a higher protein content.

- Ingredient testings is not what one sees on CSI, where one sample is examined and it tells you every chemical in it. We require tests for pre-identified risk and quality-related factors. Melamine was not one of those pre-identified risks before. Now, of course, it is and we have begun independently testing our wheat gluten from other suppliers.

When Did Chemnutra First Learn There Was A Potential Problem With Its Product

A specific timeline regarding the events accompanies this document and is available on our Web site at <http://www.chemnutra.com/media.htm> and accompanies this document.

According to Senate testimony, Menu Foods knew there was a potential problem long before we did.

- On or about March 6, Menu Foods informed ChemNutra that it didn't want any more wheat gluten. Menu Foods told ChemNutra that this was because of a need for a different water absorption factor in their wheat gluten; that type of requirement changes all the time.

- On March 8 Menu Foods told ChemNutra that our wheat gluten was one of many products it was investigating, so clearly Menu Foods already had an investigation well in progress. In response to what seemed to be an extremely remote risk at the time, ChemNutra quarantined and ceased shipments of all wheat gluten in its possession, from any manufacturer.

- Menu Foods asked ChemNutra questions for several days thereafter and each time we responded rapidly. Menu Foods wanted ChemNutra to ask XuZhou whether its wheat gluten had any of four substances that Menu Foods suspected might cause renal failure: propylene glycol, heavy metals, Ochratoxin or Easter Lily Flower. Menu Foods never asked about melamine.

- On March 16, Menu Foods issued its first product recall, but immediately after the recall, the company told ChemNutra that it was still investigating approximately 20 ingredients. As of the date of this document, ChemNutra has heard nothing further about the ingredients other than wheat gluten Menu Foods claims to be investigating.

- On March 19, an investigator from the FDA's Las Vegas office told ChemNutra the FDA wanted to visit ChemNutra to obtain ChemNutra's records regarding wheat gluten supplied to Menu Foods. ChemNutra maintains thorough, accurate and comprehensive records and complied fully and promptly with the FDA's request.

- The aminopterin found in three cans of Menu Foods, reported by the State of New York on March 23, was inaccurately associated with wheat gluten from China and, in fact, aminopterin wasn't found in the wheat gluten we supplied. Aminopterin is illegal for use in China.

- The word "melamine" wasn't mentioned by any entity until late in the day on March 29, when the local FDA investigator returned to tell ChemNutra the FDA found melamine in ChemNutra's wheat gluten. However, the FDA investigator couldn't confirm the quantities until the next day, March 30. On March 30 ChemNutra Chief Executive Officer, Steve Miller met personally with the president of XuZhou Anying to demand more information. At that time, XuZhou's president claimed no knowledge of how melamine contamination could have occurred and promised to investigate. Since then he has been unresponsive to requests for information.

How Does ChemNutra Identify And Screen Suppliers?

- XuZhou Anying was recommended to ChemNutra by one of China's leading trading companies, one with which we have had a long-term relationship. This is a standard way that American importers identify Chinese suppliers who are supposed to be reliable.

- Once suppliers are identified, ChemNutra examines samples from the recommended suppliers; checks their business certifications and conduct other research about them. XuZhou's paperwork indicated that it is ISO 9000 and HACCP certified; and ensures that they also hold Chinese certifications from five other organizations that attested to its credit quality, reliability and product quality.

- We are very distressed that to date XuZhou has not responded to our requests for more information nor, apparently, to U.S. Government requests.

What Did Chemnutra Do To Prevent This From Happening/What Will It Do Differently Now

- ChemNutra has an excellent compliance record with all applicable regulatory authorities.

- If the Pet Food Institute, the FDA or ChemNutra's customers make further recommendations as a result of this situation, we will fully comply with them. Obviously, that will now include testing for melamine in wheat gluten.

- ChemNutra knows that procedures for evaluating suppliers and products for importation will change as a result of this pet food recall. We plan to be actively involved in developing and implementing these procedures. ChemNutra, as always, will fully assist all regulatory and standards authorities, including the FDA, in de-

signing these procedures. This is a problem that needs to be resolved, and ChemNutra intends to take an active role in designing the solutions.

How Many ChemNutra Products Are Affected?

- Only one, wheat gluten from only one supplier, XuZhou Anying Biologic Technology Development Co. Ltd., was affected. Most of our other ingredients are pharmaceutical grade, from suppliers already reviewed and approved by our customers.

How Will This Affect ChemNutra's Business

- All of our customers except Menu Foods understand that ChemNutra was a victim in this situation. A number of them have been asking questions, but Menu Foods is only customer that has cancelled its contract with ChemNutra.

- ChemNutra has continued to receive new orders for wheat gluten that we obtain from other suppliers, which we will release only after we have tested it for melamine. We have also received orders for other products.

- We believe our customers understand that—just as with some of the recent e. coli cases that were tracked back to growers in California—that even when you have vendors with good reputations, product contamination does occur on rare occasion.

- ChemNutra is financially strong, and we're in this business for the long haul.
- We have excellent relationships with our suppliers in China, who also understand what happened in this situation. We represent several of them exclusively in the United States

How Do You Know Your Other Products Are Safe?

- Wheat gluten was the only product ChemNutra purchased from XuZhou Anying.

- ChemNutra currently sells only nine ingredients. Each of them have their own testing requirements as dictated by regulation, our customers and/or ChemNutra's own high standards. While this situation will certainly make ChemNutra even more vigilant with all suppliers, we have had no health-related issues with other products. Most of these products are pharmaceutical grade

- We will only add new ingredients when we can confirm quality control with Chinese manufacturers.

What Are ChemNutra's And/Or Its Principals' Qualifications To Be In The Ingredients Business?

- Steve Miller has more than 20 years of experience in business management, finance, marketing and the law. Sally Miller, president, is Chinese, with wide-ranging experience doing business in China.

- Since ChemNutra's inception, it has been bonded with U.S. Customs, and registered with the FDA under the Bioterrorism Act. ChemNutra has all appropriate business licenses and registrations and fully complies with any inspection requests from regulatory authorities on any ingredients it imports.

- ChemNutra has always offered its customers an unconditional money-back guarantee on our products—they can return them if dissatisfied at any time, for a full refund

- Our policy is to provide the best customer service available and the most reliable delivery and timing for shipments from China of anyone in the industry, and thChemNutra far many of our customers have attested that we accomplish this.

Why Does Wheat Gluten Need To Be Imported From China?

- Less than 25 percent of the United States' wheat gluten needs can be supplied domestically. As much as 30 percent of this country's wheat gluten imports come from China and the rest from Europe, Russia and Australia.

Does ChemNutra Import Rice Protein Concentrate From China?

- ChemNutra uses a large, reputable—trading company in China to import rice protein concentrate, Suzhou Textiles, which purchases ChemNutra's rice protein concentrate from Shangdong ShunFengFan. ChemNutra never bought—any rice protein concentrate from Xuzhou Anying, the manufacturer of the tainted wheat gluten. We are testing all imported rice protein concentrate through independent, third-party U.S. laboratories.

CHEMNUTRA TIMELINE OF EVENTS RELATED TO PET FOOD RECALLS

February 20, 2007: Menu Foods learns of contamination in pet food (Source: Senate Hearing)

March 6, 2007: Menu Foods informs ChemNutra to stop shipments of wheat gluten, ostensibly because of a specification change relating to the water absorption factor.

March 8, 2007: Menu Foods informs ChemNutra that wheat gluten was one of many ingredients it was investigating as suspect in cat illnesses. Menu Foods wanted information as to whether XuZhou Anying's wheat gluten had any of four substances that Menu Foods suspected might cause renal failure: propylene glycol, heavy metals, Ochratoxin or Easter Lily Flower. Menu Foods never asks about melamine. ChemNutra, notwithstanding what it believed to be a remote risk at that time, quarantines all wheat gluten—from all sources—in its possession.

March 16, 2007: Menu Foods issues first product recall and related press release, which does not ID wheat gluten as the primary suspect source. (Cite: Menu Foods)

March 19, 2007: Food and Drug Administration notifies ChemNutra that it wants records relating to wheat gluten shipments. ChemNutra immediately complies.

March 23, 2007: State of New York reports aminopterin found in three cans of Menu Foods. This was inaccurately associated by some media with wheat gluten from China, as aminopterin wasn't found in the wheat gluten ChemNutra supplied. Aminopterin is illegal for use in China.

March 24, 2007: Menu Foods recalls all varieties of "wet" pet food. (Cite: Menu Foods)

March 29, 2007: Melamine is mentioned to ChemNutra for the first time by the Food and Drug Administration, which says it has found evidence of the chemical in the wheat gluten, but does not quantify how much until the next day.

March 31, 2007: ChemNutra Chief Executive Officer Steve Miller meets in-person with the president of XuZhou Anying Biologic Technology Development Co. Ltd, who says he didn't know there was melamine or how it could have become mixed with XuZhou Anying's wheat gluten and promised to look into it.

April 2, 2007: ChemNutra recalls all XuZhou Anying wheat gluten sold to ChemNutra's customers.

April 5, 2007: All Menu Foods pet food in Canada and the United States using ChemNutra wheat gluten voluntarily recalled; expands recall to cover product distributed back to November 8, 2006. (Cite: Menu Foods)

April 10, 2007: Menu Foods voluntarily recalls additional pet food made with ChemNutra wheat gluten manufactured at a Canadian facility. (Cite: Menu Foods)

April 12, 2007: Government scrutiny, as reported by the media and at Senate hearings, focuses on possibility of deliberate contamination by XuZhou Anying Biologic Technology Development Co. Ltd and actions of Menu Foods during time period leading up to first recall.

Mr. STUPAK. Thank you all for your testimony and for being here.

Mr. Miller, you indicated that your company had four customers. One of them was Menu Foods, the other three customers that you had shipped this wheat gluten to, too, is that correct?

Mr. MILLER. Yes.

Mr. STUPAK. What do they make?

Mr. MILLER. Two of them make pet food, and the third one distributed wheat gluten to pet food companies.

Mr. STUPAK. So it is basically pet food is where it goes?

Mr. MILLER. All pet food.

Mr. STUPAK. Once you realized that melamine may have something to do with these problems with the pets and their deaths and their illnesses, what did you do with your wheat gluten that you had left?

Mr. MILLER. All of the wheat gluten has ever since March 8 been in our warehouse and basically quarantined.

Mr. STUPAK. Do you have any plans to dispose of it?

Mr. MILLER. We are working with the FDA right now to dispose of it in ways that are acceptable to the FDA.

Mr. STUPAK. OK.

Mr. Colo, on behalf of ConAgra, in October 2004, you found salmonella poisoning or, I should, say salmonella in your peanut butter, right?

Mr. COLO. That is correct.

Mr. STUPAK. And in I believe it was March 2005 the FDA came and asked about that salmonella, if you had any troubles, is that correct?

Mr. COLO. That is correct.

Mr. STUPAK. And disagreement here. FDA tells us they asked for information. I understand ConAgra says, put it in writing. Either way, the FDA never obtained the information they were looking for based on that 2004 salmonella, right?

Mr. COLO. The situation, just to be clear, was we had a positive salmonella on finished product that we held at our facility. The product was never shipped from our Sylvester, GA, facility. It was contained and destroyed in the process.

Mr. STUPAK. The FDA asked for those records in 2005.

Mr. COLO. FDA asked for the records in February 2005, that's correct.

Mr. STUPAK. And they have never been provided to the FDA.

Mr. COLO. We simply asked the FDA to request the information in writing and that we would be happy to forward them—

Mr. STUPAK. Have they ever put it in writing?

Mr. COLO. The FDA never put it into a written request to us.

Mr. STUPAK. Did they follow up after—I believe this is after March 2005. Did they follow up with ConAgra and ask for the information again without putting it in writing?

Mr. COLO. No, they did not; and it was February 2005.

Mr. STUPAK. Has there been any other time in which the FDA or USDA asked ConAgra, either on *E. coli*, salmonella, botulism, about possible contamination and ask for your records where ConAgra did not provide it to the FDA?

Mr. COLO. Again, what we would typically do in those situations is simply ask for the FDA to request that information in writing.

Mr. STUPAK. I am asking if there has been other incidences. There have been rumors circulating around here that ConAgra just sort of says, put it in writing, sort of stonewalls requests, never happens. We know of October 2004 in which they followed up in March 2005. The point I am trying to—is there any other time in which information was requested and not provided whether it is in writing or not.

Mr. COLO. I am not aware of all the requests that would come from the FDA. So I am not sure that I can answer that question appropriately at this time.

Mr. STUPAK. Could you check and follow back with the committee? We keep this record open for 30 days, so you can follow and check up for that for us.

Mr. COLO. Absolutely.

Mr. STUPAK. Mr. Henderson, you indicated that I think you used the word fraud in your testimony that this melamine put in there was a fraud. It was intentional.

Mr. HENDERSON. Yes.

Mr. STUPAK. Wheat gluten is used in things other than pet food; correct?

Mr. HENDERSON. That would be my understanding, yes. Pizza is an example.

Mr. STUPAK. I mean, food like tofu and other things like this; correct?

Mr. HENDERSON. Correct.

Mr. STUPAK. Then what happened to you, is there any way we know then if other wheat gluten or other products or other things have been intentionally altered? You don't know until after the fact; right?

Mr. HENDERSON. You don't know until after the fact. Certainly, the presence of melamine was a particular problem during this process simply because there was not—it was such a foreign additive or contaminant. There wasn't a testing protocol for identifying it. So we could have—what we are aware of is what has happened to us. Whether it happened before or is happening now, we couldn't comment.

Mr. STUPAK. You don't know. And you place your order then with Mr. Miller's company; right?

Mr. HENDERSON. That's correct.

Mr. STUPAK. And then he ships it to you?

Mr. HENDERSON. Yes, he does.

Mr. STUPAK. And Mr. Miller, you receive it from China; right?

Mr. MILLER. Yes.

Mr. STUPAK. And before this instance, did you ever do any testing of any of the products that came from China.

Mr. MILLER. No. There was no known issue to test for.

Mr. STUPAK. You indicated that your supplier in China basically was recommended by other people in the industry?

Mr. MILLER. By a trading company that we have that we worked with over a long number of years that we had a lot of confidence in.

Mr. STUPAK. Had you ever used this company before?

Mr. WHITFIELD. Mr. Chairman, I would ask unanimous consent that we each be given 10 minutes and that you—

Mr. STUPAK. No objection, go ahead.

Have you ever used these companies before that you got the wheat gluten from?

Mr. MILLER. Yes, we had.

Mr. STUPAK. And never any trouble?

Mr. MILLER. No trouble whatsoever.

Mr. STUPAK. Had there been any complaints about their products before, about the low protein content or anything?

Mr. MILLER. This was a new product for us.

Mr. STUPAK. From this company? You have used the company before in China but just not this product?

Mr. MILLER. This was the first company we imported—we just started last fall in this business. This is new product for us.

Mr. STUPAK. OK. Mr. Sweat, we heard testimony here earlier, and I have been showing this. On the back here, it says, Salinas, CA. Would this come out of your plant? Probably, this, I think it is fresh discoveries now.

Mr. SWEAT. I would have to look at the production code. Does it start with a J or a Y?

Mr. STUPAK. Y097B21.

Mr. SWEAT. That would have come out of our Yuma, AZ, facility.

Mr. STUPAK. You have a plant in—

Mr. SWEAT. We have a plant in San Juan Bautista, CA, and we have a plant in Yuma, Arizona.

Mr. STUPAK. Is San Juan Bautista, is that considered Salinas Valley?

Mr. SWEAT. It is about 25 miles north of Salinas.

Mr. STUPAK. There has been some discussion about completely washed. What does that mean?

Mr. SWEAT. What we do with the salad greens, after they are harvested and brought into our facility, we mix them into a mixing belt for the different ingredients, and then we put them through a chilled chlorinated wash, and that chlorine is used as a sanitizer for the wash system.

Mr. STUPAK. That does not take out *E. coli*, though; does it?

Mr. SWEAT. No, it is not a kill step. It is a deterrent for microbial load, but it is not a kill step.

Mr. STUPAK. Prior to this incident, did you do any testing for *E. coli*?

Mr. SWEAT. In the 22 years we have been in business, we have never had a foodborne illness, so our GAP programs that we have in our fields, our GMPs in our plant and our HACCP program on inventory control—

Mr. STUPAK. But you were in the Salinas Valley where, in the last 10 years, you have had basically 20 different recalls or things like *E. coli*, and then the company never felt necessary to do testing?

Mr. SWEAT. We weren't involved in any of those. I don't know what the issues were in those. But what we did do as a result of this outbreak is we got outside the box a little of produce, and we went to the beef industry to learn a little bit about what they were doing. And that is where the testing programs that we implemented a couple weeks after the outbreak were derived from.

Mr. STUPAK. It says, Product of U.S. and Mexico. But you said this is from Yuma. Would part of this salad have come from Mexico, too?

Mr. SWEAT. Potentially, it could. We do have farms that grow in Mexico, that we bring product into the U.S. on.

Mr. STUPAK. I understand that it comes in to your plant. Once it comes in, out of the field, it is packaged right in and shipped right out in these plastic containers. Even though it may say Dole, it is your plant; right?

Mr. SWEAT. It is our processing facility, but then Dole picks that product up at our facility, and they distribute it out.

Mr. STUPAK. Has the FDA ever inspected your facilities?

Mr. SWEAT. Yes. We have worked with the FDA on a collaborative basis on our programs over the years. They come in frequently.

Mr. STUPAK. How frequently?

Mr. SWEAT. Last time they were there was in August, reviewing our facilities.

Mr. STUPAK. August 2006?

Mr. SWEAT. August 2006 the actual week of the spinach that was linked.

Mr. STUPAK. Did they do any testing or did they come in and look around?

Mr. SWEAT. What they do is they come in and look at our documents. We provide them with all our documents on our program,

and they review all of our compliance with all our programs and controls.

Mr. STUPAK. But you're not required to do any testing.

Mr. SWEAT. Voluntary regulations and guidelines from the FDA do not require any testing.

Mr. STUPAK. So they are just looking at how you are handling a product?

Mr. SWEAT. They are looking at our processes; that is correct.

Mr. STUPAK. So other than making sure that the area is sort of sanitary, there is no testing for *E. coli* then that is done by the FDA?

Mr. SWEAT. There is none at this point in time.

Mr. STUPAK. Mr. Henderson if I may ask you on testing, now Menu Foods, you are in U.S. and Canada right?

Mr. HENDERSON. Yes, we are.

Mr. STUPAK. Are you inspected by the FDA?

Mr. HENDERSON. We have been inspected in the Pennsauken facility in 2006 by the FDA.

Mr. STUPAK. In 2006?

Mr. HENDERSON. Yes.

Mr. STUPAK. Do you recall any time before 2006 by the FDA?

Mr. HENDERSON. We have been inspected prior to that. I don't have the dates.

Mr. STUPAK. Every year do you think or——

Mr. HENDERSON. Our head of technical services estimated it was about once a year.

Mr. STUPAK. Do other agencies inspect your plant?

Mr. HENDERSON. USDA APHIS, inspects us once a year. The Canadian plant is inspected by the equivalent the CFIA. We are inspected by both the USDA and CFIA to allow us to export to Europe so they are looking at it not only from the Canadian and U.S. protocols but also from the European protocols.

Mr. STUPAK. We have had some outbreaks here with wheat gluten in San Francisco, France, Canada, Connecticut and in your place. Do you get together and share information when you hear of outbreaks in other areas, let's say, like France or up in Canada, or is it only if it involves your company?

Mr. HENDERSON. Excuse me, get together with whom?

Mr. STUPAK. Other authorities from Canada, what is going on if you detected something, something in France? It is all wheat gluten; apparently wheat gluten is a big part of your product here.

Mr. HENDERSON. Relative to this experience, which is the only one I can relate to, we have essentially coordinated through the FDA. FDA was in touch with European authorities and in touch with the Canadian authorities, and we relied on them to ensure the communication——

Mr. STUPAK. From a company-to-company point of view, there is no contact back and forth; just work through your regulatory agency?

Mr. HENDERSON. In that particular case, the company is also a member of the pet food institute. At the time that there was something to talk about, which was the presence of melamine, that was the topic for discussion. When the recall was initiated, the recall

was initiated on the basis of, we did not know what the problem was. We just have to recall.

Mr. STUPAK. All right.

Mr. Whitfield, questions, 10 minutes.

Mr. WHITFIELD. Thank you, Mr. Chairman.

And Mr. Henderson, Menu Foods, is that a publicly traded company, or is it a private company?

Mr. HENDERSON. It is a publicly traded income trust. It is essentially a publicly traded company in Canada. It is on the Toronto stock exchange.

Mr. WHITFIELD. And I think you said you have been in business 35 years?

Mr. HENDERSON. We were incorporated in 1971, so it is just over 36.

Mr. WHITFIELD. And what would be the volume of wheat gluten that your company would use per year or per month, or do you have any idea?

Mr. HENDERSON. I am afraid I don't. I can't give you a number that would be reliable.

Mr. WHITFIELD. But you obviously purchase it from more than just Mr. Miller's firm.

Mr. HENDERSON. We have been purchasing it from multiple sources in the United States, from Europe and from Mr. Miller's company.

Mr. WHITFIELD. And of the total amount of wheat gluten that you purchase, what percent would you say comes from the United States?

Mr. HENDERSON. Again, I don't have those numbers at my finger tips, so I can't give you—

Mr. WHITFIELD. Mr. Miller you had mentioned in your testimony that, of the wheat gluten that is used in the United States, that only about 25 percent of it is produced domestically. Is that correct?

Mr. MILLER. I believe that to be true.

Mr. WHITFIELD. So 75 percent of the wheat gluten used in the U.S. is imported from some other country, is that correct?

Mr. MILLER. Yes that is an approximate number that is, I believe to be, true.

Mr. WHITFIELD. Now the president of your company is your wife; is that correct?

Mr. MILLER. Correct.

Mr. WHITFIELD. And she is Chinese. She is from China.

Mr. MILLER. That's correct.

Mr. WHITFIELD. One of the things I was a little bit puzzled about, I can understand why China, the company that you purchased this wheat gluten from would not be particularly responsive maybe from a company in the U.S., even though I am sure they want to cater to their customers, but since your wife is a citizen of China, she would—you would have some recourse against this company, I am assuming. Is that true or not?

Mr. MILLER. We haven't looked into it that. It may be true.

Mr. WHITFIELD. But that is obviously something that you will be looking into.

Mr. MILLER. Yes.

Mr. WHITFIELD. OK. One area that I wanted to look at briefly relates to finished product testing programs. And Mr. Henderson, in your finished product testing program, what is actually entailed in that? And I am assuming that that testing program would not detect melamine in the final product. Would I be accurate in that or not?

Mr. HENDERSON. That would be accurate. The programs for testing it that are undertaken at Menu Foods as is the case with most pet food companies that we would certainly be aware of is the testing of the raw materials that go into the pet food, essentially the objective would be to detect it before it gets into the finished product rather than test it after the finished product is made.

Essentially there is a commercial sterilization process by which the pet food is cooked which will essentially deal with any contaminant such as bacterial or *E. coli* or anything along those lines. But it is from a perspective of control we are looking at testing the raw materials. Relative to melamine, it was simply a substance that was not known. There was no testing protocol relative to wheat gluten; we would essentially test for the toxins we would generally associate with wheat. In this case, we would test every load of wheat gluten for a vomatoin in accordance with protocols established by the appropriate authorities.

Mr. WHITFIELD. Is that the only wheat gluten that your company used that had melamine in it, came from Mr. Miller's firm; is that correct?

Mr. HENDERSON. That's correct.

Mr. WHITFIELD. Now you sell a lot of pet food in the U.S., so this final product, this finished product testing program, are there regulations relating to that that comes from the FDA? Or are these just internal programs that you have in effect?

Mr. HENDERSON. The programs that we have in effect are those that are established by Menu Foods based on essentially the experience of the organization and common practices within the industry.

Mr. WHITFIELD. So FDA does not have any regulations relating to finished product testing?

Mr. HENDERSON. Relative to finished product testing? Not that I am aware of, no.

Mr. WHITFIELD. Do you agree with that, Mr. Colo? Does FDA have any regulations relating to finished product testing?

Mr. COLO. Not that I am aware of, no, sir.

Mr. WHITFIELD. You, of course, do finished product testing, but you have indicated that you did not detect the salmonella in the Peter Pan peanut butter; correct?

Mr. COLO. In the current recall situation, that is correct.

Mr. WHITFIELD. So wouldn't you want your finished product testing to detect salmonella or—

Mr. COLO. Yes, absolutely. Our procedure is that we sample one jar of peanut butter per packing line per hour every day that the facility operates. We test for salmonella. We hold all finished product at our facility until we get the test results back to confirm that there is not the presence of salmonella prior to releasing the product for shipment.

Mr. WHITFIELD. And for you and Mr. Sweat, is there some method that you could expose your product to that would definitively remove *E. coli* bacteria as well as salmonella?

Mr. SWEAT. At this point, we don't have a kill step as that would be defined for fresh produce. That is one of the reasons we have moved forward with our testing protocols is to help to detect it to prevent it from entering the chain of commerce.

Mr. WHITFIELD. Now irradiation I guess can be used in meat products, but can irradiation be used in vegetables?

Mr. SWEAT. Radiation has not been approved for use by the FDA on fruits and vegetables.

Mr. WHITFIELD. And certainly not on peanut butter, I wouldn't think.

Mr. COLO. That is correct.

Mr. WHITFIELD. Mr. Colo, you had stated in your testimony that you first became aware of possible salmonella in your peanut butter on February 13 when the FDA contacted you. But prior to that date, did ConAgra have any consumer complaints or reports of illnesses made by consumers directly to ConAgra or through your consumer hotline?

Mr. COLO. No complaints were received relative to consumer illness for salmonella, no, sir.

Mr. WHITFIELD. OK. I have no further questions.

Mr. STUPAK. Thank you. I go to the gentlelady from Colorado, Ms. DeGette, for questioning for 10 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. Sweat, they never did find out what caused the contamination in that spinach, did they, definitively?

Mr. SWEAT. That's correct.

Ms. DEGETTE. Are they still making efforts to find that out?

Mr. SWEAT. I think what I understand now that they have published their report that they have closed their investigation on that particular incident, but I know we are working collaboratively as an industry with the agencies going forward.

Ms. DEGETTE. I'm sure you would like to know, for example.

Mr. SWEAT. Yes.

Ms. DEGETTE. You said that after your company found out about the contamination, you instituted a 24-hour voluntary recall; is that correct?

Mr. SWEAT. That's correct.

Ms. DEGETTE. I am wondering if you have any view on when, if we gave the FDA ability to do mandatory recalls, if they were aware of a situation?

Mr. SWEAT. I think, as a company, when you are concerned about public health and safety, you will recall product if there is any risk at all.

Ms. DEGETTE. For one thing there is a liability risk, but what about giving the FDA—

Mr. SWEAT. We wouldn't have any problem if there was a risk to have mandatory recall authority with the FDA.

Ms. DEGETTE. Great, thank you.

I want to follow up with Mr. Colo on the questions that Mr. Stupak was asking you about the 2005 inspection of the ConAgra plants in Georgia. Yesterday, in the Washington Post, they made

the allegation that the connection between the 2005 connection—investigation—was that this was an ongoing problem with this plant. I don't know if that is true, but I was looking at some of the reports, and I was a little bit disturbed about what this inspection shows as a systemic issue in the foods, in the food industry. So if you can take a look at No. 16 in your notebook that you have there, the exhibit 16. What that is, is that is the FDA notes from the inspection into the Sylvester, GA, plants in October 2004; is that correct?

Mr. COLO. In 2005, yes.

Ms. DEGETTE. Yes. But in that report, though, they said that they were investigating complaints that had been received anonymously about various conditions; correct?

Mr. COLO. Correct.

Ms. DEGETTE. And one of the allegations was that I guess management acknowledged that there was peanut butter that was placed on a, quote, micro hold in October 2004 and was destroyed. Is that correct?

Mr. COLO. That's correct.

Ms. DEGETTE. And a micro hold is a holding of the product due to finding of micro organisms like salmonella or *E. coli* forms in the product; correct?

Mr. COLO. Correct.

Ms. DEGETTE. And then the report goes on to say, local management refused to provide details to include the exact cause of the hold and the type, amount of product involved; correct?

Mr. COLO. Correct.

Ms. DEGETTE. Now does that mean that ConAgra did not acknowledge much less supply the testing results regarding the positive finding of salmonella to the FDA?

Mr. COLO. Our policy—which I believe you have a copy of—states that if proprietary or confidential information is requested, we simply ask that the FDA provide the request in a written form, and then we will provide them with the information. That did not occur in this situation.

Ms. DEGETTE. That was your previous policy that, even if there was an allegation of food safety problems, the FDA had to ask you in writing in case there might be proprietary concerns; right?

Mr. COLO. Correct. That is correct.

Ms. DEGETTE. So despite the fact that the FDA showed up there and related these concerns, you guys, ConAgra, never got a written request, so they just never presented any information to the FDA; right?

Mr. COLO. That's correct.

Ms. DEGETTE. Now, take a look at exhibit 17 in your notebook there. On the bottom of page 1, the FDA investigator notes that you stated you do test peanut butter for salmonella and coli forms prior to releasing the product for sale right?

Mr. COLO. Correct.

Ms. DEGETTE. And the inspector also notes that firm also acknowledged some of the peanut butter was put on a micro hold in 2004, and management would not provide the reason for the hold and the amount of product involved; correct?

Mr. COLO. Correct.

Ms. DEGETTE. Now I would assume ConAgra is one of the biggest food procedures in our country and I would assume that back in 2004 and 2005 ConAgra also had concerns about making sure that our food supply was as safe as possible.

Mr. COLO. Absolutely correct.

Ms. DEGETTE. But yet they refused to provide this information, how much product was held and what the reason was, because they didn't have a written request from the FDA; correct?

Mr. COLO. Correct.

Ms. DEGETTE. Now, on page 4 of that same document, exhibit 17, the inspector notes that Mr. Maddis, the quality assurance manager at the plant explained the testing program and showed the inspector test summaries on finished product after receiving permission from the firm's legal counsel to do that.

Do you know if your attorney told Mr. Maddis or Mr. Genoa, the plant manager or anybody else that they were not to provide test summaries that showed the salmonella findings that the FDA was asking about?

Mr. COLO. I believe what this report refers to is, they showed finished product salmonella test results related to a question the inspector had relative to some new equipment installation, and that is what they verbally communicated to the inspector.

Ms. DEGETTE. So how is that different from previous test results on product that had in fact been determined to have salmonella? Why do they get the information in that case but not in the other one?

Mr. COLO. Again, it is simply a situation where they consulted our policy, asked that they consult with our corporate, or guidance; they did in that case. And the guidance they received was to share the information with them verbally relative to the equipment questions at the inspection.

Ms. DEGETTE. So do you know, did they consult with legal counsel about the other question, about the micro hold in October 2004?

Mr. COLO. I am not aware if they did or did not.

Ms. DEGETTE. It seems a little odd that with respect to the equipment purchase, there is a call to legal counsel. Legal counsel says you can give this information but not with respect to contaminated peanut butter the year before.

Mr. COLO. I don't want to speak for the FDA, but when the question was asked of our—

Ms. DEGETTE. I am not asking you to speak for the FDA. I am asking you to speak for your company.

Mr. COLO. Which I am. When we told the inspector that we test for salmonella and coli forms and that we had product that we put on hold due to micro concerns, and it was subsequently destroyed, there is only one of two things—one of two reasons why that product would have destroyed.

Ms. DEGETTE. What are those?

Mr. COLO. salmonella contamination or coli form, and again, our policy—

Ms. DEGETTE. That doesn't really explain why they would refuse to provide the information in that instance, but why would they call legal counsel and be given the green light to provide the information with respect to the equipment?

Mr. COLO. Again, our policy is written to reflect the laws that are we are afforded today. Our plant manager was simply acting under that authority. And as we published to the committee yesterday, we have made the decision to change our disclosure of information, guidelines, relative to routine FDA inspections, as well as under a recall situation to make sure that this situation does not occur again going forward.

Ms. DEGETTE. Thank you for mentioning that. That is exhibit 33 in your notebook, and I was just getting to that. And that is what I was talking about in my opening statement because some people say to me, why do you have these hearings? And I say, all you need to look at is ConAgra's April 23, 2007, letter which says they are now reversing their policy, and now you guys are apparently going to give information without a written request. That is kind of it in a nutshell; right?

Mr. COLO. That is correct with the exception—I do want to point out that in the current recall situation, we provided all information without any written request to the FDA. So we are simply adopting the same procedure we followed during the recall—

Ms. DEGETTE. This is your procedure now and going to be going forward in all instances? That is not just in reaction to the peanut butter situation; that is going to be ConAgra's general policy?

Mr. COLO. That is correct.

Ms. DEGETTE. Thank you very much, and I appreciate your honesty. Mr. Chairman, this only shows to me two things: No. 1 giving the FDA mandatory recall authority would really help in terms of pushing industry to voluntarily report this so that there is not a mandatory recall; and second, that the FDA simply does not have enough authority to investigate these situations where it can be the company policy itself, that says, sorry, we are not going to give you information that could affect Americans' health from food. So we really have to look at beefing up the FDA's ability to oversee food. And with that, just the commercial part of the program, Congresswoman DeLauro and I have been working on mandatory reporting for meat safety. And we are going to start looking at other types of FDA oversight, and I will welcome input from all of the members of the committee on that.

Mr. STUPAK. Thank you.

Mr. Walden for questions, 10 minutes.

Mr. WALDEN. Thank you, Mr. Chairman, I have been shuttling back and forth to another hearing upstairs on telecom, and their meeting, too, as you all know that happens in this business.

Mr. Colo, after the 2004 situation, did the company change in of its product testing procedures at the plant?

Mr. COLO. Yes, after the 2004 incident, we increased the number of finished product samples that we take in the facility to one sample per hour per packing line in which the peanut butter is being produced.

Mr. WALDEN. One sample per hour per packing line?

Mr. COLO. Correct, prior to sampling protocol was three samples basically per shift per line.

Mr. WALDEN. Do you feel that, well, if you were doing that, then how did this peanut butter get contaminated and you not catch it?

Mr. COLO. Are you referencing the current situation? Well, again, when we conducted the investigation into this, what we believed is the most probable cause is that we had water contamination come into contact with dormant salmonella that was most likely in the peanuts or the peanut dust, and it was at low enough levels in the finished product that we were not able to detect it.

Mr. WALDEN. As you determine the cause of the 2004 contamination, does that have anything to do with the situation in 2007?

Mr. COLO. No. The 2004 incident was a very isolated incident that we were able to, again, through our investigation, determine that we had received some peanuts that been rained on and led to the contamination. At that point in time, there was severe weather going on in the area related to hurricane activity. It damaged one of our suppliers' storage shed. The peanuts got wet, and that was part of it as well as we had some damage to one of our exterior bulk sugar bins that we believe may have contributed it to as well.

In that situation, again, we contained all the finished product, our tests did show that it was positive under our control. Our procedures are that we do not release any product for shipment until we have the salmonella test results confirmed. In that case, they showed positive. We retained the finished product. We even went to the extreme of holding product and destroying it on both sides of the withhold period to make sure we did not release any product that was contaminated.

Mr. WALDEN. Again how does that differ from 07 where contaminated product did get out into the market.

Mr. COLO. Again, I think our belief is that the levels of contamination were so low that we were not able to detect it either in our environmental sampling programs within our facility or within our finished product testing methods.

Mr. WALDEN. And when the FDA, they came in in the 2007 recall, correct?

Mr. COLO. Correct.

Mr. WALDEN. And did you provide them with all the records they requested?

Mr. WALDEN. Yes. As I had mentioned earlier, in the 2007 recall, we provided all records to the FDA per the request.

Mr. WALDEN. Now do you require a written request from FDA?

Mr. COLO. We covered that previously here, but basically, prior to some changes that we had recently announced and discussed in this committee, our policy was to ask that any confidential or proprietary information that the FDA was requesting, that they simply provide us a written request, and we would provide them the information.

Mr. WALDEN. This question may have been asked of all of you as well, and again, I apologize that I have had to come and go, but we have had a lot of discussion in this committee as we analyze America's food safety. None of us wants to get sick, including all of you. There has been this discussion that the FDA lacks the authority for mandatory recall and maybe you all touched on this, but for my benefit, if you could, what are the pros and cons of giving that agency mandatory recall that would make you operate differently?

As you have heard, we do it for toys and tires and whatever else you want to talk about. Why not food? And maybe we can just go down the row.

Mr. Henderson.

Mr. HENDERSON. Relative to the FDA having mandatory recall authority, I can't think of a thing that we would have been doing differently had they had that, so if they were granted mandatory recall authority or not, we like to believe that the outcome would have been exactly the same.

Mr. WALDEN. You wouldn't have done anything differently?

Mr. HENDERSON. No.

Mr. WALDEN. Mr. Sweat?

Mr. SWEAT. Once we were notified of a potential problem from the FDA, we went to a voluntary recall within 24 hours even before any of our product was specifically tied in with lab tests. So I think we would have done the exact same thing out of concern for public health and safety regardless. So having the mandatory would be fine, but it would not have changed what we did.

Mr. WALDEN. Mr. Colo.

Mr. COLO. ConAgra foods in the recent recall, I just want to point out as well, we voluntarily recalled, all the product, even without any indication that there was positive salmonella in any finished product samples either from CDC, the FDA or consumers.

Having said that, I would say that it is incumbent upon ConAgra to take the responsibility for food safety and recall products when that is appropriate. The FDA having recall authority would be fine with us. It would not change anything that we have done today.

Mr. WALDEN. Mr. Miller.

Mr. MILLER. Yes.

Mr. WALDEN. Same question for you in terms of FDA's having the authority to do—the pros and cons of giving FDA authority to have mandatory recall capability. Would it affect—

Mr. MILLER. No, it wouldn't affect us in any way.

Mr. WALDEN. You would still take the same actions?

Mr. MILLER. Yes.

Mr. WALDEN. Then for the sake of consumers, what can be done differently to improve food safety from your perspectives? Because, obviously, there has been a lot in the news we see. I find it affects my shopping habits. Believe it or not, I am the one that generally goes to the grocery store when I go home, and I am making different choices now, which bothers me a little bit.

What do we tell consumers about what we are doing to improve—what else can you recommend to us to improve food safety? I mean, your companies' bottom lines are the ones in the cross hairs here.

Mr. HENDERSON. In my written statement, we gave a number of recommendations. Probably the most telling one is in regard to the ability of inspections to be undertaken by appropriate U.S. authorities in those jurisdictions in which exports are being made on the United States.

For Menu Foods, at the present time, our plant in Toronto requires import permits in order to export products to the United States. That is as a result of BSE. Relative to our shipments into Europe, at the present time, in order for our plants to ship into Eu-

rope, our plants have to be qualified by the European authorities to ship product from the United States or from Canada into Europe.

They delegate that responsibility to the USDA or the CFAA because of the trust that exists between those organizations. But essentially those activities, as is the case in the United States, of allowing product to ship from Canada to the United States already exists. And the notion that essentially the companies are obliged in order to transact business with the United States that they be accredited and certified and inspected before the product gets into the United States is a direct impact on the events that impacted on Menu foods, where you are getting into imports from China, et cetera, it would have been critical, and it would have been a very good positive step that somebody will have seen that, inspected that plant before it gets into the United States.

Mr. WALDEN. Doesn't that really lend itself, too, for the call for food labeling, mandatory country of origin labeling so we know where this food is coming from as a consumer? You all keep records; don't you? Tell me you don't know back to the box. I have had fruit processing folks tell me they know back to the box from which orchard that the pears or apples or whatever fruit they are using originated.

Don't you keep track of that anywhere?

Mr. HENDERSON. My understanding of looking at the Bioterrorism Act, you essentially go forward one, back one, so you complete that chain, and you can get back to where you need to be. It is my understanding, relative to which hog was slaughtered to get products into our pet food, no. We don't know that; we don't have that information.

Mr. WALDEN. Would you like to have that information in a situation like we see in the press these days?

Mr. HENDERSON. From a commercial perspective, there has to be some element of accountability through the chain. The individuals with whom we deal with are essentially they are known commodities as far as people that we have dealt with before or have dealt with. In this particular issue, we had been dealing with ChemNutra before this, buying other ingredients.

We buy from known suppliers. The idea that we have to go all the way back and that everybody in the supply chain has to go all the way back I don't believe is commercially practical.

Mr. WALDEN. Mr. Sweat.

Mr. SWEAT. Well, I think on the confidence with consumers on food safety and fresh fruits and vegetables what we have learned from the scientists is this bacteria lives in the environment in which fresh fruits and vegetables are grown so there is a hazard and risk. And with that hazard and risk, what we have done is we have gone out to the International Commission on Microbiological Specification For Foods and classified fresh foods and vegetables as a class 15, which is the highest risk for pathogens because that means that it can actually grow beyond its process and can continue to grow.

So with that, we have implemented raw product testing as a hurdle to prevent any sporadic contaminations from the environment on the crops from entering the process. And then we have imple-

mented a finished goods testing program following that same class 15 sampling program that actually samples our production process every 2 hours. It is about 480 samples every 2 hours off the production lines because of the high risk of bacteria with fresh fruits and vegetables. So we have to communicate that to consumers to re-install confidence in what we are doing for food safety.

Mr. WALDEN. I know my time has expired. Thank you all for your testimony. Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Walden, before you leave, I want to ask Mr. Henderson, do you wish to clarify an answer to your question about whether immediate recall is something we should have because the record is clear what we had this morning. That is why I am surprised at your answer, Mr. Henderson. If you take a look at the record and the timeline, on March 15 was your first recall for all wheat gluten manufactured between December 3, 2006, to March 6. March 24 was your second recall; you expanded to include additional dates.

On April 5, you had your third recall. On April 10, you had your fourth recall. So an immediate recall authority by the FDA would not have taken a month for you to recall your products; correct?

Mr. HENDERSON. I would have to say that is incorrect. The information that you are looking on—the recall that took place relative to the date of March 16, Menu Foods at that point in time did not know what the problem was.

Mr. STUPAK. I am not asking about the problem. The question was a recall. Should we give the FDA the right to immediate authority, and it wouldn't have made any difference in this case, you said; you don't think it would have made any difference in this case—but yet the recall went on for about a month—I don't think giving immediate recall authority for the FDA would have made any difference here.

Mr. HENDERSON. The recall that was initiated by Menu Foods was essentially as a result or following conversations with the FDA. We identified, this was the scope that we are proposing to do. Whether or not they might have come up with a different scope, that is a valid point. They might have come up and said, recall more, recall less.

Mr. STUPAK. But even before you—I don't mean to be argumentative here—even before you at Menu Foods and FDA decided to recall, Iams had already told you they would no longer accept your product, and they were going to recall all food manufactured by Menu Foods at the Kansas plant; right? So, really, Iams was the first to really start the ball rolling here. Something is wrong, and I guess maybe what we are getting at here, there is also corporate responsibility instead of waiting for the FDA if Iams, the pet food manufacturer, sees a problem, and they are recalling it, I would have hoped that the corporations would have done it without FDA authority. But even with FDA authority, if we could grant that to them, I think we could have maybe limited the scope of the harm caused throughout our country.

Mr. HENDERSON. Again, relative to the facts as they actually transpired, the conversation that took place with Iams, they essentially shared some information with us. We got together the next day, and essentially, in a rather lengthy meeting, both parties ex-

changed what they knew; that being that, individually, there wasn't enough information to draw conclusions, but together, it looked as though, from a circumstantial evidence perspective, as if we had the basis for recall. They opted to recall. We went along. We announced first.

Mr. STUPAK. Iams sees the need for recall, but almost 2 weeks before that, your own taste-testing lab, out of 20 animals, 3 died and 6 were dead. That is almost 60 percent. I would think that would cause Menu Foods to be concerned and talk about a recall and what is going on here quicker than waiting for Iams to force the issue and then the FDA and on and on.

Mr. INSLEE for 10 minutes please, questions.

Mr. INSLEE. Thank you, Mr. Sweat.

Before the outbreak happened, were you given any warnings about a possible outbreak that may occur in suggestions that you should improve your practices?

Mr. SWEAT. We did receive a letter from the FDA some time, I want to say in November 2005. And with that letter, there were some steps that they asked us in our industry to go look at. And that was to look at our compliance with the recommended guidelines from the FDA on good agricultural practices, our good manufacturing practices and our HACCP programs. And we did that as an organization. And at that time, we were meeting or exceeding all of those guidelines published by those particular agencies.

And about 2006, in the spring, as an industry, we met with the FDA and the CDHS to collaboratively share best practices within the industry and begin to work on technical committees across many companies within our industry in collaboration with the FDA and CHS to look for best practices that we could employ across the whole industry.

Mr. INSLEE. What practices are you now implementing that were not adopted then?

Mr. SWEAT. Subsequent to the outbreak, what we did was we reached out to the beef industry who had shown some success with reducing *E. coli* outbreaks and learned of a testing program that they had implemented from the international commission on microbiological specifications for food. And the scientists that had worked extensively in the beef industry helped, and we brought on board to consult with us and we had implemented a very similar testing program that the beef industry did using a class 15 high-risk statistical program.

Mr. INSLEE. And did you consider adoption of that earlier and reject it, or simply just not consider it?

Mr. SWEAT. At the time, we had not had any outbreaks in our organization for 22 years using our good agricultural practices, GNPs and HACCP programs, so we had not considered it prior to the outbreak.

Mr. INSLEE. And how many presumptive positives for *E. coli* 015787 have you found since you instituted the program?

Mr. SWEAT. We implemented a raw product testing protocol within a couple of weeks of the outbreak. To date, and this is as of yesterday, we had a total of 39 positives, of which 23 are *E. coli* related; 16 are salmonella related. They had been found in California, Arizona and Mexico, from various growers.

In our finished goods testing program that we implemented, we have found none on our finished goods testing programs.

Mr. INSLEE. And is there anything to suggest that your circumstances now are different than they were before this? In other words, would you expect that is how many that was the situation before the outbreak as well?

Mr. SWEAT. I would hate to speculate since we weren't testing on what was prior to the outbreak. What we have learned from the scientists are these bacterias are prevalent in our environment, but since we weren't testing, I would hate to speculate on what was there.

Mr. INSLEE. The microbiological testing program that you have adopted, is there any reason that that should not be standard throughout the industry?

Mr. SWEAT. We would like to see that, plus more science, that become standard for the industry, but also we need more science to see what else we can do as an industry. This testing protocol is not a kill step. It is an intervention and a hurdle to help prevent these types of contaminations from occurring, but as an industry, we still need to continue to invest more in science and research on how we can combat this bacteria.

Mr. INSLEE. And why would you like to see the standard in the industry?

Mr. SWEAT. I think it adds additional hurdles and interventions for food safety. I think the good agricultural practices, as adopted today, are going to create, under the Leafy Green Marketing Agreement in California, a baseline for growers to comply with. But we think there needs to be more, and I think if we can test for these pathogens, then we may be able to detect and learn from them and also help prevent them from entering the chain of commerce.

Mr. INSLEE. Have you considered treatment from, like, Ozone? You talk about a kill technology. Is that being considered?

Mr. SWEAT. Yes, we have looked at ozone. The challenge with Ozone in water flume systems we use to wash lettuce, it is hard to control the ozones with the lettuce water combination. But we are looking at a lot of different sanitizers with the scientific panel board that we have brought on staff. We have actually set up a bio-hazard lab level 3, and we are testing different kinds of sanitizers to see if we can get larger microbial load reductions in our wash systems.

Mr. INSLEE. There is a new Ozone technology for sterilization. It happens to be in my district. Are you familiar with that, where you use one stream of high pressure water and one of a low pressure Ozone application? Are you familiar with that at all?

Mr. SWEAT. I am not familiar with the details on that particular—

Mr. INSLEE. I may actually shoot that to you and ask you to take a look at that. They have had good success on that.

Mr. SWEAT. I would welcome that.

Mr. INSLEE. How do you handle when you have your positive from a lot, from a field?

Mr. SWEAT. That particular lot gets destroyed, and then we open up a field audit from that lot, from that field, immediately, and we go out to look at the inputs on that field to see if we can have any

trace back to the source. Unfortunately we have not been able to find anything link back to the field to those lots that we have tested positive.

Mr. INSLEE. You said that you thought it would make sense for the industry to have a standardized microbiological testing protocol like that. Would you have any difficulty, or the FDA, if we gave them the ability and they implemented the ability to adopt that as a requirement?

Mr. SWEAT. I would not.

Mr. INSLEE. I think given your experience, I can understand why that is.

If you just give me one more moment, I had one more question I want to ask you. I'm told there have been 20 *E. coli* outbreaks from contaminated leafy greens from Monterey County before this one. Is that accurate?

Mr. SWEAT. I think that number sounds about right.

Mr. INSLEE. That strikes me as a lot from a fairly confined area. I have heard people suggest that there are problems with the water source from animals in general in that area. Is there anything different about that area relative to other growing areas that we should be concerned about?

Mr. SWEAT. We started testing all of the water sources on our growers' fields for pathogenic *E. coli*, and we have not found any positives in any water test to date during this 7, 8 months since we have implemented these testing protocols. So I haven't seen anything in the test data yet that would indicate anything on the water systems, but I do think we have to look at the environment and all of those resources out there with science to better understand it.

Mr. INSLEE. Thank you.

Mr. Miller, you may have covered this, but on the gluten that came in involved in this episode, was that food-grade gluten when it entered the United States? In other words, could it legally be used in human food?

Mr. MILLER. Yes, it was food grade.

Mr. INSLEE. So in a sense we just dodged the bullet, at least from the humans' perspective, that it went not into food for human consumption, but for animal consumption?

Mr. MILLER. Yes. We believe it was because of a fraud in China that this happened. Apparently they weren't expecting it to be discovered, and maybe there was less of a chance if it was pet food, or they knew it was going to pet food, but it was food grade.

Mr. INSLEE. So they knew this was going into the pet food stream, but legally you could have taken it, sold it to somebody, and they could have put it into human consumption?

Mr. MILLER. I believe so.

Mr. INSLEE. So what should that lead us to conclude about our current standards? You said that they thought since they knew it was going to go to pet food, they could maybe sneak it through or sneak it by. In what sense?

Mr. MILLER. I don't know. That is just a surmise. We believe that this was an intentional defraud or an intentional fraud to make money, and a fraud which we're a victim of and our customers are

victims of. But I believe they were aware that our customers were pet food customers.

Mr. INSLEE. If the buyer here or the seller in China knew it was probably going into the human stream, would there have been any additional standards other than what exists right now in protocols and inspection or standards to make sure they were—I assume there were not, because if this was human, fit for human consumption, there would have been no additional standards from what they had for pet food gluten; is that a fair statement?

Mr. MILLER. I believe that is true. I mean, this was an adulteration that was just off the radar screen. No one was aware of it, no one had thought of it. I don't believe it had ever been tested for in wheat gluten.

Mr. INSLEE. So is it fair to say that as far as our concern for this episode, it ought to be just as high, we ought to consider it like a human adulterant?

Mr. MILLER. I would think that is a risk.

Mr. INSLEE. Which is bothersome. Thank you.

Mr. STUPAK. I thank the gentlemen.

Mr. BURGESS for questions, please.

Mr. BURGESS. Thank you, Mr. Chairman.

Mr. Henderson, is it safe to assume that we just heard the discussion back and forth that perhaps it was someone with larceny in their heart that decided that the melamine would be a good way to make money, but we don't really know, do we?

Mr. HENDERSON. No, we do not.

Mr. BURGESS. And, Mr. Sweat, you have as carefully as you can investigated the source of the outbreak in your industry. And although there are some cows across the way that might have been a source, you haven't really drawn a direct link from one to the other yet, have you?

Mr. SWEAT. No, we haven't been able to identify the transmission vehicle yet.

Mr. BURGESS. And I don't know about the peanut industry, but I guess if I were a conspiracy theorist, Mr. Chairman, I would start connecting dots that may be unrelated and ask if someone is trying to undermine the confidence of the United States food industry, because these are spectacularly unrelated and almost inconceivable events that have now coalesced around this hearing. I just can't help but wonder if there is perhaps something we are missing in this great debate.

The other thing that comes up, and, of course, we heard the testimony from our friends with GAO, and looking into best practices in other countries, but here we sit talking about Chinese gluten and Canadian cat food, Mexican spinach, and maybe the best practices we ought to concentrate on are the ones here in this country. And maybe, in fact, we ought to look at—well, maybe you all can help me. Why do we even import gluten from China? Is it a cost factor, or is it an inability to produce gluten in our own country? Either end of the table, please feel free to answer. Mr. Henderson, we'll go with you first.

Mr. HENDERSON. Essentially, from a wheat perspective, you are looking at the lion's share. My understanding of the numbers is that about 50 percent of the wheat gluten that is used in the

United States, both in pet food and in human food, comes from Europe. Essentially it is a matter of capacity. There simply isn't enough capacity in the United States to meet the demands.

Mr. BURGESS. Mr. Miller, would that be your—

Mr. MILLER. Yes, except that I believe some of what comes from Europe originates in other countries.

Mr. WHITFIELD. While you were out, Dr. Burgess, they said that the U.S. domestically can produce only 25 percent of the demand for wheat gluten in the United States.

Mr. BURGESS. But many of the wheat fields in north Texas are underutilized right now. I know that for a fact because I drive by them every day. But nevertheless, what steps are being taken—and this may be unrelated to this hearing—but steps are being taken to prosecute the people if there has been larceny involved in our foreign supplier? Where are we in that process? Are we trying to identify who did what to whom and whom to prosecute?

Mr. Henderson.

Mr. HENDERSON. At this stage my understanding is the FDA is trying to get into China to undertake and continue their inspections, essentially independent of their efforts. We are doing what we can, but there is very limited we can do beyond essentially understanding exactly what steps they are taking to get to the bottom of the question at hand.

Mr. BURGESS. Mr. Chairman, I hope this committee will continue to monitor that and stay closely involved in that, because it is disturbing to me that a foreign source of larceny could be inflicting such harm on our citizens.

Let me ask you, Mr. Colo, on the issue of salmonella, just for my own edification, is salmonella a frequent hitchhiker on the back of a peanut? Is that something that comes up from time to time?

Mr. COLO. Because peanuts are a raw agricultural commodity, obviously they are grown in the soil, soil and water is well known to contain salmonella, so it is a likely conclusion that in some cases peanuts will be a carrier for salmonella, yes.

Mr. BURGESS. Going back to my earlier conspiracy theory, though, you really have not yet been able to draw a bright line between—and say you know definitely where this came from in the process; is that correct? It is an assumption that there was some dust and some water and spontaneous generation, and the salmonella got into your product?

Mr. COLO. Based on the investigation that we have done, that is what we consider to be the most probable cause of the source of contamination.

Mr. BURGESS. Again, just for my background information, how do you test for salmonella?

Mr. COLO. Our sampling protocol is that for every packaging line that we are filling peanut butter jars on every day, we take one sample per line per hour within our facility. We then run the—

Mr. BURGESS. Right. I got that. But when the raw product comes into your facility, before you even start the manufacturing process for peanut butter, do you test the batch for the presence of salmonella in the raw peanuts?

Mr. COLO. We do not test raw peanuts for salmonella. We test it for apitoxin, but do not test for salmonella.

Mr. BURGESS. In testing for salmonella, in the hourly test that you do on every line, what are the levels of detection, how many parts per million, or what is the level of detection for salmonella?

Mr. COLO. It is considered negative if it is less than 1.0, and that is an absorbent value that is used in the test methods.

Mr. BURGESS. So you don't actually culture the peanut butter and grow colonies and count them off the Petri dish like we used to in high school biology?

Mr. COLO. We do actually do that.

Mr. BURGESS. You do do that. Well, what do you think? Why wasn't the salmonella detected in the hourly checks on the line runs that you all were doing?

Mr. COLO. We think that the levels were so low in the product that the tests were just not able to detect the positive salmonella.

Mr. BURGESS. So the numbers were too low?

Mr. COLO. The level of contamination was so low in the peanut butter that we were not able to detect it.

Mr. BURGESS. And then over time the colonies grew and multiplied such that they became clinically significant by the time they were ingested by the end user?

Mr. COLO. Maybe. I am not a doctor. I am not sure what manifested from our plant to the end consumer.

Mr. BURGESS. If it was so low, then why did people get sick? How did the clinical manifestation of disease occur if the count was so low to be undetectable by your routine testing methods?

Mr. COLO. That is a very good question. If you look at the water activity of peanut butter, it is extremely low. And what that is a measure of is the available water in the peanut butter itself. And what may likely have occurred is that somehow there was this contamination of water in the facility that was not detectable at the time of packaging, but later over time that maybe the salmonella was allowed to grow due to the water availability.

Mr. BURGESS. What do you think going forward? Are you going to be able to be confident that the same mysterious set of circumstances is not going to happen again?

Mr. COLO. Yes, we are very confident. And the reason for that is the approaches that we are taking prior to restarting our facility will include making sure that we have very robust food safety standards in place. We are in the process of looking at all of our both environmental and finished product testing methods and protocols.

Mr. BURGESS. So you are going to heighten the sensitivity of your testing?

Mr. COLO. Absolutely.

Mr. BURGESS. Good.

Mr. SWEAT, on the spinach issue that came up, you said that some of the spinach you get is harvested in Mexico; is that correct?

Mr. SWEAT. That is correct.

Mr. BURGESS. And have you assessed these Mexican farms with as much scrutiny as you had with the California farms about wild pigs and cows across the hill and that sort of thing?

Mr. SWEAT. Yes. Most of the growers that grow product for us in Arizona and Mexico are the same growers that grow product in

California. They migrate throughout the year based on seasonal climatic changes to grow the lettuces.

Mr. BURGESS. But my understanding, I think, from your testimony or from someone else's was that one of the possibilities was the *E. coli* existed in the stream water which may have flooded into wells which were used for irrigation. Is the same possibility present in Mexico, or is it more likely to be possible in Mexico, less likely to be possible? Is there any way to quantify the risk from the various farms from which you accumulate product?

Mr. SWEAT. What we have done is apply the same standards across all farms. So we test all the waters, the seed, the soil. Everything on our GPA program now tests for that across all farms that supply product, not just in California.

Mr. BURGESS. In November 2005, a series of outbreaks associated with the Salinas area farms, the FDA sent a letter to California farms that grow packaged spinach. Are you familiar with the letter that they sent?

Mr. SWEAT. That is correct.

Mr. BURGESS. It requested that you begin or intensify immediately various efforts. How did that intensification of efforts, how did that proceed?

Mr. SWEAT. We went back through the agricultural practices, the good manufacturing practices, in our HACCP program that we use, the FDA's guidelines and their updated guidelines as it related to leafy greens and fresh cut fruits and vegetables to make sure that we were meeting or exceeding all those standards.

Mr. BURGESS. So have you, in fact, implemented all of the guidelines that were listed by the NDA at that time?

Mr. SWEAT. They were actually already implemented when received a letter in 2005.

Mr. BURGESS. So accelerating that implementation, would that have made any difference in the September 2006 outbreak?

Mr. SWEAT. No. The GAPs and GMPs and HACCP programs that were implemented had been implemented and working for many, many years.

Mr. BURGESS. How can you be sure that area water doesn't contaminate the crops?

Mr. SWEAT. As part of our enhancements to the GAP programs that we have done is we have increased the frequencies of testing all the water for irrigation. And instead of testing for just generic *E. coli*, which is an indicator of a potential pathogen, we actually test for the pathogenic *E. coli* now.

Mr. BURGESS. Do you test for toxigenic *E. coli*?

Mr. SWEAT. We do.

Mr. BURGESS. To whom do you report that information?

Mr. SWEAT. That information actually from our growers gets reported in to us, and then we keep all that data there.

Mr. BURGESS. Do you follow on with the California Department of Health or the CDC? Do you tell someone about it?

Mr. SWEAT. If we were to have any positives on water, if it's a municipal water supply, we would notify that municipality that would be supplying it, and then we would also notify CDHS about the issues of finding anything that would test positive.

Mr. BURGESS. Just in regard to the spinach itself, how many positives for toxigenic *E. coli*, how many of those positives do you generally record in a year's time?

Mr. SWEAT. Well, we started the testing on raw product 2 weeks after the outbreak, so that was about the first week in October when we implemented the raw product. To date there have been 23 raw product samples that have tested positive for *E. coli*, and those products have been destroyed. And about 16 have tested positive for salmonella, and those have been destroyed. But none of the finished goods that we have tested have tested positive for either *E. coli* or salmonella.

Mr. BURGESS. But prior to September 2006, that data would not be available?

Mr. SWEAT. No. We were not testing prior to the outbreak.

Mr. BURGESS. And what do you do with the affected crop? How do you destroy it?

Mr. SWEAT. We actually put it into an incinerator and document the photos of it that it's being destroyed.

Mr. BURGESS. And you conform with the Clean Air Act when you do that, correct?

Mr. SWEAT. Yes, we do.

Mr. BURGESS. Thank you, Mr. Chairman.

Mr. STUPAK. I thank the gentleman.

Just a few questions from me for a wrap-up.

Mr. SWEAT, of those, I guess, 39 positives you've received now, all these washing, the good manufacturing and all these other operating procedures, none of that's going to detect *E. coli* or salmonella unless you test for it?

Mr. SWEAT. That's our understanding is that it will not detect it.

Mr. STUPAK. So all these voluntary standards, in-house testing, which I appreciate you doing, if you don't do it, there's no penalty to you, there's no stick, if you will, there's no enforcement?

Mr. SWEAT. To my knowledge we are the only company that has implemented this testing program to date.

Mr. STUPAK. I was going to ask you, we talked about Salinas Valley being the lettuce bowl of America. Do the other producers in that area do these testing that you are doing?

Mr. SWEAT. To my knowledge they don't.

Mr. STUPAK. And there's no requirement for them to do it?

Mr. SWEAT. There's no requirement. But early on we said food safety would not be a competitive advantage. Whatever we learned we would share with our industry. And we are doing that. We are sharing these testing programs that we have done with everybody in our industry and all the associations.

Mr. STUPAK. I appreciate you are doing the testing now, but if we did not have this spinach outbreak, you probably wouldn't be doing testing, would you?

Mr. SWEAT. That's a hard one to go back on now, because once you've crossed over and started it, it's hard to envision something you would do different.

Mr. STUPAK. I am not trying to discourage it.

Mr. SWEAT. But prior to that we had not had any reason not to think our GAPs and GMPs and HACCPs weren't doing their job of

detering that microbial contamination because we had not had any of those outbreaks for later tests over the years.

Mr. STUPAK. Well, it seems like our food safety in this country is reactive as opposed to proactive. I am disturbed when you tell me that FDA comes to your place, they look at things, and they never do any testing; they just look to see if you are washing this or making sure that conditions are very sanitary. They don't even do testing when they are there. It seems like we are waiting for something to happen, then we try to react. And our chance of recall can take some time, as we have shown. That's my only concern.

Mr. SWEAT. I think the testing is a way to validate the efficacy of all of the controls from field to finished product.

Mr. STUPAK. Let me ask you this. I realize you are not into marketing, but, Mr. Henderson, Mr. Sweat, Mr. Colo, has your company ever done marketing to test the attitudes of Americans? Would they pay an extra 5 cents for a package of lettuce to assure testing to be done? Is it a cost issue why it's not being done or just never been done? Mr. Henderson.

Mr. HENDERSON. No. Our company has never undertaken such a study or formal inquiry with our customer base. Recognize that the majority of the customers that we market to are essentially selling their brands, and they are essentially the brand marketers in the countries in which they transact business.

Mr. STUPAK. Mr. Sweat.

Mr. SWEAT. We haven't done any research or focus groups from a marketing standpoint on the thought process of what they would pay. We haven't really looked at the cost of all these programs we have done. It's just doing the right thing for our consumers to improve our food safety program.

Mr. STUPAK. Mr. Colo.

Mr. COLO. I am not aware of any particular marketing studies around that particular issue. Our approach is simply that you have to do everything possible to ensure that the food that you are producing is safe. So our policies are all geared towards that.

Mr. STUPAK. That's been passed by the last few Congresses. It says country of origin, but somehow that never seems to get implemented. Do you think that would help at all in this situation? Again, without testing, it doesn't make any difference where the product comes from, right? Mr. Sweat.

Mr. SWEAT. That's correct. I think the countries of origin labeling laws would help identify for the consumer where it's coming from, but you are still going to need to put in your testing protocols. And as you look at that bag of salad, Mr. Chairman, you'll notice there's lots of ingredients on there. So one of the challenges for us is that when you bring in 10 or 12 ingredients from 10 or 12 different farms, you don't have a one-to-one correlation from a field-grown product to a finished product.

Mr. STUPAK. Mr. Burgess.

Mr. BURGESS. Mr. Sweat, if I could ask one last take-home question for the bag that has been famously passed around up here today. It says triple washed or final washing. Do you advise consumers to wash your product before they consume it?

Mr. SWEAT. What we do with our consumer Web site and when consumers call and ask should they wash their lettuce, we tell them if they want to wash it, then they should wash it.

Mr. BURGESS. But that's not a recommendation on the package. And just like we heard testimony from the folks who were here earlier today, they look at the package that says triple washed, ready to eat, so they pop the bag and put it into the bowl. Would it make any measurable difference if consumers, just like we tell them now to cook their hamburger until it's done, that we wash our spinach even though the product may say it's been triple washed?

Mr. SWEAT. I don't think washing would have any further impact on it, because typically just running water over it, there's not the chlorine that we use in our agitated work system as a deterrent for a microbial load. So I don't think washing would enhance that at home. But we encourage our consumers if they want to wash it, please do so.

Mr. BURGESS. So the bug is too sticky to just wash off the leaf of spinach?

Mr. SWEAT. It can be.

Mr. BURGESS. Thank you.

Mr. STUPAK. One more question, Mr. Henderson, if I may. I have a number of constituents and my dog. When are we going to get our pet food supply back to normal? Will it take a while? I mean, there's a lot of it off the shelves, and you seem to be the main manufacturer. When will we see the wet cat and dog food back up to where they are? We are still having trouble in some parts trying to find our favorite food, if you will.

Mr. HENDERSON. Actually from a size perspective, Menu is actually quite small in the marketplace. But relative to our steps, we are still in the midst of the recall. That's going on as I sit here today. And the practice that we are going through is essentially to make sure that with working in cooperation with the retailers, that all of that product is back off the shelf so there's no possible way that it can get back. And once we have got certification that that product has been cleared from the retailers' shelves, cleared from the reclamation centers and from the warehouses, we will begin shipping them product manufactured with proven wheat gluten going forward. I expect that it will start in the next week or two.

Mr. STUPAK. For all of you, if you may, Mr. Henderson, Mr. Sweat, Mr. Colo, Mr. Miller, the committee would like you to give us the—present to the committee the inspections of the USDA and FDA at your plants, plural, if you have more than one. And if you could do that within the next week, we would appreciate it. We do have the FDA coming in in a couple of weeks. We are a little concerned about inspections; how often they occur, what do they do. There's some question whether they do any testing or not. So if you could provide those to us. So Mr. Henderson would you do that for us please, try to get that to us in a week? If you have trouble, get ahold of the committee.

Mr. HENDERSON. Certainly. Can you tell me how far back?

Mr. STUPAK. From 2000 to April 2007.

Mr. HENDERSON. Yes.

Mr. STUPAK. Mr. Sweat do you think you could do that?

Mr. SWEAT. Yes, we'll provide that.

Mr. STUPAK. Mr. Colo?

Mr. COLO. Yes.

Mr. STUPAK. Mr. Miller?

Mr. MILLER. Yes. We have already done it. If you would like us to go back further, we have already done it.

Mr. STUPAK. From 2000 through April 2007, if you would.

Mr. MILLER. Yes.

Mr. STUPAK. I appreciate that.

Mr. Burgess, I think, was questioned about the November 4, 2005, USFDA letter to California firms on the grow, pack process for fresh-cut lettuce. That will be made part of the record.

Also the statements of Representative DeLauro, Representative Pallone and Senator Durbin will also be made part of the record.

We have to have the exhibit binder that's before us here without objection be made part of the record.

That concludes all questioning. I want to thank our witnesses for coming today and thank you for your testimony. I ask unanimous consent that the record will remain open for 30 days for additional questions for the record.

That concludes our hearing. Without objection, this subcommittee is adjourned.

[Whereupon, at 1:45 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PAUL HENDERSON ANSWERS TO SUBMITTED QUESTIONS FROM HON. JAY INSLEE

Dear Congressman Inslee:

This letter is written in response to the additional questions from you set forth in the letter dated June 21, 2007 from Chairman Dingell with regard to the hearing "Diminished Capacity: Can the FDA assure the Safety and Security of the Nation's Food Supply?" on April 24, 2007.

The following are the answers to your questions:

Does Menu Foods sell "salvaged" and/or "distressed" pet food for use in livestock feed?

No.

Did Menu Foods sell "salvaged" and/or "distressed" pet food from the November 8, 2006 through March 6, 2007 production runs that have been recalled?

No.

If Menu Foods did sell "salvaged" and/or "distressed" pet food from recalled batches, has any effort been made to track down buyers and determine whether this food has crossed into the human food supply?

No.

We appreciate this opportunity to assist the subcommittee in its efforts.

STATEMENT OF HON. ROSA L. DELAURO AND HON. RICHARD J. DURBIN

Mr. Chairman, we want to commend you for calling this hearing and thank you very much for the opportunity to present written testimony.

We all saw the disturbing article in yesterday's Washington Post that the FDA has known for years about contamination problems at a peanut butter plant in Georgia and on spinach farms in California, but took only limited steps to address the problems and relied on voluntary actions by the industry. Based on the evidence being compiled so far in the pet food recall situation, the FDA appears to be failing its responsibilities to protect pets from unsafe food as much as it is failing to protect American consumers.

Mr. Chairman, the FDA's response to this situation has been tragically slow, and pet owners deserve answers. The uncertainty about which foods have been recalled and what is safe to feed their pets has gone on far too long. We also learned last week that the human food supply may be at risk because of contaminated pet food that was provided to a hog feeding operation in California. After the disturbing revelations that were outlined in the Post article yesterday, we fear that a full investigation will determine that FDA rarely, if ever, inspects pet food manufacturing plants, and that the agency desperately needs to modernize its regulations to protect our pets.

As we all know, the problems that have resulted in the pet food recall are being traced to shipments of wheat gluten and rice protein and corn gluten from China that was discovered to be contaminated with melamine. As FDA's investigation continued, pet owners kept receiving assurances from the agency that only the foods on the recall list presented a danger to their pets. However, pets remained vulnerable despite these assurances because the recalls kept expanding dramatically. One of the central reasons the recall keeps expanding is that FDA has refused to identify the companies that have purchased rice protein concentrate batches from the same contaminated shipment. Of the five companies that purchased from the contaminated shipment, only two have been identified.

The FDA knows the identity of the other companies that purchased ingredients from the contaminated shipments, but is unable to disclose the information and compel any action. Thus, consumers have not been able to avoid buying and feeding potentially contaminated products to their pets, and contaminated pet food still may be on store shelves. This is unconscionable.

And of course, we do not have to remind you Mr. Chairman that the FDA has no authority to mandate recalls and instead relies on information submitted by companies. As the Post article yesterday noted, we saw how that situation played out in 2005 with the peanut butter plant in Georgia when company officials refused to provide information to the FDA when the agency was investigating complaints about a salmonella contamination—2 years later a salmonella outbreak in peanut butter sickens over 400 people in 40 States.

Another very troubling aspect to this issue is the Chinese Government's delay in allowing FDA personnel to enter China to inspect the facilities suspected of producing the contaminated products. After FDA Commissioner Dr. von Eschenbach informed us of this situation in our meeting with him last week, we wrote a letter to the Chinese Ambassador to the United States asking that they allow our inspectors into the country. We also asked that the ambassador meet with us to discuss the larger issue of contaminated food being imported into the United States.

Just today, we learned that China has agreed to allow U.S. regulators to enter China. Unfortunately, FDA's request has been pending since April 4, 2007, an unacceptable delay of 3 weeks during which time the health of our pets has been at risk. Unlike the Food Safety Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) which has the authority to set up cooperative relationships with trading partners and inspect their facilities, the FDA has no such similar authority and must rely on ad hoc procedures when problems arise.

We are all aware of the disturbing statistics related to imported foods. The U.S. now imports far more foods than it exports, but there are fewer inspectors for imported foods. Currently, FDA inspects less than 1 percent of the food imported into this country that it is responsible for regulating. Also, the FDA does not require exporting countries to have food safety regulatory structures that are equivalent to the U.S. standards. Given that the contaminated pet food appears to be connected to products imported from China only heightens our concern about the agency's ability to inspect imported products. It is this aspect of the pet food recall crisis that is particularly troubling and will be examined further in a follow-up hearing before the House Agriculture Appropriations Subcommittee.

In addition, for the first several weeks of the pet food recall, the FDA did not clearly communicate which brands and products were on the recall list. Rather than bring together all of the relevant recall information in an easy to read, searchable document, the FDA relied on links to corporate press releases on the voluntary recalls, each of which had a different format. This format was confusing and time consuming for concerned pet owners. We are both glad that FDA has taken our advice and modified the format of their website.

It very well may be that FDA lacks the resources to adequately inspect pet food facilities and imported products. And this is an area where we could work together to make a direct impact. However, we also should examine whether this is a management issue. In response to a letter that we sent to FDA, the agency said it has not determined whether changes in current law or resources are necessary based on the pet food recall. We find it difficult to understand that this agency always re-

fuses to even consider requesting additional authorities or resources to help it do its job. This dismissive approach toward additional authorities is very frightening and could continue to have serious repercussions to the safety of both pet and human food.

The FDA likes to demonstrate its commitment to food safety by pointing out that “food” is the first word in its name. However, its actions suggest otherwise, highlighting the need for legislation that would create a single food safety agency—a bill that we have worked on for quite a long time now—the Safe Food Act of 2007.

This legislation would consolidate the various cross-cutting authorities in the area of food safety and move them within a single regulatory structure. The goal is to improve coordination, realize efficiencies, and streamline the number of oversight committees responsible for food safety. This new independent agency would better compete for resources and be in a position to strategically plot a national food safety strategy. Today’s regulatory arrangement is fractured among multiple departments and sub agencies and is in major need of reform.

In addition, we are working on legislation that will specifically address shortfalls in FDA’s authority to prevent or react to situations similar to the pet food recall. We hope to be ready to introduce a bill this week or next. As Dr. Robert Brackett, FDA’s Director of Food Safety (CFSAN), was quoted as saying, “The outbreaks point to a need to completely overhaul the way the agency does business...We have to get out of the 1950s paradigm.” Our legislation will focus on the following five proposals that, if in place, might have prevented or mitigated this recent contamination:

1. Mandatory Recall Authority;
2. Adverse Event Reporting Standards and Penalties;
3. Standing FDA Authority to Inspect Overseas;
4. Surveillance and Early Detection; and
5. Standardization of Voluntary Standards.

We look forward to FDA’s analysis of their oversight of pet food manufacturing facilities and the final report on the actions that the agency took once the crisis finally ends. We also look forward to the results of your investigation, Mr. Chairman. We feel that it will play a key role in determining the best steps to take in moving forward.

Thank you again, Mr. Chairman for allowing us to present testimony at this hearing and we look forward to continuing to work with you on this issue.

HENRY A. WAXMAN, CALIFORNIA
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DEWIS E. FITZGERALD, CHIEF OF STAFF
 GREGG A. ROTHSCHILD, CHIEF COUNSEL

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

JOHN D. DINGELL, MICHIGAN
 CHAIRMAN

June 21, 2007

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Ms. Lisa Shames
 Acting Director
 Natural Resources and Environment
 U.S. Government Accountability Office
 441 G Street N.W., Room 2T23A
 Washington, D.C. 20548

Dear Ms. Shames:

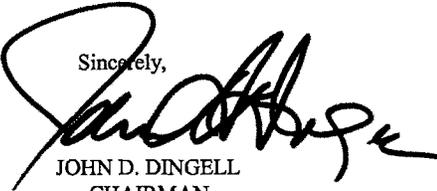
Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, April 24, 2007, at the hearing entitled "Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?" We appreciate the time and effort you gave as a witness before the Subcommittee.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from certain Members of the Committee. In preparing your answers to these questions, please address your response to the Member who has submitted the question(s) and include the text of the Member's question along with your response.

To facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business **Friday, July 6, 2007**. Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Kyle Chapman, Legislative Clerk. An electronic version of your response should also be sent by e-mail to Mr. Kyle Chapman at kyle.chapman@mail.house.gov in a single Word formatted document.

Ms. Lisa Shames
Page 2

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Kyle Chapman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations



G A O

Accountability • Integrity • Reliability

United States Government Accountability Office
Washington, DC 20548

July 6, 2007

The Honorable Ed Whitfield
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Subject: Posthearing Questions Related to FDA Oversight of the Safety and Security of the Nation's Food Supply

Dear Mr. Whitfield:

On April 24, 2007, I testified before the Subcommittee on Oversight and Investigations at a hearing addressing the Food and Drug Administration's (FDA) role in overseeing the safety of the nation's food supply.¹ This letter responds to your request that we provide answers to questions asked after the hearing. Your questions, along with my responses, follow.

1. Do you believe that we currently have in place the controls necessary to protect the American people from Asian fish that may contain melamine that was intentionally blended into the wheat gluten or other potentially banned and dangerous chemicals?

When we reexamined FDA's program for ensuring the safety of imported seafood in January 2004, we found that, while the program had shown some improvements, further improvements were needed.² For example, FDA had made little progress regarding our January 2001 recommendation³ that FDA communicate to U.S. port-of-entry personnel serious deficiencies identified during inspections so that potentially contaminated imported seafood was examined before it entered the United States. As part of our periodic follow up to determine if agencies have taken actions in response to our recommendations, it appears that FDA has not addressed most of our recommendations. For example, as of

¹ GAO, *Federal Oversight of Food Safety: High-Risk Designation Can Bring Attention to Limitations in the Government's Food Recall Programs*, GAO-07-785T (Washington, D.C.: April 24, 2007).

² GAO, *Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements Are Needed*, GAO-04-246 (Washington, D.C.: January 2004).

³ GAO, *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers*, GAO-01-204 (Washington, D.C.: January 31, 2001).

January 2007, FDA had yet to prioritize enforcement actions when violations that posed the most serious public health risk occurred. In addition, FDA had not established equivalence or other similar types of agreements with seafood-exporting countries.

- 2. In an effort to protect the public, do you believe we have an obligation to impose a temporary ban on all imported fish from China until we can assure the American people that China is meeting the standards the American people expect and deserve?**

While we have not done the work necessary to determine if a broader ban should be established, FDA placed several seafood products from China, including farm-raised catfish, on detention without physical examination on June 28, 2007. According to its public announcements, FDA will begin detaining these products at the border until the shipments are proven to be free of residues from drugs that are not approved in the United States. FDA reported that their import surveillance program repeatedly found that farm-raised seafood imported from China was contaminated with unapproved drugs or food additives from October 2006 through May 2007.

We appreciate the opportunity to comment and hope that these responses are of assistance. If you have any additional questions, please do not hesitate to call me at (202) 512-3841.

Sincerely yours,



Lisa Shames
Director, Natural Resources
and Environment



CFSAN/Office of Plant and Dairy Foods
November 4, 2005

Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce

This letter is intended to make you aware of the Food and Drug Administration's (FDA's) serious concern with the continuing outbreaks of foodborne illness associated with the consumption of fresh and fresh-cut lettuce and other leafy greens. We also outline below what we plan to do and the actions that we expect your industry will take to enhance the safety of these products.

FDA is aware of 18 outbreaks of foodborne illness since 1995 caused by *Escherichia coli* O157:H7 for which fresh or fresh-cut lettuce was implicated as the outbreak vehicle. In one additional case, fresh-cut spinach was implicated. These 19 outbreaks account for approximately 409 reported cases of illness and two deaths. Although tracebacks to growers were not completed in all 19 outbreak investigations, completed traceback investigations of eight of the outbreaks associated with lettuce and spinach, including the most recent lettuce outbreak in Minnesota, were traced back to Salinas, California.

Because these products are commonly consumed in their raw state without processing to reduce or eliminate pathogens, the manner in which they are grown, harvested, packed, processed, and distributed is crucial to ensuring that microbial contamination is minimized, thereby reducing the risk of illness to consumers. In 1998, the FDA issued guidance to industry entitled "[Guide to Minimize Microbial Food Safety Hazards for Fruits and Vegetables](#)." This Guide recommends good agricultural practices (GAPs) and good manufacturing practices (GMPs) that growers, packers, and shippers may undertake to address common risk factors in their operations, and thereby minimize food safety hazards potentially associated with fresh produce.

On February 5, 2004, FDA issued a letter to the lettuce and tomato industries to make them aware of our concerns regarding continuing outbreaks associated with these two commodities and to encourage these industries to review their practices in light of FDA's GAPs/GMPs guidance and other available guidance.

In view of continuing outbreaks associated with fresh and fresh-cut lettuce and other leafy greens, particularly from California, we are issuing this second letter to reiterate our concerns and to strongly encourage firms in your industry to review their current operations in light of the agency's guidance for minimizing microbial food safety hazards in fresh fruits and vegetables, as well as other available information regarding the reduction or elimination of pathogens on fresh produce. We encourage

firms to consider modifying their operations accordingly to ensure that they are taking the appropriate measures to provide a safe product to the consumer. We recommend that firms from the farm level through the distribution level undertake these steps.

Foodborne illness investigations rarely pinpoint the point of origin of the contamination. However, claims that "we cannot take action until we know the cause" are unacceptable. We believe that there are actions that can and should be undertaken immediately to address this issue. For example, at least some outbreaks may be related to contamination that may have occurred in the production environment. In June 2004, the California Department of Health Services, Food and Drug Branch (CDHS-FDB) initiated multi-agency, collaborative research aimed at identifying the environmental reservoirs for *E. coli* O157:H7, and understanding how lettuce may become contaminated. In a preliminary report presented at the August 2005 annual meeting of the International Association for Food Protection, *E. coli* O157:H7 was isolated from sediment in an irrigation canal bordering a ranch that had been identified in three separate outbreaks. The ranch is bowl-shaped; it sits upon a drained lake, and is highly susceptible to localized flooding. Expanded sampling in the Santa Rita Creek and the Salinas Valley area indicate that creeks and rivers in the Salinas watershed are contaminated periodically with *E. coli* O157:H7. The specific source of contamination that led to the outbreaks was not identified. However, several possible sources of contamination were identified, both on the ranch initially studied and upstream. Although it is unlikely that contamination in all 19 outbreaks was caused by flooding from agricultural water sources, we would like to take this opportunity to clarify that FDA considers ready to eat crops (such as lettuce) that have been in contact with flood waters to be adulterated due to potential exposure to sewage, animal waste, heavy metals, pathogenic microorganisms, or other contaminants. FDA is not aware of any method of reconditioning these crops that will provide a reasonable assurance of safety for human food use or otherwise bring them into compliance with the law. Therefore, FDA recommends that such crops be excluded from the human food supply and disposed of in a manner that ensures they do not contaminate unaffected crops during harvesting, storage, or distribution. Adulterated food may be subject to seizure under the Federal Food, Drug, and Cosmetic Act, and those responsible for its introduction or delivery for introduction into interstate commerce may be enjoined from continuing to do so or prosecuted for having done so.

We have worked in partnership with the fresh produce industry in the U.S. and abroad since the release of our GAPs/GMPs guidance in 1998 to promote our recommendations and to advance the scientific knowledge applicable to enhancing the safety of fresh fruits and vegetables. We recognize and appreciate the efforts that academia and some industry members have taken to date to provide fresh produce that is safe to consumers, and we are confident that you will continue to work proactively to pursue this goal. However, we are also aware that efforts by the CDHS over the last three years to engage the lettuce industry have not yet resulted in a comprehensive, collaborative plan to address the issue of *E. coli* O157:H7 in lettuce. In light of continuing outbreaks, it is clear that more needs to be done.

On October 18, 2004, FDA posted our [2004 Produce Safety Action Plan](#). FDA developed the 2004 Produce Safety Action Plan to minimize further foodborne illness associated with the consumption of fresh produce following comments from a public meeting and subsequent written comments. This Action Plan is designed to incorporate "lessons learned" in implementing the 1998 GAPs/GMPs guidance and expand on existing produce food safety programs.

There are four general objectives set out in the Action Plan: prevent contamination of fresh produce; minimize the public health impact when contamination occurs; improve communication between all parties; and facilitate research relevant to the contamination of fresh produce. For each objective, the plan identifies steps or actions by the industry as well as regulators that could contribute to the achievement of the objectives. We believe that many of the steps set out in the Action Plan are relevant to the goal of reducing foodborne illness caused by *E. coli* O157:H7 associated with lettuce and leafy greens.

Consistent with the Action Plan, we strongly encourage your industry to begin or intensify immediately efforts such as, but not limited to, the following:

- Communication - actively participate in dialog with FDA, California Department of Health Services and the California Department of Food and Agriculture (CDFA), academia, and other industry partners to ensure widespread, active participation and support of activities to address the issue of *E. coli* O157:H7 contamination of lettuce and leafy greens; develop an industry action plan with tangible measures of progress;
- Guidance - expedite completion of the industry-led lettuce and leafy green-specific supply chain guidance. (We recommend that this guidance include what to do if crops are flooded.);
- Outreach - promote implementation of the lettuce and leafy green supply chain guidance and other best practice recommendations; and
- Research - establish a coalition to identify critical, risk based research, including research to address environmental reservoirs for *E. coli* O157:H7; provide adequate support for such research to ensure it is conducted; and facilitate technology transfer of research findings.

FDA stands ready to continue to engage and assist in these endeavors. FDA will soon publish a draft guidance for the fresh-cut industry, which guidance we believe may be helpful to your industry.

We intend to meet with the California Director of Health Services and Secretary of Food and Agriculture in the near future regarding this ongoing public health problem to explore ways we can work together to prevent future outbreaks. Together with CDHS and CDFA, we also intend to meet with the lettuce and leafy greens industry in the near future to engage the industry to prevent further outbreaks.

As you are aware, food produced under insanitary conditions whereby it may be rendered injurious to health is adulterated under § 402(a)(4) of the Federal Food, Drug, and Cosmetic Act ((21 U.S.C. 342 (a)(4)). FDA is investigating regulatory options and will consider enforcement actions against firms and farms that grow, pack, or process fresh lettuce and leafy greens under such insanitary conditions.

Sincerely,

Robert E. Brackett, Ph.D.
Director
Center for Food Safety and Applied Nutrition

cc: A.G. Kawamura, Secretary, California Department of Food and Agriculture

U.S. Food Safety Strained by Imports

By JUSTIN PRITCHARD, Associated Press Writer
Monday, April 23, 2007

(04-23) 12:45 PDT LOS ANGELES, (AP) --

The same food safety net that couldn't catch poisoned pet food ingredients from China has a much bigger hole.

Billions of dollars' worth of foreign ingredients that Americans eat in everything from salad dressing to ice cream get a pass from overwhelmed inspectors, despite a rising tide of imports from countries with spotty records, according to an Associated Press analysis of federal trade and food data.

Well before contaminated shipments from China killed 16 cats and dogs and sickened thousands more, government food safety task forces worried about the potential human threat — ingredients are hard to quarantine and can go virtually everywhere in a range of brand products.

When U.S. Food and Drug Administration inspectors at ports and border checkpoints look, they find shipments that are filthy or otherwise contaminated. They rarely bother, however, in part because ingredients aren't a priority.

Because these oils, spices, flours, gums and the like haven't been blamed for killing humans, safety checks before they reach the supermarket shelf are effectively the responsibility of U.S. buyers. As the pet deaths showed, however, that system is far from secure.

Meanwhile, the ingredient trade is booming — particularly since 2001, when the Sept. 11 attacks focused attention on the security of the nation's food supply.

Over the past five years, the AP found, U.S. food makers prospecting for bargains more than doubled their business with low-cost countries such as Mexico, China and India. Those nations also have the most shipments fail the limited number of checks the FDA makes.

"You don't have to be a Ph.D. to figure out that ... if someone were to put some type of a toxic chemical into a product that's trusted, that could do a lot of damage before

it's detected," said Michael Doyle, a microbiologist who directs the University of Georgia's Center for Food Safety.

Doyle sat on several federal task forces studying threats to U.S. food security; while they discussed ingredients, he said, their findings are classified.

Read down most any food package's label and there they are: strange-sounding substances that keep soft drinks fizzy, crackers crispy and sauces from going up. Gum arabic, extracted from acacia trees, helps give light whipped cream its texture; maltodextrin is derived from starchy foods, then can be dusted on chips so spices stick; caseins, a protein from milk, help the consistency of cheese substitutes.

While Americans are consuming more imported food and drink from preserved fruit to coffee, demand among U.S. food makers for overseas ingredients is increasing even faster.

In 2001, the United States imported about \$4.4 billion worth of ingredients processed from plants or animals, AP's analysis shows. By last year that total leaped to \$7.6 billion — a 73 percent increase. Other food and drink imports rose from \$38.3 billion to \$63 billion — up 65 percent.

No single reason explains the increase. Profits are one factor; changing consumer tastes play a role, too. There's a growing expectation that seasonal products will be available year round, while immigrants may hanker for familiar flavors and others want variety.

So U.S. food makers head overseas, where labor-intensive ingredients can be cheaper to produce in low-wage countries. They're not expensive to ship, either, because they're relatively compact and don't spoil easily, said David Closs, an expert in global food supply at Michigan State University.

By its own latest accounting, the FDA only had enough inspectors to check about 1 percent of the 8.9 million imported food shipments in fiscal year 2006. Topping the list were products with past problems, such as seafood and produce.

"I don't ever remember working on ingredients," said Carl R. Nielsen, a former FDA official whose job until he left in 2005 was to make sure field inspectors were checking the right imports. "That was the lowest priority, a low priority."

On Tuesday, a House Energy and Commerce subcommittee will hold a hearing on the FDA's oversight of the food supply, with a focus on the recent cases of contaminated spinach, peanut butter and pet food. The hearing is part of a broader investigation by lawmakers into the FDA's handling of food safety.

There are other reasons ingredients aren't thoroughly examined. Unlike rotting fish or moldy vegetables, ingredient testing often requires a laboratory. Analyzing samples takes days and can irk importers who don't like the choice of holding their product or risking a costly recall if they go ahead with distribution.

To cope with limited resources, the FDA requires that overseas companies announce that a shipment is coming, notification that lets inspectors target products once they arrive.

That leaves quality control, by and large, to American buyers and their suppliers. If they don't do it, they run the risk of health problems that can devastate a brand and generate huge lawsuits.

But except in rare cases, companies don't have to prove that a shipment of ingredients is safe — no tests must show that it's pesticide-free, for example — and the FDA rarely checks whether overseas processing conditions are up to par. That contrasts with meat imports regulated by the Department of Agriculture, which must be processed under conditions equivalent to those here.

"Unless there's a known problem," Nielsen said, "it's going to fly through."

FDA records over the past year reflect that reality:

_ Inspectors refused more than 650 food or drink shipments from China; only about 20 were ingredients. Catfish, eel, shrimp and vegetable products were among the most rejected.

None of the barred shipments was either of the two tainted ingredients — wheat gluten and rice protein concentrate — that led to nationwide pet food recalls. It took the deaths of cats and dogs this spring to trigger tests that revealed an industrial chemical somehow entered the food chain.

_ While inspectors refused the most shipments from India, they didn't turn back any of the top ingredient import from there, a sticky plant extract that helps give frozen

desserts their texture. Although there were no reports of problems with those thickening agents from locust beans or guar seeds, it's unclear how many shipments were inspected and let pass. The \$118 million imported in 2006 made the category the third-largest food from India, behind shrimp/prawns and cashew nuts, and well ahead of rice.

The FDA issued two brief statements in response to interview requests, saying imported food ingredients are treated "basically the same as with any food commodity" entering the United States.

"We use a risk management approach and any regulated product, including food ingredients, IS a priority to FDA if it poses a public health risk," one statement said. "If a food ingredient were to be identified as risk to public health, we are able to quickly shift resources to handle."

Exporting countries are supposed to help. But governments such as China, where tainted food scandals are common, can have a stunning lack of oversight, said William Hubbard, a top FDA official for 14 years who now advocates for stiffer food safety regulations.

He recounted how one supplier drove a truck over tea leaves to dry them with exhaust, which leached lead into the leaves. That was an unintended consequence of a supplier taking a shortcut. Imagine, Hubbard said, what could be done by someone intent on hurting people.

By late last week, federal officials said they were investigating whether the recalled pet foods may have been intentionally spiked with the industrial chemical melamine to boost their apparent protein content.

Ingredients aren't often blamed for outbreaks of human illness.

One reason is that they may be processed enough that microbes are killed, though as the pet food case shows, chemicals can remain. Another reason is that connections can be elusive: People sickened by casein, for example, might have consumed anything from cheese to a bodybuilding shake.

Even when an ingredient is the suspected culprit, it can be hard to pinpoint.

More than 1,200 children in at least seven states were sickened in 1998 after eating school lunch burritos. Although flour tortillas were identified as the common link, public health officials never determined what was wrong with them.

"Ingredients are more likely to go under the radar screen," said Helen Jensen, an Iowa State University economics professor who studies food safety and international trade.

When they are bad, she said, they present particular problems: They're widely distributed and often used in products with a long shelf life.

When Canadian pet food maker Menu Foods recalled its products last month, they were pulled from shelves nationwide. Three weeks later, the FDA warned that contaminated food may still be circulating.

Last year's list of leading ingredient suppliers reflected the globalized food chain.

While U.S. neighbors Canada and Mexico were first and third, Malaysia was second. Forests in that Asian nation have been replaced by plantations of trees tapped for palm oil, \$250 million of which was sent here. China and India were fifth and sixth, just after New Zealand, according to the AP analysis.

The top ingredient category was the catchall "food preparations," followed by industrial-sized blocks of chocolate, cocoa butter, casein and refined palm oil. Some of the imports can be used in non-edible products; wheat gluten, for example, also is used to make biodegradable "sporks," the combination spoon-fork.

FDA officials have said none of the contaminated wheat gluten from China entered the human food chain. That's little comfort to Jeff Kerner.

Kerner read food labels, paid for all-natural ingredients and figured that would keep his Yorkshire terrier healthy. Instead, Pebbles died last month after eating tainted food.

"All of us, I think, fall into that false sense of security that 'Well, if they put it in there, it must be OK,'" he said. "I understand that it's the bottom line, but at what expense?"



AERO-ENVIRONMENTAL
CONSULTING



May 3, 2007

Mr. Charles Sweet, President
Natural Selection Foods
1721 San Juan Highway
San Juan Bautista, CA 95045

Mr. Sweet,

Aero-Environmental Consulting is an environmental consulting firm, founded in 2002. We specialize in conducting environmental assessments for microbial, asbestos, lead, and Phase I Environmental Site Assessments. Our staff members, including myself, are Registered Environmental Assessors, Certified Microbial Consultants, Certified Asbestos Consultants, and Certified Indoor Environmentalists.

You have asked us to provide clarification on whether it is acceptable to send leafy greens which your company has found test positive for *E. coli* to the landfill. While I have not had specific experience with leafy greens disposal, I do have experience with and knowledge of the disposal of other materials which have been contaminated with *E. coli* and I think the situations are analogous.

When conducting microbial investigations following a sewage loss (Category III- gray or black water), Aero-Environmental always follows industry standards set forth by the Indoor Air Quality Association (IAQA) and the American Conference of Governmental Industrial Hygienists (ACGIH). The methods used for testing for *E. coli* and *Enterococci* bacteria include a culture screen analysis using swab, bulk or water samples, a sewage assessment test to indicate the presence/absence of *E. coli/Enterococcus* species, and a quantitative bacterial culture analysis to detect, quantify, and identify bacteriological organisms.

Aero-Environmental Consulting also follows the most recognized and accepted standard for mold and bacteria remediation. This standard is called the IICRC S520 (Institute of Inspection, Cleaning and Restoration Certification). This protocol, which is also supported by the Indoor Air Quality Association, sets forth industry standards for mold and bacterial remediation, which Aero-Environmental closely follows at all times. These guidelines include proper handling and disposal of contaminated materials. The recommendations issued in this standard is to remove all of the waste materials (those contaminated with mold or bacteria) from the work area to a waste container in a manner that minimizes the possibility of cross-contamination or occupant exposure. This standard also states that "all non-regulated microbial (mold and bacteria) contaminated gypsum board and other structural materials can usually be disposed of in public landfill..." Regulated materials (those containing asbestos, lead, or other hazardous waste) must be disposed in other hazardous waste landfills. However, this category does not include bacterial contaminated materials (including *E. coli* and *Enterococcus* species).

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In any case, Mr. Sweat, I hope this information is useful to you and your company. If you have any questions please don't hesitate to contact us at (831)394-1199.

Sincerely,

[Handwritten signature]
Surge Viscaino - Owner/Director
Certified Asbestos Abatement Consultant
Registered Environmental Assessor #07624

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| Ex. # | Description | Date |
|---------------|--|-----------------------|
| 1 | Subcommittee on Oversight and Investigations Witness List | 04/24/07 |
| 2 | O&I Hearing Memo, subject: "Diminished Capacity: Can the FDA Assure the Safety and Security of Our Nation's Food Supply?" (for office use only) | 04/23/07 |
| | Spinach Related Documents | |
| 3 | SFGate.com article, subject: "Spinach Growers Warned About Product Safety Last Year." | 09/19/06 |
| 4 | Blog posting by Marler Clark, LLP; www.marlerblog.com, subject: "The 2006 Dole Spinach E.coli O157:H7 Outbreak." | 01/15/07 |
| 5 | Blog posting by Marler Clark, LLP; www.marlerblog.com, subject: "The Jungle Revisited - 100 Years Later." | 01/16/07 |
| 6 | Selected Slides by Marler Clark, LLP | |
| 7 | FDA Industry Guide, subject: "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables." | March 2007 |
| 8 | Earthbound Farm/ Natural Selection Foods food safety handout, subject: "A Four-Level Food Safety Program." | March 2007 |
| 9 | California Food Emergency Response Team Report, subject: "Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach." | 3/21/2007 |
| 10 | Center for Science in the Public Interest Press Release, subject: "New CDC Data Show Increases in E.coli, Salmonella and Vibrio." | 04/12/07 |
| 11 | Center for Science in the Public Interest handout, subject: "Behind CSPI's Outbreak Data - A Look at the Produce Outbreak Numbers." | |
| 12 | ConsumerAffairs.com article, subject: "FDA Warns of Contaminated Olives." | 4/15/2007 |
| | Peanut Butter Related Documents | |
| 13 | FDA Memorandum from Janet Gray, subject: "Follow-up for Complaint #22892." | 02/13/04 |
| 14 | Sonic Drive-In Product Recall Notice re: Peanut Butter Topping recall | 02/16/07 |
| 15 | Carvel Letter to Carvell Franchisees re: Peanut Butter recall | 02/16/07 |
| 16 | ConAgra Establishment Inspection Report - Preliminary | 02/24/05 |
| 17 | ConAgra Establishment Inspection Report-Summary | |
| 18 | ConAgra Presentation to FDA re: Peter Pan Peanut Butter recall | 03/09/07 |
| 19 | Email exchange between FDA and ConAgra re: Peanut Butter handling and disposal processes | 03/13/07 |
| 20 | ConAgra- Regulatory Agency Inspections General Manufacturing Procedure Document | 03/23/04 |
| 21 | ConAgra Letter to FDA re: Peter Pan Peanut Butter recall and microbiology analysis report | 02/27/07 |

| | | |
|-----------------------------------|--|---------------|
| 22 | ConsumerAffairs.com article, subject: "Peanut Butter Recall Extended to Products Made as Early as 2004." | 03/10/07 |
| 23 | FDA Letter to ConAgra re: Peter Pan Peanut Butter recall | 04/12/07 |
| Pet Food Related Documents | | |
| 24 | New York Times Article, subject: "Some Suspect Chemical Mix in Pet Food." | 04/12/07 |
| 25 | FDA Recall Press Release, subject: "Natural Balance Pet Foods, Inc. Issues a Voluntary Nationwide Recall on Specific Venison Dog and Cat Food Products." | 04/17/07 |
| 26 | Photograph - Wheat Gluten. Source: Menu Foods | 04/10/07 |
| Miscellaneous Documents | | |
| 27 | Center for Science and Public Interest report, subject: "Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net" | December 2006 |
| 28 | FDA Office of Legislation- Follow-up Questions from food import briefing with the House Committee on Energy and Commerce | 4/20/07 |
| 29 | FDA Office of Legislation- "Imported Food and Feed Samples Analyzed in FDA Laboratories." | 4/20/07 |
| 30 | William Marier commentary- "A Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?" | 04/24/07 |
| 31 | Washington Post article (front page), subject: "FDA Was Aware of Dangers to Food." | 04/23/07 |
| 32 | Washington Post editorial by Peter Kovacs, subject: "It's Not Just Pet Food." | 04/23/07 |

Spinach growers warned about product safety last year / State, federal officials concerned ... Page 1 of 4

SFGate.com

**Spinach growers warned about product safety last year
State, federal officials concerned by 20 reports of tainted greens**

Stacy Finz and Erin Allday, Chronicle Staff Writers
Tuesday, September 19, 2006

Just 10 months before fresh spinach started sending people to the hospital, state and federal officials warned Salinas Valley growers and packers to clean up their act after a decade of deadly E. coli bacteria breakouts.

In November 2005, the FDA sent a letter to growers, packers, processors and shippers warning them to improve produce safety.

"In view of continuing outbreaks," the agency wrote, "we encourage firms to consider modifying their operations accordingly to ensure that they are taking the appropriate measures to provide a safe product to the consumer."

The recent outbreak is the 20th time in a decade that leafy greens from Monterey County have been contaminated by the deadly O157:H7 strain of E. coli bacteria. In this instance, a number of the people infected said they had eaten packaged fresh spinach. Epidemiologists have since traced the spinach to Earthbound Farm's Natural Selection label, which according to the company is grown in the Salinas Valley and in neighboring San Benito County.

Investigators haven't been able to determine whether the source of the bacteria is in the farms or in the processing plant where the vegetable is packaged, but said they are leaning toward the fields.

"We're trying to get to the bottom of this," said Dr. Mark Horton, state public health officer for the California Department of Health Services. "But we've not been able to identify a smoking gun. A lot more has to be done."

Farmers say they are doing all they can.

"The safety of our products from the farm to the fork is our No. 1 priority," said Hank Giclas of Western Growers, a trade association that represents California farmers, packers and shippers. "We have begun an intensive process of examining everything we do to keep the bacteria from getting into our products."

The toll of people who have been infected in the recent epidemic has risen to 114 people in 21 states, including California, according to the Federal Food and Drug Administration. One of those people, a 77-year-old woman from Wisconsin, has died, and 18 people have suffered kidney failure.

Horton said he expects more cases will be reported.

Ex. 3

Spinach growers warned about product safety last year / State, federal officials concerned ... Page 2 of 4

Natural Selection has voluntarily recalled all its spinach products and River Ranch has pulled its spring mix, which contains Natural Selection's spinach. But officials warn that consumers should not eat raw spinach of any kind -- even organic. The FDA says spinach is safe to eat after cooking the vegetable at 160 degrees Fahrenheit for 15 seconds. But state health experts advise against it.

"If you have something in your refrigerator that's contaminated, you throw it out," said Dr. Kevin Reilly of the state health department.

Canned and frozen spinach are safe to eat, according to both agencies.

Inspectors from the FDA and from California health services visited farms in Monterey County on Monday evening to take samples and examine the fields for possible contamination. Investigators have been running similar tests since 1995, when the first case of E. coli was reported by people who had gotten sick after eating fresh lettuce. But the source of contamination was never found.

Attorney William Marler, who has represented a number of families infected with E. coli after eating fresh vegetables from the Salinas Valley, said he thinks it is more than likely that water is contaminating the crops.

"The common denominator in the other outbreaks was either surface water contamination, flooding or irrigation," he said.

All water sources were tested, according to experts, but nothing came back positive for the bacteria.

E. coli is spread through mammal fecal matter. Symptoms such as diarrhea, cramping and bloody stools typically occur within two to three days of exposure, but can take up to a week to manifest.

Healthy adults are more likely to recover from the bacteria, according to the FDA. Young children and the elderly are the most vulnerable.

Marler has already filed federal lawsuits against Natural Selection and Dole, which sold Natural Selection baby spinach under its own name, in Oregon, Wisconsin and Utah on behalf of victims from those states. One of his clients, Gwyn Wellborn of Salem, Ore., suffered kidney failure, requiring four blood transfusions and eight plasmapheresis exchanges, according to the suit.

Samantha Cabaluna, a spokeswoman for Natural Selection, said she wasn't aware that lawsuits had been filed. Marty Ordman of Dole said he would not discuss the claim pending litigation.

E. coli outbreaks, especially in produce, have become increasingly common in the past two or three decades. Experts in the agriculture industry said Monday they expect that trend to continue.

The country's centralized food processing system is at least partly to blame because produce from one source is distributed all over the country. If just one corner of farmland becomes

contaminated, bacteria can spread all over the United States.

"We don't see this disease in India, Africa, China. We only see it in highly technologically advanced countries, and the reason is because of this highly centralized food processing system," said Lee Riley, professor of infectious disease and epidemiology at UC Berkeley.

The FDA and state health departments need to develop more stringent regulations to control the spread of bacteria, experts generally agree. And there are precautions that growers and food processors can and should be taking -- not allowing potentially contaminated surface water to run onto farmland, for example, and aerating land that might be tainted.

But the fact remains, there's only so much a farmer can do to protect a crop.

"We're still learning about what we can do to prevent contamination in the field," said Jenny Scott, a microbiologist and vice president of food safety programs for the Food Products Association. "Animals poop in the field, we have cattle grazing in the nearby field, we have water runoff. It can be very difficult to prevent these outbreaks unless we grow everything in a greenhouse, which isn't practical."

Not only are outbreaks difficult to contain, but they're hard to investigate. In most outbreaks, government agencies are able to trace the bacteria to a specific product, but more often than not, the exact cause of the contamination is never known, said Trevor Suslow, a food safety researcher in the plant sciences department at UC Davis.

By the time researchers are able to pinpoint a source of contamination, the conditions that led to it no longer exist. On the farm, the product has been long harvested and the soil dug up and prepped for the next product. In the factory, equipment has been cleaned.

The country's major E. coli outbreaks started in the early 1980s in the meat processing industry as fast food became especially popular around the country and national regulations had trouble keeping up with diet trends, Riley said.

Through the 1980s and into the early 1990s, most E. coli outbreaks were in meat and dairy products, including a handful of highly publicized outbreaks at fast food restaurants. Now, as fresh produce has become increasingly mass-processed, more cases are showing up in fruits and vegetables.

And consumers have less control. With meat products, people can cook meat at home and kill any bacteria themselves. With produce that is supposed to be eaten raw, the only thing consumers can do is wash it -- and with E. coli, that's often not enough. The bacterium can hide in leafy green vegetables where it's difficult to wash off, and it only takes a very small number of E. coli cells -- as few as 10 -- for a person to become sick.

Spinach growers warned about product safety last year / State, federal officials concerned ... Page 4 of 4

"I don't think that the regulatory agencies are quite on top of how to approach produce yet," he said. "They're beginning to address this issue in more detail and more closely. They need to institute a more rigorous monitoring system, but it's hard. This problem is not going to go away."

<http://sfgate.com/cgi-bin/article.cgi?f=/c/a/2006/09/19/SPINACH.TMP>

This article appeared on page **A - 1** of the San Francisco Chronicle

The 2006 Dole Spinach E. coli O157:H7 Outbreak : Marler Blog:



Marler Blog

Posted at 6:31 PM on January 15, 2007 by E. coli Lawyer

The 2006 Dole Spinach E. coli O157:H7 Outbreak



On September 14, 2006 the U.S. Food and Drug Administration (FDA) released a "Warning on Serious Food borne E. coli O157:H7 Outbreak." The FDA announced that a multi-state outbreak of E. coli O157:H7 that "may be associated with the consumption of produce." The FDA stated that, "preliminary epidemiological evidence suggest that bagged fresh spinach may be a possible cause of this outbreak." As of that date, 50 cases of illness had been reported to the Centers for Disease Control and Prevention (CDC), including 8 cases of HUS and 1 death. The impacted states were noted to include Connecticut, Idaho, Indiana, Michigan, New Mexico, Oregon, Utah and Wisconsin.

In the ensuing three weeks, the FDA issued numerous press releases reporting on the expanding size and scope of the outbreak. The releases also followed the FDA as it zeroed in on its conclusion that the source of the outbreak was Dole bagged spinach.

On September 15, the FDA issues an additional press release advising, "people not eat fresh spinach or fresh spinach containing products." The FDA indicated that 94 cases of illness, including 14 cases of HUS and 1 death were now associated with the outbreak. The outbreak was identified as affecting 20 states. Concurrently, Natural Selection Foods (NSF) recalled all of its products containing spinach with "use by" dates from August 17, 2006 through October 1, 2006. The recall included Dole brand spinach.

New press releases on September 16, 17, 18, 19 updated the number of illness to 131, including 20 cases of HUS, 66 hospitalizations, and 1 death in 21 states. By this time there were two recalls, including the one initiated by NSF.

The FDA and CDC, in conjunction with local and state health agencies across the country continued its investigation of the outbreak. On September 20, the FDA reported that the New Mexico Department of Health had "linked a sample from a package of spinach with the outbreak strain of E. coli O157:H7." The package had contained spinach eaten by a New Mexico outbreak member before becoming ill. The package of spinach that tested positive was "Dole Baby Spinach, Best if Used by August 30." At the same time, the FDA indicated that it had no evidence that frozen spinach, canned spinach, or spinach in pre-made meals manufactured by food companies were affected, and announced those products safe to

ey4

eat.

The following day, September 21, the FDA confirmed that the genetic testing done on the Dole bag in New Mexico was a match to the strain of E. coli O157 that had sickened what was then a reported 157 people across the country. The list of affected states had grown to 23.

On September 22, the FDA announced that the implicated spinach had all been grown in one or more of three counties in California, Monterey, San Benito, and Santa Clara. The FDA was working with the CDC to further narrow the area of implicated spinach. The outbreak had grown to 166 illnesses in 25 states.

On September 24, the FDA announced further laboratory confirmation of the outbreak. The Utah Department of Health and the Salt Lake Valley Health Department reported that another bag of Dole baby spinach had tested positive for the outbreak strain of E. coli O157:H7. The list of victims on that date included 173 illnesses, 27 cases of HUS, 92 hospitalizations and 1 death.

On September 29, the FDA announced its preliminary conclusions regarding the outbreak. The FDA announced that:

...all spinach implicated in the current outbreak has traced back to Natural Selection Foods LLC of San Juan Bautista, California. This determination is based on epidemiological and laboratory evidence obtained by multiple states and coordinated by the [CDC].

The FDA also updated the number of illnesses, and reported on numerous new laboratory findings of the outbreak strain of E. coli O157:H7 in bags of Dole baby spinach.

Over the ensuing 10 days, the FDA continued to update the number of illnesses, as well as the growing number of Dole baby spinach bags that had tested positive for the outbreak strain of E. coli O157:H7. On October 5, the U.S. Department of Justice issued the following press release:

The US Attorney's Office for the Northern District of California announced that agents of the FBI and FDA Office of Criminal Investigations executed two search warrants today on Growers Express in Salinas, CA, and Natural Selection Foods in San Juan Batista, CA, in connection with the September 2006 outbreak of E. coli O157:H7 that the FDA has traced to spinach grown in the Salinas area...United States Attorney Kevin V. Ryan stated that "I want to reassure the public that there is no indication in this investigation that leaf spinach was deliberately or intentionally contaminated. We are investigating allegations that certain spinach growers and distributors may not have taken all necessary or appropriate steps to ensure that their spinach was safe before it was placed into interstate commerce..."

On October 12, the FDA reported that test results from the investigation of the outbreak indicated that environmental samples taken from the implicated fields on four ranches had tested positive for the outbreak strain of E. coli O157:H7. According to the FDA, the four fields were located in Monterey and San Benito counties.

The most recent tally from the FDA included 204 illnesses due to E. coli O157:H7 reported the CDC. This number included 31 cases of HUS, 102 hospitalizations, and 3 deaths. The FDA maintained its conclusion that all the implicated spinach was traced back to NSF. The FDA also reported 13 "confirmed product samples that contain the E. coli O157:H7 outbreak strain." Each of these products was bagged Dole baby spinach.



Read more about E. coli O157:H7 outbreaks at [Marler Clark](#). Read more on prior lettuce and spinach-related E. coli O157:H7 outbreaks, specifically the Dole outbreak of 2005 below:

Past Outbreaks

E. coli O157:H7 outbreaks associated with lettuce or spinach, specifically the "pre-washed" and "ready-to-eat" varieties sold under various brand and trade names, are by no means a new phenomenon. In October 2003, 13 residents of a California retirement center were sickened and 2 died after eating E. coli-contaminated "pre-washed" spinach. In September 2003, nearly 40 patrons of a California restaurant chain became ill after eating salads prepared with bagged, "pre-washed" lettuce. In July 2002, over 50 young women were stricken with E. coli at a dance camp after eating "pre-washed" lettuce, leaving several hospitalized and one with life-long kidney damage. The Center for Science in the Public Interest found that, of 225 food-poisoning outbreaks from 1990 to 1998, nearly 20 percent (55 outbreaks) were linked to fresh fruits, vegetables, or salads.

It is clear that the risks associated with E. coli O157:H7 and lettuce were well known to Dole and the industry prior to the 2005 outbreak. For some time prior to the outbreak, the FDA had been aggressively trying to get the industry to address serious deficiencies that were creating a critical risk to consumers. The response by Dole and many of its industry brethren was woefully inadequate.

In November 2005, the FDA elucidated its past efforts and present concerns in its "Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-Cut Lettuce." The letter begins:

This letter is intended to make you aware of the Food and Drug Administration's (FDA's) serious concern with the continuing outbreaks of food borne illness associated with the consumption of fresh and fresh-cut lettuce and other leafy greens.

The FDA goes on to identify 18 outbreaks of E. coli O157:H7 associated with fresh or fresh-cut lettuce, resulting in 409 illnesses and two deaths since 1995. According to the FDA, completed trace back investigations in eight of the outbreaks "the 2005 Dole outbreak included" were traced to Salinas, California. The FDA further states that the industry's role in preventing these illnesses is crucial because "these products are commonly consumed in their raw state without processing to reduce or eliminate pathogens."

The FDA efforts to lead the lettuce industry to safer practices were nothing new. In 1998, the FDA issued guidance to the industry entitled "Guide to Minimize Microbial Food Safety Hazards for Fruits and Vegetables." The guide is specifically designed to assist growers and packers in the implementation of safer manufacturing practices. On February 5, 2004, the FDA issued a letter to the lettuce and tomato industries to "make them aware of [FDA's] concerns regarding continuing outbreaks associated with these two commodities and to encourage the industries to review their practices."

The 2005 Dole outbreak prompted even more industry-admonition by the FDA: "In light of continuing

outbreaks associated with fresh and fresh-cut lettuce and other leafy greens, particularly from California, we are issuing this second letter to reiterate our concerns and to strongly encourage firms in your industry to review their current operations." This November 2005 FDA letter explicitly rejected industry excuses for not having taken prior action. Further, the FDA cited to research linking some or all of the outbreaks to sewage exposure, animal waste, and other contaminated water sources. The research further indicated that industry practices, including irrigation and field drainage methods, might have led directly to the contamination of the lettuce with *E. coli* O157:H7. As a result the FDA stated that it considers "adulterated" any ready to eat crops that have come in contact with flood waters. The FDA closed by warning industry members that food produced under unsanitary conditions is adulterated under §402 (a) (4) of the Food, Drug, and Cosmetic Act, and that enforcement actions would be considered.

The 2005 Dole Outbreak

"DOLE Classic Romaine is triple washed and ready-to-eat. As a result, it is not necessary to wash the salad prior to eating."

On September 22, 2005 the Minnesota Department of Health (MDH) Public Health Laboratory (PHL) received an *E. coli* O157:H7 isolate for confirmatory testing and Pulse Field Gel Electrophoresis (PFGE) sub typing. PFGE results were reported on September 26 and uploaded to PulseNet, a national database of PFGE patterns or "fingerprints" maintained at the federal Centers for Disease Control and Prevention (CDC). The pattern derived from digestion with the restriction endonuclease Xba I was assigned Pattern number EXHX01.0238. The isolate was soon tested with a second enzyme, Bln I, and the resulting pattern was assigned pattern number EXHA26.1040. Prior to September 19, the Bln I pattern had not been posted on PulseNet.

Isolates obtained from culture of stool submitted by two new ill patients were received at the MDH PHL on September 23, 2005 and subtyped. PFGE results showed that the two new isolates and the isolate received on September 22 were indistinguishable by two enzymes. By September 29, 2005 isolates obtained from seven more patients arrived at the MDH PHL for further analysis. Public health investigators recognized that an *E. coli* O157:H7 outbreak was underway in Minnesota.

While laboratory testing was performed, MDH epidemiologists conducted preliminary interviews with patients who were laboratory confirmed with *E. coli* O157:H7. On the morning of September 28 investigators had identified pre-packaged lettuce produced by Dole Food Company, Inc. as the likely vehicle of transmission for infection with *E. coli* O157:H7. A supplemental questionnaire focusing on the type and brand of lettuce consumed and where it was purchased, was developed and administered to case-patients previously interviewed and newly identified cases. On September 29 Minnesota Department of Agriculture (MDA) staff collected a bag of Dole lettuce at the home of a case patient and began microbiologic testing for the presence of *E. coli* O157:H7.

On September 30 the MDH issued a press release advising the public that 11 cases of *E. coli* O157:H7 had been identified in Minnesota residents who had eaten Dole lettuce purchased from at least four different stores in the Twin Cities area. See Attachment No. 2, Minnesota Department of Health News Release, September 30, 2005. Dr. Kirk Smith, an MDH food borne disease specialist, advised consumers to discard Dole pre-packaged lettuce mixes with the "Best if Used by 09/23/05" date. Persons with symptoms of *E. coli* were told to contact the MDH and their physician. Dr. Chris Braden at the Food borne and Diarrheal Disease Branch at the CDC announced that no other states were reporting outbreak-associated cases.

Meanwhile MDA microbiologists continued to process lettuce specimens obtained from households

with cases of confirmed E. coli O157:H7. On Monday, October 3 the agency reported that sample number M-05-2310, Lot Number B250215B received on September 30 had tested positive for E. coli O157:H7. The isolate obtained from the sample was sent to the MDH for PFGE analysis. The resulting pattern was indistinguishable to the pattern identified in case-patients. A second specimen, M-05-2318, lot number unavailable, would also yield positive results.

News of the positive lettuce specimen prompted the Food and Drug Administration (FDA) to issue a nationwide health alert regarding Dole pre-packaged salads on October 2. The FDA announcement reiterated warnings expressed in the MDH press release and further described the Dole products associated with illness, Classic Romaine, American Blend, and Greener Selection. Although cases had only been identified in Minnesota, the product was noted to have been distributed nationwide.

It would not be long before cases of E. coli O157:H7 in Wisconsin and Oregon would be recognized. The Wisconsin case was a 12-year-old female with E. coli O157:H7 who had a history of eating Dole pre-packaged lettuce. PFGE sub typing showed that her isolate was indistinguishable to the EXHX01.0238 pattern and one band different on the second enzyme pattern. Despite the one band difference, MDH molecular epidemiologists considered the girl to be part of the outbreak concluding that the difference was not enough to preclude the case from being considered outbreak related.

The Oregon case was indisputably associated with consumption of Dole pre-packaged salad mix. A 60-year-old Portland resident was hospitalized and laboratory confirmed with E. coli O157:H7 on September 21, 2005. The patient had experienced onset of symptoms on September 18, four days after purchasing and consuming Dole brand "Classic Romaine" salad mix. Michael Roberson, representative for Albertsons', the grocery store of purchase, confirmed that the chain's Portland area distributing center had received Dole Greener Selection and Dole Classic Romaine. A portion of the salad mix was still in the patient's refrigerator. A photograph taken of the packaging documents that Ms. Scheetz purchased Dole salad mix with a "Best if Used By" date of 9/23/05, lot number was B250215B. PFGE sub typing showed that the Oregon isolate was indistinguishable by two enzymes to other ill Dole lettuce consumers in Minnesota.

Aware of the potential severity of an E. coli O157:H7 outbreak, the FDA and the Food and Drug Branch at the California Department of Health Services initiated an investigation at the Dole processing plant. Preliminary information indicated that 22,321 cases of Dole pre-packaged lettuce with a "Best If Used By" date of 9/23/05 and a production code starting with "B250" were shipped from a single Dole processing facility in central California to 34 states in early September. Investigators estimated that since each case contained between 6 and 12 bags, approximately 244,866 bags of lettuce had made it to market.

On October 11, 2005 the MDH counted 23 laboratory confirmed cases of E. coli O157:H7 and seven epidemiologically linked cases. Illness onset dates ranged from September 16 to September 30. Two cases had developed Hemolytic Uremic Syndrome (HUS). Oregon and Wisconsin reported one case each. Case control study data show a statistically significant association between illness and consuming Dole pre-packaged lettuce with a matched odds ratio of 6.8, 95% confidence interval, 1.4-31.9, and a p-value of 0.01.

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The Jungle Revisited - 100 Years Later : Marler Blog:



Marler Blog

Posted at 6:52 PM on January 16, 2007 by Bill Marler

The Jungle Revisited - 100 Years Later



I agree with the [American Meat Institute](#)?

J. Patrick Boyle, President and Chief Executive of the American Meat Institute, wrote in part in the New York Times regarding, "100 Years Later, the Food Industry Is Still 'The Jungle,'" by Adam Cohen (Editorial Observer, Jan. 2), "Since 1999, the incidence of E. coli O157:H7 in ground beef samples tested by the Agriculture Department has declined by 80 percent to a fraction of a percent, a level once thought impossible." I agree with Mr. Boyle. In fact, according to the Centers for Disease Control and Prevention, E. coli outbreaks linked to tainted meat have declined by 42 percent.

As a lawyer specializing in food-borne illness litigation, I've seen this happen, but I'm still as busy as ever. A decade ago most of my clients had been sickened by tainted meat. In fact, between 1993 and 2002 I took over \$250 Million from the meat industry in verdicts and settlements on behalf of my clients, mostly children with kidney failure caused from consuming E. coli-tainted hamburger. Today, my business comes almost entirely from people sickened by lettuce, sprouts, tomatoes, spinach, green onions, and parsley.

To turn this mess with produce around, we need somebody like Michael Taylor, who was head of USDA's Food Safety and Inspection Service in the mid-1990s, when undercooked hamburgers from Jack in the Box sickened 650 people and killed four children. In the wake of that epidemic, Taylor stood before the American Meat Institute and announced, "We consider raw ground beef that is contaminated with E. coli O157:H7 to be adulterated within the meaning of the Federal Meat Inspection Act." Taylor was warning the industry "things were going to be different and there was going to be accountability."

Taylor and FSIS introduced mandatory Hazard Analysis Critical Control Point plans, a risk management system requiring meat processors to adopt precautions such as carcass washes, citric acid sprays, steam pasteurization, and air-exchange systems. Today, the U.S. meat industry staffs in-house microbiologists or contracts with outside labs to test for E. coli and other contaminants before meat is shipped to consumers.

To prevent future outbreaks, we need to follow FSIS' and AMI's example, and serve notice to produce processors that E. coli is an adulterant that will no longer be tolerated in our fresh produce supply. The produce industry must adopt the same precautions that meat processors adopted years ago.

Here's the reality: In recent weeks as many as 150 people across the Northeast and upper Midwest have

EXS

become ill after eating at fast food restaurants. Many of those have landed in hospitals; some attached to kidney dialysis machines. And it wasn't just fast food that made them sick – it was the lettuce.

A few months ago, 200 people got sick and at least four died from eating E. coli-contaminated spinach. A year earlier, in September 2005, over two dozen were sickened, including one young girl who suffered acute kidney failure, after eating bagged, pre-washed lettuce. Similar outbreaks occurred in 2002 and 2003.

This recent history shows us that E. coli is no longer linked exclusively to tainted meat. The Food and Drug Administration reports over 21 outbreaks related to fresh leafy produce in the last 10 years with nearly 1,000 sickened.

But, putting the burden solely on produce producers will not be the “silver bullet” to control E. coli. We need a broad approach. If I had a vote, I would demand Senate hearings to discuss not only what the produce industry can do but also the following:

- Is the production of an E. coli vaccine for cattle to reduce or eliminate one large reservoir of the nasty germ feasible?
- Is irradiation for all mass-produced foods, including produce, an option?
- Are our food safety regulations up to date given risks we face today from at home and abroad?
- Do we need mandatory State and Federal recall authority, or is industry-based, voluntary recall authority sufficient?
- Is establishing one agency at the federal level responsible for all food safety to work directly with state and local regulators and health departments to help industry prevent viral or bacterial contamination the answer?
- Would an increase in funding for state health departments and CDC help in identifying outbreaks and stopping them early?
- What is the best science available to help the victims of E. coli if they do become ill?

Having this discussion is long past due. There should be no more excuses for finding real solutions. Finding solutions will ultimately help the business bottom line, but most importantly, finding solutions will prevent innocent people from being sickened by eating what is supposed to be good for them.

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Field • Firewall • Facility • Finished Goods A Four-Level Food Safety Program

MARCH 2007



Earthbound Farm/Natural Selection Foods has reassessed our food safety program from seed to sale under the guidance of some of the most respected food safety scientists in the country. This team of experts, many of whom serve on our scientific advisory panel, is working with us to build a system which radically improves the safety of fresh produce, beginning with leafy greens and extending to all other fruits and vegetables. We will continually monitor the efficacy of these programs and improve them as necessary.



1. Seed to Harvest

- At the farm, seed, irrigation water, soil, soil amendments, and plant tissues are tested for pathogens*
- Sanitation protocols for farm equipment, packaging supplies, and transportation must meet specified GAP requirements.
- GAP efficacy will be monitored through statistical process control (trending and tracking) of test data, in-house monitoring audits, and third-party verification audits.

2. The Raw Material Firewall

- Because microbial contamination of agricultural commodities most commonly occurs at the farm level, where the environment presents challenges to total control, we have implemented a firewall to reduce the risk of contaminated raw materials entering the processing environment.
- That firewall is created by a raw product Test & Hold program, based on guidelines from the International Commission on Microbiological Specifications for Food (ICMSF). All salad greens are tested and held until results return negative for pathogens.* Only cleared product is released into production.
- The firewall approach has been used effectively by the beef industry to help prevent contaminated products from entering the market.

3. The Processing Facility

- Our buildings and processing equipment are designed to make daily cleaning and sanitation efficient and effective.
- All processes will be reviewed and validated on an ongoing basis by our consulting scientists, in-house audits, and independent third-party audits.
- The USDA's Qualified Through Verification (QTV) service validates our Hazard Analysis Critical Control Point (HACCP) program and certifies compliance throughout the year with unannounced inspections that keep us "inspection-ready" every day. Our participation in this heightened program is voluntary.
- We're guarding against foreign object contamination on every packing line with state-of-the-art optical sorting systems that offer an extremely high degree of dependability for removing any non-leafy object from the product stream.

4. The Finished Product Firewall

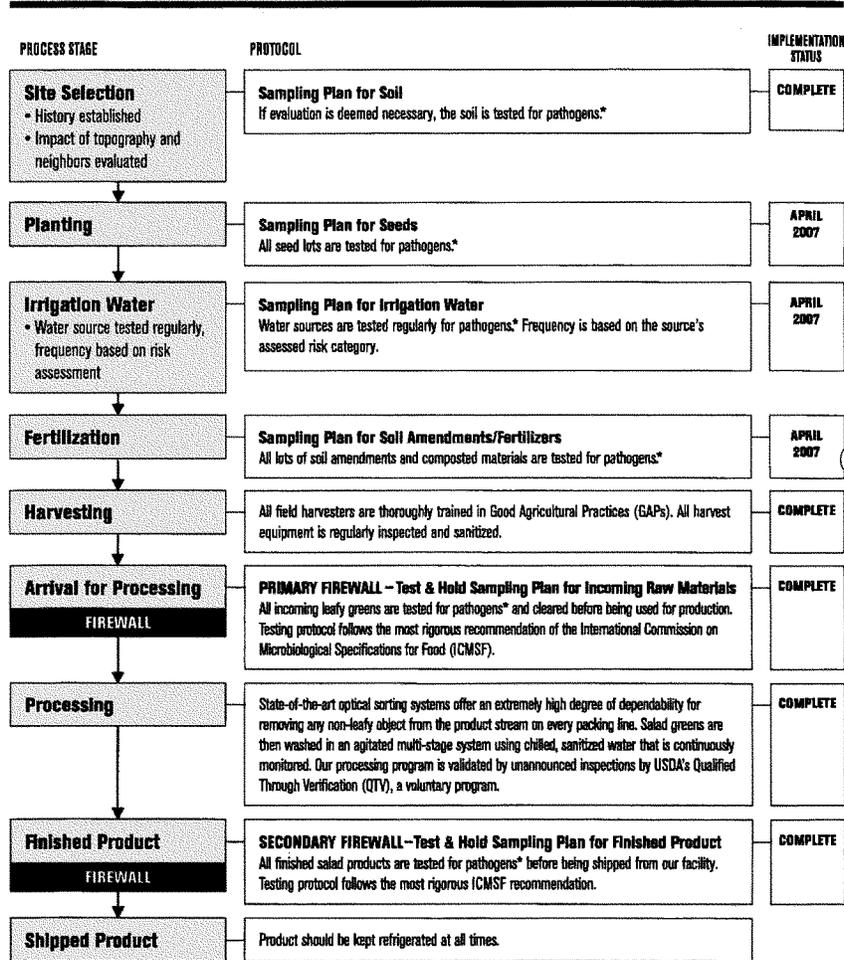
- As a final safeguard to ensure that all of our food safety interventions have been effective, we are implementing a second firewall.
- That second firewall is created by a finished product Test & Hold program, based on ICMSF guidelines. All salads are tested and held until results return negative for pathogens.* Only cleared product is released for shipping and, ultimately, use by the consumer.

*Current testing protocols include *E. coli* O157:H7, enterohaemorrhagic *E. coli*, and *salmonella*.

Ex 8

Our Food Safety Program

We are launching this program for all leafy greens and salad items. This program will be rolled out to cover all other vegetable and fruit commodities in the coming months.



*Current testing protocols include *E. coli* O157:H7, enterohaemorrhagic *E. coli*, and *salmonella*.

**Investigation of an Escherichia coli O157:H7 Outbreak
Associated with Dole Pre-Packaged Spinach**

Final

March 21, 2007

Prepared by: California Food Emergency Response Team

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Ex 9

**Investigation of an *Escherichia coli* O157:H7 Outbreak
Associated with Dole Pre-Packaged Spinach**

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Executive Summary

On September 13, 2006, the Centers for Disease Control and Prevention (CDC) alerted the U.S. Food and Drug Administration (FDA) of a multi-state *Escherichia coli* (*E. coli*) O157:H7 outbreak that appeared to be associated with consumption of bagged spinach. FDA subsequently notified the California Department of Health Services, Food and Drug Branch (CDHS) on September 13. On September 14, FDA San Francisco District Office and CDHS, working jointly as the California Food Emergency Response Team (CalFERT), initiated an investigation at Natural Selection Foods, LLC (NSF), doing business as Earthbound Farm, located in San Juan Bautista, California. NSF was one of several processors implicated early in the investigation and was ultimately the processor determined to have manufactured the contaminated spinach products. Although other investigations were undertaken by FDA districts as well as state and local health departments around the country, the scope of this report encompasses CalFERT's investigations at NSF and at potential source fields of the contaminated spinach in the central coast region of California.

CalFERT investigators examined the spinach washing, processing, and packaging process at NSF and collected finished product and environmental samples. No *E. coli* O157:H7 was identified in samples taken from the processor. No obvious sources for introduction of the pathogen were identified at the processing facility. However, a number of conditions were observed that may have provided opportunities for the spread of pathogens, if pathogens arrived on incoming spinach. Investigators conducted a traceback of spinach product codes obtained from ill consumers, to identify potential source fields of contaminated spinach. Nationwide, investigations identified thirteen bags of Dole brand Baby Spinach, manufactured by NSF, collected from ill consumer households that contained *E. coli* O157:H7 which matched the outbreak strain by pulsed field gel electrophoresis (PFGE) testing using two enzymes. Product codes were only available for eleven of these bags, all of which were Dole brand Baby Spinach bearing product codes that began with "P227A," indicating production on August 15, 2006. This code traced back to spinach harvested from four fields in Monterey and San Benito counties.

E. coli O157:H7 was found in environmental samples collected near each of the four fields that provided spinach for the P227A product code. However, *E. coli* O157:H7 isolates associated with only one of the four fields (located on the Paicines Ranch in San Benito County) had a PFGE pattern indistinguishable from the outbreak strain. The PFGE pattern was identified in river water, cattle feces, and wild pig feces on the Paicines Ranch, the closest of which was just under one mile from the spinach field. Land on the ranch was primarily utilized for cattle grazing by the large Paicines Ranch grass-fed beef operation. A relatively small amount of land on this ranch was leased for ready-to-eat crop production by Mission Organics. The ready-to-eat produce from this leased acreage was sold as conventional produce but organic growing practices were used, as the leased acreage was in the three year transition phase required for organic certification. Investigators observed evidence of wild pigs in and around the cattle pastures as well as in the row crop growing regions of the ranch. Investigators established that numerous wild pigs thrived alongside grazing cattle in the riparian habitat of the Paicines Ranch. Potential environmental risk factors for *E. coli* O157:H7 contamination identified during this investigation included the presence of wild pigs in and around spinach fields and the proximity of irrigation wells used

for ready-to-eat produce to surface waterways exposed to feces from cattle and wildlife. In the Paicines Ranch area, documented groundwater levels were higher in elevation than the San Benito riverbed on the ranch during March, 2006, fell to the riverbed level in July, 2006, and subsequently fell below the riverbed level later in the growing season. This potentially allowed surface river water from the river flowing into the Paicines Ranch valley to percolate into the ground again and recharge the groundwater basin during that period. Further assessments are needed to determine the likelihood of this occurrence. No definitive determination could be made regarding how *E. coli* O157:H7 pathogens contaminated spinach in this outbreak.

Background Information / Epidemiology

On Friday, September 8, 2006, Wisconsin state health officials identified a cluster of *E. coli* O157:H7 illnesses and submitted the PFGE patterns to CDC via PulseNet. September 12, 2006, CDC confirmed that the *E. coli* O157:H7 strains from infected patients in Wisconsin had matching PFGE patterns (Pulsenet Pattern EXHX01.0124/EXHA26.0015). By September 14, 2006, CDC had received reports from officials in eight states, reporting 50 cases of infection with *E. coli* O157:H7, with many ill individuals recalling consumption of fresh pre-packaged spinach in the week prior to symptom onset. Daily conference calls were instituted with state and federal agencies. Early in the investigation, a number of processors appeared to be implicated. As investigations into consumer illnesses progressed, it became apparent that illness was most often associated with Dole brand Baby Spinach manufactured by NSF at a facility located in San Juan Bautista, California. On September 15, following discussions with FDA and CDHS officials, NSF initiated a recall of all of the products that contained spinach in all of the brands they packed with "Best-if-used-by" (BIUB) dates of August 17 through October 1.

As of January 2007, 205 confirmed illnesses and three deaths were attributed to the outbreak. Of the 103 case patients who were hospitalized, 31 (30.1 percent) developed hemolytic-uremic syndrome (HUS). The peak occurrence of onset of illness occurred between August 30 and September 1, 2006. During the course of the investigation, 45 packages of prepackaged spinach were collected from case households in 14 states, 44 of which were analyzed for *E. coli* O157:H7. NSF manufactured 37 of the bags collected. Thirty-four of these were Dole brand, including 17 with a product code beginning "P227." Of the 44 bags of pre-packaged spinach that were tested, 13 (29.5 percent) were positive for *E. coli* O157:H7. All of the positive bags had PFGE patterns that were indistinguishable from the outbreak strain and all 13 were Dole brand Baby Spinach. Eleven of the 13 (84.6 percent) had a product code with the prefix "P227A," the other two did not have product codes (they had been cut off by the consumer) but were also Dole brand Baby Spinach. The single unopened bag collected from a case household contained baby spinach manufactured by Fresh Express. This product tested negative for *E. coli* O157:H7. For additional information on the epidemiological investigation, please contact CDC.

NSF Processing Facility

At the onset of this investigation, NSF, doing business as Earthbound Farm, operated two processing facilities in San Juan Bautista, California. The first, referred to as the "North" facility, is located at 1721 San Juan Highway, San Juan Bautista, California 95045. The second, referred to as the "South" facility, was located approximately one mile from the North

facility at 1275 San Justo Road, San Juan Bautista, California 95045. During the time period of interest, NSF was in the process of purchasing the South facility from Pride of San Juan, Inc (POSJ) and had taken over all operations at the South facility. NSF production in the South facility started April 1, 2006. Subsequent to this outbreak, NSF canceled the purchase of the South facility. California state law requires all persons engaged in the manufacture of processed foods be registered with CDHS. NSF manufactured food products at the South facility from April 1 through September 15, 2006. Records maintained by CDHS revealed that NSF did not have a valid registration during this time period. NSF management told investigators that they thought they could operate under the registration issued by CDHS to the previous operator (POSJ) while they were in the process of purchasing the facility. NSF had applied for registration with CDHS on September 12, 2006, but no inspection had been conducted. NSF withdrew the application on September 26, 2006.

As the outbreak strain of *E. coli* O157:H7 was identified in several bags of conventional Dole baby spinach product obtained from confirmed cases, the investigation narrowed to one day's production at the NSF South facility. Both North and South facilities processed a variety of prepackaged salads and spring mixes for ready-to-eat consumption, many of which either contained or were composed entirely of spinach (Exhibit 1 – Products Containing Spinach). The North facility processed organic and conventional products while the South facility processed only conventional products.

Investigators worked with William C. Daniels, Director of Quality Assurance (QA) for NSF, and Bryan S. Aguirre, Senior Vice President of Operations, to obtain the majority of NSF information in this report. At the onset of the investigation, Drew Goodman was President and Chief Executive Officer (CEO) of NSF. He held this post until early November 2006, when Charles Sweat, formerly Chief Operating Officer, became President and CEO of the company. Refer to Exhibit 2 for organizational charts of NSF, d.b.a. Earthbound Farm, as it was structured prior to November.

Operating hours at the South facility were Monday through Saturday, from approximately 8:00 a.m. through 2:00 a.m. of the following day. Two production shifts took place during this period. There was a short cleaning shift (approximately four hours) between production days and a more extensive sanitation shift each Sunday. With the exception of the receiving area, the production facility was refrigerated, with a target temperature of less than 41 °F, measured every two hours during production shifts. The Daily Room Temperature log for the month of August of 2006 was obtained by CalFERT (Exhibit 3). This log was designed to record thermometer calibration, time, and temperatures of the outside area, receiving room, preparation room, mixing room, wash room, pack room, and storage area of raw and finished product. The thermometers used to check the temperature were calibrated at the beginning of each shift in an ice water slurry. Raw and finished product storage temperatures were identified as control points on the process flow document obtained, with a target temperature of less than 41 °F. The Daily Room Temperature logs indicated an operating range between 33 – 41 °F. The Daily Room Temperature logs collected indicated that the temperature at the control points were consistently maintained below 41°F although there were occasions where temperature readings dropped below the minimum specified. On the occasions that the temperatures dropped below 33 °F, the log sheet stated that the issue was brought to a supervisor's attention.

Process Flow

NSF categorized spinach into two sizes, "baby" and "teen," although no products were marketed as "teen" spinach. There are no regulatory standards for the term "baby" and "teen" spinach. The difference between baby and teen spinach was based solely on the size of the leaf, otherwise the products were handled the same. According to Mr. Daniels, baby and teen spinach may have been used interchangeably in processing if demand made it necessary. A bag labeled, "baby spinach" manufactured at NSF, was not necessarily composed of baby spinach under the firm's specifications.

Spinach was field packed in either plastic totes (15 – 20 pounds) or bins (approximately 250 pounds). Spinach was transported from the field in refrigerated trucks except when the fields were close enough to the facility to transport the product by tractor. Product was unloaded at an outdoor loading dock, and then moved to the receiving area. The South facility receiving area was not refrigerated. In the receiving area, a sample was collected from each load and inspected as determined by Standard Operating Procedure (SOP) 106, "Raw Material Inspection and Handling" (Exhibit 4). Raw material grading was conducted based on commodity-specific specifications (see Exhibit 5 for baby spinach specifications). If the product was accepted, each pallet was affixed with a pallet tag with a unique number and the data for that bin or pallet (grade, product type, grower and grower lot number, harvest date, net weight, and expiration date). The tag affixed included a barcode but the South facility had not yet incorporated the barcode tracking technology used in the North facility. According to Mr. Daniels, if the product was rejected, the grower would have been notified and given the option to retrieve the product. If the grower did not retrieve the product, it would have been discarded.

After inspection, the product was cooled. Spinach packed in bins was received on the grounds of the North facility and held outside until it was vacuum cooled. The temperature of the product was recorded before and after cooling and recorded on the Cooling Tube Log Sheet (Exhibit 6). Once cooled, it was sent to the South facility. No water shower was used in the vacuum cooling process for spinach. Spinach packed in totes was received and cooled inside the South facility by forced air. The firm's pre-storage target temperature for cooling was less than 41 °F. After cooling, the spinach was moved to the raw material storage area where it was stored for up to 72 hours prior to reevaluation or processing. The firm used a first-in, first-out system for rotating raw product inventory. According to Mr. Daniels, the first-in, first-out system was monitored by warehouse employees whose task was to send the oldest product to production first.

As pallets of spinach were removed from raw materials storage and sent to the processing lines, each pallet number was recorded by hand on the "Daily Depletion Log" (Exhibit 8). The processing sequence at the South facility began with ■■■ mixing lines (See Exhibit 9 for the Process Flow Quality Assurance Reference, Attachment 1 for a process flow diagram). A mixing line consisted of a conveyor belt onto which salad products were dumped. For mixed salads, employees hand-dumped totes of each product onto the lines in the desired proportions for the salad mix. A mechanical bin-dumper was used to dispense the larger bins of product onto the lines. No physical mixing took place on the line, other than the act of dumping multiple products on one conveyor belt, which resulted in a mixed salad at the end of the process. To produce Dole brand baby spinach, baby spinach, alone, was dumped onto the mixing lines. Subsequently, the product moved over an inspection belt where two

employees watched for visible quality and contamination issues, particularly foreign objects among the products. Contamination observed among product at this or other points in the manufacturing process was classified by the firm into three levels of severity: green, yellow, or red (Exhibit 10). Product then traveled over a singulator, used to separate the leaves so they would not enter the wash flume in clumps.

Each mixing line fed a separate wash flume. NSF used a two stage wash composed of two wash flumes in sequence. The water in the flumes was re-circulated during the day and was drained at the end of the day, after the two processing shifts (NSF water systems diagram, Exhibit 11). The water in each flume was chlorinated (maintained between [REDACTED] parts per million (ppm) free chlorine) and pH adjusted (maintained at a pH between [REDACTED]). The chlorine level and pH were manually monitored every half hour during operation and adjusted by addition of chlorine or citric acid as needed. Chlorine and pH levels were recorded on the wash line logs (Exhibit 15). The firm used the same test kit (Hach Pocket Colorimeter II) to measure the water color in the flume as they used to measure the free chlorine content of the flume water. Mr. Daniels told investigators that NSF had determined that the water color measured by the pocket colorimeter provided a gauge that they had found to be a reliable indicator of the turbidity of the water in the flumes. The Hach Pocket Colorimeter II did not offer a turbidity standard for use with the Pocket Colorimeter II test kit. Mr. Daniels said the meter was calibrated using a chlorine standard. Mr. Daniels said they had done some validation of this method, but documentation of that validation was not received prior to the finalization of this report. The target turbidity based on the wash line monitoring log sheets was [REDACTED]. Mr. Daniels stated that the units for this number were ppm. The results recorded on the wash line monitoring log sheets were not actually turbidity, they were a measurement of water color. If the turbidity (water color as measured using a Hach Pocket Colorimeter) in the flumes approached the designated limit, it was adjusted using one of two methods. In the first method, a portion of the re-circulated water was purged, with a corresponding amount of fresh water added (along with chlorine and citric acid as needed). In the second method, all of the water in the first tank was dumped and the water from the second tank then transferred to the first tank. New water was then added to the second tank, followed by adjustment of pH and chlorine content in both tanks. According to Mr. Daniels, during a production shift NSF staff would likely use the first method because the second method created a half-hour of downtime. The target temperature for water in the second flume was 36°F, not to exceed 41°F, and was maintained by recirculating the water through refrigerated chillers. Water in the first flume was chilled prior to being added to the flume but it was not recirculated through chillers. The temperature of the first flume was maintained below 45°F (documented on the wash line monitoring log sheets) by addition of fresh chilled water or chilled water from the second flume. Investigators did not have an opportunity to test the chlorine and pH content of the flume water in the South facility as NSF stopped production in that facility early in the investigation. Sections of the wash flumes were designed to create turbulence in order to ensure separation of the leaves and to prevent a condition known as "rafting" or "lily padding" where leaves might float along on top of the flume and not get fully exposed to the wash water.

Product exited the flume over a de-watering belt and then was deposited into perforated plastic centrifuge barrels. The product was centrifuged, and then manually dumped onto a conveyor for one of the [REDACTED] packing lines. Product from a given wash line could feed multiple packing lines simultaneously, or in another case, multiple wash lines could run the same product and together feed a given packing line (Exhibit 12). Determination as to which

packing line a particular centrifuge barrel fed depended upon the raw material needs of each packing line. Once on the packing line, the product was mechanically weighed and deposited into retail bags (4 ounce to 1.5 pounds), retail clamshell packages (5 ounce to 11 ounce), or food service bags (1.5 pounds to 4 pounds). NSF did not use a modified atmosphere pack for bagged spinach. Packages were all run through metal detectors and then packed into boxes. The boxes were palletized and moved to finished product storage where they were stored at a temperature below 41 °F. Products in finished product storage were required to be shipped out within [REDACTED] hours of processing or else be evaluated and specifically allocated to West Coast customers who required shorter shipping times, according to the firm.

Processing- Procedures, Monitoring, and Controls

The NSF South facility was operating under a Hazard Analysis and Critical Control Point (HACCP) plan. According to the NSF hazard analysis document (Exhibit 13) and HACCP Plan (Exhibit 14) obtained by CalFERT, there were [REDACTED] processing critical control points (CCPs) at the South facility. The location of CCP1 was [REDACTED]. The hazard of concern was microbiological (e.g., *E. coli*, *Salmonella*, and *Listeria*) and the control measure was chlorination of the wash water with a critical limit of [REDACTED] free chlorine set for both conventional and organic product. The firm also monitored and controlled the pH (maintained between [REDACTED]), the turbidity (actually water color as measured using a Hach Pocket Colorimeter, maintained at less than [REDACTED]), and the temperature (maintained at less than 41 °F) and recorded these factors on the wash line logs (Exhibit 15). Review of the NSF wash line log sheet for the month of August 2006 showed that overall no major deviations (from limits set by NSF per parameter) were observed for pH, free chlorine levels, temperature, and turbidity (water color as measured using a Hach Pocket Colorimeter) levels in [REDACTED] flumes [REDACTED] (Attachment 2 lists deviations observed on the wash line logs). The location for CCP2 was [REDACTED], with the hazards of concern being foreign materials. Control measures were the use of functioning metal detectors, a preventive maintenance program in place, and internal audits.

Production output records were obtained from NSF for the South facility for the month of August 2006. Daily production volumes ranged from a low of [REDACTED] pounds on August 7 to a high of [REDACTED] pounds on August 24, 2006. The average daily production volume for the month of August was [REDACTED] pounds. The production volume on August 15, 2006, was [REDACTED] pounds. The weekly average for the week of August 14-19 was the highest during August at [REDACTED] pounds. The lowest average was calculated for the period between August 1 and August 5, 2006, (this average only included five days as our initial production period of interest bracket did not include July 31) and was [REDACTED] pounds.

Among the documents collected from NSF were a collection of e-mail exchanges representing short reports on production matters at the South facility. All e-mails sent during the month of August 2006 were requested, but according to Mr. Daniels, these e-mails were not sent every day. Most of the e-mails received were provided in Spanish and were translated by CDHS staff. The subjects of these e-mails were the routine problems encountered in daily production. Starting on August 13, there were a number of days where the South facility experienced personnel shortages (August 13 = nine absent; August 15 = seven absent; August 16 = five absent; August 17 = one absent, three on light duty; August 18 = one absent; August 20 = two absent). On August 17, the e-mail said that they received

help from the drivers because they did not have enough people for shift B. NSF management told investigators that the "drivers" were the forklift drivers who had been trained in Good Manufacturing Practices (GMP)'s. On August 18, the e-mail said that a new employee had started, and on August 20, the facility had six new workers. On August 22, the email noted the anticipated arrival of five temporary employees to work the B shift. There were no reports of worker shortage in the remaining e-mails. Personnel records reviewed by CalFERT investigators revealed that a number of the absences were reported as being due to personal illness or illness in the family. CalFERT investigators could not determine the nature of these illnesses.

Contamination Procedures

According to Mr. Daniels, contamination was most often observed at the inspection stations located after the mixing lines. Foreign objects observed among products at any point in the manufacturing process were documented, classified, and acted upon. Through September of 2006, observed contamination was classified into three levels of severity: green, yellow, and red. The firm's practices have since changed such that only green and red are used. SOP 112, "Contaminated Product Procedure," dated September 28, 2006, lists the new practices (Exhibit 10). Examples of green contamination would be a stick or a small non-sharp piece of wood. In Mr. Daniels' words, green contamination could not cause harm to a consumer. Red contamination refers to any foreign object observed that has potential to cause harm. This could include sharp pieces of wood, plastic, or metal, and any item resembling feces. When the classification of "yellow" contamination was in use, it referred to contamination with questionable potential to cause harm.

Mr. Daniels informed investigators that when red contamination was observed at an inspection station, the production line was halted and all product on the mixing line, wash line, and six centrifuge barrels ahead of the mixing line was discarded. The line was then cleaned and sanitized before production could resume. If a second instance of red contamination from the same lot of product were observed, then the entire lot was thrown out. If a lot caused two red contamination events, then the plant QA Manager was informed in order to authorize disposal of the lot. While the South facility was operating, Maria Ventura was in training as the QA Manager, but Greg Komar, QA Manager at the North facility, had authority in this position over both facilities. The two facility QA Managers reported to Mr. Daniels, Director of QA. (Refer to Exhibit 2 for the organizational charts). Mr. Daniels estimated that instances of red contamination classifiable as "fecal" were observed about five times per year in the North and South facilities together. He emphasized that an inspector would err on the side of caution, for example, a suspicious clump of dirt might have been classified as fecal, even if it was not a certainty. If red or green contamination was encountered anywhere throughout the process, then the NSF form QA 45, titled, "Foreign Object Investigation Form," should have been filled out. Investigators reviewed Foreign Object Investigation Forms provided by the processor for all incidents of red contamination that occurred at the South facility from their first day of production at the facility on April 1, 2006, through the final production day on September 15, 2006 (Exhibit 16). No contamination classified as "fecal" was observed in the documents provided. Of 54 incidents of red contamination documented between April 29, 2006 and September 6, 2006, 30 were plastic materials, 18 were metal (9 of which were blades or knives), 2 were feathers, 1 was glass, and 3 were not classified on the record and the item attached could not be identified on

the copy investigators received. No red contamination was reported during the P227A processing shift.

Cleaning and Sanitation

The South plant had a dedicated cleaning shift at the end of each production day. Cleaning began at approximately 2:00 a.m. and lasted about four hours. A more extensive sanitation shift took place each Sunday. The "EB-South Master Sanitation Schedule San Juan Bautista" was used to log completion of items during the weekly cleaning conducted every Sunday (Exhibit 17). Copies of this schedule were collected for the period of NSF's operation at the South facility. This document consisted of a list of rooms with subsets of areas within that room that required sanitation periodically (weekly, biweekly, monthly, or yearly). Each area was followed by a row of boxes which were filled in with the dates when the sanitation was completed.

The "EB-South Daily Master Sanitation Schedule" was used to log completion of items done during the daily sanitation shift (Exhibit 18). This schedule was obtained for the time period of July 30, 2006 through September 2, 2006. This document consisted of a schedule of sanitation activities with a checkbox for a supervisor to initial when the activity or operation had been completed. Each sheet of records showed the room type (e.g., mixing room) and location per room (e.g., Radicchio Line) where the sanitation activities took place.

Neither the daily schedule nor the master schedule were rigorous checklists that itemized every task done by the cleaning crews. These logs did not record sanitation of processing lines, conveyor belts, and food contact surfaces. While the frequency of Sanitation Standard Operating Procedures (SSOP) 001, 002, 003, 004, 011, 017, 018, 020, and 024 (corresponding to: trim line chopping tables and chutes, trim line conveyor belts, trim line "transloer," sorting shaker, trash barrels and bins, facility drains, facility eating areas, facility bathrooms, and facility hydro-vac cooling tubes) was set as daily in the SSOP, there was no specific correlation to these areas on the daily sanitation log. However, it is possible they could fall under one or more of the categories (e.g., room type and room location) outlined on the daily schedule. Discrepancies were observed between the sanitation schedules and certain SSOP's on the frequency of cleaning and sanitation for certain areas. For example, under SSOP 015, floors were required to be cleaned on a daily and a monthly schedule. However, the master sanitation schedule received by investigators listed bi-weekly for floors, monthly for assembly mezzanine floors, and quarterly for shipping cooler floors. Under SSOP 017, the drains were listed on a daily and a weekly schedule. On the master sanitation schedule, however, the frequency was bi-weekly. Mr. Daniels informed investigators that the SSOPs and sanitation schedules were not modified for the new plant; instead experienced employees from the original NSF facility (the "North Facility") were transferred to the South facility to ensure consistency of cleaning and sanitation activities between the two locations.

NSF conducted adenosine triphosphate (ATP) testing to verify sanitation (Exhibit 19). Test results were collected for the period between July 15, 2006 and August 30, 2006 (Exhibit 20). According to Mr. Daniels, ATP testing should have been conducted on a daily basis at five or more sites each day, randomly selected from the group of sampling sites used by the microbiology lab for environmental sampling (please see "Microbiological Testing" section below for details). Sites that failed the ATP test were supposed to be re-cleaned and re-

sanitized and then tested again. During the time frame for which results were obtained, the frequency of ATP testing varied from once a week to five times a week. On a given day on which testing was done, between 5 and 16 samples were collected. During the production week of August 14 -19, 2006, ATP testing was conducted on one day, Monday, August 14. The next ATP testing did not occur until August 26, 2006. The records collected showed only one occasion where a failed test was not repeated until the location passed. On August 10, 2006, a sample collected from the Mezzanine Line 3 Scale Vibrator failed but the documentation did not show that a re-test was ever done. NSF did not document the re-cleaning of the Mezzanine Line 3 Scale Vibrator so it was not possible for investigators to verify that corrective action was taken in this instance. Mr. Daniels could not determine exactly why the re-test was not conducted. He repeated that the SOP required that the area that failed would be re-cleaned and re-sanitized and then tested again, but he could not provide a record showing that this had been done.

The firm owned two tote washing machines, one located at each plant (i.e., North and South). Records for washing totes and bins at the South facility were requested by CalFERT for the month of August 2006. Documents received were for tote washing only and for the period from August 1, 2006 through August 14, 2006 (Exhibit 21). The firm stated that they were unable to locate the remaining documents. No logs were maintained for bin washing.

The tote washing log was designed to serve the North facility and included an area to designate the types of totes being washed (conventional or organic) as a water wash step was required prior to shifting from washing conventional to washing organic totes. The records obtained showed that only conventional totes were washed at the South facility and that no one filled in the verification check box on the tote washing logs.

Microbiological Testing

NSF contracted with a third party, Primus Group, Inc. (Primus), that conducted routine environmental sampling of the processing facility equipment and wash system water at the South facility on a [REDACTED] basis, as well as [REDACTED] *Listeria* (generic) tests, and [REDACTED] raw and finished product testing. SOP 011, "Third Party Microbiological Testing" provides critical limits for these tests and lists the actions to be taken when the critical limits are exceeded (Exhibit 22). Samples of the processing facility equipment were collected at a series of pre-set locations (Exhibit 23 – Sample Rotations) and were analyzed for Total Plate Count (TPC). These locations were divided into groups and the groups were rotated. Sample results were obtained for the sampling done on August 7 (n=39), 14 (n=30), 21 (n=31), 28 (n=35) and September 7 (n=25) and 11 (n=30), 2006. The majority of these samples revealed total plate counts below ten colony forming units (CFU)/50cm². The exceptions were as follows: on August 7, the L2 spinner No. 4 result was 39 CFU/50cm²; on August 21 the L4 Flume No. 2 result was 120 CFU/50cm²; on September 7 the L2 autospinner No. 9 result was 180 CFU/50cm², the L2 incline belt No. 3 result was 20 CFU/50cm², the L2 shaker before scales No. 3 result was 16 CFU/50cm², the L2 shaker before scales No. 4 was 13 CFU/50cm²; and on September 11, the L3 flume No. 2 result was 30 CFU/50cm² (Exhibit 24 - results). None of these results exceeded the critical limit listed in SOP 011. Samples were also collected from flume water and analyzed for TPC. The flume water tests were supposed to be conducted on a weekly basis but tests were only conducted on July 27, August 19, and September 14, 2006. Sample results ranged from less than one to 565 CFU/mL (Exhibit 25). Only two of the flume water samples in this date range exceed the critical limit listed in SOP

011, the first on July 27 taken from A1 tank No.1(550 CFU/mL) and the second on August 19 taken from B2, tank No. 1 (565 CFU/mL). SOP 011 required that for findings between [REDACTED] Most Probable Number (MPN), the required action was a "focus on better cleaning." Mr. Daniels explained that the units used in the SOP (MPN) were incorrect and had been transferred from a previous version when they should have been changed. No log of this action was collected. NSF conducted *Listeria* sampling on September 7, 2006. Results were reported as negative (Exhibit 26). NSF conducted microbiological analysis on raw and finished product samples on a [REDACTED]. Samples were sent to Primus for TPC analysis on July 27, 2006 (Exhibit 27). Sample results for raw spinach ranged from 4,300,000 CFU/g to 16,000,000 CFU/g. Sample results for finished product (reported as "baby spinach") ranged from 160,000 CFU/g to 5,100,000 CFU/g. The critical limit listed in SOP 011 for raw and finished product testing was [REDACTED] MPN. All sample results received exceeded these levels. As explained above, Mr. Daniels explained that the units used for this test in the SOP were incorrect. Mr. Daniels also said that the critical limit for raw and finished product testing was based on an older version of the SOP when the firm tested for total coliforms, not TPC. The required "Action if Limit is Exceeded" directed by SOP 011 for both raw and finished product was, "See improvement from Raw to Finish products."

NSF provided investigators results of environmental and raw spinach samples collected in the South facility on September 17, 19, 21, and 25, 2006, which were tested for *E. coli* O157 by JL Analytical, Inc (JL) (Exhibit 28). All results were negative.

Water – Fresh and Waste (Wash) Water

The water system for the South facility was registered with the California Department of Health Services - Office of Drinking Water as a non-transient, non-community water system. The documentation for this system was never changed from the existing POSJ name after NSF assumed control of operations at the facility. Investigators obtained the POSJ water system (No. 3500917) monthly report to the Office of Drinking Water for the months of July, August, and September 2006 (Exhibit 29). These documents included a monthly summary on the distribution system for coliform monitoring and coliform reporting. The September results included the quarterly report for disinfection residual compliance. According to the document, routine testing showed absence of coliforms and *E. coli* in the water and the firm was meeting the standards set for disinfectant residual in systems using chlorine or chloramines.

Mr. Joseph Torquato, NSF Facilities Engineer, explained that water used in the South facility was from a well, pumped into an enclosed holding tank (NSF water systems diagram, Exhibit 11). There was no meter on the South facility well or any other way to determine how much water was being drawn. Water from the South facility well was also used for POSJ farming irrigation operations. Mr. Torquato said that POSJ used three types of water for irrigation: Blue Valve water (Central Valley Project surface water used for irrigation, see Attachment 11, an addendum report relating to irrigation water issues), water from the NSF South facility well, and effluent water from the NSF south discharge water holding pond. The holding pond was filled with processing waste water. From inside the plant, waste water was deposited into trench drains and carried outside to a lift station, which pumped the water to a settling tank. From there it was pumped to the holding pond. According to Mr. Daniels, the process waste water for the NSF South facility belonged to POSJ. The "Process Waste Water" document provided to investigators by NSF included influent and effluent waste water data

from June through September of 2006 (Exhibit 30). Mr. Torquato told investigators that the figures reported on the form were provided by POSJ.

NSF operations at the South facility ceased September 15, 2006 and did not resume. CalFERT investigators observed processing equipment and collected wastewater samples there on September 21 and 22. Samples (n=13) of waste water and sediment were collected from the lift station, settling tanks, and holding pond. All samples were negative for *E. coli* O157:H7. Inside the plant, hoses used for washing equipment were observed to lack backflow prevention. All hose bibs along the outside of the building also lacked backflow prevention devices. The firm's chiller system for wash flume water was located outside the facility. The overflow pipe on one of its two tanks was open to the air and lacked a screen. A sight tube for the chiller tanks (to determine water level) had mold growing inside it. Also observed in the area were a number of chiller system flexible plastic hoses, stored uncapped with their ends touching the concrete pavement. Management stated that the facility was not processing and if it had been, the hoses would not have been stored as observed.

Product Coding and Traceability

The code used on the retail bags of Dole brand Baby Spinach was translated by NSF management for investigators. For example, in the code P227A01, (P or J), P = South processing facility, J = North processing facility; 227 = Julian date for August 15; A = shift identification (A or B); and 01 = bagging/clam shell packing machine identification (01–07). NSF also labeled retail packages with a "Best if Used By" (BIUB) date that corresponded to the production date plus the shelf life. For the Dole brand Baby Spinach, the shelf life was 15 days, so the BIUB date for the example above was August 30.

Tracing From Product Codes to Fields

Epidemiological analysis provided by CDC to FDA on September 13, 2006, implicated retail bags of baby spinach as the cause of consumer illnesses in this multi-state *E. coli* O157:H7 outbreak. Early in the investigation, a number of processors appeared to be implicated. As investigations into consumer illnesses associated with consumption of pre-packaged spinach progressed, it became apparent that illness was most often associated with Dole brand Baby Spinach manufactured by NSF. Forty-five packages of leftover spinach-containing products were collected from case-patient households in 14 states. Attachment 3 lists the product codes obtained from these packages. Thirty-seven of the packages were manufactured by NSF. Thirty-four of those were Dole brand, 17 of which had product codes beginning "P227A". Thirteen of 44 (29.5%) spinach packages tested were positive for *E. coli* O157:H7 with a PFGE pattern that matched the outbreak strain. All thirteen positive bags were Dole brand Baby Spinach and eleven of the thirteen (84.6%) bore codes beginning with "P227A". No code could be identified for the other two matching Dole brand bags, as it had been cut off by the consumer.

The inventory tracking system used by NSF allowed the firm to determine the source fields of raw products entered into production during a specific shift and day by manually linking several different documents. Beginning with a product code from a consumer bag of Dole brand Baby Spinach, for example, P227A03: NSF could identify fields that supplied baby spinach for production shift A on August 15, 2006, at the South NSF facility ("P"). It was not possible to determine just those source fields that supplied a specific bagging machine ("03"

In this example). Nor was it possible to narrow the field inputs that went into a specific varietal pack during a shift – the firm only tracked raw product input by shift.

To trace a product code, data from the firm's Daily Depletion Log was cross-referenced with the firm's receiving log (Raw Receipts Log, Exhibit 31). Depletion logs were hand written lists of pallet numbers, representing all types of raw materials utilized during a shift (baby spinach, green romaine, mizuna, etc.). For the P227A processing shift, the depletion log lists 243 pallet numbers. By matching pallet numbers from the depletion log to those in the receiving log, the type of product, source field location, identity of grower, and date received can be determined for each pallet.

NSF conducted a traceback from product code P227A to growing fields and provided the results to investigators (Exhibit 32). Four fields on the Paicines, Wickstrom, Taix, and Eade Ranches were identified as having supplied baby spinach used during the "A" shift on August 15, 2006. Investigators verified the four fields to be an accurate traceback for P227A through an analysis of processing records. An individual bag of baby spinach produced during the P227A shift might have contained spinach from one or any combination of the four fields that supplied that shift, depending on the depletion times for different lots of spinach from raw materials storage and the processing sequence.

While the P227A code was implicated by laboratory results from opened bags of product and the date range of case patient illnesses fit the expected shipping times, shelf life, and consumption of this code, baby spinach from the implicated Paicines field (Paicines lot 1) was received and processed at NSF through September 6, 2006. A relatively small amount (1002 pounds) of the spinach from Paicines lot 1, harvested on August 14, went into P227A; the remainder went into other product codes. Other types of leafy greens were also harvested from Paicines lot 1 and supplied to NSF between August 10 and September 13, 2006. (see Attachment 4 for a comparison of receipt dates of Paicines products to processing dates of product codes other than P227A obtained from case-patient households).

NSF: Receiving and Processing of P227A Baby Spinach

The fields on the Paicines, Wickstrom, Taix, and Eade Ranches were the only sources of the baby spinach utilized during shift A on August 15, 2006. There was no spinach classified as "teen" utilized during shift A, although baby and teen spinach may be used interchangeably in processing if necessary, according to Mr. Daniels. The Raw Product Receiving Log documented the receiving time and conditions for raw materials. Exhibit 33 contains the Raw Product Receiving Logs for the South facility from the month of August. Raw product from the Wickstrom Ranch was harvested in bins which were received and vacuum cooled at the North facility. Exhibit 34 contains the Raw Product Receiving Log for the baby spinach from the Wickstrom Ranch received on August 14, 2006. In tracing the baby spinach used in product code P227A back to its origin, the following information was observed. Baby spinach from the Paicines, Taix, and Eade Ranches was received in totes and forced-air cooled at the South facility. The recorded temperature range for forced air cooled product during the month of August 2006 was 37 to 42°F (Exhibit 7). Baby spinach from the Wickstrom Ranch was received in bins and vacuum-cooled at the North facility before it was transferred to the South facility. The recorded temperature range for vacuum cooled product during August was 36 to 38°F (Exhibit 6).

According to Mr. Daniels, all raw materials received at NSF were subject to certain internal quality criteria, set forth in SOP 106, titled "Raw Materials Inspection and Handling" (Exhibit 4). These criteria were listed on the "Earthbound Farm Field Grading Criteria" form (Exhibit 35) and the "Conventional Baby Spinach Raw Product Specifications" form (Exhibit 5). These grades should not be confused with official United States Department of Agriculture (USDA) grading standards which were not used by NSF. The Earthbound Farm Field Grading Criteria rated product on a scale from "A" to "D," with A being the best quality and D the worst. If the quality of the raw material exceeded the acceptable range for those defects listed on the Field Grading Criteria, the procedure directed rejection of the load. When a product was received with a C or D grade, it was reevaluated and, if possible, mixed with a product of higher quality to produce a finished product of acceptable quality. Paicines Ranch spinach was received on August 14, 2006, at 70°F, in a refrigerated truck, and was graded D for "water log" and "insect damage." Taix Ranch spinach was received on August 14, 2006 (4 different receipts), at 54 - 63°F, in flatbed trucks, and was graded B for "long stem," "dry spots," and "half leaf." Taix Ranch is located within one mile of the processor, hence the use of unrefrigerated trucks. Eade Ranch spinach was received on August 14, 2006, at 58°F, in a refrigerated truck, and was graded D for "insect damage," half leaf," and "water log." Wickstrom Ranch spinach was received on August 14, 2006 (three different receipts), at 58 - 65 °F, in flatbed trucks, and was graded B for "insect damage," "dry spots," "discoloration," and "weeds." All spinach used in product code P227A was processed within one day of receipt.

The D graded receipts from the Paicines and Eade Ranches both appeared on the firm's Raw Product Disposition Report (Exhibit 36), which documented the condition of those products considered "Out of Specification" and the action taken: "use" or "dump." The Raw Product Disposition Report was produced by NSF to provide feedback to growers of the products. Only those products received with grades of C or D appear on the disposition report, in addition to products put on "hold." Paicines and Eade spinach were marked with the action, "use." Mr. Daniels said that the receipts from Paicines graded D, for water log, indicated that the spinach had a physiological condition in which the spinach leaves retained water. This condition, characterized by a "spongy" thick leaf, would have resulted in a product that was susceptible to mechanical damage. Mr. Daniels explained that water logged spinach was commonly seen when the weather was hot and it generally affected the entire load. This condition was not one of the defects listed on the Earthbound Farm Field Grading Criteria. Mr. Daniels informed investigators that water log was not on the field grading criteria list because a water logged load would be 100 percent afflicted and would receive a "D" grade by default. He said that they could have processed water logged spinach by mixing it with a higher grade of product or by running smaller quantities of the product through the process at one time.

Of 243 pallets of raw product used in processing during shift A, 108 were pallets (approximately 36,700 pounds) of baby spinach. The other pallets were a variety of products, including but not limited to red chard, arugula, green romaine, beets (leaves), and mizuna. Attachment 5, compiled by investigators, depicts quantities of baby spinach from the Paicines, Wickstrom, Taix, and Eade fields used in shift A and shift B. Attachment 6 depicts the depletion times (and quantities) of spinach from the four fields used during shift A and shift B, broken down by field. The timeframes of depletion in the chart were obtained from the Daily Depletion Logs. Timeframes were recorded at irregular intervals. Information for product code P227B was obtained by investigators through a traceback analysis of

processing records for that shift. While baby spinach from the four identified fields was used in shift A, only baby spinach from the Paicines and Eade Ranches was used in shift B, along with "teen" spinach from additional field sources. All P227 product positive samples were for shift A and Dole Baby Spinach was not produced during shift B.

On August 15, 2006, Dole brand Baby Spinach (six ounce retail bags) was produced only on packing lines 01, 02, and 03. A review of packing records revealed that lines 01 – 03 appeared to have been dedicated to producing Dole brand products during shift A, while lines 04 – 07 produced a variety of other brands (no Dole brands) during shift A. Refer to Exhibit 37 for the "Pack Out Monitoring Form: Safety," on which the type of product and production timeframes were hand-recorded for each of the seven packing lines. Refer to Attachment 7 to see those products produced over time on packing lines 01, 02, and 03 during shift A (this chart was created by investigators through analysis of processing records). Dole brand Baby Spinach was the first item produced during shift A on the three packing lines. Production of the spinach began at about 7:00 a.m. and continued for five to seven hours on the three lines. Packing for shift A ended between 4:00 p.m. and 5:00 p.m. (the seven packing lines varied in their stop times). Packing for shift B began between 5:00 p.m. and 6:00 p.m.

In addition to six ounce retail bags of Dole brand Baby Spinach, the raw baby spinach from the four implicated fields utilized during shift A on August 15, 2006, was incorporated into a number of other P227A spinach-containing products on the seven packing lines. Spinach from Paicines, as one of the four fields, may have gone into the products. These included five ounce retail Dole Spinach with Red Leaf (on packing lines 02 and 03), five ounce retail Dole Spinach with Radicchio (03), five ounce retail Dole Spring Mix (01, 02, 03), two pound food service RAVE Spinach (04), four pound food service Pride of San Juan spinach (04), three pound food service Pride of San Juan Spring Mix (04, 05, 06, 07) and six ounce retail Emerils Spinach (07), to name a few. Exhibit 1 is a list of all spinach containing products manufactured by NSF. Attachment 8 compares the depletion data for spinach from the four fields with the production data for packing lines 01 – 03 (which were producing only Dole brand products during shift A, all of which contained spinach). Lines 04 – 07 were not implicated by the 11 packages of P227A coded spinach that had PFGE patterns matched to the outbreak strain. The bags with PFGE patterns matching the outbreak strain ended with the following packing line (bagging machine) numbers: "01" on four packages, "02" on four packages, and "03" on three packages. The bagging machine number is unknown for one package. Refer to Exhibit 38 for Packout Output Report, which quantifies each item produced during the two shifts on August 15, 2006. There were 6,960 cases (six six-ounce bags per case), amounting to 15,660 pounds of retail Dole Baby Spinach (SKU: RBSDL66) produced during shift A on August 15 and none during shift B. A small amount of six-ounce Dole Baby Spinach with bilingual packaging (SKU: RBSDLB66) manufactured for Canadian distribution was also produced during shift A: 120 cases, amounting to 270 pounds.

Shipping of Dole Brand Products

Dole brand products produced by NSF were shipped to either the Dole distribution center in Marina, California, or to the Dole distribution center in Springfield, Ohio. All Dole brand Baby Spinach with product code P227A was shipped out from NSF to Marina and Springfield between 12:00 p.m. August 15, 2006, and 5:00 a.m. August 16, 2006 (Exhibit 39). CalFERT investigators obtained records documenting the distribution of products throughout the Dole distribution system to their final destinations. P227A Baby Spinach was shipped to locations

throughout the United States and also to Ontario, Canada. Baby spinach went through one to three Dole distribution centers and possibly one or more sub-distributors before reaching the customer. Dole distribution centers that received P227A Baby Spinach from Marina or Springfield (on the second or third leg of its journey through the Dole system) included those in Yuma, Arizona; Atlanta, Georgia; New York City (Bronx), New York; and Redding, California.

CalFERT Environmental Sampling: NSF

Environmental sampling was conducted at both NSF facilities prior to the point in the investigation when the focus narrowed to the South facility. Environmental swab samples were collected from the North facility in the raw material receiving area (n=1), the vacuum cooling tubes (n=4), and the tote and bin washing area (n=2). In the South facility, nine environmental swab samples were collected from locations throughout the processing area. Eight Dole brand finished product retention samples, Baby Spinach Organics (J242A25; J242A26), Baby Spinach and Radicchio (two samples of P242A03), Baby Spinach and Radicchio (two samples of P242B03), and Baby Spinach and Red Leaf (two samples of P242B01), were also collected. The retention samples were the oldest baby spinach-containing products available, processed August 30, 2006. No *E. coli* O157:H7 was detected in any of these samples.

Harvester Investigations

Each of the four implicated fields traced from P227A was harvested by a different firm. These firms all used mechanical harvesters. The harvesting machines varied in detail by model but all could be generally described as a modified tractor with a rotating cutting blade (bandsaw) set in front, followed by a series of conveyors. All four machines observed had booms in front of the cutting blade from which either chains or ropes dangled, designed to frighten away any animals that might be in front of the machine. The front unit could be raised and lowered by the driver so that during harvesting, it could be set just above the ground, but when maneuvering at the end of beds, it could be raised. The blade was maintained between a quarter-inch and 1.5 inches above the ground for harvesting, depending on the stem length of the crop. Each machine observed also had a set of spray nozzles that was mounted above a conveyor belt. Chlorinated water was sprayed from these nozzles onto the product. According to the individuals interviewed, the purpose of the spray was primarily to prevent the product from wilting. The chlorine levels of the water spray varied by harvester and are addressed in the harvester specific sections of this report. For three of the four harvesters observed, there was a gap between the first conveyor belt and the second. The spinach was "blown" across the gap by means of upward facing fans mounted between the two belts. According to firm representatives, this air gap served to remove heavier contaminants from the product. The conveyor belts also were designed to help remove smaller debris and undersized leaves. The machines observed all had a waste chute under the belt to remove the debris that fell through the links. Three of the four harvesters field packed product into totes (15-20 lbs) for NSF; the fourth field packed into bins (approximately 250 lbs). The totes and bins were made of plastic. NSF was responsible for cleaning and sanitizing the totes and bins (see NSF "Processing Facility" section for details). NSF conducted weekly Good Agricultural Practices (GAP) harvest audits on contracted harvest crews (Exhibit 40).

Pride of San Juan, Inc. (POSJ)

375 Sixth Street, Hollister, California 95034

Contact: Steven F. Wyrick – CEO; Gary T. Shingai – Harvesting Supervisor

Implicated Field Harvested: Taix Ranch

POSJ harvests spinach and other baby leaf product using mechanical harvesting machines. The model observed was manufactured by Ramsay Highlander Inc. Mr. Shingai said that POSJ owns ■ Ramsay Highlander machines. He said that they didn't know which of the two machines was used to harvest the Taix Ranch. The harvester observed had a boom in front of the bandsaw from which chains dangled. The POSJ machine did not have an air gap between the first conveyor belt and the link belt.

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POSJ Ramsay Highlander Harvest Machine

Mr. Shingai informed investigators that the chlorinated water sprayed onto product during harvest had a target level of ■ ppm total chlorine. POSJ did not keep records monitoring the chlorine content at the time of harvest.

Mr. Shingai stated that POSJ used a "spotter" crew while harvesting spinach. The spotter crew consisted of two employees, one on each side of the bed being harvested. The spotters walked in front of the harvester with garbage bins and picked out any foreign objects observed in the spinach beds. Mr. Shingai informed investigators that POSJ does not do any manual harvesting using knives or sickles.

Mr. Shingai told investigators that the harvesters were cleaned after each day of use at the POSJ yard but would not have been cleaned in between fields harvested on the same day. He said that the machines would be pressure washed, brushed with a foaming detergent, and then rinsed. The water used to pressure wash the machine was either from a well or from the

San Benito Water District ("Blue Valve" water), and was added to a nurse tank to which chlorine was added with a target level of [REDACTED] ppm total chlorine (Exhibit 41).

Mr. Shingai informed investigators that employees wore helmets and gloves while working in the field. The gloves used were of the single-use disposable type. Employees were reportedly given a two hour GAP, sanitation, and SOP training on a yearly basis (Exhibit 42). Attendance at this training was documented on a sign-in sheet (Exhibit 43). Refresher sessions were given each week during the regular safety meeting and lasted from a half hour to one hour. These refresher sessions took place on Fridays when employees were picking up their checks. Attendance at these sessions was also documented on a sign-in sheet (Exhibit 44). Mr. Shingai said that employees would be excluded from working if they exhibited symptoms of gastro-intestinal (GI) illness as determined by the crew foreman. Mr. Shingai said that portable toilets were brought to the side of the fields for employee use during all harvests. He said that the toilets were serviced every other day. CalFERT investigators did not observe any portable toilets during this visit.

CalFERT Environmental Sampling: POSJ

On November 11, 2006, CalFERT investigators collected four environmental swab samples from various portions of one of the two harvesting machines described above. No *E. coli* O157:H7 was detected in any of these samples.

Seco Packing Company, LLC. (Seco)

510 Broadway Street, King City, California 93930

Contacts: Kevin A. Silacci – Harvesting Supervisor; Vanessa Delbosque – Human Resource and Safety Manager; Jesse Ramirez – Safety Coordinator

Implicated Field Harvested: Wickstrom Ranch

Seco was unique among the four firms visited in that their harvester machine packed into bins instead of totes (see NSF Processor Facility section for details of the distinction between bins and totes). The model observed was manufactured by Valley Fabrication (located in Salinas, California) and had tracks instead of tires. Mr. Silacci said that Seco owned [REDACTED] harvester machines used for conventional harvesting. The Wickstrom Ranch was harvested by machines numbered 01 and 14.

Photo's and figures have been redacted from this report version for users with dial-up internet connections. A version of this report which includes all photos and figures is available at: <http://www.dhs.ca.gov/fdb/HTML/Food/EnvinvRot.htm>

Bins Containing Spinach Harvested By Seco Packing Company

According to Mr. Ramirez, the spraying array on the harvester machine had a target level of [REDACTED] ppm total chlorine. On November 1, 2006, investigators observed Seco during a harvest. The most recent log entry at the time investigators were in the field was 50 ppm total chlorine. Investigators checked the spray water and detected 50 ppm total chlorine and 20 ppm free chlorine at a pH of 6.5. Seco monitored the chlorine level of this spray on a daily basis during harvesting operations (Exhibit 45).

During the harvest, two employees walked in front of the harvester on either side of the bed being harvested. These spotters picked out any foreign objects observed in the spinach beds. Mr. Silacci informed investigators that Seco did not do any manual harvesting.

Mr. Silacci told investigators that the harvesters were cleaned after each day of use. He said that Seco had a concrete slab on the Brown Ranch near the Wickstrom Ranch where equipment located in that area was cleaned. The cleaning procedure for the harvesting machines included the machine being dry cleaned, then pressure washed, brushed with "Suds N Stuff" detergent, and rinsed. The water used to pressure wash the machine was from a well and was added to a nurse tank. Chlorine was added to the nurse tank with a target level of [REDACTED] ppm total chlorine. A log was kept of the cleaning (Exhibit 46).

Employees wore hairnets, gloves, sleeve guards, and aprons while working in the field. The gloves used were re-usable. Employees were required to remove their equipment when they left the field for any reason. Prior to returning to the field, they were required to dip their gloves in a hand dip containing sanitizer. The firms last log entry for the hand dip indicated

that it contained 190 ppm total chlorine. Investigators checked the chlorine levels during their visit on November 1, 2006, and found that the concentration was greater than the strips being used could detect (200 ppm total chlorine and 120 ppm free chlorine).

According to Mr. Ramirez, employees were given GAP, sanitation, and SOP training upon hiring. This training was part of a 45 minute new hire training. An additional 1.5 hour training session was provided to supervisors and above. Mr. Ramirez said that employees were given 10 – 20 minutes of additional training each month devoted to food safety issues including Seco's illness exclusion policy (Exhibit 47). Employees were trained to stay home if sick. Mr. Silacci reported that only harvest foremen and supervisors received sick leave. Mr. Ramirez said that if employees came to work with symptoms of GI illness, they would be sent home and a log would be kept. He claimed that this had not happened in the 2006 harvest and he attributed it to the training. Portable toilets on a trailer were parked on field access road for employee usage. Mr. Silacci said that the toilets were serviced every other day. CalFERT investigators did not observe any objectionable conditions with the portable toilets present on the day of their visit.

CalFERT Environmental Sampling: Seco Harvesting

On November 11, 2006, CalFERT investigators collected six environmental swab samples from various portions of harvesting machine number 14 at the end of a harvest. No *E. coli* O157:H7 was detected in any of these samples.

Mission Organics, LLC. (Mission Organics)

1140-A Abbott Street, Salinas, California 92902

Contacts: Otto Kramm – Partner; Austreberto Lopez – Harvest Supervisor; Jaime

Ramirez – Harvest Foreman

Implicated Field Harvested: Paicines Ranch

Mission Organics uses harvester machines manufactured by Valley Fabrication. Mr. Kramm said that Mission Organics owns ■ harvester machines of various models. Mission Organics harvested into plastic totes.

According to Mr. Kramm, the spraying array on the harvester machine had a target level of ■ ppm free chlorine. The firm did not keep a log of the chlorine levels but had free chlorine test strips (Water Works Free Chlorine High strips, range 0-120 ppm). Investigators checked the spray water on October 25, 2006, and detected 40 ppm free chlorine at a pH of 6.0.

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Valley Fabrication Harvesting Machine Pictured With Empty Totes Prior to Harvesting and Packing

During the harvest two employees walked in front of the harvester on either side of the bed being harvested. These spotters picked out any foreign objects observed in the spinach beds. Mr. Kramm informed investigators that Mission Organics sometimes used sickles for manual harvesting but not on a daily basis. These sickles had a basket attached to catch the product. Mission Organics did not keep a record of sickle usage nor of the cleaning of the sickles. Mr. Kramm said that the sickles were used to harvest around a hazard or other problem in a field. He said that after use, the sickles were cleaned along with the harvester.

Mr. Kramm told investigators that the harvesters were cleaned at the yard after each day of use. They may have been used in multiple fields during a day, and if so, they would not have been cleaned between fields. The exception was if the machine moved from a conventional field to an organic field. The cleaning procedure for the harvesting machines started in the field where employees dry cleaned the machine and removed discarded product and debris. The machine was then moved to the yard area where they pressure washed the machine, then brushed it with detergent, and finally rinsed it. The water used to pressure wash the machine was from a well and was added to a 2000 gallon nurse tank. The water in the nurse tank was chlorinated. No logs were kept of the chlorine content of the water in the nurse tank but investigators checked the chlorine level and found ten ppm free chlorine.

According to Mr. Kramm, employees wore hairnets, gloves, sleeve guards, and aprons while working in the field. The gloves used were re-usable. Employees were required to remove their equipment when they left the field for any reason. Prior to returning to the field, employees were required to dip their gloves in a hand dip containing sanitizer. The firm did not keep a log of the chlorine concentration in the hand dip. Investigators checked the chlorine levels on October 25, 2006, and found that the concentration was greater than the test strips could detect (greater than 120 ppm free chlorine).

According to Mr. Kramm, the Mission Organics harvesting crew works year-round and travels to the areas where Mission Organics harvests. Mr. Kramm said that their retention rate for the baby leaf harvesting crew was close to 100 percent. Mr. Kramm said that the harvesting

employees received regular food safety updates from NSF auditors; he estimated at least monthly. Mr. Ramirez said employees were excluded from working if they displayed symptoms of GI illness but added that employees generally did not come to work if they had those types of symptoms. On October 25, 2006, when investigators observed a Mission Organics harvest, trailer mounted portable toilets were parked on the dirt road adjacent to the field for employee usage. Mr. Kramm said that the toilets were serviced twice a week. CalFERT investigators did not observe any objectionable conditions with the portable toilets present on the day of their visit.

Sebastian Harvesting, Inc. (Sebastian Harvesting)

Highway 101 North, Soledad, California 93960

Contacts: John Y. Bryce – Vice President of Operations; Carson Braga – Harvesting Manager; Laura Penner – Human Resource Manager

Implicated Field Harvested: Eade Ranch

Sebastian Harvesting uses several types of harvester machines. The model observed was manufactured by Ramsay Highlander Inc. and was the same type that would have been used to harvest the Eade Ranch. The harvester had tracks instead of tires. Mr. Bryce said that Sebastian owns [REDACTED] Ramsay Highlander machines and leased another for the 2006 harvest season. The machines were referred to by number. The machine used to harvest the implicated field was machine number two. Mr. Braga said that they harvested into totes and cardboard boxes. He said that the customer determined the type of container used and if a liner was to be used in the cardboard boxes.

According to Mr. Braga, the spraying array on the harvester machine had a target level of [REDACTED] ppm free chlorine. The most recent log entry at the time of our visit was 80 ppm free chlorine. Investigators checked the spray water and detected 40 ppm free chlorine at a pH of 7.0. Mr. Braga said that the firm did not monitor the chlorine level of this spray until after the outbreak.

During the harvest, two employees walked in front of the harvester on either side of the bed being harvested. These spotters picked out any foreign objects observed in the spinach beds. Mr. Braga informed investigators that harvest employees sometimes used sickles for manual harvesting but not on a daily basis. These sickles had a basket attached to catch the product. Sebastian Harvesting did not keep a record of sickle usage nor of the cleaning of the sickles. Mr. Braga said that after use, the sickles were cleaned along with the harvester.

Mr. Braga told investigators that the harvesters were cleaned after each day of use at the Braga Home Ranch. He said that the conventional fields they farmed were large enough that they would not switch fields in the middle of a day but that some of the organic fields were smaller and they might have moved from one organic field to another without cleaning the equipment. Mr. Braga said that after the outbreak occurred, Sebastian Harvesting created written procedures for the daily harvester wash (Exhibit 48). The cleaning procedure for the harvesting machines included the machine being dry cleaned, then pressure washed, brushed with detergent, then rinsed. The water used to pressure wash the machine was from the Braga Home Well No. 3. [REDACTED] ounces of Hesa Multi-Chlor was added to 1000 gallons of water in the nurse tank (theoretical yield = [REDACTED] ppm) with a target free chlorine level of [REDACTED]

ppm. Logs were kept of the harvester cleaning (Exhibit 49) but they did not include a test of the chlorine concentration.

According to Mr. Braga, employees wore hairnets, gloves, sleeve guards, and aprons while working in the field. The gloves used were re-usable. Employees were required to remove their equipment when they left the field for any reason. Prior to returning to the field, employees were required to dip their gloves in a hand dip containing sanitizer. The firm did not log the chlorine concentration in the hand dip prior to the outbreak. The last log entry for the hand dip on the day investigators observed a harvest (October 26, 2006) indicated that it contained 140 ppm free chlorine. Investigators checked the chlorine levels and found that the concentration was greater than the test strips could detect (greater than 120 ppm free chlorine).

According to Mr. Braga, employees were given approximately one hour of GAP, sanitation, and SOP training upon hiring and then during weekly 15 – 20 minute tailgate sessions, they were given additional food safety-related training. Mr. Braga said employees were excluded from working if they displayed symptoms of gastro-intestinal illness. On the day investigators observed a harvest, portable toilets on a trailer were parked on the dirt road that ran alongside the field for employee usage. The toilets were serviced three times per week according to the invoice from Safe Sanitation, Inc for services rendered in the month of August. (Exhibit 50). CalFERT investigators did not observe any objectionable conditions with the portable toilets present on the day of their visit.

Field Investigations

Early epidemiological information led CalFERT investigators to ten fields located on nine different ranches in California. The focus of investigations later narrowed to the four fields that supplied baby spinach for NSF product code P227A. One hundred eleven environmental samples were collected at the other six fields, all of which were negative for *E. coli* O157:H7. The remaining four fields under investigation were located on the Paicines, Wickstrom, Taix, and Eade Ranches. Extensive investigations and sampling were conducted at the four fields, which are located in Monterey and San Benito counties in California.

Independent environmental sampling was conducted in fields by IEH Laboratories and Consulting Group (IEH) for NSF and JL for Mission Ranches. IEH collected 368 samples of product, feces, and water, among other items at fields under investigation between September 22 and October 5, 2006. No *E. coli* O157:H7 was detected in these samples. JL, working as an expert consultant for Mr. Kirk Wagner, an attorney retained by Mission Ranches, attempted to duplicate samples collected by CalFERT investigators at the Wickstrom Ranch. Results of the JL tests at Wickstrom were provided to investigators; the samples were all negative for *E. coli* O157:H7. JL also conducted duplicate sampling at the Paicines Ranch. Mr. Brad Sullivan, an attorney retained by Mission Organics informed investigators that Earthbound Farms and Mission Ranches both own 42.5 percent stakes in Mission Organics. Mr. Sullivan explained that at the time investigators were collecting the field samples, Earthbound had retained JL to conduct the duplicate sampling at the Paicines Ranch. Mr. Sullivan said that he has not received a copy of those results. Investigators were unable to obtain copies of the results of the duplicate sampling.

Paicines Ranch: Lot 1

Mission Organics, LLC
 1140-A Abbott Street
 Salinas, California 93902

Paicines Ranch is located just west of Cienega Road at its intersection with Airline Highway, south of Hollister, in San Benito County. Otto Kramm, COO and Dan Soliman of Mission Organics, LLC, were interviewed during the investigation at the Paicines Ranch. The following individuals hosted investigators at the Paicines Ranch during one or more occasions, although they were not employees of Mission Organics: Kevin A. Silacci, Spinach Supervisor for Mission Ranches and John W. Eade Jr., QA Food Manager for Growers Express. Mr. Kramm stated he asked Mr. Silacci and Mr. Eade to host investigators at Paicines on a day when he was unavailable. Mission Organics, Mission Ranches, and Growers Express are separate entities; however, there is one common partner of the three firms and of NSF: Stan Pura. Mr. Kramm explained that Mission Ranches representatives were present for the investigation at Paicines because, like Mission Organics, they supplied spinach to NSF and were hosting CalFERT investigators at other fields. Growers Express had a previous business relationship with Mission Organics: the company had conducted food safety auditing for Mission Organics several years before, in a different location, for lettuce being harvested and sold to Growers Express. Mission Organics had no existing business relationship with Growers Express at the time of the investigation.

Gordon Brock, Vice President Business Development, and Lucio Premi, Research and Development, from JL were present at Paicines to replicate samples collected by investigators during field investigations. In addition, the following individuals associated with the nearby Paicines Grass-Fed Beef Ranch were interviewed: Chris Ketchum, Manager; Sallie Calhoun, Owner. Investigators made numerous visits to the Paicines Ranch, the Paicines Grass-fed Beef Ranch, and the surrounding areas for investigations between September 20 and November 29, 2006.

Mission Organics grew and harvested baby spinach on lot 1 (see Exhibit 56, the Paicines Ranch map, as well as the definition of lot in Glossary of Terms) of the Paicines Ranch. This lot was 50.9 acres in size and was one of four source fields that supplied spinach for processing into product code P227A. Lot 1 of the Paicines Ranch was subdivided into smaller portions, labeled A – U, planted with a variety of different crops (baby leaf, baby mustard, and baby spinach) on different dates (Exhibit 51). Well No. 1 is located in the center of the Paicines Ranch Lot 1 and was used as a reference point for the sub-division of the field. The sub-sections were sequentially denoted as A – I starting at the well, going south. Starting at the well and going north, the sub-sections were sequentially denoted as J – U (Attachment 9). All product grown on the Paicines Ranch was supplied solely to NSF. The baby spinach from the Paicines Ranch that supplied product code P227A was grown on segment A of lot 1. This segment was approximately 2.8 acres with a wet date of July 22, 2006, (a wet date is when seeds are first watered, usually within a couple of days of planting). It was harvested on August 14, 2006, (Lot 1 Harvest Record, Exhibit 52). The grower code for this spinach was "PA001A1".

Crops on the Paicines Ranch were grown in an organic fashion, but were sold as conventional products. Paicines Ranch was transitioning from conventional to organic, but

the land had not yet been cultivated using organic techniques for the three year period required to achieve organic certification. There were a variety of crops planted on lot 1 with staggered planting dates, all of which were harvested for NSF. Segments A, B, D, I, O, J, and U of lot 1 were planted entirely with spinach. Harvest dates ranged from August 14 to September 5, 2006. Segments C, E, H, K, N, Q, and R were planted with crops classified by the grower as baby mustard, including green chard, red chard, and mizuna. Each segment contained a combination of these crops; for example, segment E was planted with two beds of green chard, two beds of red chard, and two beds of mizuna. Harvest dates for the baby mustard ranged from August 10 to August 28, 2006. Segments F, G, L, M, P, and S were planted with crops classified by the grower as baby leaf, including lolla rosa, green oak, green romaine, red thunder, tango, and red leaf (red wood and red cloud). Harvest dates for baby leaf ranged from August 25 to September 11, 2006.

Lot 2 of Paicines Ranch, adjacent to lot 1, was planted by Mission Organics with the same assortment of crops as listed above, including spinach (Exhibits 53). Wet dates for spinach on lot 2 ranged from August 31, 2006 to September 11, 2006, but spinach was never harvested from this field, due to the onset of the outbreak. Baby mustard and baby leaf were harvested from lot 2 beginning September 9, 2006 and September 13, 2006, respectively. Harvests of these crops were halted by Mission Organics at the request of NSF following the harvest of each on September 25, 2006, due to ongoing federal and state investigations at the ranch, according to Mr. Kramm (Lot 2 Harvest Record, Exhibit 54).

Mr. Kramm explained that the acreage of crops planted on the Paicines Ranch was determined by the projected demand of the processor, NSF. Prior to planting, the processor projected the need for certain conventional products and allocated quotas of these products to Mission Organics. Mission Organics then planted the necessary acres on the Paicines Ranch to fulfill this demand. Lots 3 – 6 on the ranch were fallow during the 2006 growing season, as there was only demand enough from the processor to fill lots 1 and 2.

Spinach grown on the Paicines Ranch was irrigated with well water via sprinklers. Well test records dated July 31, 2006 showed total coliform at 2 MPN/100 ml in well number 1, an absence of total coliform in well number 2, and *E. coli* at less than 1 MPN/100 ml for both wells (Exhibit 55). Available records indicate that none of the three agricultural wells used for irrigation at Paicines Ranch were grouted. Paicines wells number 1 and number 2 are connected by plumbing and can be used to water any cultivated field on the ranch that is east of the river.

The cultivated fields on Paicines Ranch were near where the San Benito River flows through the ranch. Flow in the San Benito River in the area of Paicines Ranch was regulated by Hernandez Reservoir, which was approximately 40 miles south of the Ranch. Winter runoff was captured in the reservoir, then released in the dry season for percolation into streambeds to recharge groundwater. The Paicines area groundwater basin tended to fill up during the winter with percolation from the San Benito River (Attachment 11). As part of their routine monitoring program, the San Benito County Water District monitored groundwater levels in the area via well number 2 during 2006 (labeled by the San Benito County Water District as Observation Well for Water Level Changes number 5). Documented groundwater levels at Paicines Ranch were higher in elevation than the San Benito riverbed in March 2006. Because groundwater levels were higher than the riverbed at this time, water in the river would flow past the area rather than percolating into the ground. Over the course of the

growing season, groundwater levels tended to drop as water was pumped for irrigation. In July, the groundwater level dropped to the same level as the riverbed, and in subsequent months it fell below the riverbed level. This potentially allowed surface river water to percolate into the ground again and recharge the Paicines area groundwater basin during that period.

Heat treated, palletized chicken manure was applied to the field using a machine spreader during pre-plant on July 15, 2006. The pellets (called 8-1-1 fertilizer) were manufactured by True Organic Products, Inc., located in Helm, California. Please refer to the "Chicken Pellet Manufacturer: True Organic Products, Inc." section of this report for additional information.

CalFERT Investigators determined that Mission Organics did not contract for a third-party GAP audit on the Paicines Ranch in the time since Mission Organics took up the lease from the landowner, prior to the 2006 growing season.

The Paicines fields sit in a valley surrounded by hills. Lots 2 – 4 extend in sequence to the south of lot 1, while lot 5 sits adjacent to lot 2 on its west side. Lot 6 is separated from the rest, located southwest of lot 1, across the San Benito River at a higher elevation. Refer to Exhibit 56, a Paicines Ranch map of crop fields, obtained from Mission Organics. Grape vineyards stretch across the hills on the east side of the valley. The San Benito River runs northward through cattle grazing areas on the west side of the valley, approximately one-half mile from lot 1 at its closest point. The San Benito River is listed as being impaired by fecal coliforms and sediments/silt by the State of California, Central Coast Regional Water Quality Control Board (CCRWQCB), as designate for the U.S. Environmental Protection Agency (EPA) under provisions of the federal Clean Water Act. Cattle as well as wild animals have free access to this waterway both on the free range cattle ranch adjacent to the row crop growing region and at various points upstream. Pescadero Creek also runs through the cattle ranch, where it empties into the San Benito River. A diversion canal, used to divert water from the San Benito River into the Paicines Reservoir, runs parallel to and just east of Cienega Road on the opposite side from the crop fields. Seasonal and year-round creeks flow through the cattle pastures on the ranch. Mr. Kramm reported no flooding events during the year prior to the outbreak.

The Paicines Reservoir is located in a grazing area approximately one mile north of lot 1, at a higher elevation. The reservoir is owned by the San Benito Water District and is used to augment groundwater recharge during the dry season. Cattle drink from the reservoir, and according to Mr. Kramm, it was not used for irrigation. A smaller reservoir is located approximately one mile south of the field and adjacent to the San Benito River (slough area). According to Mr. Kramm, this water was not used for irrigation either; the reservoir functions to collect irrigation runoff from the fields, which is then piped into the San Benito River.

There were no composting or waste management facilities observed on or near the Paicines Ranch. Worker housing is located approximately 100 feet uphill and west of lot 1. Another worker housing area is about 50 feet to the east of Cienega Road. Both of the housing areas were on septic systems. No leakage of the septic systems was observed at the time of the investigation.

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San Benito River on the Paicines Ranch: Cattle Crossing

Approximately 2,000 head of cattle graze on the rangeland of the Paicines Ranch, the majority of which is west of lot 1. The rangeland covers 8,000 acres and consists of grassy pastures on the hills, along with patches of dense vegetation surrounding the San Benito River. Cattle and wildlife have access to the river at multiple points on the ranch. The cattle grazing areas closest to lot 1 include one directly across the paved road leading to the ranch office, just north of lot 1, and a second about 700 feet west of the field, on the other side of a hill below worker housing. No cattle have been present in the pasture just north of lot 1 since July 21, 2006. Cattle were observed grazing in the irrigated pasture 700 feet west of the field during investigations. Goats, sheep, and a young calf were brought into pens September 27, 2006, (new fencing was installed) across Cienega Road from lot 1. Livestock trucks do not travel on the dirt roads between lots, but they travel out of the ranch via the paved road from the ranch office that passes just north of lot 1. Dogs were seen in kennels near the worker houses. Investigators observed diverse wildlife in the cattle grazing areas on the ranch. Wild pig sightings and signs (tracks, fecal material, and rooting) were most commonly observed, followed by ground squirrels, deer, cottontail rabbits, coyotes, and raccoons. Small birds and raptors (owls, hawks, and eagles) were also frequently observed. Refer to Attachment 12, and addendum report from USDA Wildlife Services, which contains a detailed account of wildlife issues observed on the Paicines Ranch.

All cattle pastures on the ranch were enclosed by fences. Crop fields were partially surrounded by fences, along borders where they abutted cattle pasture or wildlife habitat. Field (mesh wire) fencing with barbed wire at the top and bottom extended along the western

border of the crop fields as a whole, separating them from the areas of dense vegetation where cows grazed along the San Benito River. Lot 1 was open to the paved road on its northern border, but the grazing area on the other side of the road had a barbed wire fence. The eastern and southern borders of the crop fields (lots 1 – 5) had no fencing. The vineyards to the east of the fields had no fencing around them. Many areas of the ranch had new fencing, but investigators observed that in some areas wildlife had penetrated the fences through holes created by washes from irrigation runoff or by digging under the fence (wild pigs, in particular).

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Field Fencing with Barbed Wire on Paicines Ranch

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Hole Under Field Fencing on Paicines Ranch, Apparently Repaired With Posts in the Ground

The grower reported animal sightings limited to small birds in the field while the spinach was growing in lot 1. During the investigation, there were no food crops growing in lot 1. The field had been tilled. No animal tracks were observed by investigators in the hardened dirt of the field; however wildlife tracks (primarily pig, but also some deer, raccoon, coyote, rodent, rabbit, and bird) were observed in the immediate vicinity of other crop fields on the ranch during visits in September and October. Fresh wild pig tracks were observed in recently prepared row crop beds south and west of lot 1. Wild pig tracks were also observed on the dirt road next to Paicines Ranch lot 5, where it bordered lot 3. The tracks went from the road into lot 5, which had vegetation (not crops) growing in it at the time. Wild pig fecal material and rooting were observed in a field belonging to a different grower, located approximately 1.7 miles south of lot 1, while decaying spinach plants were still present in the field. Coyote feces were seen on the dirt road between the crop fields and the river, near the small irrigation collection pond. Growers from both vineyards (southeast and northeast of the field) reported damage to their vineyards caused by pigs during thinning and harvesting in late summer and fall. Wild pig tracks observed on the roads and through prepared beds in lot 1 during visits in September indicated that the wild pigs could be crossing from the riparian areas to the vineyards on the far side of lot 1.

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Pig Tracks on Dirt Road, Heading Into Mission Organics Lot 5, Paicines Ranch

CalFERT Environmental Sampling: Paicines Ranch

Investigators collected 351 environmental samples in and around the Paicines Ranch, including cattle feces, wild pig feces, other animal feces, soil, and water. Of these, 45 (13 percent) samples were found positive for *E. coli* O157:H7 and 26 of these 45 (58 percent) matched the outbreak strain as determined by PFGE analysis (Attachment 10). Positive *E. coli* O157:H7 sample locations are mapped in Figure 1. Locations of positive samples that were PFGE matched to the outbreak strain are mapped in Figure 2.

Investigators sampled the San Benito River downstream of the Paicines Ranch and at a number of points upstream in the 40 mile stretch between the ranch and the Hernandez Reservoir. The reservoir was also sampled. Two samples of river water taken approximately 25 miles upstream were positive for *E. coli* O157:H7, but did not match the outbreak strain. The samples were taken in an area where grazing cattle and wildlife had access to the river, both above and below the sampling point. All other water samples from the San Benito River taken downstream and upstream of Paicines were negative for *E. coli* O157:H7. The CDC addendum report, "Irrigation Water Issues Potentially Related to 2006 *E. coli* O157:H7 in Spinach Outbreak," explores regional water issues in depth (Attachment 11).

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Figure 1: Paicines Ranch Positive *E. coli* O157:H7 Sample Locations

Investigation of an *Escherichia coli* O157:H7
Outbreak Associated with Dole Pre-Packaged Spinach
Final: 3.21.07

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Figure 2: Palcines Ranch Positive *E. coli* O157:H7 Samples PFGE Matched to the Outbreak Strain

Investigation of an *Escherichia coli* O157:H7
Outbreak Associated with Dole Pre-Packaged Spinach
Final: 3.21.07

Chicken Pellet Manufacturer: True Organic Products, Inc. (TOP)

20225 West Kamm Ave
Helm, California 93627

The following individual was interviewed during the investigation at TOP: Jake Evans, Owner. On February 20, 2007 a CalFERT investigator met with Mr. Evans at his facility in Helm, California.

Mission Organics purchased [REDACTED] tons of 8-1-1 chicken pellets in bulk bags (approximately one ton each) from TOP (Exhibit 57). Mission Organics was responsible for the spreading of the pellets on Paicines Ranch. The 8-1-1 chicken pellet blend spread on Paicines Ranch on July 15, 2006, was produced from feather meal and chicken manure that were both supplied by Foster Farm chicken ranches in the San Joaquin area. On July 6 – 7, 2006, the chicken pellets were shipped to the Paicines Ranch via a common carrier. Chicken manure was the only animal manure composted or stored at the 35 acre facility. Lot numbers were not assigned to finished products or shipments. Mr. Evans stated that he is able to track raw ingredients to shipment by date of incoming raw ingredients. Mr. Evans stated that he can trace shipment of finished product to raw ingredients using the shipping date. This is possible because there are usually only two shipments per year of raw manure.

Mr. Evans stated that his company did not have an organic composting certification, but did follow the composting requirements for the National Organic Program (NOP). Mr. Evans supplied composting temperature logs for chicken manure composted in January 2006 and incorporated into the 8-1-1 pellets sold to Mission Organics in July 2006 (Exhibit 58). An October 12, 2006, lab analysis showed a [REDACTED] carbon to nitrogen ratio (C:N) (Exhibit 59). The NOP standards for C:N ratio is between 25:1 and 40:1. True Organics composting operations were not monitored by an outside agency.

The chicken manure was composted on site by TOP. Chicken manure was the only animal manure composted or stored at the 35 acre facility. The composted chicken manure (containing chicken litter) and feather meal were combined in a mixer. This mixture was then pelletized and dried to produce the final product. The pelletizer heated the mixture to 180-200 °F. The pellets were carried on a conveyor belt, transferred onto the dryer belt, and then entered the multi-level dryer chamber. Gas burners heated air which blew on the pellets for approximately 30 minutes. On February 20, 2007, the air temperature of the dryer chamber was [REDACTED]. Mr. Evans stated that the target temperature was [REDACTED]. Before being dumped into an outside concrete bunker, the pellets moved over a screen to remove partial pellets. Mr. Evans stated that the [REDACTED] heat process was the critical control point for a pathogen kill step. Finished product was sold in either bulk bags (bags weighed approximately 2,000 pounds) or in bulk trailers. Shipping was either arranged by the grower or TOP. TOP did not do any spreading or hauling of finished products.

One loader was designated for finished product only and was not used for raw ingredients, according to Mr. Evans. This loader was pressure washed with hot water each day. After washing, the loader bucket and arms were sprayed with 100 percent household bleach. The tires of the finished-product loader did not enter the bunker when removing product for shipment. Once a month the raw ingredient loaders were washed and sanitized as described above.

Prior to August 2006, Mr. Evans collected one sample a month from the finished product conveyor belt for microbial testing. Only one type of product was sampled during this time. The products were tested for *E. coli* and *Salmonella*. Test results for April, May, and June 2006 were < 3MPN for *E. coli* and negative for *Salmonella* (Exhibit 60). Beginning August 9, 2006, TOP began testing finished products for *E. coli* O157:H7 and testing more than one product per month. August 9, 2006, and August 28, 2006, tests for 8-1-1 finished products were negative for both *E. coli* O157:H7 and *Salmonella* and < 3 MPN for *E. coli* (Exhibit 61). A few handfuls of finished product were composited for each sample tested. The 8-1-1 blend used on the Paicines Ranch in July 2006 was not tested. TOP SOPs requires retesting of lots with positive pathogen sample results (Exhibit 62). During the audit of the firm's records, there were no positive pathogen test results observed by CalFERT investigators.

Wickstrom Ranch: Lot 817

Mission Ranches Company, LLC
100 Broadway Street
King City, California 93930

Wickstrom Ranch is located at the intersection of Carpentaria Road and Quarry Road, in the city of Aromas, California in San Benito County. The following individuals were interviewed during the investigation at Wickstrom Ranch: Kevin Silacci, Spinach Supervisor, Mission Ranches Company, LLC (Mission Ranches) and Seco Packing Company, LLC (harvesting arm of Mission Ranches); John Hitchcock, Ranch Supervisor, Watsonville, Mission Ranches (growing arm); John W. Eade Jr., QA and Food Manager, Growers Express (separate entity providing food safety training and audits); and Stan Pura, Partner, Mission Ranches and Growers Express. Gordon Brock, Vice President Business Development, and Lucio Premi, Research and Development, from JL were present at Wickstrom to replicate samples collected by investigators during field investigations. Investigators made five visits to the Wickstrom Ranch area for investigations between September 19 and October 3, 2006.

Spinach from lot 817 of Wickstrom Ranch was grown by Mission Ranches and harvested by Seco. Lot 817 was one of four source fields that supplied spinach used at NSF in product code P227A. Lot 817 is 7.5 acres in size, subdivided into A and B. The baby spinach supplied to P227A was grown on section A, with a wet date of July 24, 2006, harvested August 14, 2006, grower code [REDACTED] (Exhibit 63). According to grower records, this was the only crop of spinach harvested from lot 817 during the 2006 growing season. Seco also supplied baby spinach from [REDACTED] to another processor, Taylor Farms.

While on the field, the spinach was irrigated via sprinklers with well water from Brown Ranch, located about 1.5 miles from the field. Investigators observed that the casing on the well was damaged. Brown Ranch well tests (Exhibit 64), dated September 18, 2006, showed an absence of *E. coli* (*E. coli* < 1 MPN/100 ml). The grower did not regularly take environmental or product samples. Chemical fertilizer was used on the Wickstrom 817. According to Mr. Hitchcock, no manure or compost was used. The grower reported that there were no flooding events during the year prior to the outbreak.

An audit of the ranch, conducted by Primus in June 2006, gave the ranch a passing score (Exhibit 65). A review of the audit by CalFERT investigators revealed no significant findings.

Bordering the south side of Wickstrom Ranch is a railroad track built on a berm, which separates the ranch from Quarry Road. About 150 feet west of lot 817 is the Pajaro River, lined with foliage and tall trees. The bed of the Pajaro River was significantly lower (15 – 20 feet) than the field. Lot 817 is bordered to the northeast and southwest by additional growing areas on the Wickstrom Ranch. A dirt road separates lot 817 from the adjacent lot (816) to the southwest (Exhibit 66). At the time of the investigation, about half of a romaine crop was left unharvested in lot 816 due to quality problems, according to the grower. Some of the romaine appeared stunted or damaged with broken leaves. Immediately to the east of lot 817 are several buildings, including trailers and a tile factory, that are on septic systems. Investigation of these systems was not pursued after *E. coli* O157:H7 with matching PFGE patterns to the outbreak strain was found in samples from the Paicines Ranch based on an assessment of the probability of finding *E. coli* O157:H7 in low-usage human septic systems. There was evidence that the road between lots 817 and 816 was used by the public to gain access to the Pajaro River. Motorized vehicle tracks were seen at the river and an area with toilet paper was observed near a trail along the river. Investigators observed workers with shovels and bags cleaning in this area during one of the ranch visits. There was also evidence of apparent homeless camps along the river below the field. Two strawberry greenhouses were located approximately 400 feet north and at a higher elevation from lot 817. A pile of horse manure/shavings compost was observed near these greenhouses. It appeared to be trucked into the location and not formally "composted."

There was no crop in lot 817 at the time of the investigational visits. No fencing was present around lot 817. The grower reported animal sightings limited to small birds in and around the field. Investigators observed canine tracks, rodent burrows, and a jack rabbit adjacent to the field. Several cattle were seen grazing on a hill in a fenced pasture about 50 feet from the field on the opposite side of Quarry Road. A drainage pipe was identified under the railroad berm, which could potentially lead from the pasture to lot 817. On the other side of the Pajaro River, about one-third mile west of lot 817, were several trailer homes with dogs chained in the yard. There were also several houses in this area, one of which had an attached animal corral with goats inside.

CalFERT Environmental Sampling: Wickstrom Ranch

CalFERT investigators collected 44 environmental and product in and around Wickstrom Ranch, including water, Moore swabs (Pajaro River), soil/sediment, and romaine lettuce from an adjacent field. One (2 percent) Moore swab sample was positive for *E. coli* O157:H7. However, the PFGE pattern of the isolate did not match the outbreak strain (Attachment 10). The positive sample location is mapped in Figure 3.

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Figure 3: Wickstrom Ranch Positive *E. coli* O157:H7 Sample Location

Investigation of an *Escherichia coli* O157:H7
Outbreak Associated with Dole Pre-Packaged Spinach
Final: 3.21.07

Taix Ranch: Lot 1TA1
 POSJ
 375 Sixth Street
 Hollister, California 95034

Taix Ranch is located on San Justo Road near Prescott Road, in the city of San Juan Bautista, California, in San Benito County. The following individuals were interviewed during the investigation at the Taix Ranch:

Stephen F. Wyrick, CEO, POSJ. (grower and harvester); Gary T. Shingai, Harvest Manager, POSJ; and Colleen Little, Safety Director, POSJ. Investigators made six visits to the Taix Ranch area for investigations between September 20 and October 4, 2006.

Spinach from lot 1TA1 of the Taix Ranch was grown and harvested by POSJ. Lot 1TA1 was one of four source fields that supplied baby spinach used by NSF for processing into product code P227A. The Taix Ranch lot 1TA1 is 27 acres in size. Baby spinach from the Taix Ranch that supplied product code P227A had a wet date of July 18, 2006, and was harvested on August 14, 2006, along with associated grower lot code [REDACTED] (Exhibit 67). The first spinach from 1TA1 supplied to NSF during the 2006 growing season was harvested August 11, 2006, (sent to the processor that day). The last harvest of spinach sent to NSF from 1TA1 for the season was the harvest on August 14, 2006. POSJ did not supply spinach from this harvest to any other processors.

Spinach grown on the Taix Ranch lot 1TA1 was irrigated with well and Blue Valve water via sprinklers. Colleen Little, POSJ's food safety manager, said a Primus GAP audit had been conducted of Taix Ranch on August 1, 2006 (Exhibit 68). Well test records, dated September 18, 2006, showed an absence of coliform and *E. coli* (Exhibit 29). Tests conducted by Primus of the spring mix in the field on September 21, 2006, were negative for *E. coli* O157:H7 (Exhibit 69). Chemical fertilizer was used. The grower reported that there were no flooding events during the year prior to the outbreak.

Taix Ranch is bordered by San Justo Road on the northeast side with farmland on the opposite side of that road (Exhibit 70). The ranches sit on farmland between the two NSF processing facilities. Taix Ranch is adjacent to the South facility. A reservoir sits just north of a neighboring ranch next to San Justo Road, within a quarter mile of Taix. San Juan Canyon Creek (also referred to by growers as the "canal"), which collects spent NSF processing water and drainage from the nearby hills, runs along the southwest side of Taix Ranch. The San Benito River flows past the Taix Ranch, approximately one-half mile northeast of lot 1TA1. Neighboring crop fields separate 1TA1 from the foliage surrounding the riverbed area. Steer/bull pens are located at Nyland Ranch, 130 San Juan Highway, San Juan Bautista, approximately one-half mile south of Taix Ranch. No composting or waste management facilities were observed near the ranch.

Baby greens (a generic term that includes such items as immature green and red lettuces, mustard greens, and kale) were observed growing in Field 1TA1 during investigations. These were voluntarily destroyed by the grower prior to harvest. No fencing existed around the field. Animal presence in and around the fields was limited to birds and squirrels, according to the grower. Investigators observed blackbirds and swallows in the fields.

Grazing cows were seen on the hills to the south, approximately one-half to one mile away on Nyland Ranch. San Juan Highway and San Juan Canyon Creek (Canal) separate Taix Ranch from the hills.

CalFERT Environmental Sampling: Taix Ranch

CalFERT investigators collected 133 environmental and product samples in and around Taix Ranch, including baby greens, cattle and bird feces, soil/sediment, Moore swabs, drag swabs, and water. Of these, four samples (3 percent) of soil adjacent to cattle feces at the Nyland Ranch were found positive for *E. coli* O157:H7. However, the PFGE patterns of the isolates did not match the outbreak strain (Attachment 10). Positive sample locations are mapped in Figure 4. Investigators sampled the San Justo and San Luis Reservoirs in San Benito County, which feed the Blue Valve water supply system. Samples were negative for *E. coli* O157:H7 at the time of investigation (Attachment 10). The addendum report, "Irrigation Water Issues Potentially Related to 2006 *E. coli* O157:H7 in Spinach Outbreak," elaborates on the reservoirs and the Blue Valve system (Attachment 11).

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Figure 4: Taix Ranch Positive E. coli O157:H7 Sample Locations

Investigation of an *Escherichia coli* O157:H7
Outbreak Associated with Dole Pre-Packaged Spinach
Final: 3.21.07

Eade Ranch: Lot 6

Braga Ranch, General Partnership
33750 Moranda Road
Soledad, California 93960

Eade Ranch is located south of San Lucas, California, approximately five miles east of Highway 101 on Cattlemen Road, near the intersection of Cattlemen and Pine Valley Roads in Monterey County. The following individuals were interviewed during the investigation at Eade Ranch: John Y. Bryce, Vice President of Operations, Braga Ranch (grower); Rod Braga, Managing Partner, Braga Ranch; Burt Silva, Ranch Manager, Braga Ranch; Carson Braga, Harvesting Manager, Sebastian Harvesting; Laura Pendera, Human Resources Manager, Braga Ranch and Sebastian Harvesting (worker training, health); Raul Garnica, Director of Harvest, Earthbound Farm; Christopher Glynn, Supply Management Senior Manager, Earthbound Farm. Investigators made five visits to the Eade Ranch area for investigations from September 21 through October 4, 2006.

Spinach from lot 6 of the Eade Ranch was grown by the company, Braga Ranch, GP and harvested by Sebastian Harvesting, a related company to Braga Ranch. The Eade Ranch Lot 6 was one of the four source fields that supplied baby spinach used by NSF for processing into product code P227A. Lot 6 is 42.1 acres in its entirety and is subdivided into sections A through E, all of which were planted with spinach. The baby spinach supplied to P227A was grown on section C which was eight acres with a wet date of July 21, 2006 and was harvested on August 14, 2006 (Exhibit 71). The first spinach supplied to NSF from lot 6 during the 2006 growing season was harvested on May 30, 2006. Lot 6 supplied spinach to NSF throughout June of 2006. Additional spinach was planted and the next harvest supplied to NSF occurred on July 31, 2006. The last harvest supplied to the processor from lot 6 for the season occurred on August 14, 2006. Sebastian Harvesting also supplied half of the spinach from the Eade 6 section C harvest to another processor, Ready Pac of Irwindale, California. Spinach was irrigated via sprinklers with well water from Eade well number 2. Investigators observed that well number 2 was not grouted and lacked good drainage and a concrete slab. Test records for well number 1, dated April 20, 2006, showed an absence of *E. coli* (*E. coli* <1 MPN/100 ml), with total coliform = 1 MPN/100 ml (Exhibit 72). No results were provided for well number 2 on this date. Following the outbreak, tests dated September 20, 2006 report well number 2 negative (<1 MPN/100 ml) for both total coliform and *E. coli* (Exhibit 73). No environmental or product sampling was conducted, according to the farm manager.

Chemical fertilizer was used on the Eade lot 6. No manure/compost was used. The grower reported that there were no flooding events during the year prior to the outbreak. NSF did not provide oversight during the growing process, but inspected the field three to five days prior to harvest.

An audit of the ranch, conducted by Primus in April 2006, gave the ranch a passing score (Exhibit 74). That audit reported that the ranch used composted animal manure fertilizer. According to Mr. Bryce, Braga Ranch has not used compost on the Eade Ranch in the past ten years. Mr. Bryce said that the Primus auditor made a mistake on the audit and he is working with them to correct that mistake.

Adjacent fields to lot 6 (lots 5 and 7) were planted with onions (Exhibit 75). To the east, at a higher elevation, was a field of bell peppers. A catch pond below the bell pepper field retained irrigation run-off. A 300-400 foot wide buffer zone of bare ground separated the bell pepper field from cattle pastureland above it on the hills. Cattle graze in the hills during spring. In May, as the grass supply decreases after the rain stops, most of the cattle are moved to a feedlot located 1.6 miles south of lot 6 section C, which contained about 3,500 head of cattle between June and September. A small herd of goats, a few horses, and some dogs were also observed on the premises.

West of Eade lot 6 is a dirt farm road, followed by railroad tracks, Cattlemen Road, another farm field, and the Salinas River. The river is three-fourths to one mile west of the field, at a lower elevation than the field. Approximately one-fourth mile northeast of the field is a reservoir used for pre-planting irrigation and dust control on the farm roads. No composting or waste management operations were observed in the area. Investigators observed a pile of compost stored approximately two and one-half miles north of the subject field, which was gone a few days later.

Red leaf lettuce was observed growing in section C of Eade lot 6 during field investigations. The field was not fenced. The pastureland on the hills to the east was enclosed with barbed wire fencing. The farm manager reported seeing coyotes, ground squirrels, hawks, and small birds around the field areas. He stated they put out 100 warfarin bait stations for ground squirrels. Investigators observed tracks of raccoon, coyote, and birds on roads, near ponds, and in mud near a standpipe in the irrigation system. The area near the catch pond had a large number of ground squirrel burrows. On October 4, 2006, wild pig tracks were observed at the catch pond above (east side) lot 6C and at another pond on the property. Wild pig tracks were also observed in the sand by the Salinas River, west of the field. Pig scat collected near the river contained partially digested carrots. In early October, the farm manager reported they started having problems with feral pigs around lot 9, which was planted with carrots. Lot 9 is about 1-1.3 miles north of lot 6C.

CalFERT Environmental Sampling: Eade Ranch

CalFERT investigators collected 102 environmental and product samples in and around Eade Ranch, including red leaf product, cattle feces from the feedlot, wild pig feces (collected in the river), water, and sediment. Of these, nine samples (nine percent) of cattle feces from the feedlot and one sample (one percent) of water from a cattle water trough were positive for *E. coli* O157. No matches to the outbreak PFGE pattern were identified in these samples (Attachment 10). Positive sample locations are mapped in Figure 5.

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Figure 5: Eade Ranch Positive E. coli O157:H7 Sample Locations

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Third Party Laboratory Techniques Discussion

A number of the firms involved in this investigation made use of third party laboratories during the course of this investigation, either as part of their own food safety monitoring or in an attempt to duplicate CalFERT sampling. A variety of methodologies were used by these third party laboratories for detection of *E. coli* O157:H7. Presumptive testing by Primus involved enrichment of a sample for 20 hours and then testing for *E. coli* O157:H7 using the "RapidChek" test kit. Following presumptive positive test results, the confirmatory methodology used a commercially available latex agglutination test (*E. coli* Pro O157). JL, which is wholly owned by IEH, provided sampling and testing services for Mission Ranches. The samples were pre-enriched for eight hours and then each sample was tested using both a lateral flow test (manufactured by Neogen, AOAC approved for recovery of *E. coli* O157:H7 from foods) and multiplex Polymerase Chain Reaction (PCR) technique. Samples that showed a reaction for *E. coli* O157:H7 were purified using immunomagnetic bead separation. The resulting concentrated sample was tested by multiplex PCR using a different set of primers.

IEH provided sampling and testing services to NSF. IEH reported using the same technique but using a USDA Food Safety Inspection Service (FSIS) Bacteriological Analytical Manual (BAM) approved method to confirm positive results. There are many quick tests in the market place for analysis of *E. coli* O157:H7. However, tests vary in sensitivity and specificity, as well as the matrices for which they have been validated.

Summary of Observations

CalFERT investigators collected information, records, environmental samples, and product samples at the NSF processing facility, implicated harvesters, and implicated fields pertaining to this *E. coli* O157:H7 outbreak associated with Dole brand Baby Spinach.

NSF Processing Facility Investigation

Dole brand Baby Spinach, manufactured at NSF on August 15, 2006, with product codes beginning "P227A", traced back to four fields located in Monterey and San Benito counties in California. The fields were located on the Paicines, Wickstrom, Talx, and Eade Ranches. NSF operated two processing facilities, both located in San Juan Bautista, California at the time this investigation began. NSF initiated operation in the South facility on April 1, 2006. Information and documents obtained from NSF revealed the firm did not update nor review procedures (HACCP plan, SOPs, SSOPs) already in use at the North facility prior to initiation of production at the South facility. The firm intended for these procedures to apply to both facilities, but the procedures were not customized for South facility operations. Environmental samples that were collected by CalFERT investigators from the North NSF facility (n = 7) and from the South NSF facility (n = 9) were negative for *E. coli* O157:H7. Finished product retention samples (n = 8), manufactured at the South NSF facility on August 30, 2006, were also collected and found negative for *E. coli* O157:H7. During the production week from August 14 – 19, 2006, the NSF South facility had the highest weekly production volume of the month. Between August 13 – 20, 2006, production email exchanges revealed that the South facility underwent a string of personnel shortages, including nine absent employees on Sunday, August 13, the date of the weekly extended sanitation shift. Personnel records revealed that a number of employee absences were due to illness or

illness in the family. Investigators were unable to determine the nature of the illnesses. NSF did not conduct ATP testing on a daily basis as required by the firm's SOP. No ATP testing was conducted from August 15 – 25, 2006. One ATP test collected from a scale vibrator failed on August 10, 2006, and no retest was documented. While the firm maintained flume water within its specifications for pH, chlorine, and temperature for the entire period of time reviewed, the parameter recorded as turbidity and used to determine the frequency of water changes was actually a measure of water color as determined using a Hach Portable Colorimeter. Mr. Daniels maintained that they had found the measurement of water color to be an acceptable substitute for turbidity but no validation of this method was provided and the firm did not have a turbidity standard for calibration. NSF maintained logs recording the washing of the harvesting totes for the month of August, but NSF was only able to provide logs from August 1 – 14. NSF did not keep a record that documented the washing of harvesting bins.

Harvester Investigations

The four harvesters of spinach that supplied P227A product codes were investigated: POSJ.; Seco Packing Company, LLC; Mission Organics, LLC; and Sebastian Harvesting, Inc. During operations observed, the blade of the spinach harvester was maintained between a quarter-inch and 1.5 inches above the beds on which spinach is planted. The driver of the harvesting machine had to rely on the spotters who walked in front of the machine to remove debris or to signal to lift the blade. The harvesting machines were observed to be complex pieces of equipment that incorporated numerous moving food contact surfaces. Cleaning and sanitation of these machines was observed to be a detailed process and all of the harvesters conducted the cleaning and sanitation outdoors.

Field Investigations

Extensive investigations and sampling were conducted at the four fields that supplied product code P227A, located on the Paicines, Wickstrom, Taix, and Eade Ranches.

On the Paicines Ranch, crop fields were partially surrounded by fences. Lot 1 was irrigated with well water. The wells were not grouted. Lot 1 of Paicines sits in a valley surrounded by hills. The San Benito River flows through the Paicines Ranch, approximately one-half mile west of lot 1. In the Paicines Ranch area, documented groundwater levels were higher in elevation than the San Benito riverbed during March 2006; fell to the riverbed level in July 2006, and subsequently fell below the riverbed later in the growing season. This potentially allowed surface water from the river flowing into the Paicines Ranch valley to percolate into the ground again and recharge the Paicines area groundwater basin during that period. The wells used for irrigation on the Paicines Ranch drew from the groundwater basin there. The San Benito River is listed by CCRWQCB as being impaired by fecal coliforms and sediments/silt. Cattle and wild animals have free access to the river, both on the cattle grazing area adjacent to the row crop growing region and at various points upstream. Seasonal and year-round creeks flow through the cattle pastures on the ranch and potentially recharge ground water during certain times of the year. The Paicines Reservoir, located in a grazing area within one mile of lot 1, is used to augment groundwater recharge during the dry season.

Approximately 2,000 head of cattle graze on the Paicines Ranch in the hills and patches of dense vegetation along the San Benito River. Wild pigs and wild pig signs (tracks, fecal material, and rooting), were observed in the cattle grazing areas, in addition to deer, small mammals, and birds. In the hardened dirt of lot 1, no animal tracks were observed by investigators. However, wild pig tracks were observed in and around other lots on the Paicines ranch. Wild pig fecal material and rooting were seen in a field belonging to a different grower, located approximately 1.7 miles south of lot 1. Coyote feces were seen near the lots. Growers from two nearby vineyards reported damage to their vineyards caused by pigs during thinning and harvesting in late summer and fall.

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Pig Rooting and Tracks, In Field Belonging to Neighboring Grower to Mission Organics

CalFERT investigators collected 351 environmental samples on the Paicines Ranch, including cattle feces, wild pig feces, other animal feces, soil, and water. Of these, 45 samples (13 percent) were positive for *E. coli* O157:H7 and 26 (58 percent) of these 45 matched the outbreak strain as determined by PFGE analysis. PFGE pattern matches were found in cattle feces, wild pig feces, soil, and river water samples.

On the Wickstrom Ranch, no fencing was present around lot 817. Investigators observed that the well used for irrigation of lot 817 had a damaged casing. The Pajaro River flows past the ranch, approximately 150 feet west of the field, in a riverbed that is 15-20 feet lower in elevation than the field. Several cattle were seen grazing on a hill in a fenced pasture about 50 feet from the field. Beyond the Pajaro River, approximately one-third mile from the field, trailer homes with chained dogs and a house with corralled goats were observed. A pile of horse manure/shavings was observed 400 feet north and at a higher elevation than the field. Forty-four environmental and product samples were collected, including water, Moore swabs, soil/sediment, and romaine lettuce from an adjacent field. One (two percent) Moore swab sample from the Pajaro River was positive for *E. coli* O157:H7. However, the PFGE pattern of this sample did not match that of the outbreak strain.

On the Taix Ranch, no fencing existed around lot 1TA1. The crops grown there were irrigated using well and Blue Valve water. San Juan Canyon Creek runs along the southwest side of Taix Ranch, containing spent NSF processing water and drainage from the nearby hills. The San Benito River flows past the Taix Ranch, approximately one-half mile northeast of lot 1TA1. Steer/bull pens and cows grazing in hills were observed one-half to one mile south of lot 1TA1, on Nyland Ranch. CalFERT investigators collected 133 environmental and product samples in and around the Taix Ranch, including baby greens, cattle and bird feces, soil/sediment, Moore swabs, drag swabs, and water. Of these, four samples (three percent) of soil adjacent to cattle feces at the Nyland Ranch was found positive for *E. coli* O157:H7. However, the PFGE pattern of the isolate did not match the outbreak strain. Investigators sampled the San Justo and San Luis Reservoirs in San Benito County, which feed the Blue Valve water supply system. Samples were negative for *E. coli* O157:H7.

On the Eade Ranch, lot 6C was not fenced. Crops were irrigated with water from a well that was not grouted and lacked good drainage and a concrete slab. The Salinas River flows past Eade Ranch, approximately three-fourths to one mile west of the field, at a lower elevation than lot 6C. To the east of lot 6C, past a neighboring field at a higher elevation, was a 300 – 400 foot wide buffer zone of bare ground, followed by cattle pastureland on the hills. A feed lot was located 1.6 miles south of lot 6C, home to approximately 3,500 head of cattle between June and September. A small herd of goats, a few horses, and some dogs were also observed on the feedlot premises. Pig tracks were observed at the catch pond above the east side of lot 6C and at another pond on the property. Pig scat was collected near the Salinas River and contained partially digested carrots. The farm manager reported problems with feral pigs during October around lot 9, which was planted with carrots. Lot 9 is about 1-1.3 miles north of lot 6C. CalFERT investigators collected 102 environmental and product samples in and around the Eade Ranch, including red leaf product, cattle feces from the feedlot, wild pig feces (collected from the edge of the river), water, and sediment. Of these, nine samples (nine percent) of cattle feces from the feedlot were positive for *E. coli* O157:H7, and one sample (one percent) of water from a cattle water trough was positive for *E. coli* O157. The PFGE patterns of these samples did not match that of the outbreak strain.

Glossary of Terms

Field: A "field" is a contiguous stretch of land used for growing crops, usually bordered by a dirt road or fence. It may be as small as a couple acres or as large as 50 or more acres. A field is usually separated from an adjacent field by a dirt road.

Grower: In this report, "grower" is used to refer to a business entity that leases or owns a particular "ranch" and cultivates crops on that land. The grower is responsible for all aspects of that cultivation, from preparing the land through harvesting. The grower usually contracts with separate business entities for services such as pesticide application or harvesting.

Harvester: In this report, "harvester" is used to refer to a business entity that is responsible for cutting spinach in the field and packing it into bins or totes. The harvester is usually a separate entity from the grower, but not always.

Lot: In this report, "lot" is used synonymously with "field." Growers number the different fields or lots on a ranch, calling them, for example: "Lot 1, Lot 2, Lot 3," etc. A lot may be

further delineated into sections "A, B, C," etc. by growers to distinguish areas in which different types of crops are planted or areas in which the same crop has been planted on different dates.

Moore Swab: A "Moore Swab" is a piece of sterilized cotton gauze with a string attached. Moore Swabs are left in flowing water for an extended period of time (usually 4 – 6 days) prior to collection and analysis. These swabs appear to "capture" *E. coli* O157:H7.

Ranch: A "ranch" is a delineated region of agricultural land with a specific name, usually owned by one entity. Investigators observed that a ranch may consist of land used to grow crops, or it may also include land used for domestic animal grazing or domestic animal operations. Growers generally lease land from a ranch owner to use for growing crops. Crops are tracked in growers' and harvesters' records by their growing locations, using ranch name and lot number.

Exhibits

| | |
|------------|--|
| Exhibit 1 | NSF: List of Manufactured Products That May Contain Spinach |
| Exhibit 2 | NSF: Organizational Charts; 3/23/06, 3/30/06 |
| Exhibit 3 | NSF South: Daily Room Temperature Check records, 8/1/06 - 8/31/06 |
| Exhibit 4 | NSF: SOP 106, Raw Material Inspection and Handling, Issued 10/23/06 |
| Exhibit 5 | NSF: Conventional Baby Spinach Raw Product Specifications, Issued 10/3/04 |
| Exhibit 6 | NSF North: Vacuum Cooling Tube Records, 8/1/06 - 8/31/06 |
| Exhibit 7 | NSF South: Pressure Cooling Tube Logs, 8/1/06 - 8/31/06 |
| Exhibit 8 | NSF South: Daily Depletion Log, 8/15/2006 |
| Exhibit 9 | NSF: Process Flow: Quality Assurance Reference (QAR) 002, Issued 3/30/06 |
| Exhibit 10 | NSF: SOP 112, Contaminated Product Procedure, Issued 9/28/06 |
| Exhibit 11 | NSF South: Water Systems Diagram |
| Exhibit 12 | NSF South: Site Diagram, Equipment Area Layout |
| Exhibit 13 | NSF: Hazard Analysis, Revised 2/20/06 |
| Exhibit 14 | NSF: HACCP Plan, Revised 3/14/06 |
| Exhibit 15 | NSF South: Wash Line Monitoring Records, 8/1/06 - 8/31/06 |
| Exhibit 16 | NSF South: Foreign Object Investigation Records, 4/29/06 - 9/12/06 |
| Exhibit 17 | NSF South: EB–South Master Sanitation Schedule San Juan Bautista, 5/7/06 - 9/10/06 |
| Exhibit 18 | NSF South: EB–South Daily Master Sanitation Schedule, 7/30/06 - 9/2/06 |
| Exhibit 19 | NSF: SOP 005, ATP Microbiological Testing, Issued 6/21/05 |
| Exhibit 20 | NSF South: ATP Testing Results, 7/15/06 - 8/31/06 |
| Exhibit 21 | NSF: Tote Washing Logs, 8/1/06 - 8/14/06 |
| Exhibit 22 | NSF South: SOP 011, Third Party Microbiological Testing, Issued 5/9/06 |
| Exhibit 23 | NSF South: Third Party Microbiological Testing Sample Rotation Schedule; Printed 10/4/06, 10/5/06 |
| Exhibit 24 | NSF South: Primus Labs Environmental Sample TPC Analysis Results; 8/7/06, 8/14/06, 8/21/06, 8/28/06, 9/7/06, 9/11/06 |
| Exhibit 25 | NSF South: Primus Labs Flume Water Sample TPC Analysis Results; 7/27/06, 8/19/06, 9/14/06 |

| | |
|------------|--|
| Exhibit 26 | NSF South: Primus Labs Environmental Sample <i>Listeria</i> Analysis Results, 9/7/06 |
| Exhibit 27 | NSF South: Primus Labs Quarterly Raw and Finished Product Samples TPC Analysis Results, 7/27/06 |
| Exhibit 28 | NSF South: JL Analytical Services Post-outbreak Raw Product and Environmental Sample Analysis Results; 9/17/06, 9/19/06, 9/21/06, 9/25/06 NSF South: POSJ water system (no. 3500917) Monthly Report/ Bracewell Engineering Well Water Sample Analysis Results, Well #1, July - August, 2006 |
| Exhibit 29 | NSF South: Process Waste Water Volume, 6/1/06 - 10/1/06 |
| Exhibit 30 | NSF South: SJB2 (South Facility) Raw Receipts Log; 8/14/06, 8/15/06 |
| Exhibit 31 | NSF South: Traceback of Spinach in Product Code P227A03 to Fields |
| Exhibit 32 | NSF South: Raw Product Receiving Log, 8/1/06 - 8/31/06 |
| Exhibit 33 | NSF South: Raw Product Receiving Log, Mission Ranches/Seco (Wickstrom Ranch), 8/14/06 |
| Exhibit 34 | NSF: QAR 126: Earthbound Farm Field Grading Criteria, Revised 9/29/05 |
| Exhibit 35 | NSF: Raw Product Disposition Report, 8/1/06 - 8/31/06 |
| Exhibit 36 | NSF South: Pack Out Monitoring Form: Safety, 8/1/06 - 8/31/06 |
| Exhibit 37 | NSF South: Packout Output Report, 8/1/06 - 8/31/06 |
| Exhibit 38 | NSF South: Product Distribution Records, All Products Manufactured 8/15/06 |
| Exhibit 39 | NSF: Harvest Audits, Good Agricultural Practices Summary, 7/10/06 - 8/26/06 |
| Exhibit 40 | Pride of San Juan Harvesting Nurse Tank Chlorine Level Log, 8/5/06 - 8/21/06 |
| Exhibit 41 | Pride of San Juan Yearly Safety Training Outline, 7/20/06 |
| Exhibit 42 | Pride of San Juan Yearly Safety Training Sign-in Sheet, 4/2006 |
| Exhibit 43 | Pride of San Juan Weekly Safety Refresher Training Sign-in Sheet, 6/7/06 - 8/25/06 |
| Exhibit 44 | Seco Packing Harvest Spray Water Chlorine Log, 7/15/06 - 9/4/06 |
| Exhibit 45 | Seco Packing Harvester Sanitation Log, 7/15/06 - 9/8/06 |
| Exhibit 46 | Seco Packing Safety Training Log, 5/12/06 - 9/18/06 |
| Exhibit 47 | Sebastian Harvesting Harvesting Machine Sanitation SOP, 10/2006 |
| Exhibit 48 | Sebastian Harvesting Harvesting Machine Sanitation Log, 8/8/06 - 8/20/06 |
| Exhibit 49 | Sebastian Harvesting Crew Toilet Maintenance Invoice, Serviced 8/2006 |
| Exhibit 50 | Mission Organics: Paicines Lot 1 Planting Records by Field Section, 7/22/06 - 8/14/06 |
| Exhibit 51 | Mission Organics: Paicines Lot 1 Harvest Record All Crops, Harvested 8/10/06 - 9/11/06 |
| Exhibit 52 | Mission Organics: Paicines Lot 2 Planting Records by Field Section, 8/15/06 - 9/11/06 |
| Exhibit 53 | Mission Organics: Paicines Lot 2 Harvest Record All Crops, Harvested 9/9/06 - 9/25/06 |
| Exhibit 54 | Mission Organics: Primus Labs Well Water Sample Analysis Results, Paicines Ranch Well #1 and #2, 7/31/06 |
| Exhibit 55 | Mission Organics: Paicines Ranch Map |
| Exhibit 56 | True Organic: Chicken Pellet Invoices and Purchase Related Documents; 7/6/06, 7/7/06 |
| Exhibit 57 | True Organic: Chicken Pellet Production Temperature Logs, 1/3/06 - 1/26/06 |
| Exhibit 58 | |

| | |
|------------|--|
| Exhibit 59 | True Organic: Manna Pro Corporation Chicken Manure Carbon/Nitrogen Lab Analysis, 10/12/2006 |
| Exhibit 60 | True Organic: Manna Pro Corporation <i>E. coli</i> and <i>Salmonella</i> Test Results; 4/10/06, 5/23/06, 6/28/06 |
| Exhibit 61 | True Organic: Manna Pro Corporation <i>E. coli</i> and <i>Salmonella</i> Test Results; 8/9/06, 8/28/06 |
| Exhibit 62 | True Organic: SOP Part 5.0 (Lab Analysis) and Part 6.0 (Lot Release and Recall), Revised 10/1/06 |
| Exhibit 63 | Seco Packing: Baby and Teenage Spinach Harvest Records, Multiple Ranches Including Wickstrom, 7/17/06 - 9/2/06 |
| Exhibit 64 | Driscoll Strawberry Associates, Inc. for Mission Ranches: Primus Labs Well Water Sample Analysis Results Brown Ranch; 4/19/06, 9/18/06 |
| Exhibit 65 | Mission Ranches: Wickstrom Ranch Primus GAP Audit, 6/7/06 |
| Exhibit 66 | Mission Ranches: Wickstrom Ranch Map |
| Exhibit 67 | Pride of San Juan: Spinach Harvest Records, Multiple Ranches Including Taix, 7/17/06 - 9/1/06 |
| Exhibit 68 | Pride of San Juan: Taix Ranch Primus GAP Audit, 8/1/06 |
| Exhibit 69 | Pride of San Juan: Taix Product Tests by Primus, 9/21/06 |
| Exhibit 70 | Pride of San Juan: Taix Ranch Map |
| Exhibit 71 | Sebastian Harvesting: Eade Ranch Spinach Harvest Records, 6/1/06 - 9/1/06 |
| Exhibit 72 | Braga Ranch: Monterey County Well Water Sample Analysis Results, Well Eade #1, 4/24/06 |
| Exhibit 73 | Braga Ranch: Monterey County Well Water Sample Analysis Results; Well Eade #1, #2, #3, #4, Reservoir; Tested 9/18/06 |
| Exhibit 74 | Braga Ranch: Eade Ranch Primus GAP Audit, 4/19/06 |
| Exhibit 75 | Eade Ranch Map |

Attachments

| | |
|---------------|--|
| Attachment 1 | NSF South Facility Process Flow Diagram |
| Attachment 2 | List of Wash Line Log Deviations (Translated) |
| Attachment 3 | All Product Codes Obtained Off Packages From Case-Patient Households (CDC) |
| Attachment 4 | Chart: Paicines Receipts |
| Attachment 5 | Chart: P227 Quantities of Baby Spinach Used in Shift A and B |
| Attachment 6 | Chart: P227 Spinach Depletion Times |
| Attachment 7 | Chart: P227 Packing Line Production |
| Attachment 8 | Chart: P227 Spinach Depletion Times Compared to P227 Packing Line Production |
| Attachment 9 | Chart: Paicines Lot 1 Sections Layout, Products, Acres |
| Attachment 10 | Environmental Samples From Farms and Watersheds |
| Attachment 11 | CDC Addendum Report |
| Attachment 12 | USDA Wildlife Services Addendum Report |



CENTER FOR SCIENCE IN THE PUBLIC INTEREST

New CDC Data Show Increases in *E.coli*, *Salmonella* and *Vibrio*

Statement of CSPI Food Safety Director Caroline Smith DeWaal

For Immediate Release:
April 12, 2007

Related Links:
CDC Report on FoodNet data in MMWR

Letter to FDA on *Vibrio*

Keep Updated:
Email updates
RSS syndication **Ex 10**

Print Version

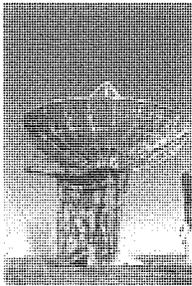
CSPI
1000 17th St NW
Washington DC 20036
Phone: 202.332.9110
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www.cspi.org
caroline@cspi.org
caroline@cspi.org
caroline@cspi.org

The Centers for Disease Control and Prevention's latest report shows that infections from *E. coli* O157:H7, *Salmonella*, and *Vibrio* are all on the rise. *E. coli* cases reported to CDC's FoodNet rose 50 percent since 2004, and *Vibrio*, another potentially deadly pathogen in shellfish, rose a whopping 78 percent since FoodNet began (1996-1998).

The new data show that federal food safety agencies are failing in their job to protect Americans from foodborne illness. In the last six months, huge outbreaks associated with spinach, tomatoes, peanut butter and lettuce shook Americans' confidence in the safety of the food supply. Even pet food has been recalled after an outbreak affecting thousand of cats and dogs. The Government Accountability Office recently put food safety on the list of high risk programs. Clearly, these programs are failing and need to be fixed.

Consider the 78 percent hike reported today in illnesses due to *Vibrio*, a dangerous, often deadly bacteria found in raw oysters and other raw shellfish. The Food and Drug Administration leaves it to an industry-dominated Interstate Shellfish Sanitation Conference to keep shellfish safe. That approach has obviously failed.

Food safety in Washington is a shell game, with one cabinet secretary in charge of *E. coli* on beef and another cabinet secretary in charge if it shows up on spinach. The food safety programs are under funded and minimally staffed. Vacancies and reductions in force are rampant. CDC's report clearly shows that the programs aren't working, and Congress should intervene to provide increased funding to the FDA in the short run and ultimately dismantle this regulatory hodgepodge and create a single, strong agency to ensure the safety of our food.



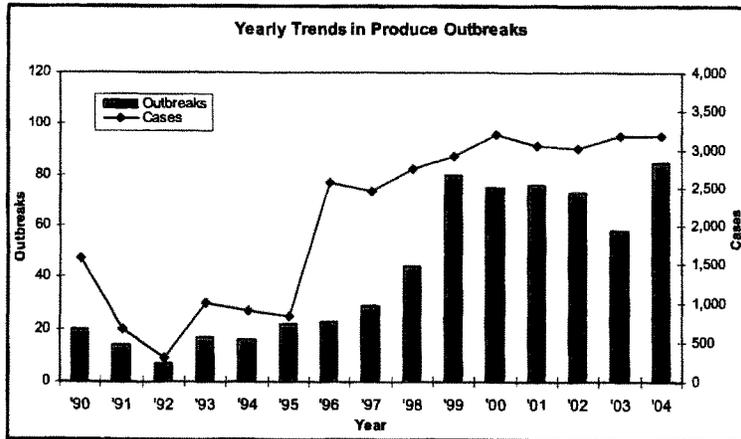
Ex 10



Behind CSPI's Outbreak Data: A look at the Produce Outbreak Numbers

- Outbreaks in produce have doubled between 1998, which had 44 outbreaks, and 2004, which had 85 outbreaks. This change may be due to enhanced outbreak surveillance efforts by the CDC starting in 1998.
- Between 1990 and 2004, there have been a total of 639 outbreaks in produce.
- CSPI's Outbreak Alert Database tracks foodborne illness outbreaks by food source using data from CDC and other highly reliable sources. Our database contains 5000 outbreaks with both food and hazard identified spanning 1990 to 2004.
- If you have questions about CSPI's database or about foodborne illness outbreak data, please contact Farida Bhuiya at 202-777-8377 or fbhuiya@cspinet.org.

| All Produce Outbreaks | | | |
|-----------------------|------------|--------------|--------------------|
| Year | Outbreaks | Cases | Cases Per Outbreak |
| 1990 | 20 | 1,563 | 78.2 |
| 1991 | 14 | 666 | 47.6 |
| 1992 | 7 | 293 | 41.9 |
| 1993 | 17 | 988 | 58.1 |
| 1994 | 16 | 900 | 56.3 |
| 1995 | 22 | 830 | 37.7 |
| 1996 | 23 | 2,557 | 111.2 |
| 1997 | 29 | 2,450 | 84.5 |
| 1998 | 44 | 2,749 | 62.5 |
| 1999 | 80 | 2,906 | 36.3 |
| 2000 | 75 | 3,185 | 42.5 |
| 2001 | 76 | 3,045 | 40.1 |
| 2002 | 73 | 3,007 | 41.2 |
| 2003 | 58 | 3,176 | 54.8 |
| 2004 | 85 | 3,181 | 37.4 |
| Total | 639 | 31496 | 49.3 |



Ex 11



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Tifton, GA Resident Post
P.O. Box 1709
Tifton, GA 31794

MEMORANDUM

Date: 2/13/04

From: Janet B. Gray, CSO
Tifton, GA RP

Subject: Follow-up for Complaint # 22892

To: Blake Bevill, SI
Atlanta, GA DO

On 1/28/04, I was notified by my supervisor, Blake Bevill, to conduct a follow-up investigation for a consumer complaint that was received by the KAN-DO on 1/12/04. The complaint involved an 18 oz. plastic jar of Reduced Fat Crunchy Peter Pan Peanut Butter that had reportedly had a misprint on the nutritional labeling for the correct amount or percentage of carbohydrates. See ATTACHMENT A for a copy of the Consumer Complaint Report. The complainant, Ms. [REDACTED], noticed on a container of reduced fat peanut butter that she had purchased from Wal-Mart Superstore in located in Jefferson City, MO, the nutritional labeling stated 5 grams of carbohydrates per 2 tablespoons instead of the normal 14 grams of carbohydrates. The manufacturer of the product is ConAgra Foods, Inc., 101 S. Seabrook Dr., P.O. Box 585, Sylvester, GA 31791. The lot code on the product was "S32202311D".

Ex 13

On 1/30/04, I contacted Ms. [REDACTED] and ask for details concerning her complaint. Ms. [REDACTED] said that she is a diabetic, and she has been controlling her diabetes by restricting the amount of carbohydrates in her daily diet. She said that the low-carbohydrate diet was recommended by her dietician and she has been on the regime since November of 2003. She says that she has been able to control her diabetes and since she has been on the diet she has not had to take insulin. She said that she has lost 15 lbs. since November. Ms. [REDACTED] informed me that since she is on a low-carbohydrate diet, she reads all nutritional labels for everything she eats, so that she will not go over her recommended intake of 195 grams or less of carbohydrates each day. She said that she routinely purchases reduced fat peanut butter, and she is aware of the normal amount of carbohydrates per serving. She said that she had just purchased a new jar of reduced fat crunchy peanut butter and she noticed that the nutritional label stated 5 grams of carbohydrates instead of the usual 14 grams of carbohydrates per 2 tablespoons. She said that she was concerned because there might be other people that are on a low carbohydrate diet for health reasons and she didn't want someone to overdo it thinking that they were getting fewer carbohydrates than they actually were. She said that she called the phone # listed on the jar for comments, and she talked to a man that looked up the lot code # for the peanut butter on a computer, and he said that their computer showed that the nutritional label listed that the product had 15 grams of carbohydrates. Ms. [REDACTED] told the man that she was looking right at her jar and it said 5 grams. The man said that he would look into it. Ms. [REDACTED] said that several days later, a woman from Peter Pan left a message on her answering machine; stating that there was a misprint with the labels and it had been taken care of. Ms. [REDACTED] added that she had recently received some coupons and a letter from the manufacturer stating that the problem with the mislabeling had been corrected and that the label should have read 14 grams not 5 grams.

Ms. [REDACTED] said that on 1/10/04 while shopping at the same Wal-Mart Superstore, she noticed that the labels on the Peter Pan Reduced Fat Peanut Butter still had 5 grams of carbohydrates instead 14 grams. At this time, she decided to notify FDA. Ms. [REDACTED] stated that she didn't know if the lot codes were the same. Ms. [REDACTED] said that she didn't know the specific dates or names of the representatives from Peter Pan that she had talked. Ms. [REDACTED] said that she went back to the same store again on 1/24/04 and she looked through all of the jars and didn't find any declaring 5 grams. She said that they now said 15 grams and that it appeared that they had gone up a gram. Ms. [REDACTED] felt that the misbranded amount of carbohydrates could throw off her diet and other people that had to watch their carbohydrate intake. I thanked Ms. [REDACTED] for her concerns and time, and told her that there would be a follow-up investigation at the manufacturer.

On 2/3/04, I visited ConAgra Foods, Inc. located in Sylvester, GA. Credentials were presented to and the FDA-482, Notice of Inspection, was issued to Mr. Selvin L. Smith, Plant Manager, and the most responsible individual for the operations at the firm, see ATTACHMENT B. Mr. Michael Matis, QC Manager, was also present during the initiation of the inspection. I explained that the purpose of my visit was to follow-up on a consumer complaint that we had received concerning a misprint for the amount of carbohydrates per serving on their Reduced Fat Crunchy Peter Pan Peanut Butter. Mr. Matis immediately knew what I was referring to and he told me that they had been notified and the problem had been corrected. He said that they were notified by their corporate office in Irvine, California on 1/7/04. Mr. Matis stated that he wasn't sure where the consumer got the 14 grams from because the product had always had 15 grams. Additionally, Mr. Matis said that he thought that the product involved was their Smart Choice brand not Peter Pan. He said that they

were never told why there was a misprint, but they had pulled all of the labels that had the incorrect carbohydrate amount on the label. He said that all of the old labels were in his office. Ms. Matis stated that the printing of labels as well as the label review are handled by their corporate office. He said that they do a cursory label review for the correct weights, product name, brand name, and kosher symbol. He said that they do not review the nutritional label. Mr. Matis showed me the misprinted labels that were pulled and kept in his office. He also took me to the label and packaging storage area to show me that all of the labels stating 5 grams had been removed. I observed that all of the labels present for reduced fat peanut butter stated 15 grams of carbohydrates. Mr. Matis ask what the lot code was on the consumers jar and I told him that it was "S32202311 (D or O)". He said that the last letter was a D because they do not use O in their coding system. Mr. Matis explained that they had developed a new coding system since the last inspection. He said that the S is for Sylvester; 3 is for the year; 220 is for the julian date; 2311 is for the time of packaging; and D is for the production line. Mr. Matis said that this particular lot was produced on 8/8/03. At this time, Mr. Matis checked to see if they still had any of this product on hand, but he said that all of this particular lot had already been shipped. He said that he was not surprised because they usually ship the product out shortly after production.

A closing discussion was held with Mr. Smith and Mr. Matis. Management said they had not received any more complaints to this nature that they were aware of. Mr. Matis said that all complaints or comments were handled by their home office located in Omaha, Nebraska. Mr. Matis said that they did not issue a recall or product removal because they didn't feel that it was a health risk, and since the product was produced in August they felt that there was probably just a small amount of product under this lot code in distribution. Management informed me if I had any other questions concerning when and how the complaint was received that I should call Dave Navarrette, Director of Regulatory Affairs, who is located in Irvine, CA. I was also informed that I would have to issue a written request for information before I would be able to get any information from their corporate office. I thanked them for their time and cooperation and concluded the inspection.

While at the firm, I collected sample #254933 consisting of 12/28 oz. plastic jars of Peter Pan Creamy Peanut Butter for aflatoxin analysis as per FY' 04 mycotoxin surveillance assignment. ATTACHMENT C is a copy of the collection report for the above sample. The FDA-484, Receipt for Samples, was issued to Mr. Michael Matis, see ATTACHMENT D.

ATTACHMENT A: Consumer Complaint Injury Report; 3 pages
ATTACHMENT B: Notice of Inspection; 1 page
ATTACHMENT C: Collection Report for Sample # 254933; 3 pages
ATTACHMENT D: Receipt for Samples; 1 page


Janet B. Gray/CSO
Tifton RP



*****PRODUCT RECALL NOTICE***
 READ IMMEDIATELY**

Date: February 16, 2007
 Memo To: Sonic Partners that sell Peanut Butter Topping from Con Agra Foods
 From: Nelson Taylor – Sonic Quality Assurance and Food Safety
 Subject: PEANUT BUTTER TOPPING CLASS I RECALL

Con Agra Foods, the supplier that produces peanut butter topping for Sonic, is voluntarily recalling all peanut butter topping in the Sonic system. The product is being recalled out of an abundance of caution due to a potential link between Peter Pan Peanut Butter and some foodborne illnesses in the United States. Originally foodservice product was not impacted, but Con Agra has since expanded the recall to include all foodservice product. There is no indication at this time that our customers are or were in any danger of becoming sick. Additionally, this recall only impacts liquid peanut butter topping. No other peanut or peanut butter products are involved in the recall.

Con Agra has asked that we remove ALL PRODUCT from service and destroy any remaining inventory. At this time, we are asking you to remove all opened and unopened peanut butter from service, Sonic product code 68585. If you have unopened peanut butter topping in your inventory, open the can and discard. *Once you have secured and recorded your inventory of opened and unopened product, please contact your distributor to arrange for a credit.* At this time, we are working to source replacement product as quickly as possible. Additional communication will follow.

Talking points to answer customer questions are attached to this memo. Please direct all media inquiries to Christi Woodworth, director – external communications, 405.627.1260.

Please complete the attached recall affidavit and send it to the fax number shown. Due to the fact that this is a CLASS I RECALL, we must ensure that all drive-ins with peanut butter topping have been contacted and the RECALL NOTICE is clearly understood.

All drive-ins and owners/supervisors that have received the impacted product are receiving this notification, and we must receive a product recall affidavit from each drive-in.

If you have any questions, please feel free to contact:

Nelson Taylor at 800-517-6642, ext. 4904 or 405-225-4904
 Randy Giwer at 800-517-6642, ext. 4906 or 405-225-4906
 Tom Hall at 800-517-6642, ext. 5326 or 405-225-5326

Thank you for your urgent response.

Ex 14



PRODUCT RECALL AFFIDAVIT

4 Digit Drive-In Number: _____

Drive-In Address: _____

I _____ (Print Name) do affirm that I have read and understand the attached Product Recall Notice concerning the Peanut Butter Topping, Sonic Item #68585. I have reviewed all peanut butter topping inventory in my drive-in. I am confirming that I DO / DO NOT (Circle One) have peanut butter topping. I am also confirming that I have taken the appropriate action as outlined in the Recall Notice. The above product has been implicated in a CLASS I RECALL. If you DO have the product in question, please note the 14 digit UPC code and quantity below and discard as instructed . The UPC code should be on the can and the case.

Product Code/Pack Date: _____ Quantity: _____

(Print Name and Title)

(Signature)

(Date)

****PLEASE RETURN VIA FAX TO (405) 225-5987****



TO: Sonic Partners who sell Peanut Butter products from ConAgra Foods
FROM: Christi Woodworth, Director-External Communications
DATE: 16 February 2007
RE: Peanut Butter products recall talking points

Attached to this memo, you will find a Food Safety Alert that Sonic has faxed to all affected drive-ins. Customers and media may have questions for the drive-in about Sonic's reaction to the recall.

Customer Q&A:

Q. I heard about the peanut butter recall on TV. Should I be concerned about my favorite peanut butter topping at Sonic?

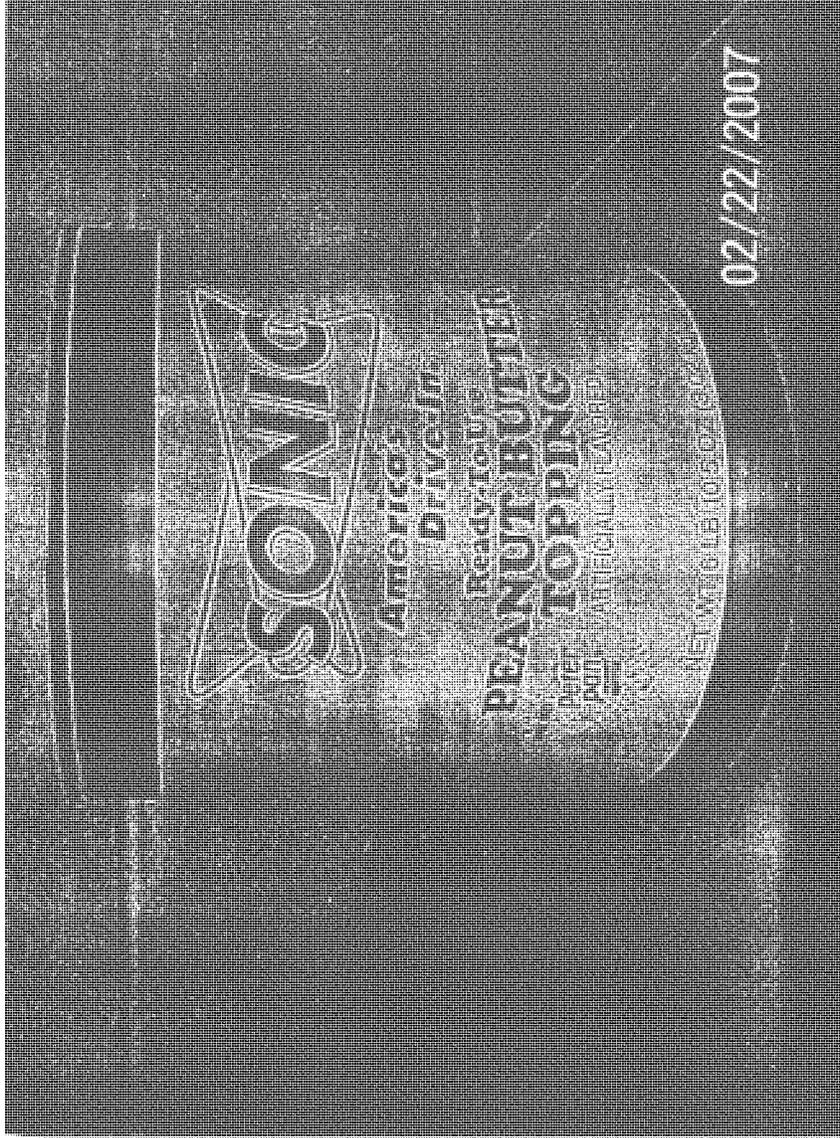
- Although we have not had any incidents related to our peanut butter products, our peanut butter supplier issued a precautionary recall and we have removed impacted peanut butter products from the drive-in.
- There is no indication at this time that our customers are or were exposed to an unsafe product.
- We can continue to serve menu items with Reese's Peanut Butter Cups and Butterfingers.

Q. So, when will I be able to order my favorite peanut butter shake or sundae?

- At this time, we aren't sure when we will receive new peanut butter topping. As soon as we have it, we'll be ready to serve your favorite peanut butter menu items.

Media Protocol – Direct All Media Inquiries to Christi Woodworth, 405.627.1260

| | Do | Don't |
|---|--|--|
| 1 | Do buy time. Tell the media it is company policy to refer all media inquiries to Sonic's corporate headquarters, and that a company spokesperson will call them back. | Don't allow photographers or reporters inside the drive-in. You can't tell what the camera lens is seeing. |
| 2 | Do interview the reporter. Ask the reporter the following questions so that you will have information that Sonic's Corporate Communications Department will need in order to assist you: <ul style="list-style-type: none"> • What is your name and the name of the media organization you represent? • What is your telephone number? • What questions do you have? • What is your deadline? | Don't say "No comment" because this implies guilt. Instead, say, "A company spokesperson will call you back. May I please have your contact information?" |
| 3 | Do call Sonic's Communications Department at (800) 569-6656, ext. 5602 or ext. 5604 or by pager at (877) 221-4552. Report all media inquiries (positive or negative) to Sonic's Communications department PRIOR to allowing the media to interview or photograph anyone or anything at the drive-in. Communications will help you determine the best way to manage the media query. | During a crisis, don't allow reporters or photographers on the drive-in lot. They can film from across the street if they wish. |





February 16, 2007

To: Carvel Franchisees
 From: Gary Bales
 President
 Re: ConAgra Foods – Peanut Butter Voluntary Class Recall

The Con Agra/Peter Pan Peanut Butter Situation:

ConAgra Foods and the Food & Drug Administration (FDA) are alerting the public that ConAgra's Peter Pan Peanut Butter products may be linked to the food borne illness salmonella. Although the peanut butter products used by Carvel are not produced in the affected Sylvester, GA plant (they are produced in the Humboldt, TN plant), ConAgra Foods is voluntarily recalling all varieties of Peter Pan Peanut Butter. Extensive product testing has not shown any salmonella, however ConAgra Foods is taking this precautionary measure because consumer health is their number one priority.

How does this affect Carvel?

Carvel utilizes ConAgra's *Peanut Butter Fudge Topping*, Item #420.

What do I do if I have this Peanut Butter Fudge Topping in my store?

If you currently have this Peanut Butter Fudge Topping in your store, please remove it from your shelves, fill out the attached "Certificate of Destruction" form to send to your distributor to receive credit, and then destroy the product. You will receive credit for the full amount of the purchase price of the Peanut Butter Fudge Topping product that you destroyed.

What about my finished ice cream flavors and products that contain Peanut Butter Fudge Toppings?

If you currently have finished ice cream flavors in your dipping cabinet that contain Peanut Butter Fudge Topping, including the flavors Chocolate Peanut Butter, Peanut Butter Treasure, or Peanut Butter & Jelly (along with any other flavors that you personally created using Peanut Butter Fudge Topping), please immediately remove and destroy them. Also, please discontinue making the Reese's Peanut Butter Sundae Dasher until this issue has been resolved.

Can I produce the flavors and products listed above using a different brand of Peanut Butter Fudge Topping?

There are currently no substitutes in our distribution system for Peanut Butter Fudge Topping, so you will not be able to produce and sell these flavors until further notice.

What about the peanut butter related toppings on my toppings bar?

Other peanut butter related products in our stores – Ground Reese's Peanut Butter Cups (Item #567), Peanut Butter Cups (Item #585), and Reese's Pieces (Item #546) – are not affected by this voluntary recall, and are safe for continued use.

What do I tell my customers if they ask if Carvel has been affected by the Peanut Butter recall?

Carvel's Peanut Butter Fudge Topping is produced by ConAgra Foods, who has issued a voluntary recall for this peanut butter based product. *Please note, however that Carvel's Peanut Butter Fudge Topping was not produced in the same manufacturing plant that experienced the salmonella outbreak.* As a precautionary measure only, ConAgra Foods and Carvel have removed the Peanut Butter Fudge Topping product from our stores until ConAgra Foods and the FDA has deemed it safe.

EX 15



What do I tell a customer who has additional questions or questions that I cannot answer?

Please direct any additional customer questions to ConAgra Foods at 1-866-344-6970, where food production experts are available to answer their specific questions.

What if I have additional questions regarding this voluntary product recall?

If you have any additional questions, please contact your Franchise Consultant, Director of Purchasing and Distribution Martin Folk (mfolk@focusbrands.com / 404-705-2057), or Director of Quality Assurance Juan Carlos Banderas (jbanderas@focusbrands.com / 770-452-9227).

We will continue to monitor the ConAgra Foods Peanut Butter recall, and will communicate any information as needed to protect the integrity of the Carvel brand. If you have any questions, please don't hesitate to call the franchisee hotline at 1-877-UCARVEL.



**** Please Post In Stores or Share with Customers As Needed ****

February 16, 2007

Dear Carvel Franchisees:

ConAgra Foods and the Food & Drug Administration (FDA) are alerting the public that ConAgra Foods' Peter Pan Peanut Butter products may be linked to the food borne illness salmonella.

Although the peanut butter products used by Carvel are not produced in the affected Sylvester, GA plant (they are produced in the Humboldt, TN plant), ConAgra Foods is voluntarily recalling all varieties of peanut butter. Extensive product testing has not shown any salmonella, however ConAgra Foods is taking this precautionary measure because consumer health is their number one priority.

Until further notice, Carvel has removed our Peanut Butter Fudge Topping and all products made with this ingredient from our stores, including:

1. Chocolate Peanut Butter hand dipped flavor
2. Peanut Butter Treasure hand dipped flavor
3. Peanut Butter & Jelly hand dipped flavor
4. Reese's Peanut Butter Cup Sundae Dasher
5. Any other store-specific hand dipped or soft serve flavor

All other Carvel peanut butter related products are not affected by this voluntary recall, and are safe for continued use, including:

1. Ground Reese's Peanut Butter Cups
2. Reese's Mini-Peanut Butter Cups
3. Reese's Pieces

If you have any additional questions regarding the ConAgra foods voluntary recall, please contact them directly at 866-344-6970 where food production experts are available to answer any questions.

Thanks for your patronage,

A handwritten signature in black ink that reads "Gary A. Bales".

Gary Bales
President of Carvel

| |
|---|
| Food and Drug Administration Establishment Inspection Report |
|---|

| | | |
|---|--|--|
| Date Assigned: 01/18/2005 | Inspection Start Date: 02/23/2005 | Inspection End Date: 02/24/2005 |
| Firm Name & Address: ConAgra Grocery Products, 101 S Seabrook Dr, P.O. Box 585 Sylvester, GA 31791-0585 US | | |
| Firm Mailing Address: 101 S Seabrook Dr/Pob 585, Sylvester, GA 31791 United States | | |
| FEI: 1038538 | JD/TA: 26 | County: WORTH |
| Phone: (229)776-8811 | District: ATL-DO | Est Size: 50,000,000 - and over |
| Conveyance Type: | % Interstate: | Inspectional Responsibility: |
| | | Profiled: No |

Endorsement

Previous inspection of this peanut butter manufacturer was 8/3/2000 and was a follow-up to collect an additional mycotoxin sample from a lot of peanut butter in which SRL reported finding 4 ppb aflatoxin B1 in an initial surveillance sample. Inspection found the lot in question had been shipped and management cited corporate policy in refusing to allow review of production and shipping records.

The current inspection was conducted in response to several complaints including most recently, number 29134, an anonymous complaint alleging poor sanitation, poor facilities maintenance, and poor quality program management. Specifics in that complaint include an alleged episode of positive findings of Salmonella in peanut butter in October of 2004 that was related to new equipment & that the firm didn't react to, insects in some equipment, water leaking onto product, & inability to track some product.

During this EI, local management acknowledged that an amount of product was placed on a "micro" hold in October of 2004 and was destroyed. Management refused to provide details to include the exact cause of the hold and the type/amount of product involved. Management did report that each day's production is tested for Salmonella and for coliforms, and allowed review of testing results for 2 specific dates in October of 2004 when new votators, or heat exchangers were installed in the peanut butter manufacturing line.

Inspection did not disclose any leaking water lines or overhead condensation, etc. leaking into any exposed product, either on packaging lines or in the raw and roasted peanut handling areas. The latter areas including product elevators and elevator boots, bins (some of which are open at the top), aspiration lines, foreign material chutes, (continued in Inspection Summary)

Class: NAI

F/U: Routine

Dist:

O: ATL-File

C: Tifton-RP

C: Complaint Coord/PS

C: CB/FMD-145

Endorsement Location: FACTS

| Inspector Name | Date & Time of Signature | Supervisor Name | Date & Time of Signature |
|------------------|--------------------------|------------------|--------------------------|
| Jackie M Douglas | 03/11/2005 03:31 PM ET | Andrew B Beville | 03/17/2005 03:45 PM ET |

Date: 04/23/2007

Page: 1 of 5

Ex 16

Food and Drug Administration Establishment Inspection Report

FEI:1038538 **Inspection Start Date:** 02/23/2005 **Inspection End Date:** 02/24/2005
Firm Name & Address: ConAgra Grocery Products , 101 S Seabrook Dr , P.O. Box 585 Sylvester, GA 31791-0585 US

Related Firm FEI: **Name & Address of Related Firm:**

Registration Type
There are no Registration Types

Registration Dates

Establishment Type
M Manufacturer

Industry Code
23 Nuts/Edible Seed

District Use Code:
3 TO BE EDITED

| Food and Drug Administration Establishment Inspection Report | | |
|--|-----------------------------------|---------------------------------|
| FEI: 1038538 | Inspection Start Date: 02/23/2005 | Inspection End Date: 02/24/2005 |
| Firm Name & Address: ConAgra Grocery Products , 101 S Seabrook Dr , P.O. Box 585 Sylvester, GA 31791-0585 US | | |

Inspection Basis: Consumer Complaint

Inspected Processes & District Decisions

| PAC | Establishment Type | Products/ Process | MQSA | Reschedule Insp Date | Re-Inspection Priority | Inspection Conclusions |
|------------------------|-------------------------------|-------------------------------|------|----------------------------------|---------------------------|---------------------------|
| 03803 | Manufacturer | 23 C D T | | | | No Action Indicated (NAI) |
| Final Decision? | District Decision Date | District Decision Type | | District Decision Made By | Org Name | |
| | 03/17/2005 | No Action Indicated (NAI) | | Bevill, Andrew B | ATL-IB-BB | |

Remarks:

| PAC | Establishment Type | Products/ Process | MQSA | Reschedule Insp Date | Re-Inspection Priority | Inspection Conclusions |
|------------------------|-------------------------------|-------------------------------|------|----------------------------------|---------------------------|---------------------------|
| 03803 | Manufacturer | 23 C H T | | | | No Action Indicated (NAI) |
| Final Decision? | District Decision Date | District Decision Type | | District Decision Made By | Org Name | |
| | 03/17/2005 | No Action Indicated (NAI) | | Bevill, Andrew B | ATL-IB-BB | |

Remarks:

| PAC | Establishment Type | Products/ Process | MQSA | Reschedule Insp Date | Re-Inspection Priority | Inspection Conclusions |
|------------------------|-------------------------------|-------------------------------|------|----------------------------------|---------------------------|---------------------------|
| 03R801 | Manufacturer | 23 C H T | | | | No Action Indicated (NAI) |
| Final Decision? | District Decision Date | District Decision Type | | District Decision Made By | Org Name | |
| | 03/17/2005 | No Action Indicated (NAI) | | Bevill, Andrew B | ATL-IB-BB | |

Remarks:

| |
|---|
| Food and Drug Administration Establishment Inspection Report |
|---|

FEI: 1038538

Inspection Start Date: 02/23/2005

Inspection End Date: 02/24/2005

Firm Name & Address: ConAgra Grocery Products, 101 S Seabrook Dr, P.O. Box 585 Sylvester, GA 31791-0585 US

Products Covered

| Product Code | Est Type | Description | Additional Product Description |
|--------------|--------------|---|--------------------------------|
| 23 C H T 07 | Manufacturer | Peanut, Butter; Nonflex Plastic; Packaged Food (Not Commercially Sterile) | |
| 23 C D T 07 | Manufacturer | Peanut, Butter; Laminated; Packaged Food (Not Commercially Sterile) | |

Assignees Accomplishment Hours

| Employee Name | Position Class | Hours Credited To | PAC | Establishment Type | Process | Hours |
|---------------------|----------------|-------------------|--------|--------------------|----------|-----------|
| Douglas, Jackie M | INV | ATL-DO | 03803 | Manufacturer | 23 C D T | 15 |
| Douglas, Jackie M | INV | ATL-DO | 03803 | Manufacturer | 23 C H T | 15 |
| Douglas, Jackie M | INV | ATL-DO | 03R801 | Manufacturer | 23 C H T | 5 |
| Total Hours: | | | | | | 35 |

| Food and Drug Administration Establishment Inspection Report | | |
|---|--|--|
| FBI: 1038538 | Inspection Start Date: 02/23/2005 | Inspection End Date: 02/24/2005 |
| Firm Name & Address: ConAgra Grocery Products , 101 S Seabrook Dr , P.O. Box 585 Sylvester, GA 31791-0585 US | | |

Inspection Result

| | |
|--|------------------|
| EIR Location Hardcopy to ATL-DO/ Turbo EIR | Trips Num |
|--|------------------|

Inspection Summary
(continued from Endorsement)

destoners, blanchers, electronic sorters, and the system that accumulates skins and dust were examined and no insect evidence or activity was noted. Peanut skins/meal collected during processing and sold locally for animal feed was examined and no insect activity was observed in this material. Insect evidence was limited to 1 moth observed flying in the enclosed garage where bulk trucks of shelled peanuts are pneumatically unloaded.

Management expressed concern over the complaints and reported that some of the allegations are time-related to a recent employee dismissal, and that recent plant mechanization resulting in a number of employees losing their jobs has resulted in some employee dissent.

No FDA 483 was issued, but several concerns were verbally discussed. Sample 308388 was collected from current production and submitted to SRL for micro analysis per PAC 03803D.

IB Suggested Actions

| Action | Remarks |
|--------|---------|
|--------|---------|

Referrals

| Org Name | Mail Code | Remarks |
|----------|-----------|---------|
|----------|-----------|---------|

Refusals

Inspection Refusals:

| Samples Collected | Recall Numbers | Related Complaints |
|-------------------|----------------|---------------------------|
| Sample Number | Recall Number | Consumer Complaint Number |
| 308388 | | 29134 |

FDA 483 Responses

483 Issued?: 483 Location:

| Response Type | Response Mode | Response Date | Response Summary |
|---------------|---------------|---------------|------------------|
|---------------|---------------|---------------|------------------|

United States Food and Drug Administration
Consumer Complaint / Injury Report
 This is an accurate reproduction of the original electronic record as of 04/23/2007

COMPLAINT # 29134

| Complaint Date | Receiving Organization | Accomplishing District | How Received | Complaint Source | Complaint Received By | Complaint Status |
|----------------|------------------------|------------------------|--------------|-------------------------|-----------------------|------------------|
| 01/13/2005 | ATL-DO | ATL-DO | Letter | Former Company Employee | Harris,Georgette P | Closed |

Complainant Identification

Name ANONYMOUS **Address** ----- GA
Phone (W) **Phone (H)** **Source POC Name** **Source Phone**

Complaint/Injury

| Complaint Description | Adverse Event Result | Adverse Event Date | Injury / Illness |
|---|----------------------|--------------------|------------------|
| Complainant, who wishes to remain anonymous, reports issues at firm, to include: poor sanitation practices, poor quality program management and poor facilities maintenance. See attachment for additional details. | None | | |

| Notify DEIO/EMOPS? | Notification Date | Attended Health Professional? | Required Hospitalization? | Emergency Room / Outpatient Visit? | Reported Complaint To? | Need addnl. FDA Contact? |
|--------------------|-------------------|-------------------------------|---------------------------|------------------------------------|------------------------|--------------------------|
| No | | | | | | |

Remarks

Complaint Symptoms

| Symptom | System Affected | Onset Time | Duration | Remarks |
|--|-----------------|------------|----------|---------------|
| Health Care Professional | | | | |
| Provider Name | Address | | Phone | Occupation |
| Hospital Informatio | | | | |
| Hospital Name | Address | | Phone | Dates of Stay |
| Emergency Room/Outpatient Visit | | | | |
| Hospital Name | Address | | Phone | ER Date |

Product and Labeling

| Brand Name | Product Name | Product Cod | Product Description | PAC | UPC Code |
|------------|--------------|-------------|--|-----|----------|
| | various | 23CYT07 | Peanut, Butter;Not Elsewhere Classified (NEC);Packaged Food (Not Commercially Sterile) | | |

Complaint # 29134

| Qty / Unit / Package | Lot/ Serial # | Exp/Use by Date | Purchase Date | Product Used | Amount Consumed/Used |
|----------------------|------------------|--------------------|------------------|-----------------|-------------------------|
| | | | | No | |

| Date Used | Date Discontinued | Amount Remained | Imported Product? | Country of Origin | Label Remarks |
|--------------|----------------------|--------------------|----------------------|----------------------|------------------|
| | | | No | | |

Retail

Name Address

Problem Ingredient GroupManufacturer/Distributor

| FEI | Name & Address | Home District | Firm Type |
|---------|---|---------------|--------------|
| 1038538 | ConAgra Grocery Products 101 S Seabrook Dr P.O. Box 585 Sylvester Georgia United States 31791-0585 | ATL-DO | Manufacturer |

Initial Evaluation/Initial Disposition

Problem Keyword Problem Keyword Details

| Initial Evaluation | Initial Disposition | Disposition Made By | Disposition Date |
|----------------------|---------------------|---------------------|------------------|
| FDA Action Indicated | Immediate Follow-Up | Harris,Georgette P | 01/13/2005 |

Initial Disposition RemarksReferrals

Org Name HHS Mail Code

There are no Cosmetics details for this Complaint.
There are no Adverse Event details for this Complaint.

Complaint #29134

COMPLAINTS FOLLOW - UP**Grouped Follow - Up Operations**

| Operation Id | Operation Code | Assignment Number | Accomplishing Organization | Performing Organization | Sample Number | PAF | Status | Status Date |
|--------------|----------------|-------------------|----------------------------|-------------------------|---------------|-----|-----------|-------------|
| 2232873 | 13 | 604839 | ATL-DO | ATL-IB-BB | | | Completed | 03/17/2005 |
| 2236760 | 12 | 604839 | ATL-DO | ATL-IB-BB | | | Completed | 03/11/2005 |
| 2291937 | 31 | 604839 | ATL-DO | ATL-IB-BB | 308388 | | Completed | 02/25/2005 |
| 2292631 | 41 | 604839 | SRL | SRL-MBTK | 308388-0 | MIC | Completed | 03/09/2005 |

Disposition Summary

| Is Consumer Responsible? | Responsible FEI | Address | Name | Firm Type |
|--------------------------|-----------------|---|--------------------------|--------------|
| No | 1038538 | 101 S Seabrook Dr P.O. Box 585 Sylvester Georgia United States 31791-0585 | ConAgra Grocery Products | Manufacturer |

| Follow-Up Disposition | Disposition Made By | Disposition Date |
|--------------------------------------|---------------------|------------------|
| Surveillance Information for Next EI | Harris,Georgette P | 03/31/2005 |

Disposition Remarks**Follow-Up Sent To**

| Organization Name | HHS Mail Code |
|-------------------|---------------|
| | |

| | | |
|--|-----------|----------------|
| Establishment Inspection Report | FEI: | 1038538 |
| ConAgra Grocery Products | EI Start: | 02/23/2005 |
| Sylvester, GA 31791-0585 | EI End: | 02/24/2005 |

SUMMARY

The current inspection of this large peanut butter manufacturer was conducted under the Domestic Food Safety Program, CP 7303.803, and in response to several complaints (FACTS Numbers 24675, 25509, 27728, 27977, and 28611, received from 4/16/04 to 12/8/04) including most recently, a written complaint (FACTS Number 29134 dated 1/13/05) from an individual requesting anonymity.

The latter complaint included some specific allegations (microbial problems at the firm in October of 2004, insect infestation, etc.) that in summary allege generally poor in-plant sanitation and maintenance and poor quality program management. To preserve the requested anonymity, the copy of the written complaint received by Tifton RP is not attached to this report, but is submitted to the district under separate cover.

The firm continues to function as the only manufacturer of Peter Pan brand of peanut butter, and one of at least two producers of Great Value (a Wal-Mart label) of peanut butter. During this inspection the firm produced Peter Pan Creamy Peanut butter in 18 and 28 oz. plastic jars and in a 6 lb. laminated can. Inspection covered general sanitation and pest control, maintenance of equipment including new equipment installation, complaint handling, and quality control activities including finished product testing and release.

Inspection revealed the following concerns: 2 areas on production lines where filled containers of peanut butter were not completely covered from overhead contamination, an accumulation of spillage and or dust at wall/floor juncture around air handling cabinet in the ingredients room, and a temporary baffle made of cardboard in use on an empty jar line. Insect evidence observed was limited to a single moth flying in the enclosed garage area where bulk trucks of peanuts are pneumatically unloaded. Examination of raw and roasted peanut cleaning, sorting and blanching equipment, including elevator boots and buckets and aspiration collection points and discharges revealed no apparent insect activity. No FDA-483 was issued and the concerns were verbally discussed with management.

During the inspection, covers were placed over the exposed areas on the 2 production lines, and the cardboard baffle was discarded.

Management verbally reported that each day's production is tested in-house for Salmonella and coliforms prior to release of the production for sale. Firm acknowledged that there was some production in October that did not meet product specifications and was put on a Micro hold, and was subsequently destroyed. However, management would not report the exact reason for the hold, nor the amount of product affected.

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| Establishment Inspection Report | FEI: | 1038538 |
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The firm did provide a review of micro testing results on 2 dates in October that were reported to be 2 dates on which new votators (heat exchangers) were placed on line after having been cleaned and sanitized. Tests on both dates were "negative" for Salmonella and coliforms.

Sample 308388, Peter Pan Peter Butter in 18 oz. jars and packaged on 2/24/05, was collected and submitted to SRL for microbial analysis per PAC 03803D.

ADMINISTRATIVE DATA

Inspected firm: ConAgra Grocery Products
 Location: 101 S Seabrook Dr
 P.O. Box 585
 Sylvester, GA 31791-0585
 Phone: 229776-8811
 FAX:
 Mailing address: 101 S Seabrook Dr/Pob 585
 Sylvester, GA 31791

Dates of inspection: 2/23/2005, 2/24/2005
 Days in the facility: 2
 Participants: Jackie M Douglas, Investigator

HISTORY

This firm is part of ConAgra Grocery Products Company, which is a division of ConAgra Foods, Inc. The division office is located in Irvine, CA. ConAgra Foods, Inc. is located in Omaha, NE, and per the Nebraska secretary of State's web posting, is a foreign corporation incorporated in Delaware in 1976, with the registered agent identified as McGrath, North, Mullin, & Kratz, PC, 1601 Dodge Street, Omaha, NE.

The Sylvester, GA firm is reported to be the only facility manufacturing Peter Pan Peanut Butter. The firm also manufactures Great Value Peanut Butter, a brand sold by Wal-Mart and Sam's Wholesale stores. The firm has no FDA regulatory history.

The previous FDA inspection here was 8/4/2000 and was limited to a follow up of 4 ppb aflatoxin B1 found in a surveillance sample of peanut butter. The firm refused to provide review of production and shipping records for the specific lot without a written request. No FDA-483 was issued. Previous

| | | |
|--|-----------|----------------|
| Establishment Inspection Report | FEI: | 1038538 |
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FDA contact here was an investigation completed 2/14/04 conducted in follow-up to complaint 22892 regarding inaccurate labeling in reduced fat peanut butter. The firm had corrected the labeling declaration on the product.

INTERSTATE COMMERCE

The firm routinely ships in interstate commerce via common carrier, and distributes peanut butter from this location to ConAgra's warehouse distribution locations, the nearest of which are located in Atlanta, GA and Jacksonville, FL. The firm ships some product directly to Wal-Mart or Sam's stores.

JURISDICTION

During this inspection the firm manufactured creamy peanut butter and packaged it under the Peter Pan label in 18 and 28 oz. plastic jars, and a 6 lb. composite can. Refer to Exhibits 4 through 6 for labeling of these products. The firm also packages Peter Pan peanut butter in 12, 40, 48, and 56 oz. plastic jars.

Great Value products are packed in 18, 28 and 40 oz. plastic jars only. I did not witness any production of Great Value product, nor any reduced fat peanut butter, or non-standardized peanut butter spreads which the firm also produces.

Management reports the firm uses only domestic peanuts in its production of peanut butter products.

RESPONSIBILITY

Upon entering the firm on 2/23/05, I was asked by the receptionist to sign in and to read and sign the attached (see Exhibit 1) Plant Confidentiality Agreement. I advised her I would read it but could not sign it. I read it and asked if I could keep a copy and she agreed.

I asked for the Plant Manager and was directed to Mr. Thomas C. Gentle. Credentials were shown to and the FDA-482, Notice of Inspection (and "Resources for FDA Regulated Businesses" document) issued to Mr. Gentle. Present also at this time were Mr. Michael J. Matis, Quality Assurance Manager, and Mr. Rick A. Young, Maintenance and Sanitation Manager. These 3 individuals accompanied throughout the inspection on 2/23. On 2/24, Messrs. Gentle and Matis accompanied. Mr. Matis and Mr. Gentle accompanied during sample collection on 2/24/05, and the FDA-484, Receipt for Samples, was issued to and signed by Mr. Gentle.

The current Food Security Guidance document was provided to Mr. Gentle, and I inquired as to the firm's registration status under the bio-terrorism rule. Mr. Matis advised the firm was registered and that had been handled by the firm's corporate office.

I explained to Messrs. Gentle, Matis and Young that this was a GMP inspection precipitated by recent complaints and I provided some background information to them. Refer to the heading

| | | |
|--|-----------|----------------|
| Establishment Inspection Report | FEI: | 1038538 |
| ConAgra Grocery Products | EI Start: | 02/23/2005 |
| Sylvester, GA 31791-0585 | EI End: | 02/24/2005 |

Complaints/ Product Defects for the content of this discussion and additional information related to the firm's handling of complaints.

Messrs. Gentle and Matis provided information related to complaint handling, history of business, chain of command, and general processing operations. Mr. Matis answered questions related to the firm's quality control operations. Mr. Young answered questions related to equipment operations, maintenance, and sanitation and pest control activities.

On 2/23/05, Mr. Matis cited corporate policy in initially delaying review of written quality procedures related to microbial testing of peanut butter. He said he would have to check with the firm's corporate offices before allowing it. On 2/24, Mr. Matis provided a verbal overview of the firm's microbial testing program and showed to me test summaries on finished product. He reported having obtained permission to do so from the firm's legal counsel, Ms. Sondra Morar, Esq., 1601 Dodge Street, Suite 3700, Omaha, NE 68102. Mr. Matis declined to answer a question as to whether or not aflatoxin test results posted on lot identifications of raw peanut bins were the results from in-house tests or from vendor/USDA supplied certificates.

Mr. Matis reports directly to Mr. Gentle. Mr. Gentle is the most responsible person present here on a day to day basis. Mr. Gentle reports to Mr. Joe McSherry (Omaha NE), Director of Operations for the ConAgra Grocery Products Division. Mr. McSherry, in turn reports to Mr. Greg Smith, Vice President of Operations, and Mr. Smith to Mr. Dean Hollis, President of the Grocery Products Division. Messrs. Hollis and Smith are located at Irvine, CA. (PO Box 57079, Irvine, CA 92619-7078). Mr. Bruce Rhode was identified as president of ConAgra Foods of Omaha, NE.

MANUFACTURING CODES

The code in use is best explained through an example, as follows:

Given the following code of "21115055 00 1037A BEST BY AUG242006", the key is: "2111" is the Sylvester, GA plant identifier; "5" is the year 2005; "055" the Julian date, in this case 2/24/05; "00" is a space filler; 1037 is a variable military time for filling; and "A" is the A line (firm also has B, C, and D lines for consumer products). The "Best By" date is 18 months from the production date. Note that at one time the firm's plant identifier character began with the letter "S". Mr. Matis speculated that this character was misread as a "5" in some of the complaints FDA had received.

Codes are inked on jar lids and on the plastic over wraps of cases. Exhibit 2 shows a case label with the code occupying the 2 lines left of the bar code. Case codes are basically the same, but with the time following the line indicator. Note display units assembled for Wal-Mart stores lack case over wraps. However, individual jars within each flat are coded and the firm records jar codes on shipping documents for each pallet of display units prepared. Mr. Matis showed this to me and explained that in some instances these displays may contain commingled codes.

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Incidentally, this is the only location that makes Peter Pan brand. The same code is used on Great Value products made here. Great Value is a Wal-Mart brand, and at least 1 other manufacturer also makes peanut butter for Wal-Mart.

COMPLAINTS / PRODUCT DEFECTS

Since the previous FDA contact here was conducted to follow-up complaint 22892 received on 1/12/04, only complaints received by FDA since were covered during the current inspection. Copies of the FACTS complaint entries for each are attached and can be reviewed for additional details.

These complaints include:

24675 dated 4/16/04, reporting a blonde or gray hair found in an 18 oz. jar of Peter Pan Peanut Butter;

25509 dated 6/7/04, reporting an open or loose jar seal and what the consumer described as injection sites in a 40 oz. jar of Great Value Peanut Butter;

27728 dated 10/15/04, reporting a small, triangular piece of plastic in an 18 oz. jar of Crunchy Peter Pan Peanut Butter;

27977 dated 10/28/04, reporting what consumer described as mouse droppings, in an 18 oz. jar of Peter Pan Honey Roasted Crunchy Peanut Butter;

28611 dated 12/8/04, reporting two pieces of uncooked rice in a 40 oz. jar of Peter Pan Creamy Peanut Butter;

29134 dated 1/13/05, an anonymous complaint reporting several issues at the firm that in summary allege poor sanitation practices, poor quality program management and poor facilities maintenance

On 2/23 I briefly summarized each of the complaints above by providing to Messrs. Gentle, Matis and Young the following information for each: date (FACTS date) of the complaint, the geographical (city & state) location, the problem reported, and any specific product identification reported by the consumers.

Regarding complaint 29134, I reported to them the allegations of microbial problems in peanut butter and firm's inadequate response to such, inadequate cleaning of new equipment, and insect activity in the plant. I summarized the complaint in the same manner it is summarized on the attached FACTS complaint report, reporting to them the complaint contained additional allegations that indicated poor sanitation practices, poor quality program management, and poor facilities maintenance.

Mr. Gentle said the firm's policy is to openly communicate complaint information it receives to employees. He said this is done at meetings with employees and with informational postings, and is done so that employees can look out for the potential sources of complaints.

Establishment Inspection Report

ConAgra Grocery Products
Sylvester, GA 31791-0585

FEI: **1038538**
EI Start: 02/23/2005
EI End: 02/24/2005

He said there was a micro hold of some product in October of 2004 and the product was destroyed, and the employees here knew this. He said the firm has and continues to install new equipment here and this activity has resulted in the reduction in the number of employees, and he reported that there has been some dissent here related to a number of people losing jobs. Mr. Gentle reported the firm is going to automated jar handling equipment including finished product palletizing and that equipment is cleaned before it is put into use, but added that is not in an area where the product is contacted.

Mr. Matis reported the firm does perform micro testing and finished product is not released until tested and found within specifications. He added that the micro information in this complaint appeared to be in the same time frame as the dismissal of a production manager in November of 2004. He reported corporate human resources personnel came to the firm to handle the dismissal. He did not elaborate other than to say the dismissal resulted from behavioral issues with other employees.

I inquired as to the reason for the micro hold and how much product was destroyed but Messrs. Gentle and Matis said they could not provide that information until checking with corporate officials. On 2/24 they subsequently reported that the product in the October incident did not meet specifications and was destroyed, but they could not provide any further specific details.

On 2/23 during the course of the inspection I was shown new votators that had been installed on the peanut butter line in October of 2004. Votators are heat exchangers that, in this application, are used to cool the butter temperature from approximately 150 degrees F prior to it being pumped to the fillers where it is filled at a temperature of about 89-90 degrees F. The interior piping of the votator is a food contact surface, with the pipe passing through a cooling medium to effect the temperature change. I inquired then as to how this new equipment had been cleaned. Mr. Young reported the votators were dismantled, cleaned and sanitized, and that documentation would record that. I asked if the equipment was swabbed or checked in some manner to validate the effectiveness of the cleaning. Mr. Matis said it was most likely swabbed. I asked to see the records of this cleaning and results of any testing verifying its adequacy as an example of the firm's procedures for new equipment installation.

On 2/24, Mr. Matis reported that the votators in question were cleaned and sanitized in place with alcohol. He said that the votators were sealed up following the sanitizing before QA got to them, so no swabs were collected. However, after consultation with his corporate office, he said he had been authorized to show me the finished product testing results from the installation date and the date the votators went on-line. One date shown to me was for the production date of 10/6-7/04, the date the units were installed, and the other for 10/12-13/04, the date the units were placed on line. He said the finished product tests on both dates were negative for Salmonella and <10 cfu/gram for coliforms. I examined these 2 pages and observed the tests for Salmonella on both dates were recorded at 0.03, and at <10 for coliforms.

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| Establishment Inspection Report | FEI: | 1038538 |
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| Sylvester, GA 31791-0585 | EI End: | 02/24/2005 |

Addressing the hair complaint (24675), Mr. Matis reported the firm has changed to requiring employees to wear the solid type hair nets as opposed to the ones with open-weaves.

Regarding complaint 25509, I advised this was handled as a retail tampering complaint, but I was providing the firm this for informational purposes. Mr. Gentle asked again what was reported and I explained that the consumer reported what looked like injection sites in the butter beneath the unsealed foil.

Mr. Gentle asked if the complainant (27728) had provided the color of the triangular piece of plastic. I told him no. He said this could possibly be a piece of plastic from the rim of the jar.

Mr. Gentle said that dark or burnt pieces of peanut would account for something that looked like mouse droppings (27977).

Mr. Matis said the creamy product (28611) is completely homogenized, so there should be no rice in it. I asked if the firm used any palletized glue, etc. in production and was told no, there was nothing that would appear as rice.

I asked to review the firm's complaint file. Mr. Matis reported the firm had no complaint file per se, and he explained how the firm receives and handles complaints. He reported the firm normally does not receive consumer complaints directly here, but at the corporate level (note a toll free number for questions or comments is printed on product labels). He said the firm receives an electronic notification from corporate headquarters advising of any complaint and the nature of the complaint. Locally, the complaint is investigated and appropriate action taken if necessary. He indicated the firm was aware already of some of the complaints I had reported.

Later, during the plant inspection, he pointed out a complaint posting on an employee bulletin board in a production area. The posting was a to-date summary (for firm's 2005 fiscal year, which runs from May to May) of the numbers and types (by several categories) of complaints. I did not record this information for every category, but thus far and since May of 2004, the firm has received approximately 40 plastic, 30 insect, 20 hair, and 30 foreign object complaints.

OPERATIONS, PERSONNEL, AND EQUIPMENT

The firm is currently operating from 4 to 6 days per week, running 2/10 hour shifts per day. The first shift runs from 6 AM to 4 PM, and the second shift from 4 PM to 2 AM. Sanitation operations are staffed 24 hours per day, with any major clean-ups performed during the down time from 2 to 6 AM. Other sanitation functions are conducted as needed and where needed throughout the production shifts.

Sanitation/Microbial Testing/Pest Control

Equipment is cleaned in place or broken down for cleaning, and sanitized with alcohol. Any wet cleaning is performed in one specific area and any equipment wet cleaned is dismantled and

| | | |
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| Establishment Inspection Report | FEI: | 1038538 |
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removed to that area for the cleaning. Any new product contact equipment installed is reportedly cleaned and sanitized with alcohol at installation, and normally microbial swabs taken. Mr. Matis reported the firm has a routine swabbing program that includes different areas and/or equipment each week. The swabs determine coliform levels and total plate counts.

On 2/24/05 and after having consulted with his corporate office, Mr. Matis provided a verbal overview of the firm's finished product microbial testing program. All finished product is tested in house for Salmonella and coliform. Samples of sealed jars are collected across the shift's production and tests are performed on composites from those samples. All product is held pending results which are returned typically in about 25 hours for 1st shift production, and 48 hours for 2nd shift production.

Product must test negative for Salmonella and must coliform test at no more than 500 cfu (colony forming units) per gram. If tested at 100 cfu/gram or lower, the product is released for distribution. Only the QA Manager or the firm's Microbiologist can release a lot based upon this testing, and one or the other is always present for this purpose.

The firm attempts to identify a cause for any findings above 100 CFU/gram in finish product, and this is addressed by an action plan which requires the plant to contact its corporate headquarters for guidance. Product testing at between 100 and 500 cfu may be sold as other than top grade product, but that decision rests with the corporate office, as is the disposition of any testing at over 500 cfu. Mr. Matis did not elaborate as to what dispositions are made.

Pest control is handled by an outside national contractor, Copesan, whose local agent is McCall Pest Control. Mr. Young reported that McCall comes to the firm every Tuesday and provides a total control package for insects and rodents. I observed rodent catch traps placed near exterior openings and Mr. Gentle reported insect pheromone traps were placed throughout the facility.

In light of the complaint alleging insect infestation, I inspected equipment in the pre-cleaning, sorting blanching and roasting areas, including bins, conveyors, elevator boots and buckets. I also examined several bulk (and previously used) cardboard boxes in which floor sweepings are accumulated for disposal. I examined the aspiration system at collection points over destoners, blanchers, etc., and traced the overhead lines to the maintenance shop where the material is collected, and from there augured on to the exterior trailer loading area where peanut skins and meal are dumped into a trailer and shipped locally for animal feed use. I examined some of this material in one of the trailers being loaded as well.

Accumulated spilled ingredient material along the wall/floor junctures on the sides and behind the air handling cabinet in the ingredient room (equipment here meters salt, sugar and stabilizer into the process) was examined. I found no insect activity in or around any of this equipment or locations, nor did I note any webbing, frass, or other evidence except for 1 moth as described below.

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|--|-----------|----------------|
| Establishment Inspection Report | FEI: | 1038538 |
| ConAgra Grocery Products | EI Start: | 02/23/2005 |
| Sylvester, GA 31791-0585 | EI End: | 02/24/2005 |

The moth was flying about an area immediately outside the door from the precleaning room to the enclosed garage where bulk trucks of peanuts are unloaded. 2 tanker truck trailers were parked in here at the time and an employee was connecting one to the firm's piping line that pneumatically unloads the peanuts into storage bins within the plant. As we exited the door from the precleaning room, an employee in the garage was closing one of the 2 fabric-type doors that trailers enter through (the other was already close). Note that when the precleaning room door is opened, an air curtain device mounted overhead automatically directs a strong air flow away from the door opening into the garage.

General Processing Flow/Equipment

The equipment and process found here appears typical to the industry. No unique or unusual equipment was observed. Only a brief description of the process follows.

Raw peanuts are received in bulk trucks and pneumatically off-loaded into bulk bins for temporary holding. Mr. Matis said the firm normally received only bulk trucks of peanuts, but in years when aflatoxins are a concern in the local crop and the firm gets in shipments from blanching facilities, it does receive peanuts in bulk cardboard totes. A system is here for unloading these totes, but it was not in use.

From the bulk holding bins the raw nuts are conveyed to a de-stoning operation that mechanically removes foreign materials through vibratory screening and aspiration. Equipment here is typical of peanut shellers (LMC Gravity Separators). Cleaned peanuts are then conveyed to a holding bin that gravity feeds the stainless belt of the firm's roasting oven. Roasting times vary depending on the desired results for product applications. The oven has 8 roasting zones and 4 cooling zones and the belt moves the peanut bed (about 4 ¼ inches in depth) through each zone in 3 to 4 minutes. Mr. Matis reported in general, peanuts are roasted up to about 350 +/- degrees F. The times and temperatures within the roaster are monitored in a control room where the information is electronically charted.

After roasting, nuts are conveyed in a vertical bucket elevator to holding bins that feed the blanchers. The firm's split nut blanchers remove the skins from the roasted nuts (skins are aspirated from the flow after blanching), and the nuts are then conveyed through an electronic sorting system (8-channel ESM Satake Scan Masters) which rejects dark nuts, foreign matter, etc. from the product. Rejects go through additional blanching and electronic re-sorts before final rejects are discarded and peanuts passing through the sorts go to the primary grinders or mills. From the point peanuts enter the primary mills the butter is made in a closed system.

Up to this point it should be noted that the firm does have some open-topped bins in which raw and roasted peanuts are held, and in places, the product flow is not totally covered, including an area near the exit end of the roaster. I examined these areas when I encountered them and this includes

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| Establishment Inspection Report | FEI: | 1038538 |
| ConAgra Grocery Products | EI Start: | 02/23/2005 |
| Sylvester, GA 31791-0585 | EI End: | 02/24/2005 |

examining the tops of some bulk holding bins. I did not find any insect evidence, leaking water pipes, condensation, flaking paint, or other potential overhead contaminants in the areas I examined.

Oil and other ingredients are added at the primary and secondary mills, and the resulting butter is pumped in stainless piping through a series of stainless holding tanks, de-aeration tanks, homogenizers, and then the votators before going to filling machines. At the filling machines the process is again open between the filling equipment and the closing equipment.

Only creamy peanut butter was observed in production. To make crunchy peanut butter, roasted peanuts are diverted in the product flow prior to the primary mill and go through a chopping process, and then mixed with butter at the filling locations.

The firm has 4 filling or packaging lines (5 counting a drum filler), designated A through E.

During this inspection the firm was filling creamy peanut butter into 18 oz., 28 oz., and 6 lb. containers. Empty jars or containers are inverted and blown out prior to filling and jars pass through a detector to insure they are right side up before filling. Empty jar/container lines are covered from the inversion points to the fillers. The firm is in the process of installing completely automated container handling systems which eliminate any manual removal of containers from cases.

Peanut butter is mechanically filled at about 89 to 90 degrees F on rotating fillers and the filled jars or containers exit the fillers and pass on a conveyor through fill weight and metal detectors before being capped or closed. With a couple of exceptions noted in the next heading and reported to the firm, the conveyors transporting the filled but uncapped containers are covered. After capping, jars pass through a dud detector that checks for proper cap seating. Jars pass through a Lepel heat sealing machine which applies heat to the tops necessary to attach the foil seal to the jar rim beneath the cap.

After heat sealing, jars are labeled (composite cans are received labeled from the supplier) jar/container lids are coded, then mechanically assembled into tray packs (cases) which are shrink wrapped in clear plastic, which is case coded.

The firm does assemble display units for Wal-Mart stores in which the individual cases are not over wrapped in order that customers may easily remove jars from the display. Consequently, these cases lack the case code, but individual jars are coded and the code information is recorded on shipping documents prepared during the display assembly. These assemblies are basically standard pallets upon which unwrapped cases of peanut butter are stacked, and contain cases of both crunchy and creamy peanut butter. These may contain commingled codes if assembly runs from one day to the next.

Finished products are initially stored on-site in the firm's warehouse. The warehouse is also used for storage of packaging materials (jars, cases, etc.).

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Management reported that in general, regular creamy and crunchy peanut butter is shipped out within a couple of weeks of production, and some of the slower moving items would go out in about a month of production. Mr. Matis said that product is shipped to ConAgra distribution sites. If the site is within 24 hours or less from Sylvester, the product is shipped by regular truck, if further, by refrigerated truck.

Mr. Matis reported the firm has not recalled any product, other than in successful episodes of mock recalls.

INSPECTIONAL OBSERVATIONS

No FDA-483 was issued at the inspection's conclusion. However, several observations were noted and discussed with the firm's management on 2/23 and on 2/24.

On 2/23/05 it was noted that there were areas on 2 packaging lines where filled, but un-closed, containers of peanut butter were not completely covered. One area was an approximate 3 foot section on the conveyor transporting filled 18 oz. plastic jars to the capper on line A, near the jar entrance to the capper. Here the jars veered at a slight angle toward the capper, away from the cover in place overhead. This resulted in the jars having no overhead protection, even though a cover was present.

The 2nd such area was on the D line, used for packaging the 6 lb. composite cans. On this line, there was an approximate 6 foot length of the conveyor exiting the filling machine that was not covered at all. Filled 6 lb. containers of peanut butter passed through this section of conveyor with no overhead protection.

As noted previously, a live moth was observed in the truck unloading garage.

There was an accumulation of spilled ingredient materials at the wall/floor junctures to the sides and behind a large air handling cabinet in the ingredient dispensing room.

A piece of cardboard was observed being used as a baffle on an empty jar line, as the jars changed direction on conveyors from an inverter to a filling machine. The jars came into contact with this cardboard.

REFUSALS

Mr. Matis cited corporate policy in refusing to provide review of written microbial testing procedures and written equipment cleaning/validation procedures. He did however, provide verbal overviews and he allowed access and review of results of finished product microbial testing on peanut butter made on dates in October of 2004 when new votators were installed.

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Mr. Matis declined to answer a question regarding whether or not posted aflatoxin test results on raw peanut bins were from USDA certificates received with the lots or the result of in-house aflatoxin testing.

GENERAL DISCUSSION WITH MANAGEMENT

During the inspection and then at the conclusion of the inspection I verbally identified the issues reported above under inspectional observations. Mr. Matis reported the firm welcomed the inspection as it afforded an outside perspective on the operations here. He reported on 2/24 that both the areas on the filling lines had been corrected between 2/23-24/05 (I confirmed this on the A line during sample collection). He reported the cardboard baffle had been removed and the jars moved along like they were supposed to anyway so he had no idea why it was there in the first place.

Mr. Matis said the area in the ingredients room was a difficult area to clean, and the material accumulated quickly there.

I did not issue any warnings. I advised of my intentions to collect a sample of peanut butter for microbial analysis.

VOLUNTARY CORRECTIONS

See the above discussion.

SAMPLES COLLECTED

On 2/24/05 I collected sample number 308388, Peter Pan Creamy Peanut Butter in 18 oz. plastic jars, from the firm's packaging line. A copy of the collection report is attached. The sample consists of 15 jars collected in duplicate at the rate of 2 from each of 15 full cases removed from the production line at approximate 5 minute intervals beginning at 10:05 AM. Approximately 90 cases passed per 5 minute interval. The sample was submitted to SRL for microbial analysis (Salmonella, Listeria, and coliforms).

Mr. Matis advised the firm would voluntarily hold the production from this date pending a report of the FDA analytical results.

EXHIBITS

- 1- Plant Confidentiality Agreement
- 2- Case Labeling
- 3- Miscellaneous Shipping Ticket (for sample 308388)
- 4- 18 oz. Peter Pan Creamy Peanut Butter Labeling
- 5- 28 oz. Peter Pan Creamy Peanut Butter Labeling
- 6- 6 lb. Peter Pan Creamy Peanut Butter Labeling

Establishment Inspection Report

ConAgra Grocery Products
Sylvester, GA 31791-0585

FEI: 1038538
EI Start: 02/23/2005
EI End: 02/24/2005

ATTACHMENTS

FDA-482, Notice of Inspection
FDA-484, Receipt for Samples
Copy of Collection Report 308388
Complaint Report 24675
Complaint Report 25509
Complaint Report 27728
Complaint Report 27977
Complaint Report 28611
Complaint Report 29134



Jackie M Douglas, Investigator

Peter Pan Recall

Update to FDA, March 9, 2007

ConAgra Foods®



81x3

Outline for Today's Presentation

- Business background
- CDC Epidemiology & Recall
- How did this happen?
- Moving forward

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Peanut Butter Business Background

- Peanut butter is a ~1 billion \$ industry in the US
- 5 major manufacturers account for 75% of production
- Sylvester, GA plant represents 15% of US production
- 50% of US Peanut crop goes to butter
- Peanut butter is found in 90% of US homes
- Average consumer eats peanut butter 27 times/year
- Peter Pan brand represented 15% market share (#3 player)
 - 19% of US households
 - #1 or #2 brand in 37 of 64 major US markets
 - Currently not in the market

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Epidemiology Results: February 14-27, 2007

*taken from CDC, last updated on March 1, 2007

370 cases in 42 states (Feb 27)

- Salmonella Tennessee serotype in patients
- 3 similar but different DNA strains (fingerprint types)
- Peanut Butter mentions in CDC interviews were high; Peter Pan mentions also high
- Salmonella Tennessee confirmation in open jars of Peter Pan from consumers (via State Public Health Departments)
- Outbreak cluster began with production date of August 1, 2006

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Recall Overview: Beginning February 14

- All recalled product pulled from retail outlets/shelves
 - Mfg dates: December 2005 - February 14, 2007
 - Ensured all customers contacted
 - Over half of the stores were visited by ConAgra for pick up of product

- All product to be destroyed (2-4 week timeframe)
 - For warehoused product – routine disposal
 - Destruction procedure includes regional FDA office

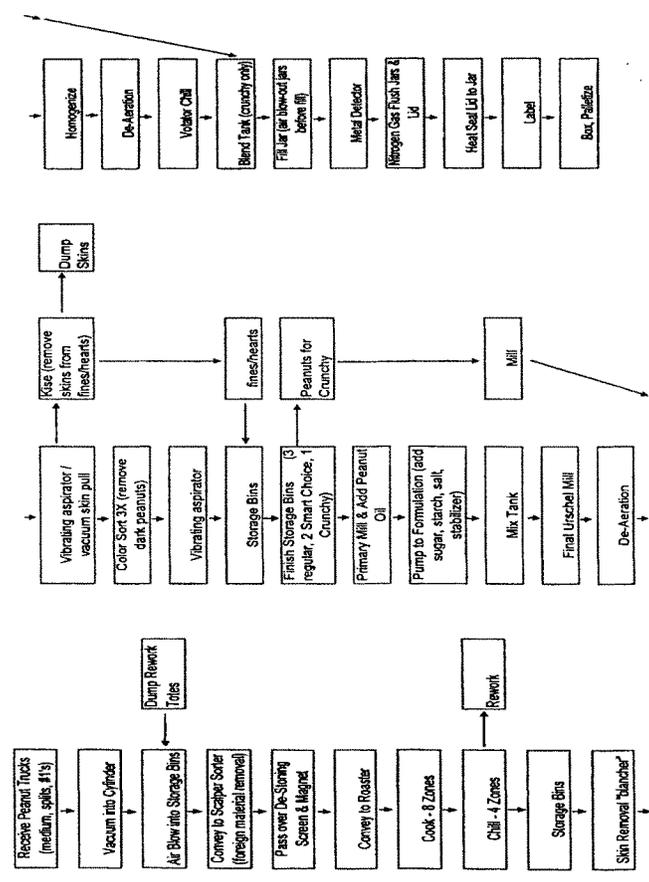
- Origin: All products made in Sylvester, GA facility
 - 172 Million pounds produced during the timeframe and recalled
 - Bulk drums shipped to 2 other ConAgra plants included in total above
 - Placentia, CA
 - 2 SKUs of “portion pack” peanut butter
 - Humboldt, TN
 - 3 SKUs of peanut butter dessert toppings, Carvel, Sonic and JHS brands

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What likely happened?

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Peanut Butter Manufacturing Process



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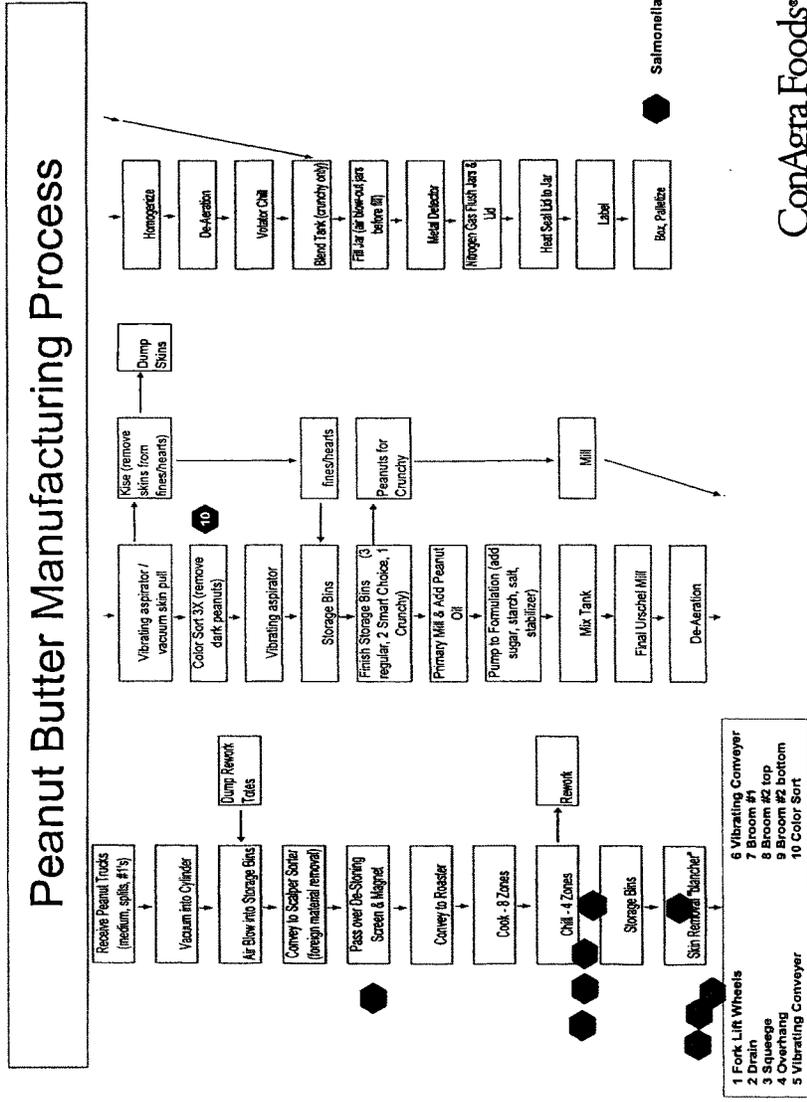
Environmental and Product Testing Results

- 10 environmental positive detects for Salmonella of 453 tested
 - Positives are 8 ConAgra, 2 FDA
 - 2 are confirmed Tennessee (FDA)
 - Of 10 identified sites
 - 1 was pre-roasting
 - 9 were post-roasting

- RAC testing (Pre-roasting)
 - 23 bins, 7 trucks
 - All negative

- Finished product testing
 - Manufacturing product testing (60-80 / day) all negative since October 28, 2004
 - Recovered product that was tested post-recall (ConAgra & FDA)
 - 1653 tested, 1 positive

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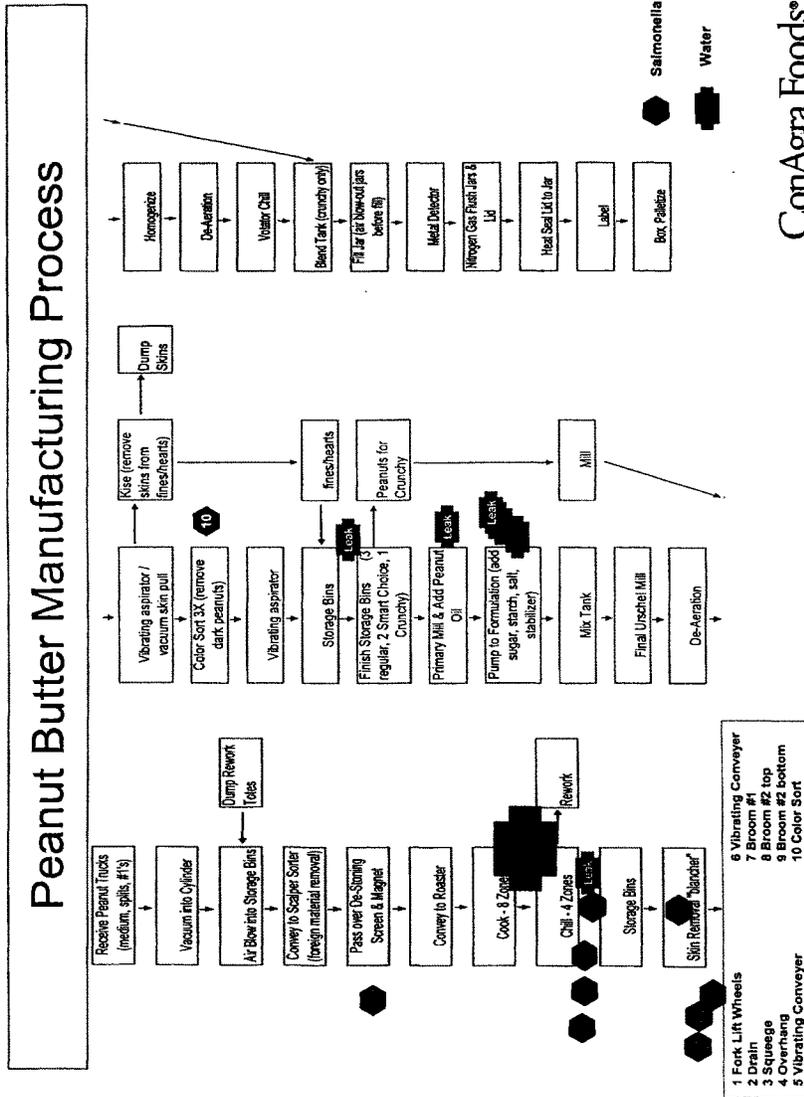


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Contributing Factors

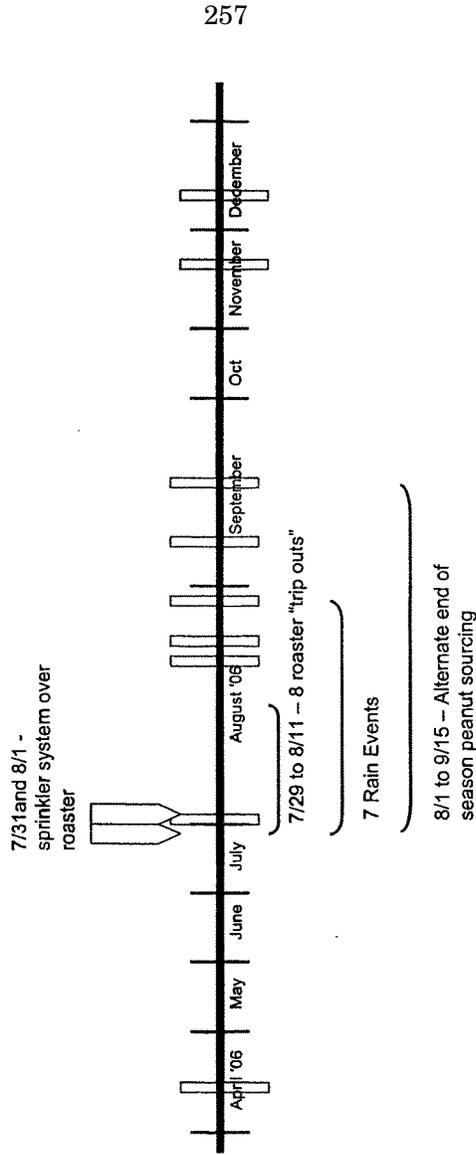
- Water
 - Sprinkler Events on July 31 and August 1, 2006
 - Sprinkler system triggered over the Roaster exit on both days
 - System was cleaned after each event and product discarded, but potential source of water entering production process
 - 7 Rain Events in August 2006
 - Potential contributing source of water post-roasting
- Low Level of Salmonella in Raw Peanuts/Dust
- Peanut Roaster Events
 - End of season peanut supply
 - Lower grade RAC quality – more fines, size variation, pieces
 - Increased frequency of power failures due to load on heating system and reduced air flow
 - As a consequence, increased risk of under-roasted product passing into system
 - 1 “Flame out” tied to sprinkler event on July 31, 2006
 - 5 “Trip out” events in August 2006
 - 2 power failures in August 2006



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2006 Timeline of Events



Summary

- *Salmonella Tennessee* was dormant in the plant environment at low levels from raw peanuts and/or dust
- Water was introduced into the peanut butter processing environment
 - The facility had two specific water related events on July 31st and August 1st, 2006 and 7 rain events during August, 2006
- The combination of these two factors likely resulted in the product and product contact surface contaminations with *Salmonella Tennessee*

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Moving Forward

Planned Improvements

- Building/Facility Upgrades
 - Roof replacement
 - Sprinkler system fixes
 - Separation of raw and finished product paths
 - GMP improvements
- Process improvements
 - Scheduled roaster replacement
 - Pipe layout improvements
 - Ingredient handling procedures (i.e., sugar)

Steps Being Defined

- Reassess HACCP plan
- Revise peanut supply strategy
 - minimize seasonality effect on grades/quality
- Michael Doyle, Center for Food Safety, UGA
 - Key advisor
 - Potential research program

Next Steps

- Questions/Discussion
- Creating alignment on best practices for peanut butter industry
- Timeframe for next FDA update meeting

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Subject: RE: CAERS Notices

Jim -

Thank you for the opportunity to read your product destruction guidelines and Instructions. We have run the guidance procedure that you supplied by a few of our scientists and have no issues with the peanut butter disposal process as written. The CDC is reviewing the precautions section related to protecting human health, as we will provide you that information as soon as we hear back from them.

Please understand that this message is not an endorsement by the agency of the practices in the document. Additionally, any guidelines or practices related to transportation of the recalled product through the U.S. that you may want to share with us can be routed through the appropriate FDA district office.

David

From: Astwood, Jim (Enterprise Services)
[mailto:Jim.Astwood@conagrafoods.com]
Sent: Tuesday, March 13, 2007 1:09 PM
To: Acheson, David
Subject: RE: CAERS Notices

Thanks. - Jim

From: Acheson, David
[mailto:david.acheson@fda.hhs.gov]
Sent: Tuesday, March 13, 2007 10:04 AM
To: Astwood, Jim (Enterprise Services)
Subject: Re: CAERS Notices

It has been changed - but there may still be some in the works.

----- Original Message -----
From: Astwood, Jim (Enterprise Services)
<Jim.Astwood@conagrafoods.com>
To: Acheson, David
Sent: Tue Mar 13 10:17:57 2007
Subject: CAERS Notices

David,

A great stack of CAERS reports landed on my desk yesterday. The stack more or less meandered its way here. For future ones, can you use my name as the primary contact for CAERS reports? Currently they are addressed to Pat Verdun who left the company about a year ago. Many thanks and regards,

- Jim

+++
James D. Astwood, Ph.D.
Vice President
Nutrition, Scientific and Regulatory Affairs

Ev19

ConAgra Foods
Center for Research, Quality and Innovation
Six ConAgra Drive, 6-475
Omaha, NE USA 68102

Phone: 402-595-6050
Mobile: 402-212-9734
E-mail: jim.astwood@conagrafoods.com

Dr. David Acheson
Chief Medical Officer
Center for Foods Safety and Applied Nutrition
US Food and Drug Administration

David,

Consumers are sending to ConAgra Foods jars of recalled Peter Pan or the lids. The jar lids have the code numbers and this facilitates the reimbursement process for consumers requesting refunds. We have a short guidance procedure for handling the full jars and lids at the fulfillment center which is based in Mexico. Could you or one of your colleagues review the attached document from Ken Juliot below with a view to agreeing with or suggesting improvements to the procedure? Our colleagues in Mexico will be interested in FDA's advice in this matter.

Thanks very much and I appreciate your time.

Regards,

- Jim Astwood

+++
James D. Astwood, *Ph.D.*
V.P. Nutrition, Scientific and Regulatory Affairs
ConAgra Foods
Center for Research, Quality and Innovation
Six ConAgra Drive, 6-475
Omaha, NE USA 68102

Phone: 402-595-6050
Mobile: 402-212-9734
E-mail: jim.astwood@conagrafoods.com

From: Juliot, Kent (Enterprise Services)
Sent: Tuesday, March 13, 2007 10:11 AM
To: Astwood, Jim (Enterprise Services)
Cc: Bond, Susan (Enterprise Services)
Subject: Instructions to Archway

Jim,

Attached are the instructions that we sent to Archway Fulfillment Center for handling and destruction of the lids and possibly some jars that people sent in to us via the mail for a refund. In addition to these instructions, Archway has place hand sanitizer on the lines.

<<Peter Pan Peanut Butter Product Destruction Guidelines and Instructions.doc>>

The Mexican Dept of Health is asking for assurance that these practices will protect the workers from incidental contact and that the FDA concurs with these recommendations.

Thanks in advance for assistance on this request.

Kent Juliot
Director, Operations Quality
ConAgra Foods
Desk: 402-595-5289
Cell: 402-980-6540
FAX: 402-517-4134

You should get a call soon from CAG to clarify. I am pretty confident that we are NOT sending the stuff down there but I've gpt folks checking. I am at ILSI today in DC but we'll get right back.

This message was sent using a ConAgra Foods wireless email device



General Manufacturing Procedure

| | |
|---|-------------------|
| Subject | Specification No. |
| INSPECTIONS, REGULATORY AGENCY | GI012 |
| Location | Revision No. |
| ALL CANNERY OPERATIONS FACILITIES | 15 |
| Nature of Revision | Issue Date |
| Document has been completely rewritten. | 03/23/04 |
| | Approval |
| Supersedes Issue of 04/20/99 | |

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I. PURPOSE

It is the purpose of this procedure to guide plant and warehouse managers (as well as other employees of the Company) in the course of their dealings with certain authorities who, by law, are authorized to enter upon plant or warehouse premises for the purpose of inspecting the same, or for the purpose of examining certain books and/or records.

It is the further purpose of this procedure to assist in the establishment of a harmonious relationship between the company and the agencies mentioned herein.

II. RESPONSIBILITY

The following management personnel have defined responsibilities in the implementation of this procedure:

Plant Manager
Quality Control Manager
Vice President Manufacturing or Operations
Supply Chain Director
Vice President Supply Chain

III. SUMMARY PROCEDURE FOR REGULATORY AGENCY INSPECTIONS

Following is a summary of the procedure to be followed in the event of a regulatory agency inspection:

- A. FDA inspectors must present proper identification and a written Notice of Inspection before beginning any inspection.
- B. FDA inspectors must be accompanied by a Production and Technical Representative at all times.
- C. Scope of inspection FOR OTHER THAN LOW-ACID FOOD PRODUCTION:
 1. FDA inspectors are entitled to the following:
 - a. Ingredient statements
 - b. Labels
 - c. Product Samples:
 - 1) A receipt signed by the inspector, indicating product, quantity and value must be obtained.

III. SUMMARY PROCEDURE FOR REGULATORY AGENCY INSPECTIONS. (Continued)

C. (Continued)

- 2) Duplicate samples are taken by the Technical Representative and held for reference. Specific sampling instructions are outlined in Table I, pages 20-21.
- d. Ingredient Samples:
 - 1) Duplicate samples are taken by Q.C. Specific sampling instructions are outlined in Table I.
 - e. Physical examination of equipment (swabs, scrapings, etc.) - the Technical Representative should attempt to take duplicate samples or make specific record of location, condition, etc., of sample. Specific sampling instructions are outlined in Table I.
 - f. Visual inspection of any and all plant and warehouse operations.
2. FDA inspectors are generally NOT entitled to the following (if the inspector insists on any of the following and he is not claiming to be acting under the authority of the Bioterrorism Act (see #3), ask that he direct a written request to the corporate office in Irvine):
 - a. Codes (However, we do supply copies of all our codes to FDA regional offices, and inspectors should be referred to their regional office to obtain a copy.)
 - b. Records - this includes:
 - 1) QC records
 - 2) Seam examination records
 - 3) Warehouse records
 - 4) Production records
 - 5) Consumer complaint records
 - c. Plant locations
 - d. Distribution center locations
 - e. Product formulae
 - f. Process specifications
 - g. Photographs (Except state inspections in California and Wisconsin. See pp. 14 and 18.)
 - h. Names of suppliers

III. SUMMARY PROCEDURE FOR REGULATORY AGENCY INSPECTIONS. (Continued)

C. (Continued)

3. Under the regulations implemented under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, an Agency inspector is entitled to inspect some records if he has a REASONABLE BELIEF that the food is adulterated or presents the threat of serious adverse health consequences or death to humans or animals. If the inspector has such a belief, he is entitled to review all records relating to manufacture, processing, packing, distribution, receipt, holding, or importation. In the event that an inspector should make a request under the Bioterrorism Act, the Vice President, Operations or Manufacturing, the Quality Control Manager and Sandra Morar at McGrath, North, Mullin & Kratz should be contacted immediately.

Questions pertaining to any other item not outlined above are to be referred to the Legal Department, Irvine, for answer. In an emergency or if the Legal Department is unavailable, refer questions to Sandra Morar at McGrath, North, Mullin & Kratz in Omaha.

D. Scope of inspection FOR LOW-ACID FOOD PRODUCTION

In addition to the rights in C.1. above, the inspector is entitled to:

1. Upon written request - The inspector may inspect and copy any and all records of processing, deviation in processing, container closure inspections, and other records which we are required to keep under Part 113 (low-acid GMPs).
2. Upon written demand - "any information" concerning processes and procedures which is deemed necessary "by the inspector to determine the adequacy of the process." Whenever possible, supply this information verbally. If the inspector starts to give you a written demand to see policies, procedures or other records (not covered by Paragraph 1. above), attempt to question the inspector to try to get him to be as specific as possible before he writes out the request. In some cases, only a small part of a procedure is all he is interested in. Once the inspector has given a written demand, give the information either verbally or in a written summary, or by showing him that part of any documents, policies or procedures that he is specifically interested in and that would go to "determining the adequacy of the process." The inspector may take notes but may not take a photocopy of the policy or record unless it is covered by Paragraph 1. above.

Any time we receive a written demand for the information or records described in Paragraphs 1. and 2. above, a letter (Attachment IV) should be given to the inspector and mailed by certified mail return receipt requested to the FDA district office.

- E. In every case, FDA inspectors are entitled to examine and copy records of interstate shipment, and state inspectors are entitled to examine and copy records of intrastate shipments, if the request is in writing. Always insist on a request in writing.

III. SUMMARY PROCEDURE FOR REGULATORY AGENCY INSPECTIONS. (Continued)

- F. Following an inspection, there should be a meeting with the inspector and Plant and QC Managers, or the representatives who accompanied the inspector, for the purpose of reviewing the inspector's findings. A complete report of the inspection is to be made by the Plant Manager, with appropriate copies to Legal, Production and QC personnel as soon as possible.
- G. In the event that an FDA inspector calls after "normal" working hours (8 a.m. to 5 p.m.), the Plant Manager and the Quality Control Manager must be notified immediately.

The Plant Manager and/or the Quality Control Manager may then designate a representative or may request that the FDA inspector wait until they arrive at the plant before beginning the inspection.

All inspectors are to be treated courteously, answering all questions they are entitled to know, referring all others to the Corporate Office, Irvine. Answer only to direct questions; never volunteer information or elaborate on answers beyond the basic question. Do not sign any documents unless it is a simple acknowledgment that samples came from a particular batch.

In the event that the FDA inspector makes a demand, i.e., destruction of merchandise, inspection of records, right to question plant personnel (other than Plant Manager, Quality Control Manager or designated representatives) which is not within the inspector's authority, the following people should be contacted immediately.

In the case of Canneries:

Vice President, Supply Chain - or -
Vice President, Operations or Manufacturing
Legal Department, Irvine

This procedure MUST be reviewed by everyone likely to be involved in inspections.

NOTE: Under California law, a State inspector has a very broad right of inspection, including certain plant records. (See page 15 on State Inspection procedures.) Also note procedure on photographs during California and Wisconsin inspections. (See pp. 14 and 18)

IV. INSPECTION OF FACTORIES AND WAREHOUSES BY FEDERAL FOOD AND DRUG INSPECTORS

The Secretary of the Department of Health, Education and Welfare is charged with the responsibility of administering the Federal Food, Drug and Cosmetic Act. For the purposes of enforcement of the Act, officers or employees duly designated by the Secretary are authorized by law to perform certain acts. The Secretary has appointed the Food and Drug Administration and the employees therein to enforce the Act. One of the responsibilities of the Food and Drug Administration (FDA) is to enter and inspect factories, warehouses or establishments in which food, drugs, devices or cosmetics are manufactured, processed, packed or held for introduction into Interstate Commerce or held after such introduction. The FDA also has the responsibility and right to enter any vehicle being used to transport or hold such commodities in Interstate Commerce.

Entry and inspection may be done only at the following times and in the following manner:

- A. To enter at reasonable times (during working hours).
- B. To inspect at reasonable times and within reasonable limits and in a reasonable manner.

Inspection generally consists of the inspection of all pertinent equipment, finished and unfinished materials, containers and labeling therein.

- C. A separate notice must be given for each such inspection.

Such written notice may be given by the FDA inspector at the time he presents his credentials to the owner, operator or agent in charge of the factory or warehouse. A sample of the general form of notice of factory inspection is attached hereto as Attachment I, page 22.

- D. The inspector must also present his credentials at the time of his request to inspect.

Inspector's credentials consist of a small card showing his connection with the FDA as an inspector.

- E. Each inspection must be commenced and completed with reasonable promptness.

- F. At the conclusion of each inspection, the inspector is required to give a report of inspection to the Plant or Warehouse Superintendent in general form, substantially as shown in Attachment II, page 23.

DO NOT CONFUSE FACTORY OR WAREHOUSE INSPECTION WITH:

EXAMINATION AND COPYING OF RECORDS OF INTERSTATE SHIPMENT BY FEDERAL FOOD AND DRUG INSPECTORS, AND OF INTRASTATE SHIPMENT BY STATE INSPECTORS.

IV. INSPECTION OF FACTORIES AND WAREHOUSES BY FEDERAL FOOD AND DRUG INSPECTORS (Continued)GENERAL INSTRUCTIONS:

Whenever a person presents himself at a factory gate or warehouse entrance and requests that he be permitted to inspect the factory or warehouse, the Plant Manager or Warehouse Manager, as the case may be, should be notified immediately. The individual should be denied entrance onto the premises except on the authority of the Plant or Warehouse Manager or, in that person's absence, the next person in authority.

Upon receiving notice that an inspector is at the plant or warehouse entrance, the Plant Manager should immediately interview the individual for the purpose of determining his authority to make such an inspection.

First, the inspector should be requested to show appropriate credentials.

Second, the inspector should be requested to produce a written notice of inspection. Such written notice of inspection should be in the same general form as Attachment I.

If the purported inspector does not have credentials, he should be denied entry into the plant or warehouse proper. If the notice of inspection is not in the same general form as notice attached, the purported inspector should be denied entry into the plant or warehouse.

If entry is denied, give the inspector the exact reason for denying entry; i.e., that the inspector does not have credentials or has not shown the written notice of inspection. At this time, request the purported inspector to give the following information:

- G. Name;
- H. The address and phone number of the FDA office he purports to represent; and
- I. The name of the person in charge of that office or a person in that office who can be contacted by the company.

The inspector who does not have proper credentials should be requested to remain until the Plant Manager has had an opportunity to communicate with the corporate office at Irvine and that office has had an opportunity to communicate with the FDA office.

Immediately telephone the Irvine Legal Department, giving full details of all information received from the inspector. The Legal Department will contact the FDA office and relay further instructions to the Plant Manager as quickly as possible. It should be noted that, due to differences in time, the Plant Manager may not be able to contact the Legal Department immediately. In such event, contact the Vice President, Supply Chain[1]. If this individual is unavailable, then contact the following: If a factory or warehouse, contact your Vice President of Operations or Manufacturing. If the Warehouse is a distribution warehouse, contact the Supply Chain Director. On receiving the report, one of the above individuals will contact a member of the legal staff. Further instructions will be received by the Manager from a member of the legal staff.

[1]Refer to Attachment VII for phone numbers.

IV. INSPECTION OF FACTORIES AND WAREHOUSES BY FEDERAL FOOD AND DRUG INSPECTORS.(Continued)

GENERAL INSTRUCTIONS: (Continued)

After the Plant Manager has ascertained that the credentials of the inspector are in order and that the notice of inspection is proper, or has received instructions from the Legal Department to permit the inspector to enter, the Plant Manager and the Quality Control representative should personally escort the inspector through the plant or warehouse. It would be well for the Plant Manager to have an assistant present at all times during the inspection for the purpose of observing inspection procedures so that more than one person in the plant or warehouse will be familiar with the activities of an inspector during factory or warehouse inspections.

There will be occasions when the inspector will be accompanied by an assistant or a superior officer. Attempt to keep the inspectors in a group. Do not permit one to wander unaccompanied by a responsible company employee.

Since the law requires the inspection to be within reasonable limits, comment will not be made with regard to the scope of inspection. Naturally, every minute phase cannot be covered and the Plant Manager must use some "feel" in the course of the inspection. As a rule of thumb, it can be stated that the inspector will generally request to see much more than is authorized by law.

The law is not intended to authorize a "fishing expedition" into private papers such as books and records, financial accounts, laboratory records, ordinary personnel records or payrolls. The law is intended to provide the FDA with sufficient inspection authority to protect the public. Basically, the inspection procedure is a visual inspection.

Although the inspector is not authorized to demand secret formulae and the like, he may demand a list of ingredients contained in the finished product. The inspector can request such information for the purpose of proving falsity of claims made for the product in question and for other legitimate purposes. (This information may be made available through the factory Quality Control Department.)

The inspector may inquire whether the person in charge of safety controls is qualified by training and experience, but he cannot inquire into that person's entire life history by an examination of his personnel records.

The inspector has no authority to order destruction of merchandise.

The inspector may attempt to bring a camera or recording equipment onto the premises and may or may not request permission to do so. The law does not require that inspectors be allowed to take photographs or record conversations and consequently this right should be politely refused. If the inspector persists, ask him to submit a written request to the Legal Department in Irvine.

IV. INSPECTION OF FACTORIES AND WAREHOUSES BY FEDERAL FOOD AND DRUG INSPECTORS (Continued)

GENERAL INSTRUCTIONS: (Continued)

The inspector has the right to obtain samples in the course of his inspection, but upon completion of inspection and prior to leaving the premises, he must give a receipt describing the samples obtained. The general form of receipt for samples prepared by FDA for use by its inspectors is shown on Attachment III, page 24. When an inspector takes samples during the course of his inspection, like samples should be taken by the person accompanying the inspector. Specific sampling instructions are outlined in Table I. The law provides that the results of analyses made on samples taken during an inspection be promptly furnished to the owner/operator of the plant. At the time the samples are taken, advise the inspector of the name of the plant Quality Control Manager who should receive the "Report of Analysis." Samples should be turned over to the Plant Quality Control Manager and will be held by him until receipt of further instructions. If no instructions are issued, samples may be disposed of after being held twelve months.

SCOPE OF INSPECTION FOR OTHER THAN LOW-ACID PRODUCTION:

For other than inspection of low-acid food production, the warehouse or factory inspection is a visual inspection. The inspector's questions regarding equipment which he is inspecting or which he desires to inspect should be answered politely and briefly. Questions regarding qualifications of personnel operating technical equipment should be answered politely and briefly. Questions involving company policy, volume of pack, codes, places of shipment, customers and other questions not calculated to aid the inspector in his visual inspection of the factory or warehouse should not be answered. He should be notified politely that the request for information regarding these matters should be referred in writing to the Corporate Office at Irvine, California.

If the inspector appears to be adamant in any request which the Plant Manager believes to be unreasonable, and for that reason was not given or answered, the Plant Manager should, at the conclusion of the inspection, invite the inspector into his office and at that time telephone the Irvine Legal Department. He will be instructed further at that time. In the event inspection is completed before or after Irvine office hours, contact the Vice President, Supply Chain. If this individual is unavailable, then contact the following: If a factory or warehouse, contact your Vice President of Operations or Manufacturing. If the warehouse is a distribution warehouse, contact the Supply Chain Director. Upon receiving the report, one of the above individuals will contact a member of the Legal Department. Further instructions will be received from the Legal Department.

SCOPE OF INSPECTION - PRODUCTION OF LOW-ACID FOODS

Under 21 C.F.R. Part 108 - Emergency Permit Control Regulations covering the thermal processing of low-acid foods in hermetically sealed containers, the scope of inspection is much broader than for other foods.

When requested by an FDA official in writing, a commercial processor engaged in the processing of low-acid foods shall provide "any information" concerning processes and procedures which is "deemed necessary" by the FDA to determine the adequacy of the process. This request may be made in writing by the inspector on the spot or it can be made by telephone and confirmed by a telegram or letter. (If the request is made by telephone, start assembling the information, but do not release it until the telegram or letter is received.) Be sure to retain the written demand.

IV. INSPECTION OF FACTORIES AND WAREHOUSES BY FEDERAL FOOD AND DRUG INSPECTORS (Continued)

SCOPE OF INSPECTION - PRODUCTION OF LOW-ACID FOODS (Continued)

Further, upon written demand, the FDA official has the right to inspect and copy any and all records of processing, deviations in processing, container closure inspections and other records which we are required to keep under Part 113 of the regulations (low-acid GMPs). Always insist that this request be in writing and be sure to retain a copy of the request in your file.

NOTE: Only the records mentioned in the preceding paragraph (and interstate or intrastate shipment records) may be copied or photocopied upon written request. If the inspector gives you a written demand for information he "deems necessary to determine the adequacy of the process" that involves information not found in these records, provide this information (after consultation with Irvine), if at all possible, either verbally or in a written summary. If the information he requests can be found in one or more of our policies or records not covered by the preceding paragraph and he insists on seeing it, try to get the inspector to be specific about the portion he is interested in. Show him that portion only, and while he may make personal notes, do not allow him to photocopy these documents. If the inspector asks to see a copy of our Recall Procedure, tell him this will be provided by Irvine upon written request.

In every case where records are inspected and copied by an FDA official: 1) Give him a copy of the letter (Attachment IV), asking him to sign the acknowledgment. (The inspector may refuse. If he does, just give him the copy.) 2) Send the same letter (Attachment IV) to the District FDA office by certified mail, return receipt requested. Keep a copy of the letter and the receipt in your file.

The inspector should be treated politely and courteously at all times and be shown through the factory or warehouse in a reasonable, courteous and casual manner. Remember always that any showing of hostility or reluctance to permit reasonable inspection will cause the inspector to be far more critical and detailed in the inspection and lead to a possible strain in the relations between the local FDA office and the company.

DO NOT VOLUNTEER INFORMATION OR SIGN ANYTHING

Upon the conclusion of the inspection, if defects are noted, the inspector is required to submit a inspection report. The Plant or Warehouse Manager should always request a copy of the inspection report if the inspector does not offer to give it. Inspection report generally takes the form as shown in Attachment II. When the inspector has observed no defects, the inspector will not prepare a report.

The law does not require the signing of any document, but it is usually not objectionable to sign an acknowledgment that samples came from a particular batch or an acknowledgment that an inspection was made. Outside these exceptions, do not sign any document without prior authority from the Legal Department in Irvine.

IV. INSPECTION OF FACTORIES AND WAREHOUSES BY FEDERAL FOOD AND DRUG INSPECTORS (Continued)

SCOPE OF INSPECTION - PRODUCTION OF LOW-ACID FOODS (Continued)

Immediately after the conclusion of the factory or warehouse inspection, the Plant Manager should prepare a written report, setting forth in detail all that transpired during the inspection. The report should indicate action taken or proposed in connection with points outlined in the inspector's report. The Plant Manager should also attach copies of any documents left by the inspector. The report should carefully note any comments the inspector made during the inspection. In the case of the Operations Division, forward copies of the report with Attachment IX as a cover sheet to the appropriate Vice President of Operations or Manufacturing, Vice President Supply Chain, the Legal Department, Supply Chain Director and Quality Control Manager and in the case of a Distribution Warehouse, forward copies of the report to Supply Chain Director, Legal Department and Quality Control Manager. Additional internal distribution may be directed in departmental supplements to this procedure. Send a copy of Attachment IX to the Senior Vice President, Technology.

In the event that defects have been noted, the Plant Manager should respond to the FDA in writing, setting forth any changes which are to be made or have been made in accordance with the inspection. In the case of future changes, a follow-up letter should be written once changes have been made. All such correspondence must be reviewed with the Legal Department prior to sending it out.

V. EXAMINING AND COPYING OF RECORDS OF INTERSTATE SHIPMENT BY FEDERAL FOOD AND DRUG INSPECTORS

Carriers engaged in interstate commerce and persons receiving food, drugs, devices or cosmetics in interstate commerce, or holding such articles so received, are required, at the request of an FDA inspector, to permit the inspector to have access to and copy records showing the movement in interstate commerce of such merchandise or the holding thereof during or after the movement, including the quantity, shipper and consignee thereof.

Inspection and copying of records of interstate shipment may be done only at the following times and in the following manner:

- A. At reasonable times (during working hours).
- B. A request to examine and copy records of interstate shipment must be accompanied by a statement in writing specifying the nature or kind of food, drug, or device or cosmetic to which such request relates.

Whenever an inspector requests permission to examine and copy records of interstate shipment in a factory or warehouse, the Plant Manager should require an inspector to present the written statement specified above before permitting examination and copying of records. Only those records specifically requested in writing should be produced for examination and copying. If at all possible, contact the Irvine Legal Department before permitting the inspector to examine and copy records, but do not unreasonably delay him to a point where he can be considered to have been denied permission to have access to and copy the records so requested. If before or after Irvine office hours, contact the persons designated in III.G. page 5.

V. EXAMINING AND COPYING OF RECORDS OF INTERSTATE SHIPMENT BY FEDERAL FOOD AND DRUG INSPECTORS (Continued)

In connection with records of interstate shipment, do not volunteer information. Let the records speak for themselves. Refer any questions the inspector may have to the Legal Department at Irvine. All records examined by the inspector should be duplicated at the conclusion of inspection and should, together with any other documents examined by the inspector, be attached to a written report prepared by the Plant Manager, setting forth in detail all that transpired during the inspection. Reports should be submitted in the same manner as in factory and warehouse inspections on page 10.

VI. INSPECTION OF FACTORIES AND WAREHOUSES BY FEDERAL DEPARTMENT OF AGRICULTURE INSPECTORS

- A. Representatives of the Department of Agriculture will inspect plant or warehouse premises or merchandise or other items therein only upon request by the Company. The Plant and Warehouse Manager will be notified in advance of any such arrangement made by the Company.

Reports should be submitted in the same manner as in factory and warehouse inspections on page 10.

- B. Inspections and re-inspections at our meat processing plants by the USDA Inspector in Charge (I. C.) are not within the scope of this procedure. Routine contacts with the I.C. are best handled by Plant Management. If non-routine issues arise, contact the Irvine Legal Department for guidance.
- C. Occasionally the USDA's Food Safety and Inspection Service (FSIS) may request access to the plant for the purpose of examination and inspection to prevent the use in commerce of any adulterated product. This investigation will be conducted by the field Compliance Officer(s) (CO) in two types of enforcement procedures: criminal investigations and HACCP enforcement.

VI. INSPECTION OF FACTORIES AND WAREHOUSES BY FEDERAL DEPARTMENT OF AGRICULTURE INSPECTORS (Continued)

C. Continued

1. A criminal investigation begins when the FSIS has reason to believe a company has violated the law. This belief may arise from a complaint by a disgruntled employee, a customer, a competitor, USDA inspection personnel, or a State official. The investigation is conducted by the field CO, who will attempt to ascertain the facts by using statements from relevant individuals, company records and if applicable, laboratory analysis. If a CO arrives at the plant with proper identification and announces the purpose of the visit is an actual or potential criminal investigation, the Plant must immediately contact the Legal Department for instructions and advice concerning legal representation. Once approval has been obtained from the Legal Department the following guidelines will be followed:
 - a. If a request is made to speak to an employee by a government official, the interview should be on company time and on the company premises.
 - b. A company representative will request to be present in any interview with an employee to ensure the employee does not accidentally divulge privileged information.
 - c. All written statements must be reviewed by Sandra Morar at McGrath, North, Mullin & Kratz before they are signed.
 - d. The CO has the same records access authority as the IIC, however, the Legal Department should be notified of the nature of the request to ensure that trade secrets or confidential commercial documents can be identified to the CO.
 - e. The CO should be accompanied by a company representative while at the plant (the same as a FDA inspector).
2. Enforcement actions under HACCP are handled differently than compliance cases. Although compliance is involved, CO's should play more of a supporting role to inspection personnel. The IIC will provide notice to the plant during the weekly meetings if there is a system failure caused by repetitive deficiencies. If the IIC's concerns are not addressed he can then contact the District Office. The District Manager (DM) will review the matter and most likely send out a CO to the plant to investigate. If the DM believes that there is a system failure due to either the shipment of adulterated product or a referral from the IIC, the DM will notify the plant in writing of the Agency intent to take enforcement action and provide the plant an opportunity to either show that a system failure has not occurred or to present a preventative action plan.

VI. INSPECTION OF FACTORIES AND WAREHOUSES BY FEDERAL DEPARTMENT OF AGRICULTURE INSPECTORS (Continued)

C. 2. (Continued)

A diligent effort should be made to cooperate with the IIC so the CO does not get involved. However, there may be times, especially when the matter involves a factual dispute with the IIC whether direct product contamination is occurring, when the company cannot avoid contact with the CO. In this case the plant should ensure that the Corporate HACCP team and the Legal Department are aware of the dispute and agree with the plant's position prior to the issue being taken to the DM by the IIC. If a CO arrives at the plant with proper identification and announces that the purpose of his visit is to investigate HACCP deficiencies, the Legal Department must be notified and the guidelines in section 1 above must be followed.

Any records copied by the inspector should be duplicated and attached to the written report prepared by the plant manager in the same manner as in the factory and warehouse inspections on page 10.

VII. ENTRY INTO FACTORIES AND WAREHOUSES BY FEDERAL IMMIGRATION AUTHORITIES

At certain locations, the immigration authorities, due to a prevalence of illegal entry the United States, are very active. The immigration authorities can enter private premises without a warrant within a distance of 25 miles from any external boundary of the United States for the purpose of patrolling the border to prevent the illegal entry of aliens into the United States. Other entry onto private premises would appear to be prohibited without a warrant.

GENERAL INSTRUCTIONS:

If immigration authorities present themselves at plant or warehouse premises, the Plant Manager should immediately be notified. The Plant Manager should first determine whether or not the purported immigration authorities have credentials. Secondly, the Plant Manager should determine whether or not the authorities are attempting to enter with or without a warrant. If no warrant is presented, the Plant Manager should detain the authorities and immediately contact the Legal Department. In the event the request for entry is made before or after Irvine office hours, contact the Vice President Supply Chain. If this individual is unavailable, then contact one of the following persons. If a factory or warehouse, contact your Vice President of Operations. If the warehouse is a distribution warehouse, contact Supply Chain Director. Upon receiving the report, one of the above individuals will contact a member of the legal staff. Further instructions will be received by the Plant Manager from a member of the legal staff.

In a case where immigration authorities have a warrant for the arrest of an individual and that individual is on the plant premises, the Plant Manager should cooperate with the authorities, but the arrest should be made as quickly and quietly as possible. Attempt to get the person to be arrested out of the general plant or warehouse area. If at all possible, the arrest should be made out of the sight of the other employees.

Although immigration authorities should be given every courtesy and the fullest cooperation, every attempt should be made to limit the scope of their activities on the premises.

VIII. INSPECTION OF FACTORIES AND WAREHOUSES BY STATE AND LOCAL INSPECTORS

State inspectors carry out the same type of inspection as federal inspectors. Inspections by state and local inspectors should be generally treated in the same manner as inspections by Federal Food and Drug Administration inspectors.

Specifically, state inspectors have the right to examine and copy records of intrastate shipments, identical to the right of Federal FDA inspectors to examine and copy records of interstate shipments as outlined in V. B., page 10.

Remember, however, that certain state inspectors do have the right to inspect retort and other records in connection with supervised packs.

Always limit the records you furnish for examination to those specifically requested and do not volunteer any records or information.

Any records copied by the inspector should be duplicated and attached to the written report prepared by the Plant Manager and submitted in the same manner as in factory and warehouse inspections on page 10.

A. CALIFORNIA

In California, foods are regulated by the state's Sherman Food, Drug and Cosmetic Law, which is administered by the California Department of Health Services.

Plants operating under the California Cannery Inspection Act have daily visits when operating on low-acid and pH controlled products, since they are required to check processing records and the operations before release of merchandise. All State inspectors carry identification but do not have factory inspection forms. Arrangements are usually made for access of inspectors without the usual formalities when the plant is operating under the California Cannery Inspection Act.

The California law on factory inspections is broader than the federal law. In California, inspectors have the right to "inspect all records, files, papers and processes which have a bearing on whether or not the food is adulterated, misbranded, or falsely advertised." Thus, they do have the right to see batch production records and formulae, for example, without submitting a written request. Attempt to contact the Legal Department in Irvine for guidance prior to inspection of any records. They are not entitled to:

1. Financial data
2. Sales data
3. Pricing data
4. Personnel data, except generally as to qualifications of technical and professional personnel.

VIII. INSPECTION OF FACTORIES AND WAREHOUSES BY STATE AND LOCAL INSPECTORS (Continued)

B. CALIFORNIA (Continued)

California inspectors are required to take the position that they have the right to take photographs of significant violations, while making an inspection. If an inspector requests the right to take photographs, tell him he may do so if he insists that he has the legal right to do so. Once the inspector advises you that it is the Department of Health's position that they have the legal right to take photographs, give him a copy of the letter (Attachment V) and allow him to proceed with the picture taking. Ask him to sign the acknowledgment, showing that he received the copy. (If he refuses, just hand it to him.) A second copy of the letter (Attachment V) is to be sent by certified mail to the State of California Department of Health, Attention: Chief, Food and Drug Branch, 714 P Street, Sacramento, California 95814.

The inspectors are only supposed to photograph specific alleged violations. When the inspector takes a picture, ask him what the alleged violation is and make a note of it. Then take your own photograph or photographs of the same alleged violation as well as the general area to get a broader view for perspective. At the conclusion of the picture taking, ask the inspector to send you copies of his photographs. They will do this and bill you for the cost of the copies.

California inspectors have the right to obtain samples during inspections, but upon completion of inspection and prior to leaving the premises, the inspector must give a receipt describing the samples obtained. When an inspector takes samples during the course of his inspection, like samples should be taken by the person accompanying the inspector. Samples should be turned over to the Plant Quality Control Manager and will be held by him until receipt of further instructions. If no instructions are issued, samples may be disposed of after being held twelve months. After the inspection is completed, a written request should be made for the results of analyses made on samples obtained. See Attachment VI, for letter to be sent to the appropriate regional office.

When you are requested to sign the "Report of Observations" form prepared by the inspector at the completion of his inspection, add the words "Copy Received" above your signature.

Company representatives accompanying these inspectors should take notes of the inspector's comments as the inspection is being made. Reports should be submitted in the same manner as in factory and warehouse inspections on page 10.

B. GEORGIA

Food in Georgia is regulated under the state's Food Act administered by the Department of Agriculture.

The inspector shall have free access at all reasonable hours to any factory, warehouse or establishment in which food is manufactured, processed, packed or held for introduction into commerce and any vehicle being used to transport such foods for the purpose of (1) inspecting such factory, warehouse, establishment or vehicle; and (2) of securing samples of any food after offering to pay for such samples. There is no right to inspect or copy records.

VIII. INSPECTION OF FACTORIES AND WAREHOUSES BY STATE AND LOCAL INSPECTORS (Continued)C. ILLINOIS

In Illinois, foods in commerce are regulated under the state's Food, Drug & Cosmetic Act, administered by the state's Director of Public Health.

For purposes of enforcement of this Act, inspectors, upon presenting appropriate credentials and a written notice to the Plant or Warehouse Manager, are authorized (1) to enter at reasonable times any factory, warehouse or establishment in which foods are manufactured, processed, packed or held for introduction into commerce and (2) to inspect at reasonable times and within reasonable limits and in a reasonable manner such factory, warehouse, establishment or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling. There is no right to inspect or copy records, except that records regarding the movement of a product in commerce must be provided after a request to inspect those records is made in writing.

Upon completion of the inspection, and before leaving the premises, the inspector shall give a written report to the Plant or Warehouse Manager that sets forth any practices observed by him which in his judgment indicate that any food may have become contaminated or rendered injurious to health. A copy of such report shall be sent promptly to the Director of Public Health.

If the inspector has obtained any samples, he shall give a receipt describing the samples obtained before leaving. If an analysis is made of such samples, a copy of the results shall be furnished promptly.

D. MINNESOTA

Food in commerce in Minnesota is regulated under the Minnesota Food Law, administered by the state's Department of Agriculture.

For purposes of enforcement of the Minnesota food law, an inspector, upon presenting appropriate credentials, is authorized to (1) enter at reasonable times any factory, warehouse or establishment in which food is manufactured, processed, packed or held for introduction into commerce or to enter any vehicle being used to transport such food; (2) to inspect at reasonable times and within reasonable limits and in a reasonable manner such establishment or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling; and to obtain samples; and have access to and to copy all records of carriers in commerce showing the movement, the quantity, shipper and consignee. There is no right to inspect or copy other records.

At the conclusion of the inspection, and prior to leaving, the inspector shall give a written report setting forth any conditions or practices observed by him which in his judgment indicate that a food may have become contaminated or rendered injurious to health. A copy of such report shall be sent promptly to the Commissioner of Agriculture. If the inspector took any samples, he shall give a receipt to the Plant or Warehouse Manager. If any analysis is made of any samples taken, a copy of the result of such analysis shall be promptly furnished.

VIII. INSPECTION OF FACTORIES AND WAREHOUSES BY STATE AND LOCAL INSPECTORS (Continued)E. MISSOURI

In Missouri, the laws governing food are administered by the state's Department of Health and Senior Services.

Inspectors shall have free access at all reasonable hours to any factory, warehouse, or establishment in which foods are manufactured, processed, packed, or held for introduction into commerce, or to enter any vehicle used to transport or hold food. The inspector may also secure samples or specimens of food after offering to pay for the samples. The samples will be examined to determine whether the food is adulterated or misbranded. The inspector, after providing a specific written request, may have access to and copy all records showing the movement of goods in commerce, including the quantity, shipper, and consignee.

F. OHIO

In Ohio, foods are regulated under the state's Pure Food and Drug Law by the Director of Agriculture.

The inspector shall have free access at all reasonable hours to any factory, warehouse, or establishment in which foods are manufactured, processed, packed or held for introduction into commerce, or to enter any vehicle being used to transport such food for the purpose of (1) inspecting such establishment or vehicle; and (2) to secure samples or specimens of any food after offering to pay for the samples or specimens. The samples shall be examined to determine whether or not any provisions of the Pure Food and Drug Law are being violated. There is no right to inspect or copy records.

G. PENNSYLVANIA

Pennsylvania law governing adulteration and misbranding of food is administered by the state's Department of Agriculture.

Inspectors have free access at reasonable hours to enter a food establishment or a vehicle used to transport food for the purpose of (1) inspecting such establishment or vehicle and (2) securing samples or specimen of food. The inspector is authorized to seize any food that is suspected of being adulterated or misbranded. There is no right to inspect or copy records.

H. TENNESSEE

Foods in Tennessee are regulated under a basic act administered by the state's Commissioner of Agriculture.

Inspectors shall have free access at all reasonable hours to any factory, warehouse or establishment in which foods are manufactured, processed, packed or held for introduction into commerce, or to enter any vehicle being used to transport such foods for the purpose of (1) inspecting such establishment or vehicle; and (2) to secure any samples or specimens after offering to pay for such samples. The samples shall be examined to determine whether or not provisions of the statute are being violated. Inspectors have the right to inspect and copy intrastate shipment records. Always ask that this request be put in writing before producing the shipment records. Inspectors do not have the right to inspect or copy any other records.

VIII. INSPECTION OF FACTORIES AND WAREHOUSES BY STATE AND LOCAL INSPECTORS (Continued)

I. TEXAS

Foods in Texas are regulated under a basic statute administered by the state's Commissioner of Health.

An inspector shall have free access at all reasonable hours to any factory, warehouse or establishment in which foods are manufactured, processed, packed, stored or held for introduction into commerce, or to enter any vehicle being used to transport such foods for the purpose of (1) inspecting such establishment or vehicle and (2) taking samples or specimens of any food after offering to pay for such samples. The sample must be examined to determine whether or not any provision of the statute is being violated. Whenever samples are taken, an equal amount of the product sampled may, upon request, be given to the Plant or Warehouse Manager. There is no right to inspect or copy records except that a person receiving or holding food in commerce must permit an agent access to and the copying of records showing movement in intrastate commerce after such a request is made in writing.

J. WISCONSIN

Food in Wisconsin is subject to statutory provisions administered by the state's Department of Agriculture.

For the purpose of enforcing the statutory provisions, an inspector may, at reasonable hours, enter and inspect any farm, factory, warehouse, building or establishment where foods are manufactured, processed, packed, stored or held for sale, and may enter any vehicle used to transport the foods. The inspector may also secure samples or specimens of food and any product or substance that may affect food, examine and copy relevant documents and records, and obtain photographic and other evidence needed to enforce the statute.

IX. INSPECTION OF FACTORIES AND WAREHOUSES BY U.S. ARMY VETERINARY CORPS

Inspections by the U.S. Army Veterinary Corps should be generally treated in the manner as inspections by Federal Food and Drug inspectors. These inspections usually follow along sanitation lines for plant approval under government purchasing requirements.

Reports should be submitted in the same manner as in factory and warehouse inspections on page 10.

X. REGULATORY VISIT FOR NET WEIGHT COMPLIANCE (FEDERAL, STATE OR LOCAL)

When visited by one of the above regulatory agencies for net weight compliance, the visit should be handled in the same manner as a Food and Drug inspections. Your written report should be the same as detailed on factory and warehouse inspection on page 10 and include Attachment IX.

This attachment is intended to further detail the manner samples were secured, especially if the inspector did not take them in a random sequence.

XI. SAMPLING OF RAW PRODUCTS OR BY-PRODUCTS USED FOR ANIMAL FEED FOR PESTICIDE RESIDUES BY FEDERAL FOOD AND DRUG INSPECTORS OR STATE INSPECTORS.

Food and Drug Administration inspectors or a State Inspector may present themselves at plants and field receiving stations for the purpose of obtaining samples of raw products or by-products used for animal feed. The purpose of this sampling is for analysis of pesticide residues. At the time the samples are taken, advise the inspector of the name of the Plant Quality Control Manager who should receive the "Report of Analysis." Samples should also be taken by the person accompanying the inspector as specified in Table I (pages 20 and 21).

Notice of sampling should be given immediately to the Quality Control Manager, and the shipment from which the sample was taken shall be handled in the manner directed. Your written report should be the same as detailed in the Factory and Warehouse Inspection section on page 10.

XII. SAMPLING OF FINISHED PRODUCT FOR PESTICIDE RESIDUES BY FEDERAL AND STATE AGENCIES

Food and Drug Administration or a State Inspector may present themselves at plants for the purpose of obtaining samples of finished product. If the purpose of this sampling is for analysis of pesticide residues at the time the samples are taken, advise the inspector of the name of the Plant Quality Control Manager who should receive the "Report of Analysis." Samples should also be taken by the person accompanying the inspector as specified in Table I.

Notice of sampling should be given immediately to the Quality Control Manager and the lot from which sample was taken shall be handled in the manner directed. Your written report should be the same as detailed in the Factory and Warehouse Inspection section.

XIII. DUPLICATE SAMPLING INSTRUCTIONS (See Table I)

In the event a Regulatory Agency takes samples, duplicate samples must always be taken, following the plan outlined in Table I.

All product which is sampled by a Regulatory Agency must be placed on hold. Notify the Supply Chain Director with the identity of the affected lot.

In the event a records examination reveals an out-of-specification incident of significance to a Regulatory Agency, or codes of product are recorded for the same reason, the product involved should be placed on hold and the Supply Chain Director notified immediately.

TABLE 1. DUPLICATE SAMPLING INSTRUCTIONS

| <u>Reason for Sampling</u> | <u>Duplicates Required*</u> | <u>Q.C. Action[1]</u> | <u>Other Action</u> |
|--------------------------------------|-----------------------------|-----------------------------|---|
| <u>FINISHED PRODUCT</u> | | | |
| Mold | 12 samples | Analyze 6 samples[2] | Forward 6 samples to MAL |
| Extraneous or other foreign material | 12 samples | Analyze 6 samples | Forward 6 samples to MAL |
| Weights | 1/sample drawn | Weigh samples | - - - |
| Rot | 12 samples | Analyze 6 samples | Forward 6 samples to MAL |
| Rodent and Insect Infestation | 12 samples | Analyze 6 samples | Forward 6 samples to MAL |
| Chemical Residue | 12 samples | Contact Product Disposition | Retain remaining samples |
| Bacteriological Frozen Foods | 12 samples | Analyze 6 samples | Freeze remaining samples |
| Unknown | 12 samples | Retain Samples | - - - |
| Aflatoxin | 12 samples | Analyze 6 samples | Forward 6 samples to approved outside Lab. Retain remaining samples. |

[1] Place product representing the production period sampled on hold and submit a C-2 to Product Disposition.

[2] Count 100 fields per sample per HM009.

*Duplicate samples should be retained for a period of 12 months.

MAL = Microanalytical Laboratory

TABLE I. DUPLICATE SAMPLING INSTRUCTIONS (CONTINUED)

| <u>Reason for Sampling</u> | <u>Duplicates Required*</u> | <u>Q.C. Action[1]</u> | <u>Other Action</u> |
|---|-----------------------------|-----------------------------|---|
| <u>INGREDIENT, RAW MATERIALS, OTHER</u> | | | |
| Extraneous or other foreign material | 3# sample | Analyze 3 composite samples | Forward remaining samples to MAL |
| Rot/Mold | None | Record regulatory results | - - - |
| Rodent and Insect Infestation | 3# sample | Analyze 3 composite samples | Forward remaining samples to MAL |
| Chemical Residue | 5# sample | Contact Product Disposition | Freeze remaining samples |
| Geotrichum | Obtain duplicate | Analyze duplicate | Refrigerate remaining sample and notify MAL |
| Bacteriological | 5# sample | Analyze 3 composite samples | Retain remaining samples |
| Unknown | 5# sample | Retain sample | - - - |

[1] Place product representing the production period sampled on hold and submit a C-2 to Product Disposition.
*Duplicate samples should be retained for a period of 12 months.
MAL = Microanalytical Laboratory

ATTACHMENT IV

GI012
Page 27

Date _____

TO: Food and Drug Administration

We acknowledge receipt of your written request dated: _____
for information or to inspect and copy records pursuant to 21 C.F.R. 108.35 (c) and (h) purportedly
issued on the authority of Section 404 of the Federal Foods, Drug and Cosmetic Act. We intend to comply
with the regulations by furnishing such information or furnishing for inspection and copying the requested
records of processing, deviations in processing, container closure inspections and other records kept
pursuant to Part 113, but the constitutional right to object to use of any of this information or these records
in any prosecution of a natural person is, however, specifically reserved for the protection of anyone
adversely affected in any appropriate forum pursuant to section 701(e), (f) (1), (3), (4) and (6), or charged
in any such prosecution under Section 303 of the Act, or otherwise as permitted by law.

Signature _____

In California, add the following paragraph:

We further reserve the right to challenge the applicability of the record keeping and request for information
or records provision of Section 108.35 to California facilities in light of Section 108.35 (j).

Copy Received:

By: _____

Date: _____

ATTACHMENT V

Date _____

TO: State of California Department of Health

This is to acknowledge your demand to take photographs of our facility purportedly under the authority of Section 26234 of the California Health and Safety Code. We have complied with your demand but specifically reserve the right to challenge your interpretation of your rights under California law. We further reserve the constitutional right to object to the use of any such photographs as evidence in any prosecution or proceeding.

We claim these photographs to be exempt from the provisions of California Government Code Section 6250 et. seq., "Inspection of Public Records," under Government Code Section 6254 (b) and Evidence Code Section 1060.

Copy Received:

By: _____

Date _____

ATTACHMENT VI

FOR USE IN CALIFORNIA ONLY

Date _____

State of California
Department of Health, Food and Drug Section
2151 Berkeley Way
Berkeley, CA 94704

State of California
Department of Health, Food and Drug Section
1449 West Temple Street
Los Angeles, CA 90026

State of California
Department of Health, Food and Drug Section
714/744 "P" Street
Sacramento, CA 95814

To Whom It May Concern:

During an inspection of our facility completed by your department this date, the following described samples were collected, the receipt of which was acknowledged by your inspector on the attached form.

(Briefly describe samples, enclose copy of receipt
for Department's identification)

It is requested that the results of any analyses made on these samples be promptly provided the undersigned.

Very truly yours,

ATTACHMENT VII
COMPANY CONTACTS

Office Telephone Numbers

Vice President Supply Chain

Vice President Operations or Manufacturing

Supply Chain Director

Legal Department, Irvine

Georgia Ingram (949) 437-2230

McGrath, North, Mullin & Kratz, PC, LLO

S. Morar (402) 341-3070

Home Telephone Numbers: A list of home telephone numbers
for the above persons will be maintained in _____

ATTACHMENT VIII

NET WEIGHT - REGULATORY

Net Weight Regulatory Information Form

Date: _____ Plant: _____

Hour: _____ a .m. or p.m. Product: _____

Regulatory Agency: _____

Samples: Taken random - yes _____ no _____

If no, explain how it was taken: _____

Signed _____

ATTACHMENT IX

ConAgra Grocery Products Company

REPORT OF PLANT/WAREHOUSE REGULATORY INSPECTION

PLANT/WAREHOUSE LOCATION: _____

DATE(S): _____ TIME STARTED: _____ ENDED: _____

IRVINE INDIVIDUAL CALLED WHEN INSPECTOR ARRIVED AT PLANT. NAME: _____ TIME: _____

INVESTIGATOR'S NAME(S): _____

PLANT PERSONNEL ACCOMPANYING
INVESTIGATOR(S): _____

TYPE OF INSPECTION: FEDERAL STATE COUNTY CITY

OTHER: _____

AGENCY REPRESENTED: _____

PURPOSE OF INSPECTION: _____

AREAS INSPECTED: _____

INGREDIENTS AND/OR PRODUCTS EXAMINED BY
INVESTIGATOR: _____

SAMPLES TAKEN BY INVESTIGATOR: _____

PURPOSE OF TAKING SAMPLES: _____

CODE OR LOT NUMBER OF DUPLICATE SAMPLES TAKEN BY PLANT
PERSONNEL: _____

(Over)

ATTACHMENT IX (Continued)

DISPOSITION OF DUPLICATE SAMPLES COLLECTED BY PLANT
PERSONNEL: _____

TYPE OF PRODUCT LABELS TAKEN BY INVESTIGATOR: _____

DISPOSITION OF DUPLICATE LABELS TAKEN BY PLANT PERSONNEL: _____

TYPE OF PLANT RECORDS REQUESTED AND SHOWN: _____

PLEASE ATTACH YOUR REPORT OF THE INSPECTION INCLUDING QUESTIONS ASKED AND
ANSWERED,
OBSERVATIONS AND COMMENTS MADE, WHAT ACTIONS YOU HAVE TAKEN AS A RESULT OF
THIS INSPECTION, AND ALL DOCUMENTS LEFT BY THE INVESTIGATOR.

SIGNATURE: _____ DATE _____

NAME: _____

MAIL THIS REPORT AND ALL ATTACHMENTS
TO;

VP OF MANUFACTURING OR VP OF
DISTRIBUTION
VP SUPPLY CHAIN

MAIL A COPY OF THIS REPORT ONLY TO:

R. BILLINGSLEY, EXECUTIVE VICE PRESIDENT,
TECHNOLOGY
3353 Michelson Drive
Irvine, CA 92612

**ConAgra
Foods**

ConAgra Foods Enterprise Quality
Six ConAgra Drive - Mail Stop 6-405
Omaha, NE 68102-5006

Phone: (402) 595-6001
FAX: (402) 595-7660

please copy
David Arneson
Nega Bern
Jade Quinich
Don Zink
ORO Deborah Kalster
~~XXXXXXXXXX~~

DATE: 2 / 27 / 07

TO:

Name: Joseph Bace
Company: CFSAN, FDA
FAX No.: (301) 436-2717

FROM:

Name: Don Jones
Phone number: 402 595-6818

Number of pages including this cover letter: 14

COMMENTS:

EX 21



To: Jack Douglas, Inspector, FDA
Joe Baca, Director, Office of Compliance, CFSAN, FDA

From: Don Jones, Sr. Director Enterprise Quality and Food Safety 

Date: February 27, 2007

Re: Peter Pan Peanut Butter Recall -- Sylvester, GA facility 2004 Salmonella product positives

As discussed, and in response to FDA's request, we are providing documentation of the results of Salmonella testing for two production dates, October 2, 2004 and October 29, 2004, at the Sylvester, GA ConAgra Foods facility.

In summary, ConAgra Foods' routine monitoring for Salmonella in finished product manufactured at its Sylvester, GA facility identified a potential issue for the two production dates noted above. In connection with the company's investigation of each incident, 677 additional product samples were tested, with 22 Salmonella positives found. The results of the additional product testing (which reflects both individual and composite samples) are attached.

In each case, ConAgra Foods was able to isolate the potentially affected finished product and place it on hold at the plant during the testing. Once the additional product testing confirmed the presence of Salmonella, the affected finished product was disposed of in a landfill. Further, the following cleaning process was used to clean the plant following each event:

- 1) Certain accessible areas of the plant were wet cleaned,
i.e., the equipment that could be disassembled and taken to the COP "clean out of place" washroom.
- 2) Other open areas were alcohol cleaned.

Closed equipment between the mill and the filler were not wet washed due to concerns of introducing water into the process. The following process was used on the closed equipment after each event:

- 1) Product was emptied from the mill to the filler and destroyed.
- 2) The pipe line was filled again between the mill and the filler with clean product
- 3) Product was emptied from the mill to the filler and destroyed
- 4) The pipe line was filled again between the mill and the filler with clean product
- 5) The finished product was placed on hold and tested. The product was released only after the testing confirmed negative for Salmonella.

Please note that the information provided above and in the attached documents is confidential and proprietary information of ConAgra Foods, and that the documents are stamped as such. Given the confidential and proprietary nature of the documents, they cannot be provided by the Food and Drug Administration (FDA) to any third parties, including in response to any request for such documents or the information contained therein pursuant to a Freedom of Information Act (FOIA) request. Should FDA receive an FOIA request for such documents/information, please promptly inform ConAgra Foods. Otherwise, once FDA has completed its review of the documents, please return them to ConAgra Foods or shred.

Please also note that ConAgra Foods' willingness to provide the attached information in connection with FDA's investigation in this matter is not intended to, and does not, waive any applicable privilege or other legal basis under which the information may not be subject to production. By the production of these documents, ConAgra Foods does not intend to and has not waived the attorney-client privilege or any other protections.

If you have any questions please feel free to call me directly.



Microbiology Analysis Report

OMAHA MICROBIOLOGY
LABORATORY
Six ConAgra Drive PDL-105
Omaha, NE 68102
(402) 595-7822

To: Mats, Mike

Cc: Omaha Microbiology Laboratory

Date: October 11, 2004

Subject: Microbiology Analysis Report

Work Request #: 880

Work Type: Product/ingredient analysis - By Sample Number

Samples Received: 10/6/2004

Analysis Completed:

| Sample Number | General Description | Test Type | Results | Comments |
|---------------|--|------------|----------|----------|
| 1 | A-Line Beginning (opened) 21114276 001603A B | Salmonella | Negative | |
| 2 | A-Line Middle (opened) 21114276 002107A M | Salmonella | Positive | |
| 3 | A-Line End (opened) 21114276 000002A E | Salmonella | Positive | |
| 4 | B-Line Beginning (opened) 21114276 001556B B | Salmonella | Negative | |
| 5 | B-Line Middle (opened) 21114276 002054B M | Salmonella | Positive | |
| 6 | B-Line End (opened) 21114276 002353B E | Salmonella | Positive | |
| 7 | A-Line Beginning (unopened) 21114276 001603A B | Salmonella | Negative | |
| 8 | A-Line Middle (unopened) 21114276 002107A M | Salmonella | Positive | |
| 9 | A-Line End (unopened) 21114276 000002A E | Salmonella | Negative | |

REPORTED

Monday, October 11, 2004

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| Sample Number | General Description | | Test Type | Results | Comments |
|---------------|-----------------------------|--------------------------|------------|----------|----------|
| 10 | B-Line Beginning (unopened) | 21114276 001550B B | Salmonella | Negative | |
| 11 | B-Line Middle (unopened) | 21114276 002054B M | Salmonella | Positive | |
| 12 | B-Line End (unopened) | 21114276 002353B E | Salmonella | Negative | |
| 13 | ICS Broth | ICS | Salmonella | Positive | |
| 14 | Composite Sample | Composit e | Salmonella | Positive | |

CONFIDENTIAL AND PROPRIETARY



Microbiology Analysis Report

OMAHA MICROBIOLOGY
LABORATORY
Six ConAgra Drive FDL-105
Omaha, NE 68102
(402) 595-7832

To: Matis, Mike
 Ce: Chris Horan; Jeff Miller
 From: Omaha Microbiology Laboratory
 Date: October 11, 2004
 Subject: Microbiology Analysis Report

Work Request #: 928
 Work Type: Product/Ingredients analysis - By Sample Number
 Samples Received: 10/7/2004
 Analysis Completed:

| Sample Number | General Description | Mfg Code | Hour | Test Type | Results | Comments |
|---------------|-------------------------------|--------------|------------------|--------------------------------------|----------|----------|
| 1 | 18 oz Peter Pan Peanut Butter | 21114427 600 | 16:00 | A-Line Composite of 10 Salmonella | Negative | |
| 2 | 18 oz Peter Pan Peanut Butter | 21114427 600 | 17:00 | A-Line Composite of 10 Salmonella | Negative | |
| 3 | 18 oz Peter Pan Peanut Butter | 21114427 600 | 18:00 | A-Line Composite of 10 Salmonella | Negative | |
| 4 | 18 oz Peter Pan Peanut Butter | 21114427 600 | 19:00 | A-Line Composite of 10 Salmonella | Negative | |
| 5 | 18 oz Peter Pan Peanut Butter | 21114427 600 | 20:00 #541-50 | A-Line Composite of 10 Salmonella | Negative | |
| 6 | 18 oz Peter Pan Peanut Butter | 21114427 600 | 20:00 #551-60 | A-Line Composite of 10 Salmonella | Positive | |
| 7 | 18 oz Peter Pan Peanut Butter | 21114427 600 | 21:00 #s 61-70 | A-Line Composite of 10 Salmonella | Positive | |
| 8 | 18 oz Peter Pan Peanut Butter | 21114427 600 | 21:00 #s 71-80 | A-Line Composite of 10 Salmonella | Positive | |
| 9 | 18 oz Peter Pan Peanut Butter | 21114427 600 | 21:00 #s 81-90 | A-Line Composite of 10 Salmonella | Positive | |
| 10 | 18 oz Peter Pan Peanut Butter | 21114427 600 | 22:00 #s 91-100 | A-Line Composite of 10 Salmonella | Negative | |
| 11 | 18 oz Peter Pan Peanut Butter | 21114427 600 | 22:00 #s 101-110 | A-Line Composite of 10 Salmonella | Negative | |
| 12 | 18 oz Peter Pan Peanut Butter | 21114427 600 | 23:00 | A-Line Composite of 10 Salmonella | Negative | |

REPORTED

Monday, October 11, 2004

me-10/11/04

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ENTERPRISE QUALITY

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| Sample Number | General Description | Mfg Code | Hour | | Test Type | Results | Comments |
|---------------|-------------------------------|-----------------|-------|--------|-------------------------------|----------|----------|
| 13 | 18 oz Peter Pan Peanut Butter | 21114427 601 | 24:00 | A-Line | Composite of 10 Salmonella | Negative | |

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Monday, October 11, 2004

Page 2 of 2



Microbiology Analysis Report

OMARA MICROBIOLOGY
LABORATORY
Six ConAgra Drive PDL-105
Omaha, NE 68102
(402) 595-7822

To: Metis, Mike

Cc:

From: Omaha Microbiology Laboratory

Work Request #: 927

Work Type: Product/Ingredients analysis - By Sample Number

Date: October 13, 2004

Samples Received: 10/11/2004

Subject: Microbiology Analysis Report

Analysis Completed: 10/13/2004

| Sample Number | General Description | | | | Test Type | Results | Comments |
|---------------|-------------------------------|---------------|----------------------|--------|------------------------------------|----------|----------|
| 1 | 28 oz Peter Pan peanut butter | 21142760 0 | 16:00 hour | B Line | Composite of 10 jars Salmonella | Negative | |
| 2 | 28 oz Peter Pan peanut butter | 21142760 0 | 17:00 hour | B Line | Composite of 10 jars Salmonella | Negative | |
| 3 | 28 oz Peter Pan peanut butter | 21142760 0 | 18:00 hour | B Line | Composite of 10 jars Salmonella | Negative | |
| 4 | 28 oz Peter Pan peanut butter | 21142760 0 | 19:00 hour | B Line | Composite of 10 jars Salmonella | Negative | |
| 5 | 28 oz Peter Pan peanut butter | 21142760 0 | 20:00 hour #41-50 | B Line | Composite of 10 jars Salmonella | Negative | |
| 6 | 28 oz Peter Pan peanut butter | 21142760 0 | 20:00 hour #51-60 | B Line | Composite of 10 jars Salmonella | Negative | |
| 7 | 28 oz Peter Pan peanut butter | 21142760 0 | 21:00 hour #61-70 | B Line | Composite of 10 jars Salmonella | Positive | |
| 8 | 28 oz Peter Pan peanut butter | 21142760 0 | 21:00 hour #71-80 | B Line | Composite of 10 jars Salmonella | Negative | |
| 9 | 28 oz Peter Pan peanut butter | 21142760 0 | 21:00 hour #81-90 | B Line | Composite of 10 jars Salmonella | Positive | |

10/13/04

Wednesday, October 13, 2004

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| Sample Number | General Description | | | | Test Type | Results | Comments |
|---------------|-------------------------------|---------------|---------------------------|--------|------------------------------------|----------|----------|
| 10 | 28 oz Peter Pan peanut butter | 21142760 0 | 22:00 hour | B Line | Composite of 10 jars Salmonella | Positive | |
| 11 | 28 oz Peter Pan peanut butter | 21142760 0 | 23:00 hour | B Line | Composite of 10 jars Salmonella | Positive | |
| 12 | 28 oz Peter Pan peanut butter | 21142760 0 | 00:00 hour | B Line | Composite of 10 jars Salmonella | Negative | |
| 13 | 28 oz Peter Pan peanut butter | 21142760 0 | 22:00 hour #121-130 | B Line | Composite of 10 jars Salmonella | Positive | |

CONFIDENTIAL AND PROPRIETARY



Microbiology Analysis Report

OMAHA MICROBIOLOGY
LABORATORY
Six ConAgra Drive PDL-105
Omaha, NE 68102
(402) 595-7822

To: Malik, Mike

Cc: Chris Horan

From: Omaha Microbiology Laboratory

Date: November 15, 2004

Subject: Microbiology Analysis Report

Work Request #: 1383

Work Type: Product/Ingredient analysis - By Sample Number

Samples Received: 11/11/2004

Analysis Completed:

| Sample Number | General Description | Mfg Code | Time / Line | UPC | Test Type | Results | Comments |
|---------------|---------------------------------|------------|-------------|------------|--------------------------------------|----------|----------|
| 1 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 1949 / D | 4530000227 | Composite of 12 Salmonella / 375g | Negative | |
| 2 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2007 / D | 4530000227 | Composite of 12 Salmonella / 375g | Negative | |
| 3 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2021 / D | 4530000227 | Composite of 12 Salmonella / 375g | Negative | |
| 4 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2024 / D | 4530000227 | Composite of 12 Salmonella / 375g | Negative | |
| 5 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2035 / D | 4530000227 | Composite of 12 Salmonella / 375g | Negative | |
| 6 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2036 / D | 4530000227 | Composite of 12 Salmonella / 375g | Negative | |
| 7 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2044 / D | 4530000227 | Composite of 12 Salmonella / 375g | Negative | |
| 8 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2048 / D | 4530000227 | Composite of 12 Salmonella / 375g | Negative | |
| 9 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2101 / D | 4530000227 | Composite of 12 Salmonella / 375g | Negative | |
| 10 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2102 / D | 4530000227 | Composite of 12 Salmonella / 375g | Negative | |
| 11 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2104 / D | 4530000227 | Composite of 12 Salmonella / 375g | Negative | |
| 12 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2114 / D | 4530000227 | Composite of 12 Salmonella / 375g | Negative | |

Monday, November 15, 2004

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| Sample Number | General Description | Mfg Code | Time / Line | UPC | Test Type | Results | Comments |
|---------------|---------------------------------|------------|-------------|-----------|---------------------------------------|----------|-------------------|
| 13 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2120 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 14 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2134 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 15 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2144 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 16 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2148 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 17 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2224 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 18 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2226 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 19 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2235 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 20 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2240 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 21 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2248 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 22 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2252 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 23 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2303 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 24 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2308 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 25 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2318 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 26 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2322 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 27 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2329 / D | 453000027 | Composites of 12 Salmonella / 375g | Positive | ID 3. enteritidis |
| 28 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2330 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 29 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2335 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |
| 30 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2336 / D | 453000027 | Composites of 12 Salmonella / 375g | Negative | |

| Sample Number | General Description | Mfg Code | Time / Line | UPC | Test Type | Results | Comments |
|---------------|---------------------------------|------------|-------------|-----------|--------------------------------------|----------|----------|
| 31 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2348 / D | 453000027 | Composite of 12 Salmonella / 375g | Negative | |
| 32 | 18 oz Reduced Fat Peanut Butter | 2111427600 | 2348 / D | 453000027 | Composite of 12 Salmonella / 375g | Negative | |



Microbiology Analysis Report

OMAHA MICROBIOLOGY
LABORATORY
Six ConAgra Drive PDL-105
Omaha, NE 68102
(402) 595-7823

To: Matis, Mike

Cc: Chris Horn
From: Omaha Microbiology Laboratory

Work Request #: 1286

Work Type: Product/Ingredient analysis - By Sample Number

Date: November 8, 2004

Samples Received: 11/2/2004

Subject: Microbiology Analysis Report

Analysis Completed: 11/8/2004

| Sample Number | General Description | Mfg Code | Time | Line | UFC | Test Type | Results | Comments |
|---------------|------------------------------|-------------|------|------|-------------|------------|----------|-----------------------------|
| 1 | 18 oz PP Creamy Opened Jar | 21114303 00 | 1600 | A | 45300299 11 | Salmonella | Negative | |
| 2 | 18 oz PP Creamy Opened Jar | 21114303 00 | 1600 | A | 45300299 11 | Salmonella | Negative | |
| 3 | 18 oz PP Creamy Opened Jar | 21114303 00 | 2055 | A | 45300299 11 | Salmonella | Negative | |
| 4 | 18 oz PP Creamy Opened Jar | 21114303 00 | 2055 | A | 45300299 11 | Salmonella | Negative | |
| 5 | 18 oz PP Creamy Opened Jar | 21114303 00 | 0100 | A | 45300299 11 | Salmonella | Negative | |
| 6 | 18 oz PP Creamy Opened Jar | 21114303 00 | 0100 | A | 45300299 11 | Salmonella | Negative | |
| 7 | 18 oz PP Creamy Unopened Jar | 21114303 00 | 1600 | A | 45300299 11 | Salmonella | Positive | ID: S. Enteritidis group C1 |
| 8 | 18 oz PP Creamy Unopened Jar | 21114303 00 | 2055 | A | 45300299 11 | Salmonella | Negative | |
| 9 | 18 oz PP Creamy Unopened Jar | 21114303 00 | 0100 | A | 45300299 11 | Salmonella | Negative | |
| 10 | 28 oz PP Creamy Opened Jar | 21114303 00 | 1600 | B | 45300299 04 | Salmonella | Negative | |
| 11 | 28 oz PP Creamy Opened Jar | 21114303 00 | 2054 | B | 45300299 04 | Salmonella | Positive | ID: S. Enteritidis group C1 |
| 12 | 28 oz PP Creamy Opened Jar | 21114303 00 | 0056 | B | 45300299 04 | Salmonella | Negative | |

Monday, November 08, 2004 *PK*

| Sample Number | General Description | Mfg Code | Time | Line | UPC | Test Type | Results | Comments |
|---------------|--|-------------|------|------|-------------|------------|----------|-----------------------------|
| 13 | 28 oz PP Creamy Unopened Jar | 21114303 00 | 1600 | B | 45300299 04 | Salmonella | Positive | ID: S. Enteritidis group C1 |
| 14 | 28 oz PP Creamy Unopened Jar | 21114303 00 | 2054 | B | 45300299 04 | Salmonella | Negative | |
| 15 | 28 oz PP Creamy Unopened Jar | 21114303 00 | 0056 | B | 45300299 04 | Salmonella | Negative | |
| 16 | 6 lb PP Creamy Opened Jar | 21114303 00 | 1555 | D | 45300002 98 | Salmonella | Positive | ID: S. Enteritidis group C1 |
| 17 | 6 lb PP Creamy Opened Jar | 21114303 00 | 2050 | D | 45300002 98 | Salmonella | Negative | |
| 18 | 6 lb PP Creamy Opened Jar | 21114303 00 | 0042 | D | 45300002 98 | Salmonella | Negative | |
| 19 | 6 lb PP Creamy Unopened Jar | 21114303 00 | 1555 | D | 45300002 98 | Salmonella | Negative | |
| 20 | 6 lb PP Creamy Unopened Jar | 21114303 00 | 2050 | D | 45300002 98 | Salmonella | Negative | |
| 21 | 6 lb PP Creamy Unopened Jar | 21114303 00 | 0042 | D | 45300002 98 | Salmonella | Negative | |
| 22 | Original Composite in Buffered Peptone Water | | | | | Salmonella | Negative | |
| 23 | ICS Broth | | | | | Salmonella | Negative | |

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News

Peanut Butter Recall Extended to Products Made as Early as 2004

Peter Pan, Great Value Peanut Butter Linked to Wide-Ranging Salmonella Outbreak

**By James R. Hood
ConsumerAffairs.Com**

March 10, 2007

ConAgra is extending its recall of all Peter Pan and Great Value peanut butter beginning with product code 2111, including peanut butter toppings, back to October 2004, the U.S. Food and Drug Administration (FDA) said.

The extension was a result of the agency's "ongoing investigation" of a Salmonella outbreak that has been linked to the two brands of peanut butter, both produced at ConAgra's Georgia plant.

Consumers who have purchased any of the products since October 2004 should discard them, FDA said. The agency is advising consumers not to eat any Peter Pan or Great Value peanut butter beginning with the 2111 product code.

FDA is still looking into how the peanut butter became contaminated and said it will issue advisories if it finds any other products that may have been made with potentially contaminated peanut butter, such as candies or ice cream toppings.

Three deaths and hundreds of illnesses have been unofficially linked to the outbreak.

Mary Halstead, 85, of Weston, WV, died Jan. 10 after becoming ill on December 23, 2006, according to her son, Larry Halstead.

Halstead said his mother became ill after eating a peanut butter sandwich, one of her favorite foods. During her hospitalization at Stonewall Jackson Memorial Hospital in Weston, she repeatedly asked the staff to serve her a peanut butter sandwich but they refused, saying peanut butter was not on their standard menu.

"So, dumb old me, I made her a peanut butter sandwich at home and brought it to her at the hospital, because it was just about the only thing she wanted to eat," Larry Halstead said. "In no time, she got just 100% worse." Halstead said his mother then became semi-comatose and died.

After his mother's death, Halstead heard the news of the

Ex 22

Salmonella infestation and looked at the jar of peanut butter he had used to make his mother's sandwich. It was Peter Pan peanut butter with the "2111" serial number.

An elderly Chicago area man, George Baldwin, was said to be in relatively good health just before his recent death from complications of food poisoning, shortly after he ate a peanut butter sandwich.

"He puts the peanut butter on toast, eats the toast, in six hours he develops fever, nausea, diarrhea and vomiting -- all of which are signs of salmonella poisoning," Baldwin family attorney Don McGarrah said.

A 76-year old Pennsylvania woman, Roberta Barkay of Philadelphia, died in January from complications of food poisoning, and family members contend she too ate peanut butter shortly before her death. The family has hired an attorney who has filed suit against the manufacturer, ConAgra.

Investigation Continues

FDA inspectors found salmonella samples at ConAgra's Sylvester, Georgia, plant, where the recalled Peter Pan and Great Value peanut butter was made, FDA said. At the same time, the agency said peanut butter from the contaminated plant was spread to at least one other plant, located in Tennessee.

It was at the Humboldt, Tenn., plant that peanut butter was processed for ice cream and dessert toppings.

The FDA says the fact that its inspectors found Salmonella in the plant environment further suggests that the contamination likely took place prior to the product reaching consumers.

Last week, tests by several states identified Salmonella in many open jars of Peter Pan and Great Value peanut butter recovered from consumers. In these instances, the Salmonella found in the plant and in the open jars matched the outbreak strain recovered from consumers who became ill.

The following products were used by the affected businesses until Feb. 16, 2007 when the products were recalled:

- Sonic Brand Ready-To-Use Peanut Butter Topping in 6 lb. 10.5 oz cans.
- Carvel Peanut Butter Topping in 6 lb. 10 oz. cans.

The following Carvel products, purchased before Feb. 16, 2007 can be returned to a Carvel outlet for a refund:

- Chocolate Peanut Butter
- Peanut Butter Treasure
- Peanut Butter & Jelly
- Reese's Peanut Butter Cup Sundae Dasher
- Any other customized products containing the Peanut Butter Topping, including peanut butter flavored ice cream in ice cream cakes
- J. Hungerford Smith Peanut Butter Dessert Topping in 6 lb. 10 oz. cans. The topping is used by retail outlets and restaurants nationwide but is not available for direct purchase by the public, the FDA said.

Carvel's Reese's Peanut Butter Cup Sundae Dasher is not being recalled because of the peanut butter found in the Reese's Cups, but rather, because of the peanut butter topping applied to the sundae, Carvel spokeswoman Karen Gailey said.

ConsumerAffairs.Com has not received any related complaints on the above products.

What To Do

Persons who think they may have become ill from eating peanut butter should consult a physician if they do not get better in a few days. If the illness affects small children, the elderly, pregnant women or those with compromised immune systems, a doctor should be consulted promptly.

The FDA and other agencies have been advising consumers who have Peter Pan peanut butter or Great Value peanut butter with a product code beginning with 2111 to discard the jar and keep the lid.

However, attorneys advise that, if consumers were seriously harmed by their illness, they should seal the jar in a plastic bag and store it out of the reach of children or others in the household, so that it is available as evidence.

Although a few lawsuits seeking class action status have been filed, one experienced consumer attorney who asked not to be identified expressed doubt such actions would be successful.

"The vast majority of suits will be individual actions. A class suit would be difficult to certify," he said.

ConAgra has publicly offered to repay the money consumers

spent on the peanut butter and any attempt to recover medical costs and wages lost to illness would require the filing of an individual personal injury suit. Such suits are usually not economically feasible unless consumers have suffered serious injury or death.

Consumers could also file in **Small Claims Court** (http://www.consumeraffairs.com/consumerism/small_claim_01.htm) if they have well-documented expenses and a firm diagnosis. Consumers should note that they cannot claim punitive damages for pain and suffering in most small claims cases.

Symptoms

Most persons infected with Salmonella develop diarrhea, fever, and abdominal cramps 12 to 72 hours after infection. The illness usually lasts 4 to 7 days, and most persons recover without treatment. However, in some persons the diarrhea may be so severe that the patient needs to be hospitalized. The elderly, infants, and those with impaired immune systems are more likely to have a severe illness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR 12 2007

Mr. Gary Rodkin
CEO
ConAgra Foods, Inc.
1 ConAgra Drive
Omaha, Nebraska 68102-5003

Dear Mr. Rodkin:

This is to inform you that the Food and Drug Administration (FDA) considers the Peter Pan brand and Great Value brand of peanut butter that your firm recalled beginning on February 14, 2007, to have posed an acute, life-threatening hazard to health. Your recall included all varieties of Peter Pan Peanut Butter and Great Value Peanut Butter beginning with product code 2111 as well as individual packets of Peter Pan Peanut Butter.

The FDA has designated this recall as class I due to the potential for the peanut butter to be contaminated with *Salmonella* Tennessee. The Centers for Disease Control and Prevention have linked your peanut butter to an outbreak of *Salmonella* Tennessee illness. Additionally, several states have reported finding the outbreak strains of *Salmonella* Tennessee in opened jars of peanut butter collected from ill individuals. FDA has found the outbreak strains in the environment of your Sylvester, Georgia facility and in intact jars of peanut butter.

Salmonella infection can cause gastroenteritis and can result in several serious clinical conditions including septicemia, arterial infections (i.e., infected aneurysms), endocarditis, and septic arthritis. Debilitated patients and individuals who have compromised immune systems are particularly subject to terminal infections with this pathogenic organism.

Due to the seriousness of this situation, you should assure that all of your direct accounts have been notified of this recall and that those direct accounts who have subdistributed the product are conducting effective subrecalls.

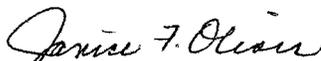
FDA's Atlanta District office will remain in contact with you until this matter is resolved.

E423

Page 2 - Mr. Gary Rodkin

Information regarding your recall will be listed in the weekly FDA Enforcement Report.
The FDA's policy regarding recalls is published in Title 21, Code of Federal Regulations, Part 7.

Sincerely yours,



Janice F. Oliver
Deputy Director for Operations
Center for Food Safety
and Applied Nutrition

4 of 5 DOCUMENTS

The New York Times

April 12, 2007 Thursday
Late Edition - Final

Some Suspect Chemical Mix In Pet Food

BYLINE: By DAVID BARBOZA**SECTION:** Section C; Column 6; Business/Financial Desk; Pg. 1**LENGTH:** 1214 words**DATELINE:** XUZHOU, China, April 10

Behind an unmarked gate in this booming city well north of Shanghai lies a large building at the heart of an investigation over tainted pet food that has killed at least 16 cats and dogs in the United States, sickened 12,000 and prompted a nationwide recall.

This is the property of the Xuzhou Anying Biologic Technology Development Company, a small agricultural products business that investigators have identified as the source of contaminated wheat **gluten** that was shipped to a major pet food supplier in the United States.

Some American regulators suspect there was deliberate mixing of substances. They are looking into the possibility that **melamine**, the chemical linked to the pets' deaths, was mixed into the wheat **gluten** in China as a way to bolster the protein content, according to a person who was briefed on the investigation.

Though American and Chinese regulators are searching for answers, local residents and workers are unwittingly providing clues about how the pet food supply may have become contaminated.

The case is also exposing some of the enormous challenges confronting the global marketplace as China becomes a worldwide supplier of agricultural products.

There are strong indications that Xuzhou Anying, a company with a main office that seems to consist of just two rooms and an adjoining warehouse here, possessed substantial supplies of **melamine** and even sought to buy quantities of it over the Internet.

If **melamine** was intentionally blended into the wheat **gluten**, the findings could become a vast setback for agricultural trade between the United States and China, a country known for lax food-safety regulations.

Stephen Sundlof, director of the Center for Veterinary Medicine at the Food and Drug Administration, said at a news conference last week that the agency had found unusually high concentrations of **melamine** in some batches of wheat **gluten**, as much as 6.6 percent.

Xuzhou Anying, though, has tried to distance itself from the pet food recall in the United States, saying it does not manufacture or export wheat **gluten** and acts only as a middleman trading in agricultural goods and chemicals.

In a telephone interview last week, the company's manager, Mao Lijun, said he had no idea how wheat **gluten** with his company's label ended up in the United States or how **melamine**, a chemical commonly used to make plastics, fertilizer and fire retardant, was mixed into a product that was eventually shipped there.

2424

Mixing **melamine** and wheat **gluten** is an unlikely practice here, according to local industry participants. Nonetheless, the company's wheat **gluten**, tainted with **melamine**, ended up in millions of packages sent to the United States and Canada, leading to one of the biggest pet food recalls ever.

ChemNutra, the Las Vegas-based company that acknowledges it imported the wheat **gluten** from Xuzhou for sale to pet food producers in North America, says Xuzhou Anying provided chemical analyses that showed no impurities or contamination in the packages of wheat **gluten**.

Though some American scientists still question whether **melamine** is toxic enough to kill pets, the chemical is not approved for use in human or pet food in the United States. The F.D.A. says it may have led to kidney failure in some animals.

The question that regulators, agriculture experts, and food producers and distributors may now be asking is whether other substances added to food imports can broadly contaminate the American food supply. The F.D.A. has said none of the contaminated wheat **gluten** leaked into human food.

Here in Xuzhou, a metropolitan region of about 1.6 million, Mr. Mao turned away visitors to his office, declaring that he had nothing more to say on the matter.

But there are indications that Xu-zhou Anying has manufacturing facilities in this area and also had access to **melamine**, which is sometimes used as a fertilizer in Asia. For instance, in recent months Xuzhou Anying has posted several requests on Web trading sites seeking to purchase large quantities of **melamine**.

In a March 29 posting on a site operated by Sohu.net, a big Chinese company, officials of Xuzhou Anying wrote, "Our company buys large quantities of **melamine** scrap all year around." There were also postings on several other trading sites like ChemAbc.net.

A truck driver parked across the street from the company's main office here said that Xuzhou Anying did operate manufacturing facilities and that he carried goods for the company.

"Yes, they have a factory that makes wheat **gluten**," said the man, who did not give his name and then telephoned the manager of Xuzhou Anying to check whether he could take visitors to the factory.

On Tuesday, a reporter visited one of the facilities the truck driver identified in the village of Wangdian, about 10 miles south of company headquarters, but the gate to the building was padlocked.

Storage sacks that appeared to hold grain or agricultural supplies were stacked outside the site in a vast wheat- and garlic-growing region here in Jiangsu Province.

"They used to have their headquarters right over there," said Chen Wei, a technology director at Nanjing Shibide Biologic Technology, an animal-feed company next door. "They're pretty well known for their products."

Chinese regulators say they are now carrying out a nationwide inspection of wheat **gluten** supplies. American regulators have banned all wheat **gluten** from China, but there has been no domestic recall so far of **gluten** produced by Xuzhou Anying; the company's wheat **gluten** can be used to make bread, baked goods and other food.

Li Jundang, manager of Shandong Binzhou Tianjian Biotechnology, a wheat **gluten** producer in the city of Binzhou, about 200 miles north of here, said, "We never heard the news of tainted pet food." Another **gluten** exporter, Shandong Rongchang, also said it was unaware of any problems with Chinese wheat **gluten**.

Nor, it seems, have journalists in Xuzhou, who work under state censorship. "I didn't know this news about Xuzhou Anying," said Li Ning, news director at

The City Morning Post, a daily newspaper here. 'And even if we had heard about the news, we wouldn't be able to report on it because it's negative news.'

Most experts on wheat **gluten** in the region said they had never heard of mixing it and **melamine**.

'If you add chemicals into the wheat **gluten**, it is no longer called wheat **gluten** protein,' says Jiang Shaotong, a professor of food engineering at Hefei University of Technology in nearby Anhui Province. 'I can't think of any reason why **melamine** is needed in the production process.'

Chinese customs officials do inspect or sample products planned for export, but those inspections are not thought to be stringent enough to detect the presence of every chemical or impurity.

Asked about the investigation, a Chinese official working for the inspection and quarantine bureau declined to comment.

But lax food-safety regulation and standards are a problem; food producers sometimes dye meats to make them look fresher and even sell fake milk powder for babies.

This week, the Chinese government reported that an elderly woman died and 202 people were sickened at a hospital north of here after they consumed a breakfast cereal that turned out to be laced with rat poison.

URL: <http://www.nytimes.com>

LOAD-DATE: April 12, 2007

LANGUAGE: ENGLISH

GRAPHIC: Photos: A wheat **gluten** processing factory, left, near Xuzhou, China. The Xuzhou Anying Biologic Technology Development Company there has recently come under scrutiny in connection with **gluten** exports for pet food. (Photographs by Ryan Pyle for The New York Times) (pg. C4)

PUBLICATION-TYPE: Newspaper



Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Natural Balance Pet Foods, Inc. Issues A Voluntary Nationwide Recall on Specific Venison Dog and Cat Food Products

Contact:

Consumer Inquiries:
(800) 829-4493

Media Inquiries:
Daniel Bernstein
310-275-0777

FOR IMMEDIATE RELEASE -- Pacoima, CA -- April 17, 2007 -- Natural Balance, Pacoima, CA, is issuing a voluntary nationwide recall for all of its Venison dog products and the dry Venison cat food only, regardless of date codes. The recalled products include Venison and Brown Rice canned and bagged dog foods, Venison and Brown Rice dog treats, and Venison and Green Pea dry cat food. Recent laboratory results show that the products contain melamine. We believe the source of the melamine is a rice protein concentrate. Natural Balance has confirmed this morning that some production batches of these products may contain melamine.

The recall was prompted by consumer complaints received by Natural Balance involving a small number of cats and dogs that developed kidney failure after eating the affected product.

Dogs or cats who have consumed the suspect food and show signs of kidney failure (such as loss of appetite, lethargy and vomiting) should be seen by a veterinarian. We recommend our customers immediately stop feeding our recalled venison products regardless of date code and return unused product to their retailer for a full refund.

The products are packaged in bags, cans and zip lock treat bags and sold in pet specialty stores and PetCo nationally.

No other Natural Balance products are involved in this voluntary recall as none of our other formulas include the rice protein concentrate.

Although the problems seem to be focused on a particular production period of the venison products, over the last four days we have notified our distributors and retailers by phone and e-mail to immediately stop selling and return all recalled Venison dog foods and treats and the Venison dry cat food. Venison canned cat food is not involved.

The source of the melamine appears to be a rice protein concentrate, which was recently added to the dry venison formulas. Natural Balance does not use wheat gluten, which was associated with the previous melamine contamination.

2x25

None of Natural Balance's other dry formulas, none of our other canned or roll products and none of our other treats are involved with this voluntary recall.

We continue to work closely with the FDA in their ongoing investigation.

Consumers with questions may contact the company at 1-800-829-4493 or visit the website at www.naturalbalance.net.

###

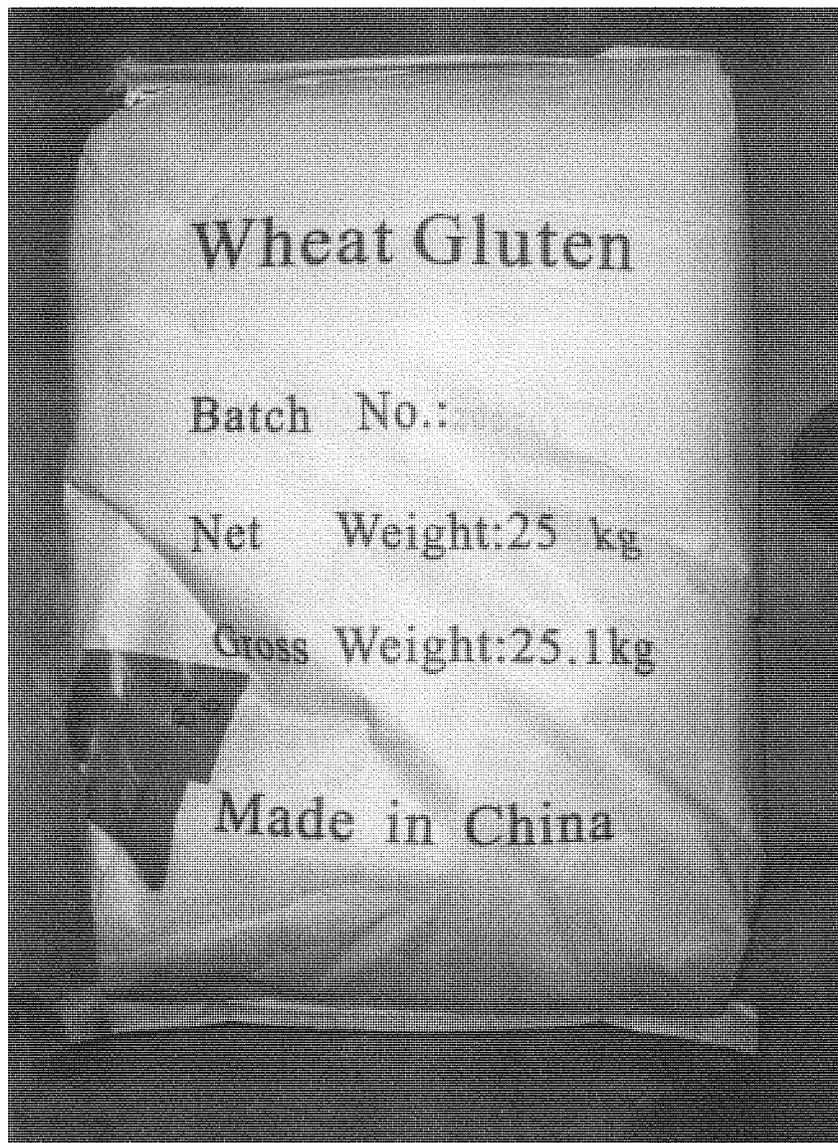
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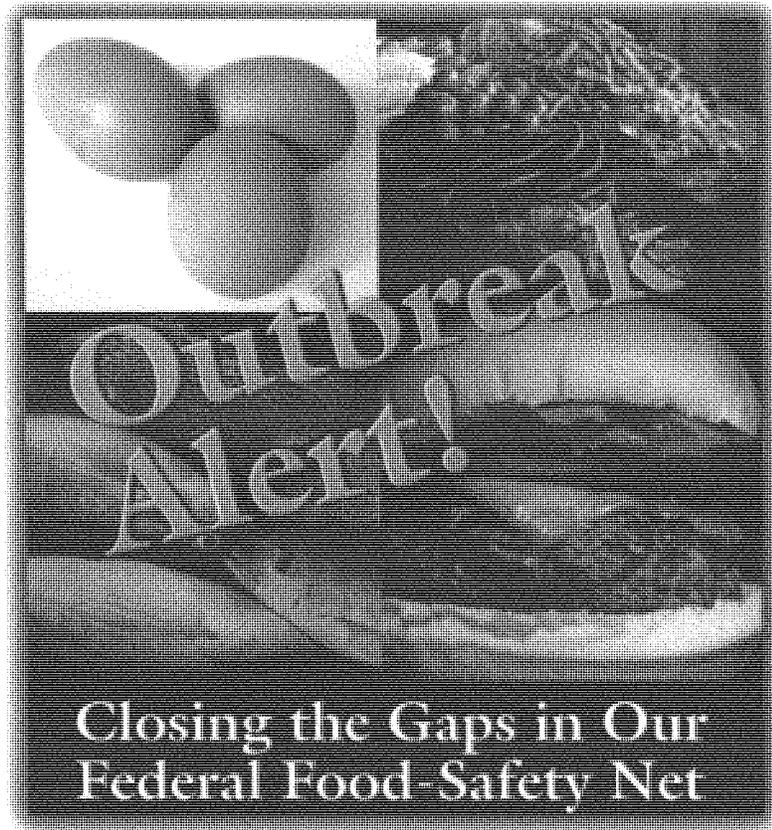
Wheat Gluten

Batch No.:

Net Weight: 25 kg

Gross Weight: 25.1kg

Made in China



Updated and Revised – December, 2006

E427

Outbreak Alert! 2006 was researched and written by Caroline Smith DeWaal, Kendra Johnson, and Farida Bhuiya. We gratefully acknowledge the assistance of Michael F. Jacobson in preparing this report. We also thank the scientists in government public health agencies who provided information and inspiration for this report.

Center for Science in the Public Interest (CSPI) is a non-profit organization based in Washington, DC. Since 1971, CSPI has been working to improve the public's health, largely through its work on nutrition and food-safety issues. CSPI is supported primarily by the 900,000 subscribers to its Nutrition Action Healthletter and by foundation grants.

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Eighth Edition, December 2006

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EXECUTIVE SUMMARY

In the United States, foodborne illness has been estimated to cause 5,000 deaths and 76 million illnesses per year. Responsibility for food safety is divided among at least a dozen federal agencies involved in monitoring, surveillance, inspection, enforcement, outbreak management, research, and education. Despite recent improvements, significant gaps in the federal food-safety structure continue to put consumers at risk. To help fill one of these gaps, the Center for Science in the Public Interest (CSPI) maintains a database of foodborne illness outbreaks that have been linked to specific foods.

Findings

CSPI tracked a total of 5,000 foodborne illness outbreaks, involving 152,097 individual cases that occurred between 1990 and 2004. The food categories most commonly linked to foodborne illness outbreaks were:

- **Seafood and seafood dishes: 984 outbreaks involving 9,969 cases of illness**
- **Produce and produce dishes: 639 outbreaks involving 31,496 cases of illness**
- **Poultry and poultry dishes: 541 outbreaks involving 16,280 cases of illness**
- **Beef and beef dishes: 467 outbreaks involving 13,220 cases of illness**
- **Eggs and egg dishes: 341 outbreaks involving 11,027 cases of illness**

Multi-ingredient foods (such as salads, pizza, and sandwiches) where the contaminated ingredient was not identified were linked to 948 outbreaks and 27,812 cases of foodborne illness.

Foods regulated by the U.S. Food and Drug Administration (FDA), such as seafood, produce, eggs, and dairy, were associated with more than twice as many outbreaks as foods regulated by the U.S. Department of Agriculture (USDA), which include meats and poultry.

Recommendations

The Centers for Disease Control and Prevention (CDC) should continue to improve outbreak reporting and surveillance. The CDC has made improvements in its reporting and surveillance system, but gaps still remain. For example, nearly half of all states do not follow national standards to track disease outbreaks. Those gaps are particularly troubling, given current concerns about bioterrorism.

Congress should pass legislation to form a unified, independent food-safety agency with increased authority. Outbreaks occur, in part, because of inadequate regulatory authority, inadequate monitoring, and inadequate funding. Those problems will not be corrected until the underlying government structure is fixed. Congress needs to create a single food-safety agency, and to invest that agency with greater authority (such as the ability to recall food from the market and to penalize companies that produce contaminated products) than existing regulatory agencies have.

INTRODUCTION

In recent decades, changes in food production and consumption have impacted the safety of food. The food industry has evolved from being local to global, where production and processing are centralized in different parts of the country and world. Large-scale “farms” and feedlots can be breeding grounds for pathogens that are further dispersed in fast-paced slaughterhouses and processing plants. Additionally, large-scale processing can easily spread germs into large volumes of processed food, as evidenced by the September 2006 outbreak of *E. coli* 0157:H7 in prepackaged spinach which sickened over two hundred people across the country. Furthermore, some foodborne pathogens have become more virulent, while our population is aging and increasingly vulnerable to foodborne illness.³

Unsafe foods cause an estimated 76 million illnesses and 5,000 deaths each year in the United States.⁴ Although people from all walks of life can develop foodborne illness, those who are most at risk include the elderly, young children, pregnant women and their fetuses, and the immunocompromised. While most illnesses occur as isolated cases, outbreaks of foodborne illness are clusters of illness that result from ingestion of a common contaminated food. A single outbreak can affect hundreds, or even thousands, of people.

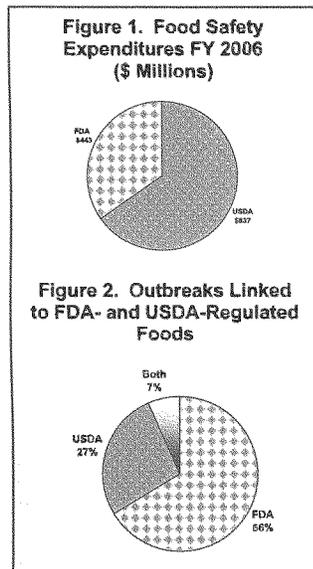
Foodborne illness outbreaks are primarily investigated by state and local health departments. These local officials sometimes call on the federal Centers for Disease Control and Prevention (CDC) to help investigate large or multi-state outbreaks. The CDC is also responsible for nationwide surveillance of outbreaks and for tracking new and emerging pathogens. But many, perhaps most, outbreaks fall through the cracks because the states are not required by law to report foodborne illness outbreaks to the CDC.

In the United States, at least a dozen federal agencies have jurisdiction over some aspect of food-safety regulation. That highly fragmented system divides regulatory responsibility based on food products. However, the CDC’s system for reporting outbreaks does not synchronize easily with the regulatory system. Instead of emphasizing the foods that cause

2

outbreaks, the CDC's lists of outbreaks are organized by pathogen and include outbreaks with unknown etiology and foods.

The primary agencies that inspect and regulate food are the United States Department of Agriculture (USDA), which oversees meat, poultry, and



"We are working under a Meat Inspection Act that pre-dates the Model T."

-Ann Veneman, USDA Secretary of Agriculture, March 2003⁵

processed egg products, and the United States Food and Drug Administration (FDA), which oversees all other foods. Although FDA-regulated foods are linked to two-thirds of the outbreaks with known causes, the FDA's budget is just 38 percent of the total federal budget for food safety.⁶ And while meat-processing plants are inspected by USDA daily, plants processing potentially contaminated seafood, eggs, lettuce, or processed foods containing less than two percent meat are inspected by FDA on average just once every five to ten years.⁷ When foodborne illness outbreaks do occur, neither the USDA nor the FDA has the power to order recalls of contaminated food. They must ask food companies to *voluntarily* remove foods from the market. The current system of voluntary recalls can delay the recall and increase the number of illnesses in an outbreak. Also, lawsuits brought by the meat industry have curbed USDA's ability to close down plants producing contaminated meat. The regular occurrence of foodborne illness outbreaks in the United States today is evidence that the current food-safety system needs to be improved.

The Center for Science in the Public Interest (CSPI) has examined outbreaks linked to specific foods. Such data alert consumers to food-safety hazards, allow consumers to make informed risk decisions about the foods they eat, and provide better information to government for setting priorities for food-safety

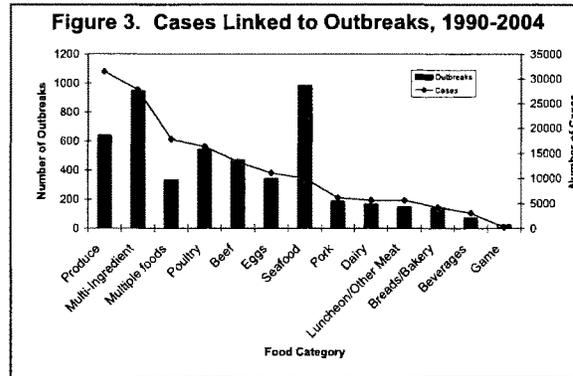
resource allocation. The findings presented here are from the 2006 *Outbreak Alert!* database, and are accompanied by a list of the most common foods associated with foodborne illness outbreaks, suggested food-safety interventions for each type of food, and CSPI's recommendations for improving the safety of America's food supply.

A DATABASE OF FOODBORNE ILLNESS OUTBREAKS

Data Collection

CSPI maintains a database of foodborne illness outbreaks, compiled largely from CDC and state health department annual outbreak line listings, reports by the CDC's Foodborne Outbreak Response and Surveillance Unit, and peer-reviewed journal articles. Since 2001, CDC outbreak data for 1990-1998 and subsequent years have been available as yearly line listings on the Internet.⁸ Prior to 2001, the CDC outbreak data was unpublished, and obtained by CSPI via Freedom of Information Act requests. Additional outbreaks were obtained from scientific articles, federal government

publications, state health department postings, and newspaper reports verified by public health officials; data from these additional sources constitute about 9% of the database. Each outbreak entry was assigned a reference number indicating the data source where the information was obtained.



Incidents of foodborne illness were only included in the CSPI database if they met the CDC's definition of an outbreak: when two or more people have consumed the same contaminated food and come down with the same illness.⁹ In addition, each outbreak must have an identified etiology and food vehicle,¹⁰ must have occurred in the U.S. or its territories between 1990 and 2004, and must have been reported by a reliable source. Outbreak reports that met CSPI's inclusion criteria were further evaluated to determine whether they were already listed in the database or whether they represented new outbreaks. Outbreak reports from different sources may contain slightly different information about the same outbreak. When such discrepancies were discovered, a public health official at the state, local, or federal level was contacted to determine which information was correct.

Excluded from the CSPI database were sporadic cases of foodborne illness

(individual cases not linked to an outbreak), outbreaks that had no identifiable etiology or food vehicle, and waterborne outbreaks.

Food Categorization

Each outbreak in the CSPI database was categorized by the implicated food, and the regulatory agency with primary responsibility for that particular food item. In general, meat, poultry, and processed egg products are regulated by the United States Department of Agriculture (USDA), while all other foods are regulated by the U.S. Food and Drug Administration (FDA).¹¹ There are thirteen food categories in the CSPI categorization scheme, the majority of which were further divided into food subdivisions (see Appendix A).

Food categorization enables identification of the specific food-pathogen combinations causing large numbers of illnesses. Most reported foodborne illness outbreaks do not have complete outbreak information.¹² In most years, 27 percent to 46 percent of outbreaks have no known etiology or vehicle. In addition, the majority of foodborne illness outbreaks go unreported due to their small size, long incubation period, geographic dispersion, an inability to identify the pathogen, or mild cases of illness which do not prompt individuals to seek medical care.¹³ For these reasons, the outbreaks included in the CSPI database represent only a small proportion of the actual foodborne illness outbreaks that occurred between 1990 and 2004.

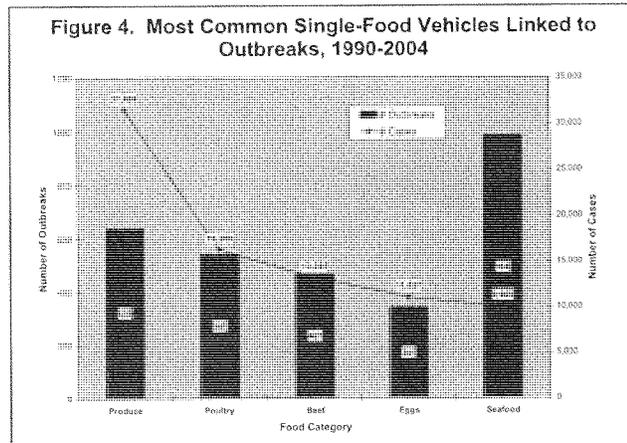
RESULTS

Overall Findings

A total of 5,000 outbreaks, involving 152,097 cases of illness and occurring between 1990 and 2004, were included in the CSPI database. Nine percent of these outbreaks were from sources other than the CDC. The five food categories, excluding multi-ingredient foods, linked to the most foodborne illness outbreaks were seafood, produce, poultry, beef, and eggs. These five food categories were responsible for 59% of all outbreaks in CSPI's database, and 54% of the cases. The produce category alone was linked to the largest number of foodborne illnesses associated with outbreaks, constituting 21% of all cases in CSPI's database.

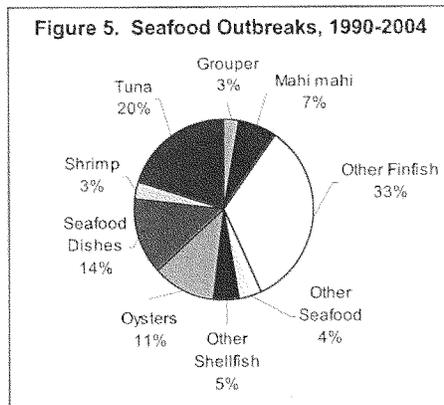
FDA-regulated foods were linked to 3,322 outbreaks with 93,221 cases, while USDA-regulated foods were linked to 1,345 outbreaks with 41,123 cases. Foods such as seafood, non-meat multi-ingredient foods, produce,

eggs, dairy, breads, and beverages were linked to more than twice as many outbreaks and cases as meats and poultry. Outbreaks due to multiple foods, including both meat (USDA-regulated) and non-meat (FDA-regulated) items, comprised 7% of the database.



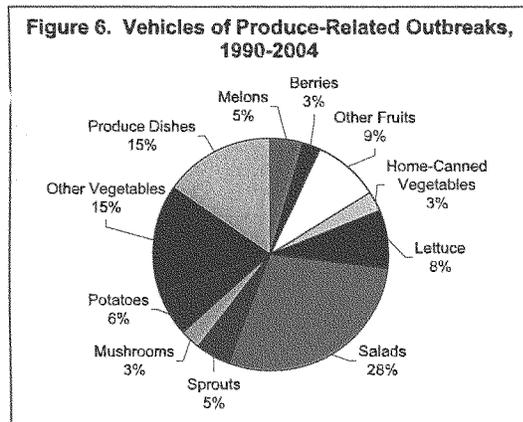
FDA-Regulated Foods

Seafood and seafood dishes. A total of 984 foodborne illness outbreaks with 9,969 cases were linked to seafood and seafood dishes. The average number of cases per seafood-linked outbreak was ten. Of the outbreaks associated with seafood, 622 outbreaks and 3,182 cases were linked to finfish such as tuna and grouper, and 155 outbreaks with 3,399 cases were linked to molluscan shellfish including oysters, clams, and mussels. Seafood dishes like crabcakes and tuna burgers were linked to 138 outbreaks with 2,516 cases. Other seafood, such as shrimp and lobster, were linked to 69 outbreaks with 872 cases. Hazards in seafood included scombrototoxin and ciguatoxin in finfish and *Vibrio* spp. and Noroviruses in shellfish. The majority of seafood outbreaks were caused by natural toxins, rather than by bacteria or viruses.



Multi-ingredient foods. A total of 948 foodborne illness outbreaks with 27,812 cases were linked to multi-ingredient foods. The average number of cases per multi-ingredient food outbreak was 29. Foods including rice, beans, stuffing, and pasta dishes were linked to 191 outbreaks and 4,696 cases. Multi-ingredient salads such as potato salad and coleslaw were linked to 215 outbreaks with 9,771 cases, while multi-ingredient sandwiches were linked to 129 outbreaks and 3,365 cases. Sauces, dressings, and oils caused 55 outbreaks with 1,875 cases. Multi-ingredient dishes, including lasagna, tacos, and lo mein, were associated with 223 outbreaks with 4,433 cases and 135 outbreaks and 3,672 cases were linked to other foods such as soups, puddings, and dips. *Salmonella* spp. and Noroviruses were the most common hazards associated with the multi-ingredient food category.

Produce and produce dishes. A total of 639 foodborne illness outbreaks involving 31,496 cases were linked to produce and produce dishes. The



produce category had an average of 49 cases per outbreak. Vegetables were linked to 231 outbreaks with 11,957 cases, while fruits were identified as the vehicle in 103 outbreaks with 8,284 cases. Of the 103 fruit-associated outbreaks, 16 were linked to berries and 29 were linked to melon. Produce dishes were implicated in 305 outbreaks involving 11,255 cases. In produce-linked outbreaks, *Salmonella* spp., Noroviruses,

and *Escherichia* accounted for the majority of foodborne illness cases.

Eggs and egg dishes. A total of 341 foodborne illness outbreaks with 11,027 cases were linked to eggs and egg dishes. The average number of cases per egg-linked outbreak was 32. Egg-based dishes such as french toast and egg salad were linked to 267 outbreaks with 8,910 cases, and eggs themselves were linked to 74 outbreaks with 2,117 cases. *Salmonella*

Enteritidis was the most common hazard among the egg-related outbreaks, accounting for 82 percent of the egg outbreaks.

Dairy. A total of 168 foodborne illness outbreaks and 5,580 cases were linked to dairy products such as cheese, milk, and ice cream. Dairy products had an average of 33 cases per outbreak. Milk was identified as the vehicle in 56 outbreaks with 1,457 cases, cheese was identified in 50 outbreaks with 1,791 cases, and ice cream was identified in 44 outbreaks with 1,807 cases. Unpasteurized items were associated with 30% of the dairy-related outbreaks. In outbreaks associated with dairy items, *Salmonella* spp. and *Campylobacter* spp. were the most common hazards.

Breads and Bakery. A total of 142 foodborne illness outbreaks with 4,136 cases were linked to breads and other bakery items. The bread and bakery category had an average of 29 cases per outbreak. Breads were associated with 32 outbreaks and 980 cases, while bakery items such as cake, pie, and cheesecake were linked to 110 outbreaks and 3,156 cases. *Salmonella* spp. and Noroviruses were the most common hazards in bread and bakery items.

Beverages. A total of 74 foodborne illness outbreaks and 3,015 cases were linked to beverages. The average number of cases per beverage-related outbreak was 41. Juices were associated with 22 outbreaks and 1,514 cases, among which almost a third were linked to unpasteurized juices. Other beverages such as alcoholic drinks, coffee, and soda were linked to 52 outbreaks with 1,501 cases. Contamination from chemicals, Noroviruses, *Salmonella* spp., and *E. coli* O157:H7 were the most common hazards in beverages.

Game. A total of 26 foodborne illness outbreaks with 186 cases were linked to game. This category includes walrus, bear, moose, venison, and cougar meats. The game category had an average of 7 cases per outbreak. In game-related outbreaks, the parasite *Trichinella* was the most common hazard.

USDA-Regulated Foods

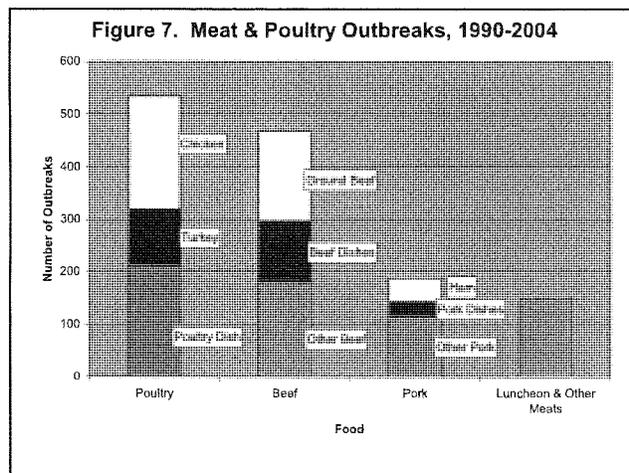
Poultry and poultry dishes. A total of 541 foodborne illness outbreaks with 16,280 cases were linked to poultry. The average number of cases per poultry-related outbreak was 30. Chicken was linked to 214 outbreaks with 3,975 cases, while turkey was identified as the vehicle in 109 outbreaks with 5,832 cases. Seven outbreaks with 114 cases were linked to

other types of poultry, such as duck, game hen, and goose. Poultry dishes were linked to an additional 211 outbreaks with 6,359 cases. The most significant hazards in the poultry category were *Salmonella* spp., *Clostridium perfringens*, *Staphylococcus aureus*, and Noroviruses.

Beef and beef dishes. A total of 467 foodborne illness outbreaks with 13,220 cases were linked to beef. The average number of cases per beef-related outbreak was 28. Ground beef was linked to 171 outbreaks with 3,425 cases, while other types of beef such as roast beef, veal, and beef jerky were linked to 178 outbreaks with 6,439 cases. Beef dishes including casseroles, gravies, and stews caused 118 outbreaks with 3,356 cases. In beef-related outbreaks, the most common hazards were *E. coli* O157:H7, *Clostridium perfringens*, and *Salmonella* spp.

Pork and pork dishes. A total of 188 foodborne illness outbreaks with 6,081 cases were linked to pork. Ham was identified as the vehicle in 46

outbreaks with 2,107 cases. Other types of pork were linked to 112 outbreaks with 3,170 cases. Pork dishes were linked to 30 outbreaks with 804 illnesses. The pork category had an average of 32 cases per outbreak. The most common hazard in pork was *Staphylococcus aureus*.



Luncheon and other meats. A total of 149 foodborne illness outbreaks with 5,542 cases were linked to other meats. Of these, 50 outbreaks with 1,014 cases were attributed to hot dogs and other ready-to-eat luncheon meats such as bologna and salami. Thirty-six outbreaks with 2,193 cases were linked to other meats including lamb, goat, and sausage. Meat dishes were linked to 63 outbreaks with 2,335 cases. The other meats category

had an average of 37 cases per outbreak. *Clostridium perfringens* was the most common hazard for outbreaks linked to other meats.

Foods Regulated by Both FDA and USDA

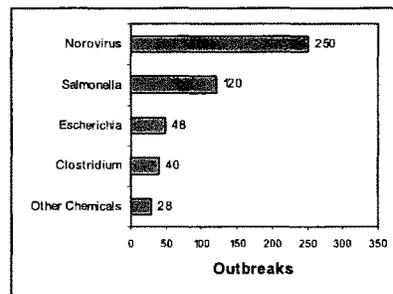
Multiple foods. A total of 333 foodborne illness outbreaks with 17,753 cases were linked to meals containing foods regulated by both FDA and USDA. These foods included such meals as chicken served with salad, pork with coleslaw, and ground beef with potatoes. This category had an average of 53 cases per outbreak. In foods regulated by both the FDA and USDA, *Salmonella* was the most common hazard.

FOODS MOST FREQUENTLY LINKED TO FOODBORNE ILLNESS OUTBREAKS

Produce

Although diets rich in fruits and vegetables provide clear health benefits, those foods occasionally carry harmful microorganisms, including *Salmonella*, Noroviruses, and *E. coli*. Pathogens can jump from animals to produce via contaminated irrigation water, direct application of inadequately processed manure to soil, or even cross-contamination from raw meats in the kitchen. In fact, approximately 30 percent of the produce outbreaks identified by CSPI were caused by pathogens commonly found in meat and poultry.¹⁴ Viruses, like Norovirus and Hepatitis A, often are transferred to produce from human sources. Pathogens can adhere to the rough surfaces of fruits and vegetables, so consumers should take precautions, such as washing produce under running water. Despite the risk, consumers should still eat plenty of fruits and vegetables. But with mandatory farm-based controls, consumers could enjoy the benefits of raw produce with less risk of foodborne illness.

Figure 8. Leading Produce Pathogens



In September 2006, tainted prepackaged Natural Selections spinach triggered an *E. coli* O157:H7 outbreak resulting in at least three deaths and 204 illnesses. The spinach was traced back to Salinas Valley, California, where samples of cattle feces found near a field that produced the

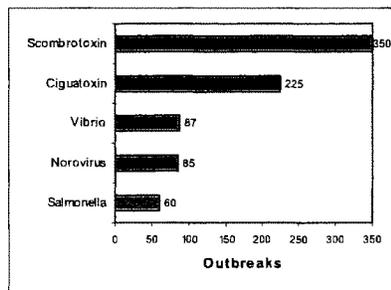
contaminated spinach matched the genetic pattern of the strain of *E. coli* found in the people who became ill.¹⁵

Soon after the September spinach outbreak, consumers were sickened with a different hazard – *Salmonella* Typhimurium, found in tomatoes. In September and October 2006, over 183 people in 21 states became ill from *Salmonella*-contaminated tomatoes served in restaurants. Minnesota, Massachusetts, Kentucky, and Connecticut had large numbers of infected consumers.¹⁶

Seafood

Seafood is one of the leading causes of food-borne illness outbreaks in the U.S. Outbreaks can result from naturally occurring toxins, such as scombrototoxin and ciguatoxin in finfish, and microbial hazards, such as *Vibrio* bacteria and Noroviruses, in shellfish. In finfish, harvesting conditions or improper handling after harvest can cause toxins to form. Once formed, the toxins are not destroyed by cooking.¹⁷ Shellfish can become contaminated with bacteria and viruses in harvesting beds. If not refrigerated shortly after harvest, levels of pathogens can increase. For example, the deadly bacterium *Vibrio vulnificus* can grow in shellfish to numbers 10 to 100 times higher over several hours if the shellfish are not refrigerated after harvest.¹⁸

Figure 9. Leading Seafood Pathogens



To help keep seafood safe, the FDA should increase its inspection of processors and implement testing programs to verify that firms are controlling the hazards in their products. Consumers can help protect themselves by not eating tropical or subtropical reef fish like barracuda, by refrigerating all seafood, and by only eating cooked shellfish or raw shellfish that have been treated to eliminate hazardous bacteria.

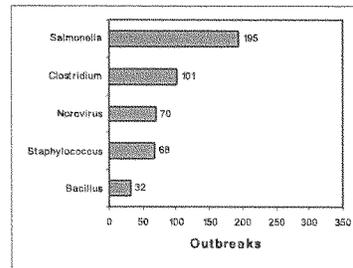
Poultry

Hazards commonly linked to poultry outbreaks include *Salmonella* spp., *Clostridium perfringens*, and *Staphylococcus aureus*. *Campylobacter jejuni* is a hazard frequently associated with raw poultry, however

virtually all illnesses occur as sporadic cases and not as part of large outbreaks. Thus, the effects of that pathogen are not captured in outbreak data. Farm practices, such as crowding and the use of antibiotics, also can affect the safety of poultry products. Farmers and processors must recognize the critical role they play in maintaining a safe food supply. Government food-safety programs should be expanded to improve conditions on farms, as well as in the slaughter plants.

During the summer of 2002, an outbreak of *Listeria monocytogenes* caused over 120 illnesses and 13 deaths. In the aftermath of that outbreak, Wampler Foods recalled 27.4 million pounds of fresh and processed poultry products, making this one of the largest recalls in history. Consumers can decrease the risk from contaminated poultry by avoiding cross-contamination when handling raw poultry and by cooking all poultry thoroughly.

Figure 10. Leading Poultry Pathogens

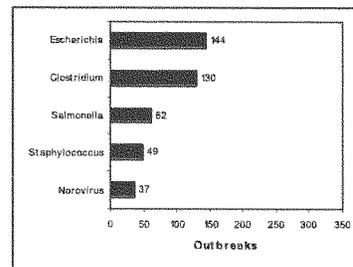


Beef

E. coli O157:H7 and *Clostridium* spp. are the biggest hazards in beef. These bacteria live in the intestines of animals without causing illness to the animal, but can cause diarrhea, vomiting, painful abdominal cramps, and sometimes kidney failure and death if ingested by humans. Many beef outbreaks listed in *Outbreak Alert!* might have been avoided if the government and the beef industry were more vigilant about keeping hazards out of meat, and increased their testing of beef products. Consumers can help protect themselves by cooking all beef to 160°F, using a meat thermometer to verify temperature, to ensure all bacteria are killed.

Beef and beef dishes have caused many large, well-publicized outbreaks of foodborne illness and recalls.¹⁹ In September 2004, an outbreak of *Salmonella* Typhimurium resulted in 31 illnesses in nine states. An investigation conducted by state health departments, CDC, and the USDA Food Safety and Inspection Service (FSIS) identified ground beef

Figure 11. Leading Beef Pathogens



purchased at a national chain of supermarkets as the source of *S. Typhimurium* infections. Traceback results found that the product originated from a common supplier; however, plant practices conformed to FSIS production guidelines, and no product recalls were made. Without recalls, tainted meat can continue to be sold at supermarkets, served at countless restaurants, and grilled at homes.²⁰

Eggs

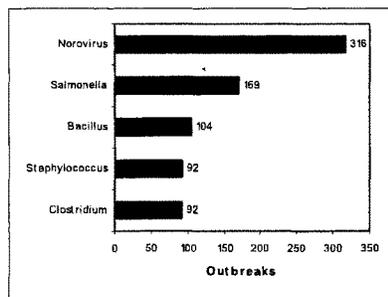
Eggs and egg dishes cause large numbers of outbreaks every year. The primary hazard associated with the consumption of raw and undercooked eggs is *Salmonella* Enteritidis (SE), which caused 96% of outbreaks in eggs. In 1998, the USDA estimated that approximately one egg in 20,000, or about 2.3 million eggs annually, contained SE.²¹ To better protect consumers, FDA should finalize plans to increase oversight on the farm, including ensuring that chicken flocks are tested for SE, increased immunization of flocks, and ensuring that eggs from SE-contaminated flocks are pasteurized prior to sale. In the meantime, consumers can protect themselves by fully cooking eggs and egg dishes; by avoiding foods containing raw eggs, such as Hollandaise sauce and raw cookie dough; or by using pasteurized eggs.

Multi-Ingredient Foods

Multi-ingredient foods, including pizza, salads, and sandwiches, cause a large number of outbreaks. Pathogens of concern include Noroviruses and *Salmonella*. Many practices in home and restaurant kitchens can make multi-ingredient foods hazardous, including cross-contamination, under-cooking, inadequate cooling and storage, and worker contamination. Some states and counties have adopted grading systems to inform

consumers about restaurants' compliance with health codes and to encourage restaurants to improve their practices. At home, consumers can protect themselves by cleaning all cutting boards, utensils, hands, and other surfaces that touch raw meat before using them to prepare or serve other foods; by cooking foods thoroughly; and by refrigerating leftovers promptly.

Figure 12. Leading Pathogens in Multi-Ingredient Foods



RECOMMENDATIONS

With the continuing occurrence of foodborne illnesses and more recent concerns about bioterrorism, bovine spongiform encephalopathy, and avian influenza, changes are needed in government systems to increase public health protections. Implementing the following recommendations would help close holes in the federal food-safety net and, ultimately, decrease the number of illnesses and deaths caused by contaminated food.

The CDC Should Continue To Improve Outbreak Reporting and Surveillance

Outbreak information serves several important functions. It can alert consumers to food safety hazards and help policymakers and public health officials to (1) identify emerging problems, (2) evaluate existing programs, and (3) set goals and priorities for food safety. Having a timely and comprehensive inventory of foodborne illness outbreaks would allow food regulators to monitor trends, issue consumer alerts, and improve production practices. Historically, the CDC's foodborne illness outbreak reporting and surveillance programs have fallen short of meeting those goals, but in the past several years, CDC has made several improvements.

- The CDC has dramatically increased its use of the Internet to gather foodborne illness outbreak reports. The agency's website offers state public health officials an outbreak investigation tool kit and online reporting forms.
- The CDC has resumed publishing its line listing of foodborne illness outbreaks, a practice that was ended in the mid-1980s due to funding constraints.²² The CDC has published new outbreak information on its website, including line listings for 2004.
- Reporting by the states has also increased. As a result, the CDC updated its line listings for 1990-1997 to include over 500 outbreaks that were not on the older version of the listings.²³
- The CDC has expanded systems such as FoodNet and PulseNet, which provide information needed for faster nationwide tracking of foodborne illness.

Those improvements are important, but the CDC also should mandate reporting by states, provide real-time reporting of outbreaks, and organize

outbreaks by food hazard to increase the utility of its information. Those gaps are particularly troubling, given the threat of bioterrorism to our food supply.

While better monitoring and reporting of foodborne illness outbreaks are important, the most important goal is to develop a preventative system that reduces the toll of foodborne illnesses.

The Recipe for Safe Food: A Unified, Independent Food-Safety Agency

Currently, food is regulated by at least a dozen different federal agencies and 35 different statutes. A single, independent food-safety agency – administering a unified statute – could better address the problems with

"[O]ne official should be responsible for federal efforts in food safety and have control of resources allocated to food safety."

- Institute of Medicine, Report on Ensuring Safe Food from Production to Consumption, 1998

food-safety inspection and regulation, including gaps in consumer protections, inadequate coordination, conflicting public health standards, regulatory redundancies, and slow approvals of new technologies. A strengthened food-safety net should help decrease the numbers of foodborne illnesses and provide better protection against

bioterrorism. A 1998 Institute of Medicine (IOM) report on food safety called for the consolidation of food-safety responsibilities under a single statute, with a single budget and single leader. The IOM report concluded that the "current fragmented regulatory structure is not well equipped to meet the current challenges."²⁴ In October 2001, the General Accounting Office reported that:

A single food-safety agency responsible for administering a uniform set of laws is needed to resolve the long-standing problems with the current system; deal with emerging food-safety issues, such as the safety of genetically modified foods or deliberate acts of contamination; and ensure a safe food supply.²⁵

The transition to a new and more effective federal agency offering more comprehensive protections to public health requires both organizational and statutory changes.

Organizational Changes

The Bush Administration and Congress should unify all of the federal food-safety activities within a single, independent agency – the Food Safety Administration (FSA). Legislation to create a unified agency has been introduced in Congress by Senator Richard Durbin (D-IL) and Representative Rosa DeLauro (D, 3rd-CT). That

“A single food safety agency is the single best way to protect families from food-related illness or attack.”

- Sen. Dick Durbin (D-IL), co-chair of the Congressional Food Safety Caucus²⁶

agency would be responsible for setting food-safety and labeling standards, approving new food technologies, conducting food-safety inspections, and enforcing the relevant laws. A presidentially appointed, congressionally confirmed Administrator should lead the new agency. The FSA should integrate units from numerous federal departments, including:

- USDA’s Food Safety and Inspection Service and the egg inspection program of USDA’s Agricultural Marketing Service;
- FDA’s food regulatory components (including the Center for Food Safety and Applied Nutrition, components of the Center for Veterinary Medicine, and the food-related laboratory and field resources of FDA’s Office of Regulatory Affairs);
- Environmental Protection Agency’s pesticide tolerance setting program; and
- Department of Commerce’s voluntary seafood inspection program.

The non-regulatory, foodborne illness surveillance program of the CDC should remain separate to provide ongoing information on the nature and magnitude of food-safety hazards. Similarly, food-safety research activities conducted by the National Institutes of Health, Agricultural Research Service, and other research agencies should not be incorporated into the FSA, but should provide research responsive to the needs of that agency.

Statutory Changes

The food-safety and inspection provisions of the Federal Food, Drug and Cosmetic Act, the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act need to be replaced by a unified and modernized food-safety statute. The new statute would

build on the strengths of the existing laws, while modernizing the mandates and authorities of the new FSA. The unification of the food-safety system should be accomplished over several years, with full participation by many stakeholders, including the food and agriculture industries, scientists, and public health experts. Key elements would include:

Clear definition and empowerment of the roles of government, consumers, and the food industry, including: (1) the food industry's responsibility to produce safe products by using up-to-date preventive process controls; (2) the government's authority to establish and oversee compliance with food-safety standards, such as limits on pesticide residues and performance standards for reducing microbial pathogens; (3) the government's responsibility to use its regulatory tools in ways that systematically reduce the risk of foodborne illness; and (4) consumers' right to transparent government decision-making and accountability.²⁷

A modernized mandate for food inspection to: (1) require that inspection resources be allocated across the food supply based on risk; (2) set a minimum frequency of inspection for food-production establishments, taking into account the food-safety risks and companies' past performances; (3) establish a statutory mechanism to ensure that inspection resources are increased as needed to allow for risk-based reallocation and that future funding levels are adequate to meet the modernized inspection mandate; and (4) coordinate inspections and resource allocation with state and local food-safety agencies.

Enhancement of enforcement authorities and other tools of accountability, including: (1) authority to mandate recalls of contaminated food; (2) adequate civil and other penalties for repeat or egregious violators of food-safety standards; and (3) citizen-suit provisions to enforce food-safety statutes.

Strengthened oversight of imported foods to ensure they are at least as safe as U.S.-produced foods, including: (1) authority to ensure that imported foods meet U.S. safety standards; (2) increased inspection of foreign food-production establishments, especially in countries whose food-safety regulatory systems have not been demonstrated to be equivalent to the U.S. system; and (3) increased border inspections of imported food.

Refinement of the procedures for evaluating and approving new food technologies, for example, carcass treatments to reduce bacteria, in order to: (1) maintain high scientific standards; (2) increase opportunities for public participation; (3) expedite the availability of technologies that can improve food safety.

A mandate to regulate animal production practices that cause or contribute to human illness, including (1) the authority to require feedlots, factory farms, and other producers to raise and transport livestock in ways that prevent or minimize pathogen contamination; and (2) a broad mandate to address the misuse and overuse of antibiotics in livestock production.

While creating a single food-safety agency with new authorities must be done thoughtfully, it also must be done expeditiously. Gaps in current systems are leaving consumers vulnerable to outbreaks of foodborne illness from both bioterrorism and unintentional contamination.

Consumers cannot afford to wait years or even decades for the agencies to resolve their competing agendas. It is time for the government to enhance CDC programs and create a single food-safety agency that enforces a modernized and unified food-safety statute.

**APPENDIX A: SUMMARY OF FOODBORNE OUTBREAKS AND
CASES, 1990-2004**

| FDA-Regulated Foods | | | | USDA-Regulated Foods | | | |
|------------------------|-------------------------------------|---------------|---------------|---|--------------|---------------|-------|
| Category | Subdivision | Outbreaks | Cases | Category | Subdivision | Outbreaks | Cases |
| Beverages | Juices | 22 | 1,514 | Beef | Ground Beef | 171 | 3,425 |
| | Other Beverages | 52 | 1,501 | | Beef Dishes | 118 | 3,356 |
| | Beverages Total | 74 | 3,015 | | Other Beef | 178 | 6,439 |
| Breads & Bakery | Bakery | 110 | 3,156 | Beef Total | 467 | 13,220 | |
| | Breads | 32 | 960 | Luncheon | 50 | 1,014 | |
| | Breads & Bakery Total | 142 | 4,136 | Meat Dishes | 63 | 2,335 | |
| Dairy | Cheese | 50 | 1,791 | Other Meats | 36 | 2,193 | |
| | Ice Cream | 44 | 1,807 | Luncheon & Other Meats Total | 149 | 5,542 | |
| | Milk | 56 | 1,457 | Pork | Ham | 46 | 2,107 |
| | Other Dairy | 18 | 525 | | Pork Dishes | 30 | 804 |
| | Dairy Total | 168 | 5,580 | | Other Pork | 112 | 3,170 |
| Eggs | Eggs | 74 | 2,117 | Pork Total | 188 | 6,081 | |
| | Egg Dishes | 267 | 8,910 | Chicken | 214 | 3,975 | |
| | Eggs Total | 341 | 11,027 | Turkey | 109 | 5,832 | |
| Game | Game Total | 26 | 186 | Other Poultry | 7 | 114 | |
| Multi-Ingredient Foods | Rice/Beans/Stuffing/Pasta Dishes | 191 | 4,696 | Poultry Total | 541 | 16,280 | |
| | Salads | 215 | 9,771 | USDA Total | 1,345 | 41,123 | |
| | Sandwiches | 129 | 3,365 | | | | |
| | Sauces/Dressings/Oils | 55 | 1,875 | | | | |
| | Multi-Ingredient Dishes | 223 | 4,433 | | | | |
| | Other Foods | 135 | 3,672 | | | | |
| | Multi-Ingredient Foods Total | 948 | 27,812 | | | | |
| Produce | Fruits | 103 | 6,284 | | | | |
| | Vegetables | 231 | 11,957 | | | | |
| | Produce Dishes | 305 | 11,255 | | | | |
| | Produce Total | 639 | 31,496 | | | | |
| Seafood | Finfish | 622 | 3,182 | | | | |
| | Molluscan Shellfish | 155 | 3,399 | | | | |
| | Seafood Dishes | 138 | 2,516 | | | | |
| | Other Seafood | 69 | 872 | | | | |
| | Seafood Total | 984 | 9,969 | | | | |
| FDA Total | 3,322 | 93,221 | | | | | |

| Multiple Foods | | | |
|----------------|-------------------|------------|---------------|
| Category | Subdivision | Outbreaks | Cases |
| Both | Both Total | 333 | 17,753 |

| All Foods | Total Outbreaks | Total Cases |
|--------------------|-----------------|----------------|
| Grand Total | 5,000 | 152,097 |

4/20/2007

Follow-up Questions from food import briefing with the House Committee on Energy & Commerce

Request:

5-year trend data re: outbreaks linked to imported food vs. domestic food

Response:

Between 2002 and 2006, there were a total of 152 outbreaks associated with FDA-regulated foods. Of these 152 outbreaks, 33 (22%) were associated with imported products, 98 (64%) were associated with domestic products, and 21 (14%) were associated with products of unknown source.¹

Table 1.

Outbreaks associated with FDA-regulated products by import/domestic source and year, 2002-2006

| | Imported | Domestic | Unknown | Total |
|--------------|----------|----------|---------|-------|
| 2002 | 4 | 29 | 4 | 37 |
| 2003 | 8 | 26 | 6 | 40 |
| 2004 | 6 | 18 | 10 | 34 |
| 2005 | 7 | 16 | 1 | 24 |
| 2006 | 8 | 9 | 0 | 17 |
| Total | 33 | 98 | 21 | 152 |

¹ **Caveats for foodborne outbreak/illness data collected by CFSAN:**

1. The data only represent those outbreaks and illnesses associated with FDA-regulated foods.
2. The data do not contain information on outbreaks/illnesses where the point of contamination is the retail food setting or home.
3. The data do not include illnesses transmitted from person-to-person.
4. Illness data represents only the number of illnesses reported to CDC, FDA, and state/local health departments in association with an outbreak. The data does not include illnesses that may have occurred but were not reported.
5. Information on outbreaks/illness reported prior to 2004 has been compiled from paper records; information on outbreaks/illnesses since 2004 has been entered into the CFSAN Outbreak Surveillance Database.
6. The data do not include sporadic *Vibrio* infections.
7. The outbreaks tracked by FDA are a subset of all the outbreaks tracked by CDC.

EY28

Table 2.

Outbreaks associated with FDA-regulated products by import/domestic source and product, 2002-2006

| | Imported | Domestic | Unknown | Total |
|------------------------|-----------------|-----------------|----------------|--------------|
| Produce | 6 | 22 | 8 | 36 |
| Sprouts | 5 | 3 | 1 | 9 |
| Dairy | 6 | 7 | 4 | 17 |
| Eggs | 0 | 42 | 0 | 42 |
| Processed foods | 0 | 14 | 2 | 16 |
| Seafood | 16 | 10 | 6 | 32 |
| Total | 33 | 98 | 21 | 152 |

Table 3.

Outbreaks associated with FDA-regulated products by import/domestic source and product, 2002

| | Imported | Domestic | Unknown | Total |
|------------------------|-----------------|-----------------|----------------|--------------|
| Produce | 1 | 4 | 1 | 6 |
| Sprouts | 1 | 1 | 0 | 2 |
| Dairy | 1 | 2 | 1 | 4 |
| Eggs | 0 | 21 | 0 | 21 |
| Processed foods | 0 | 1 | 0 | 1 |
| Seafood | 1 | 0 | 2 | 3 |
| Total | 4 | 29 | 4 | 37 |

Table 4.

Outbreaks associated with FDA-regulated products by import/domestic source and product, 2003

| | Imported | Domestic | Unknown | Total |
|------------------------|-----------------|-----------------|----------------|--------------|
| Produce | 1 | 4 | 2 | 7 |
| Sprouts | 2 | 2 | 1 | 5 |
| Dairy | 3 | 1 | 0 | 4 |
| Eggs | 0 | 15 | 0 | 15 |
| Processed foods | 0 | 3 | 0 | 3 |
| Seafood | 2 | 1 | 3 | 6 |
| Total | 8 | 26 | 6 | 40 |

Table 5.
Outbreaks associated with FDA-regulated products by import/domestic source and product, 2004

| | Imported | Domestic | Unknown | Total |
|------------------------|-----------------|-----------------|----------------|--------------|
| Produce | 1 | 5 | 4 | 10 |
| Sprouts | 2 | 0 | 0 | 2 |
| Dairy | 0 | 3 | 3 | 6 |
| Eggs | 0 | 2 | 0 | 2 |
| Processed foods | 0 | 3 | 2 | 5 |
| Seafood | 3 | 5 | 1 | 9 |
| Total | 6 | 18 | 10 | 34 |

Table 6.
Outbreaks associated with FDA-regulated products by import/domestic source and product, 2005

| | Imported | Domestic | Unknown | Total |
|------------------------|-----------------|-----------------|----------------|--------------|
| Produce | 2 | 4 | 1 | 7 |
| Sprouts | 0 | 0 | 0 | 0 |
| Dairy | 2 | 1 | 0 | 3 |
| Eggs | 0 | 4 | 0 | 4 |
| Processed foods | 0 | 4 | 0 | 4 |
| Seafood | 3 | 3 | 0 | 6 |
| Total | 7 | 16 | 1 | 24 |

Table 7.
Outbreaks associated with FDA-regulated products by import/domestic source and product, 2006

| | Imported | Domestic | Unknown | Total |
|------------------------|-----------------|-----------------|----------------|--------------|
| Produce | 1 | 5 | 0 | 6 |
| Sprouts | 0 | 0 | 0 | 0 |
| Dairy | 0 | 0 | 0 | 0 |
| Eggs | 0 | 0 | 0 | 0 |
| Processed foods | 0 | 3 | 0 | 3 |
| Seafood | 7 | 1 | 0 | 8 |
| Total | 8 | 9 | 0 | 17 |

Imported Food and Feed Samples Analyzed in FDA Laboratories

| Laboratory | FY 2005 | | FY 2006 | |
|---|---------------|------------------|---------------|------------------|
| | Human Food | Animal Food/Feed | Human Food | Animal Food/Feed |
| Arkansas Regional Laboratory | 3,070 | 110 | 3,130 | 140 |
| Atlanta Regional Laboratory | 2,717 | 31 | 2,190 | 42 |
| Denver | 1,664 | 108 | 1,279 | 66 |
| Detroit | 159 | | 95 | 2 |
| Kansas City | 352 | 5 | 277 | 14 |
| National Forensic Chemistry Center | 4 | | 9 | |
| New York Regional Laboratory | 5,941 | 335 | 5,021 | 147 |
| Pacific Regional Lab Northwest | 1,991 | 131 | 1,318 | 79 |
| Pacific Regional Lab Southwest | 4,937 | 4 | 3,765 | 4 |
| San Francisco | 1,218 | 20 | 724 | 3 |
| San Juan | | | 53 | |
| Winchester Electronic Analytical Center | 358 | | 371 | 1 |
| Total | 22,411 | 744 | 18,232 | 498 |

Human Food: All foods including additives, vitamins, dietary supplements, etc. but excludes miscellaneous food-related items (e.g. baby bottle nipples, cookware, etc.)

Animal Food/Feed: Includes Type A medicated articles for medicated feeds, medicated feeds, non-medicated feeds, animal by-products and pet food.

Ex 29

"A Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?"

My name is William Marler. My law firm Marler Clark, located in Seattle, Washington, specializes in foodborne diseases, especially E. coli, Salmonella, Hepatitis A, Campylobacter, Shigella, Norovirus, and Listeria. Unfortunately, we at Marler Clark have been "in business" since The Jack in the Box E. coli outbreak of 1993. I was here in 1994 during the last set of serious hearings about the safety of our food supply. Demand for our litigation services on behalf of witnesses such as Ashley and Isabella Armstrong, Sean Pruden and Terri Marshal's mother-in-law has continued to grow at an alarming rate.

Today, the U.S. Center for Disease Control estimates that there are 76 million cases of foodborne illness annually. That means one in four Americans will contract a foodborne disease every year. Hundreds of thousands will be hospitalized and thousands will die.

My clients who will testify before this committee are but a small slice of your constituents who will suffer and die needlessly each year and every year unless action is taken. That's the human suffering part. There is also the business part. Billions of dollars will be spent on medical treatment and many more billions will be lost in wages and in sales of food. When American business poisons its customers and when our regulatory agencies do not have the manpower or the ability to help business perform, people die and market share is lost, nationally and internationally.

My goal in testifying here today is that you put Marler Clark "out of business." It is time that you help government, help business, help consumers and make me unnecessary. I will do that by presenting best practices and other recommendations that can make that possible. Therefore, I thank this committee for inviting me to help with a dialogue about making the food chain safer for consumers.

The issue of food safety is not new, of course. A century ago Upton Sinclair's book "The Jungle" exposed both contamination of meat processing and the corruption that lead inspectors to look the other way.

Three-quarters of the nation's lettuce and spinach come from California. When consumer confidence in the safety of the produce food chain declines, so does the profitability of a key industry. There is also damage to the brandnames of a state's specific products. These business implications extend beyond California. More companies, ranging from food processors to retailers, are asking for help to regain their "reputational capital" after foodborne disease problems. Will the brandnames of the fast-food chains involved in the recent E. coli outbreaks fully recover? The jury is out on that one.

What has changed since Upton Sinclair's "Jungle" are two things.

One, the source of disease has shifted from the meat that Sinclair described to produce. As usually happens, it took a crisis for incidences of E. coli in meat to decline. That crisis occurred in the early 1990s. Undercooked hamburgers containing E. coli from Jack in the Box sickened 650 people, four of them children who died.

Shortly, I will discuss how that problem was fixed, perhaps not completely, and the important lessons we as a nation should learn from that. Incidentally, that has been one of the major food safety success stories of our time. According to the CDC, E.

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coli outbreaks linked to tainted meat have declined by 42 percent. The American Meat Institute puts that figure at 80 percent. Currently, the single largest source of food-borne disease is produce such as lettuce, spouts, tomatoes, spinach, green onions and parsley. Here are some figures. In the past 10 years, the Food and Drug Administration - the FDA - reported 21 outbreaks related to fresh leafy products. In 2006, 205 people became sick and five died from eating E. coli contaminated spinach. Late last year and throughout this year, the CDC reported that over 425 people in 44 states have become infected with Salmonella Tennessee found in peanut butter. More than 70 have been hospitalized. From experience, we know cases of Salmonella Tennessee go under-reported. It is likely that the sick may well be over 15,000. In the Northeast there was an outbreak of sickness from milk from a dairy processor that has had recurrent food safety issues.

The second development that's new in food safety has been the result of changing times. Here are just a handful of new variables we're dealing with:

1. The threat of terrorist attacks via the food system. Just as too many couldn't imagine the horror of 9/11, too many cannot envision this kind of disaster.
2. Growth of food imports. The latest problem came from contaminated wheat gluten from China. That affected animals not humans. That might do the trick in getting us to be duly concerned about imports of everything from pesticide-sprayed pea pods to salmonella infection in pigs from the European Union.
3. The well-intentioned but scientifically questionable use of "environmental-friendly practices" such as recycled water and planting native grasses.

So, how can we ensure that the gains in food safety that have already been made are preserved and the new problems addressed? From research and experience, here are eight recommendations.

First of all, there exist two "best practices" in meat that should be extended to produce. Following the Jack in the Box crisis, the head of the U.S.D.A.'s Food and Safety Inspection service took a regulatory and systems approach to food safety. That "hero" was Michael Taylor. Taylor declared that raw ground beef that is contaminated with E. coli would be classified and treated as "adulterated" within the meaning of the Federal Meat Inspection Act. Taylor also introduced a mandatory Risk Management System. The required meat processors to adopt comprehensive precautions. Those included carcass washes, citric acid sprays, steam pasteurization and air-exchange systems. Following Taylor's example, we must serve notice to produce and other food processors that E. coli, salmonella, etc. will be classified and treated as adulterants. In addition, the same kind of comprehensive Risk Management System must be established and implemented. Penalties must be criminal and civil. When these best practices are adopted, firms will have to certify that not only they, but that every aspect of their supply chain, also are in compliance. Branding can and should reflect this certification of both the firms and their suppliers. This would be a new kind of "Seal of Approval." This "Seal of Approval" can also apply to such issues as the location of produce fields near animal farms, what kinds of procedures are used, and the method of irrigation as well as the type of water used.

Two, we need the same kind of food safety champion that Taylor was. This person would be a highly visible symbol of our commitment. Along these lines, it is useful to

consider consolidating responsibility in one federal-level agency. That would be the central point for communication about best practices and the point of contact for state and local regulators and health departments.

Three, the track record of business for issuing warnings and recalls rapidly isn't good. The federal and state governments should have authority to do this. That means increased funding, particularly at the state level. Most outbreaks are regional, not national.

Four, produce an E. coli vaccine for cows. I would say that the lion's share of produce problems result from this contaminant passed on through cow feces.

Five, the nation requires education about the benefits of irradiation of all mass-produced food including produce. Resistance to this practice seems to be rooted in public perception, not science.

Six, attention has to be paid to the vulnerability of our food supply system to acts of terrorism. Denial and lack of common sense seem to dominate thinking at all levels - business and federal and state government.

Seven, why haven't we applied our economic and political muscle to imposing more stringent regulations on food imports? This is a central trade issue that has been neglected.

And, eight, there's an urgent need to improve the resources available to foodborne disease victims. At the top of the list are the out-of-pocket medical costs. Those are usually not immediately or even eventually reimbursed by medical insurance if victims have coverage. By time compensation comes from litigation, the person could be heavily in debt. Next on the list is the expense of missing work. Marler Clark has been encouraging food processors and retailers to provide this help as a gesture of goodwill.

Let me wrap this up with one thought. Just as the boldness, courage and relentlessness of Michael Taylor made meat safer, these eight recommendations can ensure the integrity of the rest of the food chain. And better care for victims. Let me say again: "I ask this committee to put us at Marler Clark out of business." Thank you.

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FDA Was Aware of Dangers To Food

Outbreaks Were Not Preventable, Officials Say

By Elizabeth Williamson
Washington Post Staff Writer
Monday, April 23, 2007; A01

The Food and Drug Administration has known for years about contamination problems at a Georgia peanut butter plant and on California spinach farms that led to disease outbreaks that killed three people, sickened hundreds, and forced one of the biggest product recalls in U.S. history, documents and interviews show.

Overwhelmed by huge growth in the number of food processors and imports, however, the agency took only limited steps to address the problems and relied on producers to police themselves, according to agency documents.

Congressional critics and consumer advocates said both episodes show that the agency is incapable of adequately protecting the safety of the food supply.

FDA officials conceded that the agency's system needs to be overhauled to meet today's demands, but contended that the agency could not have done anything to prevent either contamination episode.

Last week, the FDA notified California state health officials that hogs on a farm in the state had likely eaten feed laced with melamine, an industrial chemical blamed for the deaths of dozens of pets in recent weeks. Officials are trying to determine whether the chemical's presence in the hogs represents a threat to humans.

Pork from animals raised on the farm has been recalled. The FDA has said its inspectors probably would not have found the contaminated food before problems arose. The tainted additive caused a recall of more than 100 different brands of pet food.

The outbreaks point to a need to change the way the agency does business, said Robert E. Brackett, director of the FDA's food-safety arm, which is responsible for safeguarding 80 percent of the nation's food supply.

"We have 60,000 to 80,000 facilities that we're responsible for in any given year," Brackett said. Explosive growth in the number of processors and the amount of imported foods means that manufacturers "have to build safety into their products rather than us chasing after them," Brackett said. "We have to get out of the 1950s paradigm."

Tomorrow, a House Energy and Commerce subcommittee will hold a hearing on the unprecedented spate of recalls.



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"This administration does not like regulation, this administration does not like spending money, and it has a hostility toward government. The poisonous result is that a program like the FDA is going to suffer at every turn of the road," said Rep. John D. Dingell (D-Mich.), chairman of the full House committee. Dingell is considering introducing legislation to boost the agency's accountability, regulatory authority and budget.

In the peanut butter case, an agency report shows that FDA inspectors checked into complaints about salmonella contamination in a ConAgra Foods factory in Georgia in 2005. But when company managers refused to provide documents the inspectors requested, the inspectors left and did not follow up.

A salmonella outbreak that began last August and was traced to the plant's Peter Pan and Great Value peanut butter brands sickened more than 400 people in 44 states. The likely cause, ConAgra said, was moisture from a roof leak and a malfunctioning sprinkler system that activated dormant salmonella. The plant has since been closed.

The 2005 report shows that FDA inspectors were looking into "an alleged episode of positive findings of salmonella in peanut butter in October of 2004 that was related to new equipment and that the firm didn't react to, . . . insects in some equipment, water leaking onto product, and inability to track some product."

During the inspection, the report says, ConAgra admitted it had destroyed some product in October 2004 but would not say why.

"They asked for some of our documentation and we made the request to them that they put it in writing due to concerns about proprietary information," ConAgra spokeswoman Stephanie Childs said last week. "We did not receive a written request, . . . they filed the report and that was that."

Until February of this year. That's when the Centers for Disease Control and Prevention notified the FDA of a spike in salmonella cases in states near the ConAgra plant. The agencies contacted the company, which initiated a recall and shut the plant for upgrades.

Brackett said that if the FDA inspector had seen anything truly dangerous the agency would have taken further action. But, he said, the agency cannot force a disclosure, a recall or a plant closure except in extreme circumstances, such as finding a hazardous batch of product.

The problem in 2005, he added, "doesn't necessarily connect to the salmonella outbreak right now. It's not unusual to have it in raw agricultural commodities."

The FDA has known even longer about illnesses among people who ate spinach and other greens from California's Salinas Valley, the source of outbreaks over the past six months that have killed three people and sickened more than 200 in 26 states. The subsequent recall was the largest ever for leafy vegetables.

In a letter sent to California growers in late 2005, Brackett wrote, "FDA is aware of 18 outbreaks of foodborne illness since 1995 caused by [E. coli bacteria] for which fresh or fresh-cut lettuce was implicated. . . . In one additional case, fresh-cut spinach was implicated. These 19 outbreaks account for approximately 409 reported cases of illness and two deaths."

"We know that there are still problems out in those fields," Brackett said in an interview last week. "We knew there had been a problem, but we never and probably still could not pinpoint where the problem

was. We could have that capability, but not at this point."

According to Caroline Smith DeWaal, who heads the Center for Science in the Public Interest, a consumer-advocacy group, "When budgets are tight . . . the food program at FDA gets hit the hardest."

In next year's budget, passed amid discovery of contamination problems in spinach, tomatoes and lettuce, Congress has voted the FDA a \$10 million increase to improve food safety, DeWaal said. The Agriculture Department, which monitors meat, poultry and eggs and keeps inspectors in every processing plant, got an increase 10 times that amount to help pay for its inspection programs. The FDA visits problem food plants about once a year and the rest far less frequently, Brackett said.

William Hubbard, who retired as associate commissioner of the FDA in 2005 and founded the advocacy group Coalition for a Stronger FDA, said that when he joined the agency in the 1970s, its food safety arm claimed half its budget and personnel.

"Now it's about a quarter . . . at a time in which the problems have grown, the size of the industry has grown and imports of food have skyrocketed," Hubbard said.

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It's Not Just Pet Food

By Peter Kovacs
Monday, April 23, 2007; A17

Lost amid the anxiety surrounding the tainted U.S. pet food supply is this sobering reality: It's not just pet owners who should be worried. The uncontrolled distribution of low-quality imported food ingredients, mainly from China, poses a grave threat to public health worldwide.

Essential ingredients, such as vitamins used in many packaged foods, arrive at U.S. ports from China and, as recent news reports have underscored, are shipped without inspection to food and beverage distributors and manufacturers. Although they are used in relatively small quantities, these ingredients carry enormous risks for American consumers. One pound of tainted wheat gluten could, if undetected, contaminate as much as a thousand pounds of food.

Unlike imported beef, which is inspected at the point of processing by the U.S. Agriculture Department, few practical safeguards have been established to ensure the quality of food ingredients from China.

Often, U.S. officials don't know where or how such ingredients were produced. We know, however, that alarms have been raised about hygiene and labor standards at many Chinese manufacturing facilities. In China, municipal water used in the manufacturing process is often contaminated with heavy metals, pesticides and other chemicals. Food ingredient production is particularly susceptible to environmental contamination.

Equally worrisome, U.S. officials often lack the capability to trace foreign-produced food ingredients to their source of manufacture. In theory, the Bioterrorism Prevention Act of 2001 provides some measure of traceability. In practice, the act is ineffective and was not designed for this challenge. Its enforcement is also shrouded in secrecy by the Department of Homeland Security.

Even if Food and Drug Administration regulators wanted to crack down on products emanating from the riskiest foreign facilities, they couldn't, because they have no way of knowing which ingredients come from which plant. This is why officials have spent weeks searching for the original Chinese source of the contaminated wheat gluten that triggered the pet food crisis.

That it was pet food that got tainted -- and that relatively few pets were harmed -- is pure happenstance. Earlier this spring, Europe narrowly averted disaster when a batch of vitamin A from China was found to be contaminated with

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Enterobacter sakazakii, which has been proved to cause infant deaths. Thankfully, the defective vitamin A had not yet been incorporated into infant formula. Next time we may not be so fortunate.

Currently, most of the world's vitamins are manufactured in China. Unable to compete, the last U.S. plant making vitamin C closed a year ago. One of Europe's largest citric acid plants shut last winter, and only one vitamin C manufacturer operates in the West. Given China's cheap labor, artificially low prices and the unfair competitive climate it has foisted on the industry, few Western producers of food ingredients can survive much longer.

Western companies have had to invest heavily in Chinese facilities. These Western-owned plants follow strict standards and are generally better managed than their locally owned counterparts. Nevertheless, 80 percent of the world's vitamin C is now manufactured in China -- much of it unregulated and some of it of questionable quality.

Europe is ahead of the United States in seeking greater accountability and traceability in food safety and importation. But even the European Union's "rapid alert system" is imperfect. Additional action is required if the continent is to avoid catastrophes.

To protect consumers here, we must revise our regulatory approaches. The first option is to institute regulations, based on the European model, to ensure that all food ingredients are thoroughly traceable. We should impose strict liability on manufacturers that fail to enforce traceability standards.

A draconian alternative is to mount a program modeled on USDA beef inspection for all food ingredients coming into the country. This regimen would require a significant commitment of resources and intensive training for hundreds of inspectors.

Food safety is a bipartisan issue: Congress and the administration must work together and move aggressively to devise stricter standards. Rep. Henry Waxman (D-Calif.), chairman of the House Government Reform Committee, has deplored dangerous levels of lead in vitamin products originating in China. We must get to the bottom of this pressing public health issue, without self-defeating finger-pointing.

The United States is sitting on powder keg with uncontrolled importation and the distribution of low-quality food ingredients. Before it explodes -- putting more animals and people at risk -- corrective steps must be taken.

The writer was president of NutraSweet Kelco Co. from 1994 to 1997. He is a management consultant to many large food ingredient companies.



ConAgra Foods, Inc.
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April 23, 2007

TEL: 202-223-5115
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The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
United States House of Representatives
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Ed Whitfield
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives
2322 A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Stupak and Ranking Member Whitfield;

We understand Members of the Subcommittee on Oversight and Investigations have concerns about the adequacy of the Food and Drug Administration's access to company records, and we are writing to clarify ConAgra Foods' policies for providing FDA representatives access to company information. ConAgra Foods fully supports the efforts of regulatory authorities, whether at the federal, state, or local level, in carrying out their mandates in protecting the public health. With particular regard to the production of company documents that may assist regulatory authorities such as the Food and Drug Administration in their efforts, ConAgra's policy has always been to fully cooperate with any such requests within the structure of a protocol that is responsive to the request, while still providing the company with the necessary protections afforded by law.

With respect to the 2005 FDA inspection of the Sylvester facility, ConAgra's staff correctly followed our company's policy at the time. That policy, which required a written request for information, was designed to establish order to the production of documents to the FDA, especially where there may be sensitive proprietary information involved. Importantly, the policy was not designed to withhold any information from the FDA, but rather to simply obtain a written request so that (1) we would have an opportunity to follow necessary Freedom of Information Act protocol to protect appropriate competitive information, such as recipes and trade secrets, from public disclosure and (2) to assure that all responsive documents, regardless of whether they were located at the plant, would be produced. Although this is consistent with common practice in the food industry, the procedure was suspended in the recent recall of our peanut butter.

In the recent recall, we did not require any written requests for information. We were and are aligned completely with the FDA in the priority of responding without qualification in this setting. We can confirm that this kind of response will be forthcoming should we

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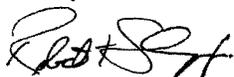
face a similar situation. In reviewing our policy moving forward we have decided to formalize our recent actions to make certain plant level personnel understand their authority in responding to FDA's investigatory needs. Specifically:

(1) In a recall-related situation, we will not require any written request for documentation; rather, we will authorize each plant manager and every plant quality control officer to provide immediate access to all plant information upon a verbal request from FDA and provide copies of such information upon request. Depending on the information being requested, our plant personnel still may confer with company headquarters personnel for guidance, but we will not require procedural protocols for any information that may be important to the FDA. This is the approach that we followed with the FDA in connection with the peanut butter recall.

(2) For routine inspections, we will instruct our plant managers and quality personnel to provide the FDA on-site review of our records and continue to answer all of the FDA's questions to the best of our ability. This will further ensure that the FDA investigators can conduct a complete review of our manufacturing processes. After reviewing the records, if the FDA still needs a copy, our plant personnel will be authorized to provide copies of routine, non-sensitive information upon a verbal request from the FDA. For sensitive proprietary information (such as trade secret processes and specific recipes), we will continue to ask for a written request for copies of records, so that we can be sure that production of documents is responsive, orderly, and complete, and that any such documents are properly marked to protect them from inappropriate disclosure under the Freedom of Information Act.

As with all interaction with government regulators, if the plant personnel at any time are uncertain as to how to proceed, they will be instructed to place an immediate call to corporate headquarters, with the goal of obtaining speedy resolution.

Sincerely,



Robert F. Sharpe, Jr.
Executive Vice President, Legal & External Affairs

DIMINISHED CAPACITY: CAN THE FDA SURE THE SAFETY AND SECURITY OF OUR NA- TION'S FOOD SUPPLY?—PART II

TUESDAY, JULY 17, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 9:30 a.m., in room 2123 of the Rayburn House Office Building, Hon. Bart Stupak (chairman) presiding.

Members present: Representatives DeGette, Melancon, Waxman, Green, Schakowsky, Inslee, Markey, Dingell, Whitfield, Walden, Murphy, Burgess, Blackburn, and Barton.

Staff present: David Nelson, Kevin Barstow, Richard Wilfong, Joanne Royce, Paul Jung, Scott Schloegel, Kyle Chapman, John Sopko, Alan Slobodin, Kristen Carpenter, and John Stone.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. Today we have a hearing on Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply? Before I begin the hearing, I would like to make a special announcement. As frequently happens with our Oversight and Investigation hearings, there is a change in policy that occurs on the eve of the hearing. This hearing is no exception.

For more than a year, Chairman Dingell and I have been calling on the FDA to end the practice of allowing meat which is treated with carbon monoxide and being sold in American groceries stores. Treating meat with carbon monoxide allows the meat to keep its freshly ground red color even though the meat may have spoiled.

I have a picture on the screen, or I should have a picture on the screen here. There are two packages of ground meat that were left out at room temperature for 27 hours. You can see the one which was treated with carbon monoxide looks fresh and red, while the other meat has turned brown and quite nasty looking. Late yesterday afternoon, following inquiries and discussions with the committee staff, Safeway Foods sent us this letter announcing that they will discontinue the sale of fresh meat products packaged using carbon monoxide. I wish to thank Safeway Inc. for their decision to stop selling fresh meat treated with carbon monoxide.

And with that, we will begin our hearing. With each member, we will have 5 minutes for an opening statement. I will begin.

Today we hold the second hearing by the subcommittee on whether FDA can assure the safety and security of the Nation's food supply. Since the subcommittee began investigating this issue early this year, the news on the food safety front has grown progressively worse.

A steady stream of food safety disaster followed the tragic deaths and illnesses caused by the spinach outbreak last fall. Fresh spinach packaged in California was contaminated with a deadly strain of *E. coli* bacteria. The spinach tragedies were quickly followed by an outbreak of life-threatening illnesses caused by salmonella in Peter Pan peanut butter. Both of these outbreaks were preventable.

Then there were the mysterious deaths of hundreds of cherished pets. We later learned that the American pet food had been contaminated by a wheat gluten from China. Wheat gluten is a vegetable protein found in everything from dietary supplements to baked goods to children's candy. Unfortunately, the Chinese exporters added a little something extra to its products: a poisonous chemical called melamine.

Shortly thereafter, it was discovered that the same deadly additive, melamine, was fed to hogs, chickens, and fish destined for human consumption. Commissioner von Eschenbach claimed that the tainted pet food case "demonstrated FDA's effectiveness at detecting and containing a problem."

His sunny prognosis has certainly been put to the test. The pet foods were soon followed by recalls of tainted cantaloupes, toothpaste, and the snack food Veggie Booty. And recent revelations about the scope of contaminated seafood imported from China are staggering. Our first hearing on April 24, 2007 exposed a fragmented food safety system beset with inconsistent oversight, ineffective coordination, and ineffective use of minimal resources.

How did the FDA respond? It announced, with great fanfare, the appointment of a food safety czar. In fact, Dr. David Atchinson, who received a glorified new title, has been central of FDA's food safety program for years. Promoting Dr. Atchinson does not begin to address the depth and chronic shortcomings in FDA's food safety program.

Nearly 10 years ago, the National Academy of Sciences concluded that the Federal food safety system was not equipped to meet the emerging challenges. Since then, these challenges have expanded exponentially, while FDA's ability to protect the American people has declined even further. Dr. David Kessler, FDA commissioner under both former Presidents Bill Clinton and George Bush recently called the food safety system as broken.

Sadly the primary findings of our investigations support this assessment. Investigators with the subcommittee traveled to interview FDA field personnel in San Francisco; Los Angeles; Denver; Kansas City; Winchester, MA; Atlanta; New York; and San Jose, Puerto Rico. FDA field personnel were more forthcoming about gaping holes in FDA's food safety net than were headquarter officials.

We learned, for example, that while the FDA inspects less than 1 percent of all imported foods, only a small fraction of that 1 percent is actually tested for contaminants. FDA requires only that a private laboratory test the suspect food for possible contamination.

These private labs that are testing are not subject to Federal oversight. FDA field personnel were highly critical of private laboratory testing, which they described as shoddy or even scary.

Another significant finding by staff investigators confirmed a concern that Chairman Dingell and I share with regarding the use of carbon monoxide to make meat and seafood appear fresh. I have repeatedly requested, to no avail, that FDA or HHS rescind the ruling that carbon monoxide can be used to treat meat, poultry, and seafood to make them look fresh regardless of their age or condition. In San Francisco, subcommittee investigators discovered large numbers of seafood imports from Asia and elsewhere arriving in airtight packages containing carbon monoxide. When tested, fully 20 percent of the seafood had to be refused because of contamination of decomposition. In other words, this was rotten seafood made to look fresh with the use of carbon monoxide.

Our investigation also confirmed that FDA's food safety program is woefully understaffed. Entry reviewers, investigators, and compliance officers simply cannot keep up with the flood of imported food. We confirmed that the FDA's ill-conceived decision to close 7 of its 13 laboratories would likely expose Americans to even more dangers from unsafe food, particularly imports.

We also learn from FDA staff that importers have found ways to circumvent even this minimal FDA authority all together by importing through ports with no FDA testing facilities. FDA field personnel, who answered our questions in a forthright and cooperative manner, were invaluable to our investigation. However, several FDA employees were fearful of retaliation and requested not to testify today, despite Commissioner von Eschenbach's promises of zero tolerance for retaliation against whistle blowers.

This subcommittee has heard far too many reports of FDA retaliation against employees who criticized the agency. We do not wish to risk the careers of FDA field staff who talk to our investigators. So our first panel will be committee staff testifying about their investigation. Our second panel will consist of two expert witnesses and four FDA officials from labs that the administration plans to shut down. They have shown tremendous courage by agreeing to testify today. The last panel will be comprised of four officials from FDA headquarters, including Dr. Andrew von Eschenbach who will provide the administration's testimony regarding the efforts of FDA to protect Americans from unsafe food.

The globalization of the American economy has resulted in dramatic increase in the volume of imported foods. Last year, China alone exported to the United States \$2.3 billion worth of agricultural products, not including seafood, compared with \$133 million in 1980. However, while food imports grew exponentially, FDA inspections dropped from 50,000 in 1972 to 5,000 in 2006, a 90 percent reduction. Is it any wonder that one out of every four Americans suffer a food borne illness every year?

There is a lot of question that our Federal food safety system is in need of a broad-based reform to reduce the risk to public health, national security and the economy. Today's hearing is to explore these risks and effort to pave the way for a reform.

That is the end of my opening statement. I next turn to my friend, Mr. Whitfield from Kentucky, for his opening statement. Mr. Whitfield, sir.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. WHITFIELD. Chairman Stupak, thank you very much for holding this important hearing on the ability of the FDA to protect the safety and security of America's food supply.

Recent problems with imports in our food supply have been making national headlines, and I must say that a lot of those headlines comes from China. Tainted wheat gluten originating in China was found to be killing animals in America. Since then, Chinese shipments of toxic toothpaste, toys, and seafoods have caused safety scares in America.

In 2004, bogus baby formulas killed dozens of infants in China. More recently, the Chinese media have reported half a dozen dead and many ill from a flawed antibiotic, 11 dead from tainted injections, 56 people ill from contaminated meat, toxic snacks pulled off shelves, and fake blood protein discovered in hospitals. Now, that is all domestic in China.

And in May the head of the agency that regulates Chinese food and drugs was sentenced to death and was executed for accepting bribes in exchange for licenses, produce fake drugs and medical devices. He was executed, but we don't know what happened to those people who did the bribing.

The general administrator of inspections and quarantines in China, China's standard watchdog, said that 20 percent of their domestic products have failed to meet safety standards. That kind of information should cause us pause to what is coming into America from China. Now, the FDA has the responsibility of regulating the safety of all domestic and imported articles used for food and drink, except for meat and poultry, and these include both animal and human foods. This means that FDA oversees 80 percent of the Nation's food supply. But the information I have, they only have 20 percent of the U.S. food safety budget. The U.S. Department of Agriculture has the biggest part of that budget.

And over the past 35 years as biotechnology became a focus of FDA regulation, the food safety share of FDA's budget declined from about half of FDA's budget to about a quarter. As FDA's resources for food safety has declined, America has become more of an importer of food products. Food imports have risen 15 percent annually over the last 10 years, and it is suggested that today literally 50 percent of our food supply imported.

So FDA has received more than 10 million imported food entries in fiscal year 2006 and just over 1 percent of those shipments were physically examined. FDA's main mission in food imports is, if possible, to prevent or lessen the chance of public health risks from FDA-regulated imports. FDA has relied upon border operations as a primary line of defense. The surge and volume, variety and complexity of imports as well as threats of terrorism are good reasons to overhaul FDA's system for the 21st century. Dr. Mark McClellan, when he was FDA commissioner, was right, I believe, when he

said that FDA needed to adopt a risk-based import system to replace the current import program.

Unfortunately, in 2007, the FDA lacks the health and safety information to make systematic risk-based decision. FDA makes initial screening decisions based only on the imports invoiced data, which is limited to seller, a description of the goods, and identification of the buyer. Recall information, laboratory results, facility inspection histories, and publicly available information related to possibly adulterated products from specific regions are not used to make decisions on which shipments to inspect.

FDA needs also to profile food control agencies in foreign countries, understand what they do, and where they are developing new programs. Such a systems approach was recommended by the GAO in 1983 for the Department of Agriculture's Food Safety and Inspection Service.

Second, FDA should establish an online training course for foreign regulators and food processors on good manufacturing practices. FDA may not be effectively using the authority even that it has today. While the Bioterrorism Act of 2002 gave FDA dramatically more authority over imported food, it took FDA 5 years before it invoked the Acts Authority for the first and only time in the pet food investigation.

There may also be gaps in FDA's law. Congress should pass legislation to make clear that FDA has authority to prosecute foreign food producers who tamper with food bound for the U.S., even when these acts occur outside U.S. territory.

I would like to thank, at the outset, all of our witnesses today including FDA Commissioner von Eschenbach who have come this morning to talk about the steps that FDA has taken and will take in the future to further increase the safety of our food supply. We appreciate the witnesses' testimony. We look forward to it, and, Mr. Chairman, I have gone over my time.

Mr. STUPAK. I thank the gentleman for his opening. Next we will turn to Mr. Inslee from Washington for opening statement, please, sir.

OPENING STATEMENT OF HON. JAY INSLEE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Mr. INSLEE. Thank you. I think that what Americans may be asking now is who needs Al Qaeda when you have *E. coli*? Who needs Al Qaeda when you have melamine? And the reason I say that is if Osama bin Laden was responsible for the *E. coli* poisonings of the Americans that is taking place and the melamine and the other contaminants that have come from foreign manufacturers, this country would act. We would actually do something. We wouldn't close half of our FDA offices in response to that threat. We wouldn't continue to allow the Federal agencies to have no meaningful requirements for policies and practices for leafy and green vegetables that lead to repeated *E. coli* poisonings. We would actually act.

And I just think in light of the information that is now apparent the sieve that we have for food protection of Americans, that we have got to take some action. If we spent, invested one-tenth of the amount of time, money, and effort that we do on the war on terror-

ism on these food safety poisonings, we would reduce probably by a factor of 10 the poisonings of Americans, which are in the tens of thousands every year. So I would suggest during this hearing that if we think of this threat in these terms, and we will respond accordingly.

I will be asking questions about why it makes sense to divide the compliance function in FDA to chop up the compliance responsibility between offices, which makes no sense to me. Why it makes sense in the first place to do this consolidation, I haven't seen evidence to support that. And why it makes sense to continue this path of having no practices to require certain clean policies when you handle vegetable material in the United States.

We have adopted and we have seen where a risk-based management program can be effective in reducing poisoning in our meat-borne toxins. We have not done that for our green foods. We have got to do that. I know that this committee will be acting shortly to do that, and I will look forward to success. But I hope in this, we are invested with the theory during this hearing that we are going to act with the same degree of diligence we will as we do in the war on terrorism. Having a war on *E. coli* is not such a bad idea when you talk to the tens of thousands of Americans who have been affected by food poisoning in the last several years.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Inslee. Next turn to the ranking member of the full committee, Mr. Barton of Texas, for an opening statement please.

**OPENING STATEMENT OF HON. JOE BARTON, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. BARTON. Thank you, Mr. Chairman. Before I give my opening statement, I want to take a point of personal privilege to introduce a special guest that is with me today. I have Lieutenant Colonel Miguel Howell with me. He is a White House Fellow. He is a West Point graduate. He is a special services officer. He has been posted in Latin America and in the Middle East. He is one of a dozen or so White House Fellows this year. He is working at the Millennium Corporation.

The White House Fellows Program was established by President Johnson in the mid-1960s, and it gives bright, young American men and women an opportunity to work with the President and the executive branch for a year, and then go back and pursue their ambitions in the private sector; although, some do go on into the public sector. Colin Powell is a former White House fellow. Senator Tim Wirth, who was a member of this committee, is also a former Fellow. So we want to welcome Lieutenant Colonel Miguel Howell to the Energy and Commerce Committee. I appreciate you being here.

Mr. Chairman, I want to thank you and Mr. Whitfield for this important hearing as we look into the FDA's efforts to assure the safety and security of our drug supply and our food supply. And we also look into some of the management practices at the FDA. I am glad that we have Commissioner von Eschenbach here personally so he can listen to the testimony and participate in the hearing later on.

Much of the focus of our hearing is going to be on the imported food primarily from China because of the recent news about tainted pet foods, antifreeze, fake toothpaste, and antibiotics and seafood. Fortunately, in this country when we have a problem, we try to solve it with civil means. One of the top Chinese officials was executed last week because of his alleged deficiencies in doing some of these things over in China. So we hopefully are not going to come to that here, certainly not in this hearing.

We have to get this right, and we have to get it right sooner rather than later. This is easier said than done. It is a big challenge. The volume of our imports is surging. The variety and the complexity of the products that are arriving on our shores from overseas is increasing every day. We have to take a new look at this, and we have to do it hopefully in this Congress.

I don't have all the answers, but in shopping for new ideas, some of the things that we have come up with on our side of the aisle starts with some of these type of ideas.

First, we think that the FDA needs to make information about good manufacturing practices more available to our foreign food control agencies and foreign food processors. So that we can start to begin to build competency in those systems. FDA should consider training courses, both on-site and through the Internet, about the basics of safe manufacturing. We should translate some of these courses into more than just the English language, just as the FDA did when it published the rules for its Bioterrorism Act.

Second, we think that the FDA needs to get more information about food safety risks by profiling food control agencies in all foreign countries, understanding what each agency can do. This type of information would help the FDA better manage its limited resources by targeting those countries that have particular problems with particular food product categories.

Third, and this, I think, is a very important idea. It is time for the FDA to separate its foreign inspection activities from domestic activities. Currently, the FDA does not have a core of inspectors who specialize in foreign inspections. Instead, they treat foreign inspections as a stepchild of their domestic inspection program by borrowing inspectors from various districts here in the United States. I don't think this works in today's world. I think they should create a separate division of foreign inspectors who develop expertise about foreign regions and the products that come in from overseas and spend a fair amount of their time overseas working with foreign governments on sharing information and conducting these inspections.

FDA would also need performance standards and objectives and a way to measure progress. For reasons that remain unclear, the FDA has not published a performance plan for the last three fiscal years on which it evaluates its own performance, especially in imports. I think this is a mistake, and I am puzzled that they haven't done so. It is one of the things that I am going to ask Commissioner von Eschenbach if I am here when he takes questions. I would like the FDA to be accountable and in compliance with the Government Performance and Results Acts.

Finally, FDA should ensure that its import system is on solid legal ground by either publishing a rule on when the FDA can de-

tain shipments without physical examinations or by working with the Congress on appropriate legislation. I read in the trade press that Chairman Dingell is considering legislation in this area. I can assure the chairman that we on the Republican side will work with him and other members of the majority if, in fact, that is their intention to move legislation in this area. I think that Congress should legislate in this area.

So, Mr. Chairman, again this is an important hearing. Both political parties have been holding hearings on this for the last 15 to 20 years. Chairman Dingell held hearings when he was chairman back in the 1980s. You are not that old. I held hearings in my chairmanship, and now in Mr. Dingell's new chairmanship once again and rightfully so, he and Mr. Stupak are holding hearings. So we think it is important, and we also think it is time to legislate.

With that, Mr. Chairman, I yield back.

Mr. STUPAK. I thank the ranking member for his opening statement. Next, Mr. Green from Texas, opening statement, sir.

**OPENING STATEMENT OF HON. GENE GREEN, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. GREEN. Thank you, Mr. Chairman, for holding this hearing on food safety, which builds on our previous hearing on this topic earlier this year. That hearing was focused primarily on the contamination of produce and peanut butter in this country, and I join a number of my colleagues requesting that the FDA officials appear before us to give us some answers. And I am glad that the FDA is represented at the hearing; however, it seems that events of the past 3 months have raised more questions than answers.

The cases of food safety lapses have only increased, and these cases are shining a bright light on imported food, with most of the high-profile problems stemming from Chinese imports. Unfortunately, the FDA simply isn't meeting its mission to protect the safety of the Nation's food supply regardless of the food's origins. Chinese imports of goods regulated by FDA was increased by 400 percent in the last 10 years, yet the FDA has just over 1,300 field investigators that monitor food and other FDA-regulated items arriving in 320 ports of entry.

This lack of resources results in the inspection of less than 1 percent of all imports falling within in the FDA's jurisdiction. Despite the obvious need for more resources to ensure the safety of our Nation's food supply, the FDA has put forward a reorganization plan that would close regional labs at the very time we need to boost our monitoring and testing of potentially contaminated food.

It is no surprise that the idea of reorganization that would not only close labs but would also cut the jobs of 200 microbiologists, chemists, and engineers would have provoked the committee to express concerns and request more information. However, the FDA's release of information in dribs and drabs suggests the agency is withholding critical information from the committee. If I know our subcommittee and our full committee chairmen, I bet they would be the first to warn that the committee is not interested in a cat-and-mouse game with the FDA, that we expect full compliance with our request for information.

The problem we are facing is too real. It requires immediate action, especially given the enormous amount of food imported from China where many of these problems have been uncovered. I am particularly troubled by the reports of contaminated Chinese seafood. China is the No. 1 exporter of seafood to our country with \$2 billion worth of Chinese seafood entering our borders, restaurants, and grocery stores each year.

Time magazine recently profiled a restaurant along the Gulf Coast in Mississippi that serves only U.S. farm-raised catfish because of the growing concerns over fish imported from China. This restaurant did not have the confidence in our Federal Government's ability to ensure the safety of the imported catfish. Apparently neither did State officials, which conducted a test of their own in most grocery store samples of catfish, and Mississippi State officials found residues of two antibiotics banned in the U.S. but widely used in China. This failed attempt at regulation leaves all our families, friends, and neighbors at a risk of consuming contaminated products and contracting potentially fatal illnesses.

We need to do better by the American people, and if the FDA isn't going to do it on its own, we in Congress have to use our legislative power to steer the agency in the right direction. I want to thank our witnesses for being here today. Mr. Chairman, I yield back my time.

Mr. STUPAK. Thank the gentleman. Next, Mrs. Blackburn from Tennessee for an opening statement. Five minutes, please.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman. Thanks for holding the hearing, and I want to thank our witnesses for taking the time to come before us today. As you are hearing, food safety is an extremely high priority issue from a public health standpoint, as well as a national security issue. And as we talk about a security agenda, we hear more rather than less about this from our constituents.

And as you are hearing also, the recent episodes of food contamination have highlighted weaknesses in the FDA's food safety review system. And we all are fearful, and we are all aware that terrorists could easily inflict harm upon our Nation's food supply because of the gaps that are becoming evident in this system. We know that we are vulnerable to harm from abroad where rules and regulations governing food production are often more lax than they are here at home.

As you know, the FDA only has enough inspectors to check about 1 percent of the 8.9 million imported food shipments each year, and that was last year's number. According to USDA, the U.S. is expected to import a record 70 billion in agricultural products this year, which is nearly double the 36 billion purchased overseas in 1997. In addition, total food imports in the U.S. have risen by about 50 percent over the last 5 years. We are all aware that last year, our Nation was a net importer of food rather than having a domestically grown food supply.

And while our food supply has generally been safe in the past, as you are hearing from other members, the Chinese-made food

products have become the subject of an ongoing investigation and, of course, of the international news attention in recent months. The dangerous chemicals such as melamine and glycol have been found in food products intended for both human and animal consumption. This has led to an unprecedented recall of pet foods, toothpaste, pizza, protein bars, baby formula, and most recently, seafood.

We must seek greater accountability in the food supply through FDA reform of its antiquated food safety review system. The FDA must enter the 21st century where globalization has changed the needs of the food review process and presents very different challenges. Gone are the days when we can say our food supply is homegrown. We now live in a global economy, and free trade has opened the doors to increased interdependence among nations.

The FDA is going to have to transition from defense to offense, like it or not. And they are going to have to implement a risk-based import control system to stop dangerous food imports from reaching our shores. It is vital that we work with other countries to prevent future bioterrorism opportunities in the country of origin and not when it has entered our food supply.

A reformed import system will improve knowledge and assessment of public health risk. The FDA must focus on maximizing its resources toward this effort. They are behind in this. This is something that they are going to have to put their energy into, have more communication among their different branches and get in front of this problem. Make the changes that are necessary for policing this food supply. They should work with foreign governments to establish acceptable international food safety standards that encourage good manufacturing practices.

The FDA should improve data collection from farm producers to ensure they have all the information necessary to conduct risk assessment abroad. It is imperative that the FDA improve dialog with these foreign governments to raise the bar on adequate standards and review of our food supply. Americans believe they can trust their food supply and place quality control in the hands of American buyers and their suppliers.

We must keep all Americans safe by ensuring we have a strong risk-based food import review system. Thank you, Mr. Chairman. I yield back.

Mr. STUPAK. Thank you. Next we will turn to Ms. Schakowsky for an opening statement. Please, Ms. Schakowsky of Illinois.

OPENING STATEMENT OF HON. JAN SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Thank you, Mr. Chairman, for holding this hearing on FDA's ability to secure the Nation's food supply. This serious public health issue brings into sharp relief our reliance on other nations to keep our food safe. Recent high profile cases of tainted food have brought this issue that has been lurking in cupboards and cabinets to the public's attention. Poison toothpaste, antibiotic-laden seafood, and toxic pet food have brought FDA testing practices and the vulnerabilities of our system into American homes and lives.

Although I was happy to see that the FDA stopped imports of certain seafood from China, unfortunately, it appears that action

occurred only after this committee and members of Congress sounded the alarm on the issue of tainted fish. All too often, the FDA is only reactive and does not catch dangerous products before they cause illness or even death.

Every year, 76 Americans suffer from food-borne illness. Of those individuals, approximately 325,000 will be hospitalized, and more than 5,000 will die. If lax inspections and disjointed oversight continue, if we continue to allow imported ingredients to enter our markets without inspection, we could see those numbers skyrocket.

Tainted imports enter our borders from countries around the world, but recent cases of food and product poisoning point to China in particular as a repeated source of poison food and ingredients. And we can't rely on China to come up with a solution. As Newsweek documents in their July 23 special report, China lacks "the will to overhaul a political structure that gives party officials down to even the smallest villages huge influence over many facets of economic life" which has led to the problems we are facing today. A few high profile executions of agency heads in China will not reform a system plagued by corruption or where enforcement of food regulations is left to local governments who are susceptible to buyoffs from local businesses.

In order to get a handle on this problem and protect Americans from dangerous products, we must change the way we inspect imported food and ingredients. In February of this year, the Government Accountability Office deemed Federal oversight of food safety as "high risk" to the economy and public health and safety. We need to change our regulatory system so that it can effectively screen for dangerous substances and products. We must ensure that the FDA has the resources and authority it needs to increase inspections of imported foods and drugs.

Finally, we must make sure that the FDA has access to sophisticated testing techniques to help inspectors identify adulterated imports. As the investigations by the subcommittee have shown, the FDA is a bureaucracy that is not responsive to investigators in the field. The FDA uses outdated computer programs to determine which foods are high risk. There are gaping holes in the FDA policy that allows importers to get around regulations. The agency is planning to close seven of its labs. Instead of working actively to reduce the risk of food-borne illness, the FDA has become almost totally reactive.

I look forward to hearing the testimony of FDA officials, investigators, and food safety advocates to get answers to questions about the factors that have allowed unsafe foods to make it to our kitchen tables. It is time that we act to ensure that our food supply is safe.

Thank you, Mr. Chairman. I yield back.

Mr. STUPAK. I thank the gentlewoman. Next Ms. DeGette from Colorado for opening statement please.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you so much, Mr. Chairman, and I appreciate your continued diligence in these important investigative

hearings on food safety. It is a topic that is of utmost concern to the American people.

At our first hearing on this topic in April, we heard why we are doing this. Gut-wrenching stories from people whose children have been permanently disabled because of unsafe food.

Today the focus is on the FDA itself where serious concerns have surfaced with regard to the recent spate of food-borne illnesses. It has become clear that the FDA's efforts to anticipate, prevent, and respond to these outbreaks is frankly far from adequate. The agency has also been far from forthcoming with this subcommittee in our attempt to investigate its actions leading up to and following the incidents.

I expect to find out today why there has not been more cooperation with our investigation and maybe more importantly why the FDA has not been more proactive in its efforts to safeguard the Nation's food and drug supplies.

I want to discuss one aspect mentioned by Ms. Schakowsky that is particularly disturbing in the investigation. In light of the problems with the FDA's oversight of food, which have been discussed by every other member on both sides of the aisle of this committee, it is just incredible to me that the FDA is proposing to close over half the food and drug safety field laboratories.

One of those seven laboratories is located right outside my congressional district. It is the Denver laboratory, and its offices are at the Federal center in Lakewood, Co. Closing this lab would affect approximately 50 chemists, microbiologists, and analysts and the important work that they do for our community. These dedicated employees perform highly specialized analysis of BSE, or mad cow disease, food pathogens like *E. coli* and salmonella, food additives, and human and veterinary drugs. Seems like some work we need to be doing given the recent revelations.

Today I would like to find out how the FDA can justify closing one of the Nation's preeminent food and drug research laboratories at a time when we have almost daily revelations about contaminated food. Today Ms. Belinda Collins, the director of the Denver district of the FDA, will testify about the important work currently being done at the Denver lab, as well as the risk to public health of shutting the facility. Welcome, Belinda, and thank you so much for being here.

I am sensitive to the budgetary pressures facing Federal agencies, and frankly I am a reinventing government type. I am always willing to consider meaningful agency changes if there is demonstrated evidence that the changes will eliminate waste and duplication or trim costs or increase efficiency while improving public health, but in this case, I have not seen this evidence.

In fact, just the opposite seems to be true. The FDA itself rated the Denver lab as in good condition, while the Atlanta lab, which will remain open under the current plan, was rated fair to poor. The GAO has determined that midsized regional labs like the Denver lab are more appropriate than the mega labs that the FDA wants to create. And in addition, Ms. Collins will tell us this morning that food safety and indeed homeland security in the Rocky Mountain region, where I might add, Mr. Chairman, the Demo-

cratic National Convention will be held next year, and in the Nation, will be compromised if the plan is carried out.

So despite the overwhelming evidence of the Denver lab's effectiveness, the FDA is holding its position in moving forward with the closure, citing simply nebulous future cost concerns without providing this committee or the American people with evidence to back it up. I think we should look very, very closely at that, given the risks of the next food-borne outbreak and the hope of detecting it quickly, and also the whole issue of losing employees who have years of scientific expertise who can help us in this endeavor.

I also want to say, Mr. Chairman, that it is disconcerting that the U.S. at Food and Drug Administration does not feel compelled to answer questions put to it by the legislative branch. I have had questions for the last two hearings, not about food safety but on medical devices and other issues, that you might recall. I specifically asked the FDA to respond in writing to these questions, and I haven't had any response at all. This goes back to April, and I know Mr. von Eschenbach is testifying later. I want to know why we can't get questions by this committee answered.

And finally, Mr. Chairman, people often say why do you have these oversight hearings? Is it just a grandstand? Well, every time we have a hearing, there is some new revelation, and something is fixed. Just by chance today, for example, Safeway announced that it is no longer going to package food with carbon monoxide, one of our committee's greatest concerns. And so you can see these hearings at least have some effect, and I hope they will have a lot more effect.

Finally, Mr. Chairman, I would like to ask unanimous consent to insert into the record a statement by my colleague, Ed Perlmutter, whose Seventh Congressional District includes the FDA lab.

And with that, I yield back the balance of my time.

Mr. STUPAK. The gentlelady yields back. Mr. Waxman for an opening statement please, sir.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman. When the American people hear about dangers in their food, a lack of food safety, whether it is from domestic-sourced food or imported food, they want to know where the Government is. They know the Government has to act. The Government is supposed to act. They want to the Government to protect the American people from unsafe foods.

While we have for most foods in this country the Food and Drug Administration, with that responsibility, and it is easy to see that the Food and Drug Administration is not doing enough to protect our citizens from exposure to unsafe foods. But I think there is a responsibility that is a shared one because Congress hasn't done its part to make sure that FDA has both the authorities and the resources to do a job well.

For example, FDA lacks the authority to demand access to a firm's records and data during routine inspections. It lacks the ability to detain a shipment of imported foods without evidence that

the specific shipment of food is contaminated or may pose some other threat to the public health. The lack of these authorities limits FDA's ability to be proactive rather than reactive in protecting the food supply. Congress has also failed to give the FDA the needed resources. Of all the centers at FDA, the center for foods has been the most starved for resources. FDA oversees 80 percent of the food consumed in the United States. The U.S. Department of Agriculture overlooks 20 percent, and yet USDA gets approximately 80 percent of the Federal dollars allocated to food safety, while FDA gets the remaining 20 percent.

When it comes to the safety of the foods we eat every day, this funding structure makes no sense, and this has got to be a concern. To be sure, the administration and the FDA bears significant responsibility for the recent food safety crises. The administration has not asked for additional resources. They have not come forward with suggestions for how Congress should strengthen the FDA's authorities so that it can be more effective in dealing with these crises.

And FDA itself bears significant responsibility here. One of FDA's major failures is in the area of inspections and enforcement. My own oversight committee conducted an investigation in FDA's mission, effectiveness, and challenges for the future. And as part of that investigation, we are going to release a report later this week that identifies major weaknesses in FDA's inspection and enforcement practices with respect to fresh produce firms. The report will demonstrate that FDA has failed to carry out its responsibilities for enforcement in this particular clinical area.

Further, as this committee will hear today, the FDA has not always been forthcoming in getting us the information on its activities. Despite repeated requests, FDA has failed to get this committee information on important topics such as the closure of FDA labs, the safety of imported seafood, and efforts to safeguard fresh, leafy greens and other domestic foods. It is absolutely critical that this committee receive complete information in these areas, and I hope we get it in short order.

We here in Congress stand ready to work with the FDA to ensure that the agency has everything it needs to fulfill its congressional mandate to protect American citizens from unsafe foods. But in order for us to do our job, we need FDA to be forthcoming in getting us the information. We need FDA to tell us about what actions it has and has not taken to prevent unsafe foods from entering the market. We need FDA to tell us what the agency needs, both in terms of authorities and in terms of funding to do this job, and to do it well. FDA needs to help us so we can help the FDA.

So hearings like this, we will have an opportunity to get the facts. Once we get the facts, we can figure out what actions are needed. But it is important that Congress do this job, and I want to commend you for holding this hearing, for doing this investigation because the American people expect and demand that when they buy their food, whether it is from the United States or from China or from anywhere else, that somebody in this U.S. Government is making sure that this food is safe. Thank you, Mr. Chairman.

Mr. STUPAK. Next we turn to the chairman of the full committee of the Energy and Commerce Committee, Mr. Dingell from Michigan, for an opening statement please.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Mr. Chairman, I commend you for this hearing. It is extraordinary importance, and it could not be any timelier. Almost every day brings news of another threat to the public health posed by contaminated food products and parenthetically by prescription pharmaceuticals and other matters relative to the inadequacies of food and drug and the inadequacies of their budget. The recent series of tainted food recalls has focused America's attention on the sorry state of Federal oversight of the domestic food supply. Even more disturbing, however, is the virtual abdication by the Food and Drug Administration of oversight or inspection of the ever-increasing flood of imported food.

We could look back at the sorry mess which we saw when Food and Drug devoted almost its entire resources to finding just a few cyanide-contaminated grapes supposedly from Chile. And we are finding that a lot of this is not an inadequacy in terms of the dedication of the personnel at the agency, not much of it due to weakness of law, but a very large part of it due to inadequacies of funding and the inadequacies of the ability of Food and Drug to carry out its important responsibility.

From time to time, this committee has had to go into the question of the inadequacies of the Food and Drug Administration. It appears that that is something which is becoming very timely at this time. The reality is at this time that the amount of food imported into the United States is double that which was imported 10 years ago. More than a quarter of all food purchased by Americans is imported. More than 80 percent of all seafood consumed in the U.S. is imported.

Between 2002 and 2006, FDA-regulated food imports from China rose approximately from 100,000 shipments to nearly 235,000 shipments. Experts expect and predict that these shipments will reach 300,000 this year. The number of personnel, the budget, and the ability to address these questions and the safety of these shipments, is, I think, fictional at best.

The FDA examines less than 1 percent of these imports, and those imports examined bear test for only a small fraction. This is unacceptable, especially in the light of the horror stories coming out of China, such as poisonous melamine in food products, the anti-freeze chemical diathylene glycol in toothpaste, and illegal antibiotics and suspected carcinogens in farm-raised shrimp and fish.

Even worse, China released a study recently showing that nearly one-fifth of all food and consumer products sold to its own people are tainted and substandard. Their cure appears to be to shoot the head of the Food and Drug Administration or whatever it might be called. Another Chinese Government reports rivers in China so contaminated with sewage, heavy metals from industrial byproducts, and pesticides, that fish farmers no longer have any choice

but to use chemicals and antibiotics to keep fish alive. One must ask what are those doing to the United States and to our citizens.

I would note that while all this is going on, the FDA is proposing to close labs because of budgetary constraints, and one must ask how is that going to better consumer safety in the United States. I would note that this country is supposed to have the best and the strongest laws to protect our consumers with regard to food products, with regard to drugs, and with regard to other matters under the jurisdiction of FDA. Clearly that situation is being worsened by budget inadequacies and probably statutory failures in terms of the ability of this country to address the situation as we now find it.

Since is more than 20 percent of U.S. seafood imports come from China, I shudder to think how much of this tainted Chinese seafood has already reached American tables, and what the consequences of that are to American consumers. How has FDA responded to this increasing threat to American consumers? Well, they propose to name a food czar. Now, I note that they give him no real authority. They will propose a sweeping reorganization of their food inspection operations, close some of their most crucial laboratories including one at the third largest port in the United States that could be used to address the question of dangerous imports and threats to the well-being of our consuming public.

As we will hear from the committee staff who have interviewed numerous FDA field employees as well as from a number of witnesses with actual hands-on experience in our Nation's ports, the FDA reorganizations programs and proposals will shift resources away from ports of entry, actions that will in all likelihood worsen our food safety crisis.

Further, their proposal will eliminate much of the scarce laboratory expertise currently found at FDA. The Federal food safety system is in dire need of reform. It is fragmented, understaffed, inefficient, and lacking in state of our tracking programs in large part due to the inadequacies of its budget and the fact that the administration thinks that a leaner and meaner system is going to protect American consumers, but in fact, it puts them at still greater risk.

Furthermore, FDA has largely abdicated its regulator role to the food industry itself. In other words, the fox is going to be addressing the safety of the chicken coop. This must change. I will soon introduce legislation to address this situation. I have sent a Dear Colleague letter out to my colleagues asking them to join in this because this is something that desperately needs to be done.

Amongst other things, it will provide additional resources and authorities for FDA to ensure that it can effectively monitor and control food and drug imports entering the United States. It will also provide for additional research on effective testing techniques at the border to aid inspectors in identifying adulterated imports.

I think we must hope together that senior FDA officials who comprise our third panel today will acknowledge the glaring structural deficiencies in existing food safety regime, stop the dangerous and wasteful reorganizations in their field inspection service, and work with us to craft a system truly capable of meeting the challenges of the global food market. I expect the assistance of the agencies. I look forward to cooperating with my colleagues, and I

expect to have a vigorous effort to correct the abuses, which you are about to show today.

Mr. Chairman, I thank you for your kindness and for your vigorous leadership in this matter.

Mr. STUPAK. I thank the gentleman from Michigan. Next Mr. Murphy, do you want to give an opening statement?

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF PENNSYLVANIA

Mr. MURPHY. Thank you, Mr. Chairman. Just briefly, I wanted to point out that certainly the importance of this hearing can't be underestimated or understated not only because we have seen recent outbreaks of contaminated food from *E. coli* in spinach and salmonella in peanut butter and contaminated foods in pet foods, but understand the complexity of the importance of this all the way down the line, beginning with farms or ranches where we look at everything from farming practices and pesticides, hormones, herbicides, and washing of food there, to factories and processing centers to shipping things across the sea, what is done at our ports, what is done at our truck and train terminals and transporting those foods across and handling foods at warehouses and food distributors and grocery stores and restaurants, and then all the way down to food handlers and the households themselves.

Every step of the way, the safety and cleanliness of foods must be protected, and it is important that we have an FDA and other Government agencies that review the whole food chain all the way through to make sure we are providing safe and secure food supply for our Nation.

I wish that we had some jurisdiction over what other nations do when we are importing foods from other countries, and I am hoping along the way of this hearing and others that we can obtain more ideas of how to make sure we are securing the safety of that food supply as well.

So with that being said, I am looking forward to this hearing and ideas that may come out of this panel of what we may do to move that forward. I thank the chairman.

Mr. STUPAK. I thank the gentleman.

Any other statements for the record will be accepted at this time. [The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Thank you Chairman Stupak and Ranking Member Whitfield.

With the ever increasing number of recalls, I continue to be extremely concerned with the safety and security of normal household products. While I remain confident that America has the safest food supply in the world, what I am more concerned about is the safety of imported goods, especially those from the Republic of China. My friend and colleague, Mr. Greg Walden, and I sent a letter to the committee calling for an investigation regarding the many food and consumer product safety recalls from China. I continue to urge the leadership of this committee to fully examine this matter.

Today, however, we are focusing on the FDA's duty to safeguard our food supply. While I am pleased that we have Dr. von Eschenbach and others with us today I still believe that they should have had the opportunity to appear before us at the last hearing. This committee has many questions for the FDA regarding a host of issues, including the reorganization efforts. I look forward to discussing the need to reorganize; however, I also hope that an adequate amount of time is spent

on discussing the FDA's role and responsibility for ensuring that our imported foods are safe for the citizens of this country.

Mr. Chairman, unfortunately I will have to leave this hearing in a little while to go up the road to Walter Reed; however, I have made arrangements to be back here in time for the third panel. I sincerely apologize to the witnesses on the first and second panel for my absence.

Thank you, Mr. Chairman, and I yield back the remainder of my time.

Mr. STUPAK. Before we have our first panel, the gentlewoman from Colorado mentioned the fact that Representative Perlmutter would like a statement in the record without objection. We will do that. Also I mentioned the Safeway letter addressed to myself and Chairman Dingell as to they are going to discontinue use of the carbon monoxide in the sale of their fresh meat products. I would ask unanimous consent to place that letter in the file. And Mr. Whitfield, you had a unanimous request?

Mr. WHITFIELD. I do, Mr. Chairman. This is a letter from Congress Luis Fortuno who represents Puerto Rico, and I would ask unanimous consent that we include in the record his letter expressing concern about the lab in San Juan, Puerto Rico.

Mr. STUPAK. Without objection, Mr. Perlmutter's statement, the letter from Safeway, and the letter from Congressman Fortuno about Puerto Rico be entered in the record. With that, we will call our first panel.

And as all opening statements have been concluded by members, our first panel, would the witnesses please come forward? On our first panel, we have Mr. David Nelson, senior investigator for the Committee on Energy and Commerce; Mr. Kevin Barstow, investigative counsel for the Energy and Commerce Committee; Mr. Richard Wilfong, investigator with the Energy and Commerce Committee.

Now, gentleman, it is the policy of this subcommittee to take all testimony under oath. Please be advised that witnesses have the right under the rules of the House to be advised by counsel during their testimony. Do any of you wish to be represented by counsel? Witnesses indicated they do not. I will ask you to rise, raise your right hand, and take the oath.

[Witnesses sworn]

Mr. STUPAK. Let the record reflect that witnesses replied in the affirmative. You are now under oath. We will begin with an opening statement for 5 minutes. You may submit a longer statement for inclusion in the hearing record. I understand that, Mr. Nelson, you will be giving the statement on behalf of the three committee members there. And you may begin any time, sir.

TESTIMONY OF DAVID NELSON, SENIOR INVESTIGATOR, COMMITTEE ON ENERGY AND COMMERCE, ACCOMPANIED BY KEVIN BARSTOW, INVESTIGATIVE COUNSEL, COMMITTEE ON ENERGY AND COMMERCE; AND RICHARD WILFONG, INVESTIGATOR, COMMITTEE ON ENERGY AND COMMERCE

Mr. NELSON. Thank you, Mr. Chairman. As many of you may be aware, I am David Nelson. I am an investigator on the Energy and Commerce Committee staff. With me on my right are Kevin Barstow and on my left Richard Wilfong. They and several other members of the majority staff and Krista Carpenter of the minority staff

have been investigating questions of food safety for the committee for the last 4 months.

As part of the inquiry, we have reviewed tens of thousands of pages, some of which were delivered only last week of documents. We have conducted numerous interviews of industry experts, current and former FDA employees, per your instructions. We visited numerous ports, FDA laboratories, and field offices around the country. Minority staff participated in most of these interviews and site visits.

Chairman Stupak, you asked us to focus on three critical areas of food safety that were raised by the testimony during the April 24 hearing of this committee. First was the extent to which FDA is protecting Americans from contaminated food imports. Second the extent to which FDA's proposed reorganization of its field operations, including FDA's decision to shut down or proposal to shut down 7 of its 13 laboratories is consistent with the agency's charge to ensure the safety of the Nation's food supply.

Finally, you asked us to explore the extent to which FDA's continued use of voluntary guidelines are adequate to ensure the safety of the Nation's food supply. And in the course of that inquiry, we examined a number of products in FDA's regulation thereof, domestic and imported leafy greens, peanut butter, imported vegetable proteins like wheat gluten, imported seafood and imported toothpaste containing a deadly chemical diethylene glycol.

The preliminary findings confirm the results of the subcommittee's April hearing, that FDA has failed to adequately respond to increased imports of foreign food products. Recent accounts of tainted imports from China provide additional evidence. Simply stated, the FDA lacks sufficient resources and authority to ensure food safety, and legislation will be needed to correct these deficiencies.

The current proposal to change FDA's structure and management would appear to exacerbate the current food safety situation.

Lastly, FDA's current regulatory approach which relies upon voluntary guidelines, promotes domestic and imported foods, appears inadequate in responding to the changing food industry.

I only have time to make a very few points that are made in the written testimony, Mr. Chairman. So let me just concentrate on a few. Our review of the operations in San Francisco reveal that it is physically impossible for that office to perform more than a cursory review of most imports. The San Francisco office has four entry reviewers to oversee 4,000 entry lines per day. A typical reviewer's day involves examining 600 food entries, 300 medical device entries, 25 reagent entries, and 25 drug entries on a computer screen. That is about one entry every 30 seconds. That is the time they have to decide whether or not they even recommend sending an inspector out to inspect, physically look at the goods, or to take a sample.

One of the problems that we found in every lab we traveled to was the unverified reliance by FDA on the use of private laboratory tests to release suspect imports. FDA permits importers to take possession of even highly suspect goods that arrange for their testing by private laboratories. Import alerts that contain the instruction, detention without physical examination, does not mean detain

the ordinary use of that word. It means allow delivery to the importer. The importer then has to contract with a private lab, which FDA does not oversee, does not license, does not audit, and has no legal authority to direct importers to specific labs or away from specific labs, regardless of what the record of those labs are.

If those laboratories provide a negative finding of pathogens or toxins in five consecutive shipments, then that exporter is removed from the import alert, and the Oasis system assures that all future shipments from that exporter are going to come into the United States without any further testing.

Mr. Chairman, the rest of the report goes on and deals with the problems with the Oasis system, deficiencies we found in at least the enforcement of country-of-origin regulations, the seafood problems that are especially problematic, the carbon monoxide being used as atmosphere around imported fish was particularly troubling. Some 20 percent of the imports into the United States in San Francisco coming in in these atmospheres were found to be disguising decomposed fish. Now, despite the fact that that was the record in San Francisco and we confirmed it to a certain extent in New York, FDA nonetheless in 2001 determined that consumers would be able to purchase fish that was made to look fresher than it probably is in those atmospheres. And in 2004, said it was OK for meat.

The written testimony contains a lot about the proposed reorganization, the field staff, which I will be glad to answer any questions about, as will my colleagues. We don't have time to highlight those here.

[The prepared statement of Mr. Nelson follows:]

STATEMENT OF DAVID NELSON

Mr. Chairman and members of the subcommittee, today the subcommittee begins the second in a series of expected hearings concerning the adequacy of Food and Drug Administration's (FDA) efforts to ensure the safety of the Nation's food supply. As part of this inquiry, committee staff have reviewed thousands of pages of documents and conducted numerous interviews of industry experts and current and former FDA employees. Per your instructions, we also visited numerous ports of entry and FDA laboratories and field offices. The FDA offices visited included the Detroit, San Francisco, Los Angeles, Denver, Kansas City, Winchester, MA, Atlanta, New York, and San Juan, Puerto Rico district offices and/or laboratories. Minority Staff participated in most of these interviews and site visits.

Chairman Stupak asked the staff to focus on three critical areas of food safety that were raised by the testimony of the April 24, 2007, hearing:

- The extent to which FDA is protecting Americans from contaminated food imports;
- The extent to which FDA's proposed reorganization of its field operations, including FDA's decision to shut down seven of its 13 laboratories, is consistent with the Agency's charge to ensure the safety of the Nation's food supply;¹
- The extent to which FDA's continued use of voluntary guidelines of certain products that have been implicated in recent food poisoning outbreaks are adequate to ensure the safety of the Nation's food supply. These products include both domestic and imported leafy greens, peanut butter, imported vegetable protein, imported seafood, and imported toothpaste containing the deadly chemical diethylene glycol.

Preliminary findings confirm the results of the subcommittee's April 2007 hearing that FDA has failed to adequately respond to increased imports of foreign food products. Recent accounts of tainted imports from China provide additional evidence,

¹ Federal responsibility for food safety is shared by FDA and the U.S. Department of Agriculture (USDA). FDA's authority extends to approximately 80 percent of the food supply.

simply stated, that FDA lacks sufficient resources and authority to ensure food safety and legislation will be needed to correct these deficiencies.²

The current proposal to change FDA's structure and management would appear to exacerbate the current food safety situation. Lastly, FDA's current regulatory approach, which relies upon voluntary guidelines for most domestic and imported foods, appears inadequate in responding to the changing food industry.

FDA Regulation of Food Imports is Minimal

Committee staff learned that FDA inspects less than 1 percent of all imported foods and samples only a fraction of those it inspects. While the number of FDA inspectors has been falling since 2003, the importation of food products into the United States has nearly doubled.

Our review of operations in San Francisco typifies the problem with the current FDA inspection system. It was apparent from interviews and observations that it is physically impossible for FDA's San Francisco staff to perform more than a cursory review of most imports. The San Francisco office has four entry reviewers to oversee thousands of entry lines per day. A typical reviewer's day involves examining 600 food entries, 300 medical device entries, 25 reagent entries, and 25 drug entries on a computer screen. This is about 1 entry line every 30 seconds. However, due to the volume of entries and the time required to take action, less than 30 seconds is spent on most of them. A single entry of Chinese herbs can take more than an hour to review. Even the simplest action involves several minutes, e.g., e-mailing a broker for additional information. If an entry review results in a recommendation for a site visit, the Compliance office must make a determination of whether to send an investigator. Compliance must also decide on whether to sample the shipment.

Determining what requires further examination is also complicated by differences and discrepancies in the way imported food is identified. For food, FDA categorizes entries by product codes, but Customs and Border Protection (CBP) categorizes entries by tariff codes, an entirely different system. Brokers often miscode entries and product descriptions are poor, particularly for products imported from China.

FDA's Uncritical Reliance on Private Laboratories Causes Problems

One particularly important problem that staff field investigation uncovered dealt with the unverified reliance by FDA on the use of private laboratory tests to release suspect imports. Committee staff was told by FDA inspectors that FDA permits importers to take possession of even highly suspect goods and arrange for their testing by private laboratories. Import alerts that contain the instruction "detention without physical examination," such as the import alert issued on April 27, 2007, with regard to vegetable protein (wheat gluten, et cetera),³

Once there have been five consecutive analyses by private laboratories that find no violations, the importer is no longer required to conduct testing on products of that exporter and the goods may proceed into the consumer market without further action, even if the food is covered by an alert. FDA does not require a separate bond be posted by the importer taking delivery. Further, FDA neither accredits nor debar private laboratories that analyze imported food samples, despite the fact that these laboratories often use incorrect methods or report incorrect results.

Officials at all FDA labs visited by committee staff were critical of private laboratory testing. An FDA Deputy Lab Director, who performs private laboratory reviews, said that some private laboratory work is "decent," while some is "scary". He believes that none of the private laboratory analyses are completely accurate. In general, he described private laboratory work as "not good" and "spooky". An FDA Science Branch Director concurred with this assessment. He commented that private laboratory work is "shoddy" because results are driven by financial rather than scientific concerns.

FDA has the option of sending an inspector to gather samples to be examined in a FDA lab, but rarely does so—only a minute fraction of the 25,000 daily food shipments are ever tested by a Government laboratory. When analyzing samples of imported food, FDA labs often find problems that private labs did not uncover.

Another problem related to imports identified by FDA field staff was that only 20 percent of food imports appear in FDA's food import computer system (OASIS) for review by the field inspection force. Review criteria are established by FDA's Division of Import Operations and Policy (DIOP) in Washington and FDA field input is

² See appendix to staff statement that summarizes a sample of recent news articles concerning unsafe food products from China.

³ See FDA Import Alert No. 99-29 (April 27, 2007). do not literally mean "detain," but allow delivery to the importer.

minimal. FDA field inspectors complained to committee staff that 75 to 80 percent of all individual import entries are not flagged, and therefore, have never been subject to cursory computer inspection of their paperwork by field inspectors who are experts at identifying suspect shipments.

FDA Can Learn from Other Federal Agencies to Better Screen Imports

FDA's approach to this complex, large, and growing problem is strikingly different from the approach taken by other Federal agencies charged with equally important border inspection responsibilities. Although FDA's entry reviewers, investigators, and compliance officers are clearly unable to keep up with the flood of imports, FDA has no plans to increase its import staff, but does plan to shut its San Francisco laboratory. In contrast, CBP will be adding 35 new "agricultural specialists" in San Francisco, funded by the user fees that CBP is authorized to charge. FDA has no user fees to pay the cost of monitoring food imports and its proposed fiscal year 2008 budget and proposed reorganization indicate that it is not seeking additional resources for this purpose.

Compared to USDA, FDA's resources and activities appear to be woefully short of its food import responsibilities. FDA is responsible for assuring the safety of 80 percent of the food supply, but lacking a user fee system, is able to inspect only about 1 percent of all food imports, and does not ensure that foreign food processors and suppliers meet U.S. food safety standards. In contrast, USDA is responsible for only 20 percent of the food supply, but has a user fee system that allows it to inspect 16 percent of meat imports. In addition, USDA will not permit meat to be shipped to the U.S. unless the exporting country meets USDA regulatory standards. USDA also restricts the ports of entry of meat products to 10 ports. In contrast, FDA does not require comparable regulatory standards and permits imports to enter into the Customs territory of the United States at any of the 326 ports of entry, despite the lack of FDA presence at most of these ports.

Pet Food, Wheat Gluten, and other Vegetable Proteins May Highlight FDA Over-Reliance on OASIS

The recent recall of contaminated wheat gluten and other vegetable proteins highlights the dangers from an over-reliance on the OASIS system that removes 80 percent of the so-called "low risk" imports from any field inspection.

On March 15, 2007, FDA was informed that pets had been dying from kidney failure from eating what was eventually determined to be 95 varieties of pet food manufactured by Menu Foods. Moreover, the common ingredient was wheat gluten, a widely used vegetable protein obtained from ChemNutra, a Las Vegas importer of Chinese ingredients for the pet food and dietary supplement industries. FDA labs in Cincinnati and Kansas City discovered that an industrial chemical, melamine, had been mixed with the wheat gluten in order to artificially elevate its protein content.

An April 27, 2007, Import Alert issued by FDA provided that 8 vegetable proteins (wheat, rice, corn, soy, and mung glutes and proteins) covering 10 tariff codes be "detained without physical examination," as described above. Despite the regularly accepted meaning of the word "detain," this designation did not result in these vegetable proteins being embargoed. These products were delivered to the premises of the importer, and the importer was required to submit samples to private laboratories for testing. As noted above, FDA laboratory officials believe this is not a reliable means for determining the safety of food products.

In contrast to FDA's handling of these imports, CBP, on its own initiative, decided to detain all such imports from China in the 10 tariff codes, pending testing by Government laboratories. All such imports were to be detained at a Customs Examination Station (a warehouse under CBP control), and samples from each lot would be taken and supplied to both Customs and FDA laboratories. FDA officials in San Francisco and Los Angeles were initially unaware of the CBP initiative and did not appear pleased with the deviation from established the FDA procedure. Ultimately the Agencies coordinated their efforts.

CBP informed committee staff that those 10 tariff codes produced about 21,000 entry lines on 17,000 entries (many CBP entries contain more than 1 line because they contain more than 1 product) from approximately 1,000 different exporters to the United States annually. This does not include human food, pet food, or animal feeds at risk of containing the suspect vegetable proteins.

Until the high number of pet deaths became evident in March 2007, these vegetable proteins and the animal feeds that contained them had been among the imports FDA never inspected under their OASIS review system. Testimony from the April 24, 2007, hearing reflects that there is no difference in the wheat gluten sold for

human food, pet food, or animal feed. Vegetable proteins containing melamine have now been found in chicken, hog, and fish feed.

On April 30, 2007, FDA made assignments to all Districts to inspect and gather samples from food processors that use the suspect vegetable proteins as ingredients in their food products. The number of firms to be inspected, however, is small. For the entire West Coast and for States as far away as Hawaii and Utah, only 34 food processors have been selected for inspection. Fortunately, no vegetable protein was found to contain melamine in any human food processor. A bakery in Seattle was found, however, to have a single unopened bag of ChemNutra wheat gluten.

Country of Origin Regulations Appear Inadequate

The true country of origin of imported wheat gluten and of vegetable proteins is also a matter of some controversy. Committee staff was told that Europe generally, and the Netherlands specifically, is the principal source of wheat gluten imports. Staff witnessed, however, the unloading of wheat gluten declared as coming from China in 50 pound bags marked with the “Wind Mill” brand of a Dutch firm, Meelunie (see attached photos). The bags gave no indication that the product was from China, but indicated the supplier was in “Amsterdam-Holland.”

Customs officials informed committee staff that the Country of Origin regulations now merely require that the purchaser be aware of the correct source of the goods. When the staff inquired as to how any downstream purchasers were to know the true origin of this apparently- Dutch wheat gluten, CBP informed them that if the importer were not the end user of the product, they would have an obligation to inform all their customers of the true country of origin and so on throughout the supply chain. Once the Wind Mill bags enter commerce, however, CBP loses control. Apparently there is no requirement that the consumers of the bread, candy, dietary supplements, or other final products be told of the actual original source of the ingredients. Furthermore, the purchasers of pet food, meat, or fish that have been fed Chinese vegetable proteins are never informed of the country of origin of the final product components. CBP did indicate the importer might be required to mark the bags, since CBP had no assurance that the true origin would be known downstream.

Since food processors are not required to inform consumers of the origin of its ingredients, Americans have no avenue with which to seek damages from companies that sell products whose ingredients are suspect. Further, the minimal inspection of imported food also means that false country-of-origin labeling is rarely detected.

Seafood Imports Remain Especially Problematic

On July 10, 2007, FDA issued Import Alert No. 16-131 requiring that all catfish, shrimp, and other specified farm-raised fish from China be “detained without physical examination.” China had been importing fish that were contaminated with fluoroquinolones and other antibiotics as well as malachite, an anti-fungal treatment that is a suspected carcinogen. Malachite is found in ponds and tanks containing fish not intended for human consumption. Other chemicals that are not approved for use in food have also been found in these imports. Antibiotics in food are a public health problem because they promote resistance to drugs that kill infections.

The July 10, 2007, alert notes that 80 percent of the seafood consumed here is imported and 40 percent of that is farm-raised. China produces 70 percent of the farm-raised fish worldwide and exports about 80 percent of its production. The timing of the import alert, however, is curious. From the staff field investigation, it was learned that FDA has known for years about the widespread use of antibiotics and fungicides to treat farm-raised fish from China. It appears, however, that only after the subcommittee and other congressional committees began to investigate FDA’s less-than-aggressive approach to the regulation of fish imports, did FDA issue its alert.

FDA field staff expressed their hope that this will mark a renewed concern by their Agency of other known problems with the safety of fish imports. For example, melamine has recently been discovered in the feed for farm-raised fish in Canada, Washington, Alaska, and Oregon. The Canadian producer of the feed has recalled the product, but FDA has yet to announce plans to deal with the fish that were fed the contaminated feed. Committee staff learned that China and Vietnam are also the major source of fish with dangerous levels of histamines due to improper storage.

Another safety concern uncovered by the staff’s fieldwork relates to seafood products and the manipulation of laboratory testing. As noted earlier, one of the questionable activities that FDA policy permits is for importers to become exempt from import alerts by having their product test negative in a private lab five consecutive

times. Import alerts have long applied to Mercury and other heavy metal contamination in large fish. Tuna and other large fish, such as Mahi-Mahi and swordfish, with time accumulate mercury from contaminated water. Smaller fish have less time to accumulate such toxins.

FDA laboratory staff warned committee staff that one of the schemes employed by importers to evade the import alert is to import five separate entries of smaller fish from a certain country or importer covered by an import alert to more easily pass the private laboratory testing. Once their import alert status is removed, they can return to importing larger varieties of fish. One FDA San Francisco laboratory seafood expert told committee staff that over half of the swordfish on American tables would likely fail mercury testing because of this scheme.

Carbon Monoxide Processing Masks Decomposition

Committee staff learned from its field interviews that large numbers of seafood imports from Asia are arriving in airtight packages containing significant concentrations of carbon monoxide. Carbon monoxide treatment makes seafood appear fresh, regardless of its condition. In San Francisco, the staff learned that fully 20 percent of the fish tested that were imported in a carbon monoxide environment were rejected because of decomposition or histamine contamination. Based upon its investigation, the staff believes that this problem is not unique to San Francisco, but is widespread throughout the Nation.

The issue of using carbon monoxide to manipulate the appearance of food products is not new. For example, Chairmen Dingell and Stupak, along with a number of food safety experts, questioned the safety of meat and fish packaged in an environment containing carbon monoxide with the FDA Commissioner and the HHS Secretary last year. In response, FDA assured them that there was no health concerns associated with artificially disguising the color of meat with carbon monoxide.

Since then, the committee has sought from FDA any records regarding problems with seafood imports, generally, and those packed in atmospheres containing carbon monoxide, specifically. Although both Majority and Minority staff were shown such records in the field by concerned FDA inspectors, none of the documents examined or discussed during two staff visits to San Francisco have been delivered to the committee to date.⁴

The problems involving packaging fish in an environment of carbon monoxide raise additional questions about FDA's approval of this process as GRAS (Generally Recognized As Safe) for food products. In San Francisco, the staff was told that the entry of decomposed fish packed in an atmosphere of carbon monoxide dates back to the 1990s. The problem reached such a level of concern in 1999 that FDA issued an import bulletin, advising inspectors to watch out for tuna packed in carbon monoxide.

Despite the import bulletin issued in 1999, in 2001, the Center for Food and Applied Nutrition (CFSAN) approved the retail sale of tuna treated with carbon monoxide as GRAS. Technically, the CFSAN approval was for tuna packaged in "tasteless smoke," a packaging atmosphere containing carbon monoxide that, in fact, does not cure the fish, but merely preserves the color indefinitely like any other carbon monoxide-containing airtight packaging. The GRAS determination was made by FDA, despite the fact that the European Union bans this dangerous and deceptive practice. Although FDA has subsequently cancelled the import bulletin, the staff was told by FDA field officials in San Francisco and New York that the spoilage problem with carbon monoxide-treated fish has not abated.

Despite these events, in 2004, FDA accepted petitions regarding meat packaged in carbon monoxide as GRAS. This decision permits meat that is well past the time when it is safe to consume to appear as red and fresh as when it was first packaged. The committee is in the process of trying to determine exactly what CFSAN analysts knew about the problem with decomposed fish, when they permitted both fish and meat packaged in an atmosphere of carbon monoxide to be sold to unsuspecting consumers.

Poisoned Toothpaste Highlights Additional Problems

While not a food per se, FDA handling of the toothpaste from China laced with diethylene glycol (DEG) is demonstrative of several shortcomings of FDA's handling

⁴ FDA has furnished the committee with documents reflecting their refusing entry to nine shipments of fish packed with carbon monoxide because of decomposition so far this year in the port of New York, but not the records in San Francisco or elsewhere. Given the paucity of testing done by FDA in general, even these records from one port demonstrate a troubling number of harmful entries disguised by this FDA-approved method.

of imports. In 1997, FDA witnessed 88 deaths in Haiti from cough syrup laced with diethylene glycol, the chemical most often found in antifreeze. The children's medicine was imported from China. The diethylene glycol was apparently substituted for the more expensive ingredient, glycerin. Last year, 100 people in Panama and 5 people in China died from ingesting medications contaminated with this same chemical. This year, toothpaste imported from China into the United States and seven other countries has been found to contain this poison.

It was not until June 7, 2007, however, that FDA issued an import alert to detain, on the importers' premises, toothpaste containing DEG and named several Chinese exporters of the product to the U.S. The import alert was amended to include toothpaste packaged with toothbrushes after the San Juan FDA District decided, on its own authority, to inspect retail stores and discovered the presence of diethylene glycol in products that combined toothbrushes with the deadly toothpaste. Their investigation revealed that this combination product was still entering the U.S. market because brokers were declaring the shipments as brushes, not toothpaste.

Counterfeit Colgate-brand toothpaste, labeled as originating from South Africa, that may contain DEG was also discovered during this investigation. Its true country of origin is in doubt. Pictures of some of the toothpaste entries from San Juan are attached.

Committee staff has learned that the San Juan FDA laboratory is no longer permitted to analyze food samples—even though Puerto Rico, as an island, imports most of its food. Thus, FDA now requires that samples of fresh produce that regularly contains illegal concentrations of pesticides from the Dominican Republic must be shipped to Atlanta for analysis.

2. FDA's Proposed Reorganization of its Field Staff would Likely Expose Americans to Even More Danger from Unsafe Food, particularly Imported Food

No Justification Given for Major Reorganization

FDA has announced its intentions to conduct a sweeping reorganization of its field operations in the midst of probably one of the most serious assaults upon food safety since the Agency's creation. FDA proposes eliminating 5 current regional offices and reduce the districts from 20 to 16. The district offices to be eliminated in the consolidation are San Juan, Northern New Jersey, Cincinnati, and either Denver or Kansas City. As part of its reorganization plan, FDA is also proposing to close 7 of its 13 laboratories. These include Detroit, San Francisco, Denver, Kansas City, San Juan, Philadelphia, and Winchester, Massachusetts.

Despite repeated requests from the committee, FDA has failed to provide any analysis justifying this radical reorganization. FDA has failed to provide us with any independent cost-benefit analysis for their proposal. The rationale for choosing which districts to close is not discernable from the documents supplied to the committee. Decisions regarding district closures appear to be related, in part, to prospective retirement or current vacancies among District Directors.

On the surface, the proposed closings appear to be counterproductive and may needlessly increase taxpayers' costs. For example, even though a very high percentage of drug manufacturing occurs in San Juan and New Jersey, FDA is proposing the closure of these offices and laboratories in Philadelphia and San Juan. The Puerto Rico closures will transfer oversight of drug inspections to the Orlando, Florida, District Office and testing to the Atlanta laboratory. Gathering relevant personnel will either result in tremendous additional expenses or, more likely, less enforcement.

Committee staff was told that among the more indefensible parts of the reorganization proposal is the consolidation of the compliance function into 10 locations. This means, for example, that compliance recommendations regarding Agency action from a San Francisco inspection will be applied in Seattle. Compliance officers make decisions regarding which shipments to inspect, which to sample, and what actions should be taken in response to the inspection findings. No compliance officer that staff questioned thought having the Compliance Director located in a separate office made sense. It would appear that this proposal would make the decision to take regulatory action—an already cumbersome task—even more difficult.

FDA is also proposing to consolidate the entry review function into six locations. Under the current program, a very high percentage of import review is already conducted at headquarters. As previously mentioned, the OASIS system currently removes 80 percent of so-called "low risk" imports from any field inspection. Thus, a very high percentage of food entries are not examined by inspectors at the port who are best positioned to judge the bad actors, the importers that cheat, the brokers

that misclassify, and imported products that arrive in unusual locations. Under the new consolidation, those port inspectors will be totally removed from the identification process. All decisions concerning such inspections will be decided at the six designated locations, not in the field. Committee staff was told that this consolidation is equivalent to having bureaucrats in Washington and a few regional locations determine the assignments for the local police forces.

Likewise, the committee staff was told that it would appear that the retirement of the District Director in Denver has prompted a decision to split the Kansas City District and move Denver into the District with Kansas and Nebraska, and placing Iowa and Missouri in the Chicago District. Given the character of the primary regulated industries in those States, it is difficult to understand how splitting up a District that requires experts in veterinary medicine and animal feed industries (and now apparently pet food as well) would be productive.

The rationale for closing more than half of FDA's laboratories, at a time when food safety is considered a public health crisis, is not discernible from the records provided to the committee. The ostensible rationale is that there are a limited number of laboratories that FDA can maintain at a world-class level. Since FDA has not provided an analysis demonstrating any cost-savings associated with the lab closures, their rationale implies that synergies exist in mega-labs; however, no documents have been produced by FDA to support that suggestion. When the Government Accountability Office examined this question, they found that midsize labs were more efficient.

Committee staff was informed by FDA field staff that there will be a tremendous loss in experience as laboratory analysts retire or resign, rather than be relocated. In addition, recent history suggests that it will be extremely difficult to replace the scientists necessary to conduct high-level laboratory activities. When FDA closed labs in 1994, only 17 percent of the affected laboratory analysts elected to transfer. Under the current lab closure proposal, only two analysts in San Francisco, one in Denver, two in Massachusetts, and six in Kansas City have indicated that they may accept a transfer to another lab. Hence, a significant level of expertise is expected to be lost.

Also, taxpayers will not benefit from the substantial sums of money FDA has recently spent accrediting these labs, signing new leases, and rebuilding or refurbishing offices that they now propose to close. For example, the staff noted that the food laboratory equipment, and all but one of the lab structures visited, appear to be modern with long-term leases or outright ownership at each location.

FDA was given 4 months to produce the documents relating to the lab closures. Prior to last week, FDA has produced only four boxes of paper. Each production included an assurance that the production was essentially complete. The early document productions were noteworthy for the absence of internal documents critical of the reorganization and documents from the field.

More importantly, FDA has not furnished the committee with documents that suggest the Agency has any plans to hire personnel with equivalent skills at its new locations. In fact, the experience it claims will be replaced cannot be duplicated by new hires over a reasonable period of years. Many of the laboratory employees are renowned in their fields.

The staff was repeatedly told that the only credible explanation for this seemingly incredible decision is that the Office of Regulatory Affairs management intends to contract out the work. The staff was told, however, that State labs will not purchase the millions of dollars in equipment and hire the necessary analysts unless there is an expectation that the transferred work will be permanent. Private laboratories have the drawbacks noted previously.

The critical question of how the work of half of FDA's current labs is to be performed after they are closed remains unanswered by FDA reorganizers. It is difficult to avoid the conclusion that, in fact, FDA management has decided to drastically reduce the sample analyses performed in its own labs and to contract out the remainder.

Labs Due to Be Closed Possess Unique Capabilities

The committee staff was able to visit all of these labs, except for Philadelphia, in the course of the subcommittee's investigation and questions the justification for such drastic actions, especially in light of the recent recalls and import alerts. Two of the labs visited by staff, Detroit and San Juan, are almost exclusively devoted to analyzing drugs. Detroit has been an important food lab given the volume of food imported over the Ambassador Bridge from Canada. In this regard, it is important to note that while Canada has a comparable regulatory system, not all imports crossing the border into Detroit originate in Canada.

FDA has limited most of the Detroit laboratory's work to "drug stability analysis," which involves testing related to Government stocks of drugs. The staff has been advised by the Department of Defense that such activity saved the Government \$600 million last year, or about one-third of the total FDA budget—a very profitable endeavor for the United States Government. The drug stability work was performed by eight full-time equivalents (FTEs) in Detroit and three FTEs each in Philadelphia and San Juan.

It should be noted that 60 percent of U.S. pharmaceuticals are manufactured in Puerto Rico. Many of the inspections cannot be done without a laboratory analyst. Most of the private sector laboratory employees are far more comfortable explaining their work in Spanish. If the seasoned laboratory staff currently in Puerto Rico is lost, FDA will be forced to find comparably skilled bilingual chemists and, once trained, and pay their travel expenses to Puerto Rico. It should be noted that many inspections of drug manufacturing take longer than the FDA estimate of 5 days.

Committee staff was initially sent to these laboratory locations to examine the work that FDA had done in the melamine investigation. Only Kansas City, a laboratory in the heart of the pet food and animal feed industries, was allowed to analyze food and feeds for melamine.

Although the Kansas City lab has done yeoman's work, analyzing more than 400 samples in a little over 6 weeks time, it was not the only FDA lab capable of performing this work. Notwithstanding their capability, however, it appears that, for unexplained reasons, other FDA labs due to be closed under the proposed reorganization were denied the \$20 standard test needed to detect melamine and were forbidden to analyze samples of pet food, vegetable proteins, or other materials that may have been contaminated by Chinese imports. Instead, the Agency spent some fraction of the \$2.6 million in Food Emergency Response Network grants to pay some or all of the eight university laboratories that have cooperative agreements with FDA to complete testing. To what extent the results of these laboratories could be used in court is problematic, given the chain of custody issues raised by a number of FDA officials during the course of the committee's investigation.

At best, this was a decision to waste Federal tax dollars, since the work was contracted out to State and university laboratories when in-house was available to perform at least some of the work. Moreover, there are indications that this type of out-sourcing is ineffective. It was an outside laboratory that first pronounced the contaminant in pet food as rat poison. The Cincinnati and Kansas City FDA laboratories discovered the melamine and developed the methods for detection. The Denver lab developed the method for analyzing melamine in fish.

Kansas City, like other FDA labs, was the beneficiary of modern equipment and an expanded work force 5 years ago as part of the ramp-up decreed by Congress in the Bioterrorism Act. It is a centerpiece for rapid analysis of threats to our food security. Nevertheless, and again for no apparent reason, Kansas City has been identified for closure.

The staff investigation also highlighted the importance of the San Francisco lab in dealing with unsafe imports, especially from the Far East, and with domestic issues related to the Salinas Valley. That laboratory has been a significant force in the interdiction of problematic seafood. The staff was told that FDA lab analysts are regularly recruited by FDA investigators to conduct pre-dawn inspections of seafood importers and processors because of their experience and training in identifying problem seafood. Committee staff learned that the lab's reputation for effectiveness is so well known that many unscrupulous importers of farm-raised shrimp and other fish are now sending their questionable products via air or "in bond" to be "entered" in Las Vegas, in part to avoid the scrutiny that the seafood would face in San Francisco and the other West Coast seaports.

Both the State of California and FDA inspectors involved in the produce investigation told committee staff that the closure of the San Francisco lab would be a great loss to the California Food Emergency Response Team. Committee staff were told that laboratory analysts are often needed to go into the field with investigators. These officials feared that this would be unlikely if the lab were closed. They warned of a significant loss of expertise.

Officials also advised the staff that it is crucial to have a local lab to analyze the samples. It takes less than 2 hours to get to the San Francisco lab from the Salinas Valley. The time it takes to get samples from the field to the lab is crucial because enrichment of the samples must be complete within 24 hours. If samples had to be shipped, it is likely that enrichment would not be timely. Further, samples cannot be shipped on the weekend. The FDA officials told committee staff that when samples are collected on the weekend, San Francisco provides an analyst in the lab. Another concern regarding samples that must be shipped is that they are temperature sensitive. The San Francisco lab puts a priority on analyzing produce and fish sam-

ples collected and warned that other labs may assign priority to the collections of investigators in their own District.

The San Francisco lab employs a seafood sensory expert inspector with such unique skills that he appears to be the only FDA employee qualified to identify where to take samples in seafood shipments. In addition, State officials indicated their concerns that outbreaks in California involving produce will overwhelm the five microbiologists in the State lab, if San Francisco is shut down, and other labs are too distant to effectively analyze lettuce or spinach produce.

Committee staff also learned that the Winchester Engineering and Analytical Center (WEAC) in Massachusetts is the only FDA lab that performs radionuclide analysis on food. This means that the WEAC lab is the only facility that has full analytical capability and expertise in detecting radiological contaminants in food products. Over 350 samples per year are analyzed for radionuclides in food. Analysis is done on both imported and domestic food, with domestic foods being analyzed the majority of the time. During and after the Chernobyl disaster and the Three Mile Island Accident, WEAC performed radionuclide analyses on food and ensured that the Nation's food supply was free from radiological contamination. WEAC's analytical capabilities and expertise are relied upon by Federal, State, and local governments for the investigations of food safety violations linked to radiological incidents.

WEAC is part of the Food Emergency Response Network (FERN). FERN is a network of Federal and State labs that is responsible for analyzing food samples in the case of a biological, chemical, or radiological attack. WEAC's radionuclide section is the Lead Project Coordinator for the radiological component of FERN. In the event of an emergency, WEAC has emergency response responsibilities. WEAC is the sole FDA laboratory for radionuclide analysis in the event of a nuclear disaster and/or counterterrorist event. WEAC has a memorandum of understanding with USDA/Food Safety and Inspection Service, whereby WEAC would analyze USDA regulated products for radiological contamination as part of an emergency related to an actual or threatened act of deliberate contamination of the food supply. WEAC also will assist New England in the radionuclide analysis of food samples collected as part of an emergency. WEAC performs other FERN activities as well. WEAC is conducting counterterrorism food research at the University of New Hampshire due to a concern that the Plague bacterium might be used to deliberately contaminate the Nation's food supply. WEAC is evaluating a capture system in the hope that more laboratories might be capable of isolating and identifying the bacterium.

The Denver lab is also a member of FERN. The Denver lab is the only full-service FERN laboratory slated to close under ORA's current plan. Six analysts at the lab currently are assigned to FERN work. The Denver FERN lab specializes in the analysis of cold sterilants used to decontaminate pathogens such as anthrax. The only other FERN lab that performs this type of work, WEAC, is also listed for closure.

The Denver lab is also home to the Animal Drug Research Center (ADRC). While one or two other individuals within FDA do the same type of work as ADRC, no other lab has a center dedicated to the work. ADRC is staffed by three research chemists with doctoral degrees in analytical chemistry. None of these three doctors would transfer were the Denver lab to close. ADRC develops methods to detect animal drug residues in animal and seafood tissues and in products such as milk and honey. In the past 15 years, ADRC has developed methods for over 30 drug residues in fish and shellfish. The methods that are developed and validated by ADRC are then transferred to regulatory programs within FDA and to State, Federal, and international laboratories. ADRC is responsible for developing more than 60 percent of all seafood testing methods used by FDA. As noted earlier, ADRC recently developed a method for detecting melamine in fish tissue—a procedure the Center developed in only 4 days.

The Denver Lab also has a Veterinary Drug Section. This section is responsible for analyzing products for illegal residues of various drugs, fungicides, and growth promoters. Animal feeds, farmed fish, seafood products, dairy products, honey, and a variety of other products are all analyzed at the lab. The Denver lab is the only FDA lab to have a section devoted to testing animal feeds and is the only lab to test milk for antibiotics. Analysts in the section average 22 years of experience and the section has two GS-13 Specialists.

Other areas of expertise in the Denver lab include the following: a BSE (Mad Cow Disease) team; a Salmonella Serology Team that identifies organisms found in foods and animal feeds; and an Antibiotic Resistance Team that analyzes the susceptibility of organisms to antibiotics to track trends of antibiotic resistance. The Denver lab has a National Salmonella Expert and is the only FDA lab performing antibiotic resistance testing. Other food work that the Denver lab performs includes a variety of procedures to detect pathogens in domestic and imported food and filth detection.

The Spinach and Peanut Butter Food Poisoning Outbreaks May Highlight FDA Flaws in Voluntary Compliance Approach to Regulation

The recent outbreaks of *E. coli* 1057H7 in spinach, the Tennessee strain of salmonella in peanut butter, and melamine contaminated pet food were highlighted at the committee hearing on April 24, 2007. The hearing featured the testimony of victims of the food poisoning and the companies responsible for processing the contaminated food.

Committee staff was asked to analyze the two domestic incidents to understand their regulatory implications. In doing so, the staff visited both San Francisco and Atlanta and interviewed FDA personnel involved with inspection of the Natural Selections plant that shipped the contaminated spinach and the ConAgra plant that shipped the contaminated Peter Pan peanut butter.

The staff investigation raises questions about the adequacy of FDA's regulatory approach to both domestic and imported food. Except for four food groups—fish, citrus juice, low-acid canned foods, and infant formula—FDA relies almost entirely on the voluntary efforts of domestic food processors to self-police their activities. Many industry experts and FDA staff insist that recent events require a different approach from FDA in the future.

Committee staff learned that produce from the Salinas Valley of California has been the source of 10 food poisoning outbreaks over the past 11 years. FDA officials attributed the increase in outbreaks of contaminated spinach, and other leafy greens to a variety of reasons: changes in the diet of consumers, widespread distribution of produce around the country and world, larger lots of produce, and increased reporting and better tracking of outbreak statistics.

The staff was told that FDA has refused to issue binding rules for the production and processing of fresh produce. Ironically, because of the serious serial outbreaks, some in the California produce industry have sought compulsory rules, but FDA still insists on only issuing voluntary guidelines. The most recent guidelines do not provide guidance for testing protocols.

The California Department of Food and Agriculture does have a Marketing Agreement for the industry (<http://www.cdffa.ca.gov/mkt/mkt/pdf/lgph-agreement.pdf>). Apparently, 90 to 95 percent of the total volume of leafy greens produced in California is covered by the agreement. Buyers may only purchase produce from certified growers/producers. Being too close to a ranch or a stream and various other factors are reasons a grower would not be certified. Audits are performed and a certification stamp appears on the packaging of qualifying products.

Investigators and compliance personnel in San Francisco advised committee staff that until compliance with good agricultural practices is mandatory, nothing will change. Likewise, they told the staff that FDA must be more forceful in demanding access to sites and records in the course of their inspections.

Committee staff learned that during inspections, prior to the spinach outbreak last fall, Natural Selections had refused to supply test results. The staff was informed in late May 2007 that the firm had not followed its own Standard Operating Procedures (SOPs) in that it used recirculated water that was not sanitized prior to its reintroduction into the production process. Apparently, Natural Selections added chlorine, by hand, whenever the operator thought it necessary, rather than employing an automated injector. Further, the individuals employed as quality assurance analysts were not professionally trained and did not have scientific credentials. While the staff was informed of the aforementioned regulatory breach, we were told that the Establishment Inspection Report (EIR) of Natural Selections spinach investigation was not complete, despite that fact that CalFERT issued its report on March 21, 2007.

The inspectors were also hampered by the firm's refusal to permit photographs. Inspectors apparently found mold and other evidence of improper sanitizing in tubing and nooks and crannies of processing equipment. Produce investigations are hampered by the lack of mandatory good manufacturing practices and the right to examine test data and other records. Fortunately, the State of California has authority that FDA lacks, so they are a regular source of information and cooperation.

PEANUT BUTTER

A similar lack of aggressiveness on the part of FDA may have contributed to the peanut butter contamination deaths and illnesses. At the April 24, 2007, hearing, the committee learned that FDA received a tip from a former ConAgra employee that salmonella was found in the company's finished product testing on 2 days in October 2004. When FDA sent an inspector into the plant in February 2005, ConAgra refused to supply him with the October 2004 microbiological testing records except for 2 days that showed no contamination. The company claims that

its plant management merely followed company protocol and asked that the request be submitted in writing.

When interviewed, the FDA inspector did not recall that ConAgra agreed to supply the records upon written request, and the request is not noted in the Establishment Inspection Report. The inspector concedes, however, that such a request would have been a common occurrence for ConAgra and other food processors.

Subsequently, committee staff learned that it is FDA policy not to request such records in writing. Section 703 of the Federal Food, Drug, and Cosmetic Act provides that if a firm supplies records in response to a written request, they cannot be criminally prosecuted for the information contained in such records. Large food processors understand this provision and have policies, such as ConAgra had in place in 2005, that dictate test results and other critical records such as the Standard Operating Procedures (SOPs) for plants only be furnished to FDA in response to a written request. ConAgra announced a change in policy shortly before they testified on April 24, 2007.

In an attempt to understand why FDA does not routinely request such critical records in writing, particularly when a threat to the public health has been alleged and/or when the failure to obtain such records results in a NAI (No Action Indicated) for an investigation, the committee staff directed the question to officials in Atlanta, Kansas City, San Francisco, and ORA headquarters. The field inspection manual only provides that an investigator obtain his or her supervisor's permission to request records in writing. In practice, any such request would go to the District Director. Inspectors told committee staff that most often they had never heard of such a request being approved or, if they had heard of such an approval, it was a "once in a career event."

Committee staff was told in San Francisco that if an allegation were received regarding such a serious health threat as salmonella being found in testing and the lot destroyed, as was the case in the 2004 Peter Pan peanut butter case, they would notify the State of California, who would acquire the records under separate authority. This was not described as the usual practice elsewhere.⁵

ConAgra maintained that their micro testing had not turned up any salmonella since the October 2004 results. When confronted with the outbreak phenomena, the company blamed a roof leak in late July or early August as the source of the contamination. The positive FDA test results, however, involved lots of peanut butter with production dates as late as January 2007. This EIR and test results indicate that the problem was not related to a finite period of time. More importantly, the fact that ConAgra did not detect the salmonella in their in-house testing suggests that the testing protocol was not sufficiently sensitive.

With the exceptions of the four food categories noted above, FDA has no rules governing testing protocols, record retention, SOP adequacy, manufacturing, quality assurance and control, or the right to examine any records that a food-processing firm chooses to keep voluntarily. While the impact of the absence of effective regulation is more obvious in fresh produce, the staff learned that even fully-processed foods such as peanut butter can be a threat to the public health when voluntary controls fail.

CONCLUSION

It is important to stress the preliminary nature of these findings. As of the writing of this testimony, the committee has not yet received all of the documents requested from FDA. Some of these requests are nearly 6 months old. In addition, committee staff has not had the opportunity to fully explore new technologies or industry proposals potentially available for better food safety, or to fully explore FDA's international program and the unique challenges and opportunities that it may face both logistically and politically.

⁵ When CDC traced the food poisoning outbreak to Peter Pan Peanut Butter last winter, ConAgra shut down the plant and FDA went in for another inspection. FDA withheld the inspection report from the committee, claiming that the inspection was still on going. During the Atlanta visit, committee staff was provided with a copy of the EIR for the plant inspection from February 14, 2007, through March 2, 2007. In fact, this EIR was approved on April 10, 2007, 2 weeks before the April 24, 2007, hearing. ORA headquarters was upset that the committee obtained the report even well after the hearing. Atlanta also furnished the staff with the lab results of the peanut butter jars obtained from the ConAgra inventory during and after the inspection. The FDA lab analysis found 14 out of 130 jars tested were contaminated with the Tennessee strain of salmonella.

Mr. STUPAK. I thank the gentleman for his statement. In order to proceed in a more orderly and efficient manner, each member will be recognized for 5 minutes. We will more than likely go more than one round with this panel. Mr. Wilfong, if I may, have you had an opportunity to review the report, provide input, and review the final product as submitted here as a staff report?

Mr. WILFONG. Yes, I have.

Mr. STUPAK. Same with you, Mr. Barstow?

Mr. BARSTOW. Yes, I have.

Mr. STUPAK. OK. Mr. Nelson, if I may, you had a chance to visit Puerto Rico district lab in San Juan?

Mr. NELSON. Yes, we did.

Mr. STUPAK. OK, did you see any counterfeit toothpaste there?

Mr. NELSON. We did and in—

Mr. STUPAK. Exhibit 62, 63, 64, 65. Is that correct?

Mr. NELSON. That is correct.

Mr. STUPAK. We have those up on the chart?

Mr. NELSON. That is correct, and the members should have them in their folders as well.

Mr. STUPAK. And this toothpaste contained diathylene glycol?

Mr. NELSON. That is correct.

Mr. STUPAK. OK, and I am going to ask that exhibit No. 63 be put up, and I want the toothpaste—did you see the combination toothpaste and toothbrush kits?

Mr. NELSON. Yes, and initially after the FDA put out its initial import alert only dealt with toothpaste, and what the San Francisco office found, because they went on a sweep with the commonwealth of Puerto Rico's health officials—

Mr. STUPAK. OK, I am going to interrupt you there. They put out an alert for toothpaste containing the diathylene glycol, right?

Mr. NELSON. Right.

Mr. STUPAK. OK, then what happened to get around this alert?

Mr. NELSON. The importers were entering the combination toothpaste and toothbrush as toothbrushes, and therefore they weren't being detained.

Mr. STUPAK. So if they had the toothpaste with the toothbrush attached, they would call it toothbrush. Therefore they avoided the FDA's import alert?

Mr. NELSON. Initially that is true until the Puerto Rican FDA, the office in San Juan discovered the fraud.

Mr. STUPAK. All right, now, have the combinations been recalled or an import alert issued on—

Mr. NELSON. Yes, they are not covered.

Mr. STUPAK. OK, because there has also appeared in my district in Penn County, MI, these combinations like this has also been. Where would these products be found?

Mr. NELSON. In small stores. In the U.S., they are called dollar stores, and actually I think that is a trade name. In Puerto Rico, you don't have big Wal-Marts, K-marts, Safeways. Food and drugs are purchased in relatively small stores, and so there is a lot of them. And the Puerto Rican authorities did a good job in trying to get this stuff out of those stores.

Mr. STUPAK. But they are not just confined to Puerto Rico. They are found throughout the country.

Mr. NELSON. Throughout the country. Yes, sir.

Mr. STUPAK. OK, Mr. Barstow, if I may, explain a little bit more about the FDA import alerts, specifically where you first learn of import alerts with the detention of the wheat gluten. And that import alert was issued on April 27 regarding the vegetable proteins wheat gluten, and then an import alert was issued on July 10 regarding certain farm-raised fish from China. Both of these are import alert. Is correct?

Mr. BARSTOW. Yes, they are.

Mr. STUPAK. The word detention, because in import alert, it says "detention without physical examination" correct?

Mr. BARSTOW. Correct.

Mr. STUPAK. The word detention, does it actually mean that the FDA detains the product?

Mr. BARSTOW. No, it does not.

Mr. STUPAK. What does it mean?

Mr. BARSTOW. It means that the FDA allows the product to be shipped to the importer. The importer then hires a private laboratory to test the product.

Mr. STUPAK. OK, so the private lab then tests the product, correct?

Mr. BARSTOW. That is correct.

Mr. STUPAK. Is there any way for a firm to free itself from requirement of having its products tested?

Mr. BARSTOW. Yes, there is.

Mr. STUPAK. How does it go?

Mr. BARSTOW. If a firm has five consecutive clean test results that are released by the FDA, then they are not subject to the requirement any longer.

Mr. STUPAK. OK, then after five tests, is it automatically lifted, or does the FDA lift the import alert?

Mr. BARSTOW. The import alert stays, but that firm who was exporting the goods into the United States is no longer subject to having their products tested.

Mr. STUPAK. OK, you had the opportunity to visit some of the FDA field labs. Is that correct?

Mr. BARSTOW. Yes, I did.

Mr. STUPAK. Which labs did you visit?

Mr. BARSTOW. I visited the San Francisco district laboratory, the Denver district laboratory, the Winchester Engineering and Analytical Center, and the Northeast Regional Lab in New York.

Mr. STUPAK. At these labs, were you able to speak with FDA lab analysts regarding the private lab work?

Mr. BARSTOW. Yes, I was.

Mr. STUPAK. What did you find out from speaking with these analysts?

Mr. BARSTOW. Well, every analyst I spoke to about this issue on private laboratories was very critical. I can think of one deputy lab director who performs private lab reviews said that none of the testing results are completely accurate that he has seen. I think he used the words "not good" and "spooky".

Mr. STUPAK. OK, and these very private labs are responsible for analyzing dangerous and potentially deadly food that enters into the country?

Mr. BARSTOW. That is correct.

Mr. STUPAK. Does the FDA accredit these labs?

Mr. BARSTOW. No, they do not.

Mr. STUPAK. Did this deputy laboratory director, does he go through and inspect these private labs?

Mr. BARSTOW. No, he doesn't.

Mr. STUPAK. Does the FDA debar, so to speak, or prevent certain labs from performing tests on food coming into the United States?

Mr. BARSTOW. No.

Mr. STUPAK. So these private labs are free without any kind of accreditation, review of procedures, process, or anything from the FDA?

Mr. BARSTOW. Yes.

Mr. STUPAK. OK. Well, my time is up. I still have many more questions. We may come back for a second round. I next turn to Mr. Whitfield for questioning please.

Mr. WHITFIELD. Thank you, Mr. Chairman. And, Mr. Nelson, in our hearing binder, you have already referred to a number of pages regarding toothpaste, and these toothpastes were discovered in Puerto Rico. But all of them came from China. Is that correct?

Mr. NELSON. Well, you have pictures there of the Crest knockoff that is called "Crust". The Colgate knockoff is called "Colgate", and the country of origin on the tubes—remember these were pulled from shelves. They were pulled from store shelves. They weren't pulled out of an import shipment coming in. The country of origin is listed as South Africa. Colgate/Palmolive tells us that they do not produce in South Africa that size of tube, and it is suspected that they have come from China.

Mr. WHITFIELD. So it is suspected, but we don't have proof that it came from China?

Mr. NELSON. No.

Mr. WHITFIELD. But we do have some verification that some toothpaste recently came from China.

Mr. NELSON. Yes, all the rest of the pictures shows toothpaste that was imported from China.

Mr. WHITFIELD. And in this toothpaste, there was actually diathylene glycol in the toothpaste?

Mr. NELSON. There was diathylene glycol largely replacing the glycerin that is a more expensive component in things like cough syrup and toothpaste.

Mr. WHITFIELD. So it could simply be manufactured more cheaply?

Mr. NELSON. That is right.

Mr. WHITFIELD. And yet the diathylene glycol obviously is harmful to people?

Mr. NELSON. It is antifreeze.

Mr. WHITFIELD. Yes, it is antifreeze. Now, how did you first discover this? It was brought to your attention by merchants in Puerto Rico?

Mr. NELSON. Well, the initial attention was spurred by pressure ports and then FDA's import alerts.

Mr. WHITFIELD. OK. Now, in your testimony, you also stated that the Center for Food and Applied Center for Nutrition, that they had known for some time about the carbon monoxide processing of

meat and fish and the problems that arise from there, that they had known about that for years. Is that accurate?

Mr. NELSON. FDA has known about that. We know for sure that the San Francisco lab has been finding about 20 percent of such fish imported that they have tested to be decomposed, and the carbon monoxide atmosphere to hide that decomposition. We have not received any of the documents that we have requested relating to carbon monoxide in fish, except for nine entries that have come in just this year and were rejected by the New York lab for decomposition.

In 2001, the FDA went ahead and approved as GRAS, generally recognized as safe, the use of carbon monoxide atmospheres for retail sales of tuna.

Mr. WHITFIELD. And why would they do that?

Mr. NELSON. I have no idea. It is an ongoing inquiry. We don't have the documents from the FDA yet.

Mr. WHITFIELD. And they designated the treatment as generally regarded as safe since when?

Mr. NELSON. For fish, since 2001. For meat, since 2004.

Mr. WHITFIELD. But we don't have any documentation on the reasons for that?

Mr. NELSON. We have some documentation they supplied us last year when Mr. Stupak and Mr. Dingell, as the ranking members of this committee and subcommittee, wrote them. So they have delivered a few of the meat documents but none of the fish documents.

Mr. WHITFIELD. Well, from your analysis and your investigation with minority staff and your staff, you only have about a minute left, but what would you say would be the three or four most important recommendations that you would make to this committee based on your investigation?

Mr. NELSON. The investigation is very preliminary. One of the more immediate recommendations would be to stop the reorganization of the FDA that has been proposed. We have found in the documents they have supplied us no justification, no hard cost, no hard savings estimates that would show that the Government save money. A lot of indication that it would cost far more than it would save.

More importantly, the structural changes that take place are not easily reversible. So if in the end the FDA decides that the experiment didn't work, the cost of returning to the status quo would be extraordinary.

Mr. WHITFIELD. Mr. Chairman, my time is expired.

Mr. STUPAK. Thank the gentleman. Next Mr. Inslee for questions please.

Mr. INSLEE. Thank you. I would like to ask you first about the issue of leafy and green vegetables and these horrific injuries we have heard testimony about for some children and others coming out of places. There have been 10 outbreaks in Salinas Valley and others. And I am reading your staff report where you say that the staff was told that FDA has refused to issue binding rules for the production and processing of fresh produce. You go on to say that "investigators and compliance personnel in San Francisco advised

committee staff that until compliance with good agricultural practices is mandatory, nothing will change.”

Now, do I take it from that that the word from the inspection people is that they believe we have got to have mandatory protocols for the inspection and processing of this material, or we are going to continue to have episodes of this *E. coli* damage to Americans. Is that correct?

Mr. NELSON. To a person, yes.

Mr. INSLEE. You seem sort of unequivocal about that. You say it is to a person. We are hearing from the inspectors, the cops on the beat, and they are telling us that if we don't get mandatory requirements, people are going to continue to get sick. And you are telling me that was a unanimous opinion from the people on the beat?

Mr. NELSON. Yes, during my discussions of produce with the San Francisco district, we probably had 20 people in the room that had some relationship to either the labs, the inspectors, the compliance personnel, and the management of the district. And they were all very concerned that issuing one more round of voluntary guidelines, which the FDA did in March, would have no real impact. In fact, we were told that the industry itself would prefer mandatory guidelines and that the agency has refused to issue such.

When Mr. Barstow spoke with them, he actually spoke with the State inspectors as well.

Mr. BARSTOW. Yes, I did, and they also agree with the FDA inspectors that there should be some sort of mandatory guidelines.

Mr. INSLEE. Well, I agree with them, and I think that the cops on the beat needs to be listened to in this regard. And Congress has got to mandate these, and it is just unforgivable to me that the administration refuses to move forward when there is such unanimity in their own enforcement staff and now it is increasingly in the industry as well to have mandatory protocols. So Congress is going to have to act if the administration is not, and we are prepared to do so, I think. Mr. Nelson?

Mr. NELSON. One question that we have not examined that was just raised in a newspaper article—you may want to ask the third panel about this—was that FDA had gone to the Department of Health and Human Services with a proposal for mandatory rules. And it was rejected by higher levels in the Department of HHS.

Mr. INSLEE. Tell me again now which level was proposing it, and which level was rejecting it?

Mr. NELSON. FDA was proposing it. The powers that be in the Department of Health and Human Services rejected it.

Mr. INSLEE. Well, that is disturbing given the depth of this injury to Americans and the obvious risk and the fact that we are on a path of failure. This is a known path of failure, and continuing on this path of failure makes no sense to me whatsoever. And it is regrettable that the administration will not act. If they will not act, we will. I will be proposing, with some of my colleagues, a proposal in that regard shortly.

I want to ask you about the splitting of the compliance function. I was very impressed with the FDA inspectors themselves individually. I used to be regional director of HHS for the northwest region and got to know some of the FDA inspectors in the Bothell

labs in Bothell, WA. And they showed me how sensitive their noses were, and really finding out if fish was unfit or not is pretty incredible sensitive instrument, the human nose.

But tell me how it is going to work now that you are going to separate the decision for compliance between the inspection, the people right there who really know the traders, know the brokers, know this histories of these people, know the history of the product, and then send that decision somewhere else geographically across the country. It seems to me a very awkward and unmanageable proposal.

Mr. NELSON. Well, it seems to us that way too. They are proposing to set up 10 regional offices that will handle the compliance function. In the case of the west coast, San Francisco's investigators will report to a compliance officer in Seattle. They are proposing even more drastic changes in their entry review process. Right now, the inspectors acting as an entry reviewer, reviewing the computer screens deciding which entries should be inspected, they don't determine that. They send that recommendation to a compliance officer who is looking at a national work plan that comes to them from Washington, and if that inspection of that kind of establishment or that kind of food entry fits within the work plan, then it is probably going to be inspected. If it doesn't we are told it takes an extraordinary justification to go out and inspect something outside of the work plan. That compliance officer is probably going to be Seattle and even further removed from the information that local officials have about local trade.

Mr. INSLEE. I don't think it is a good idea if cops on the beat are told if it is not in the work plan, they can't pay attention to a miscreant who is causing suspicion. And I trust these people. These people are pros. If we give them the resources and the authority, maybe they can do their jobs. Thank you.

Mr. STUPAK. Thank the gentleman. Next ranking member of the committee, Mr. Barton of Texas, please.

Mr. BARTON. Mr. Chairman, I am not going to have any questions for this panel. I would hope that in the future, apparently for mechanical reasons we only have one of the big data notebooks, and I hope that we could get several more so that members could have them. I understand it was tough to get ready for this hearing, but I don't have any questions for this panel.

Mr. STUPAK. Point well taken. Next we will go to Mrs. Blackburn. Questions?

Mrs. BLACKBURN. Thank you, Mr. Chairman. I do have just a couple of quick questions that I wanted to ask you all. Listening to your responses and the way the staffs deal with some of the technicalities in looking at the product and the items that are moving into the consumption check here at the U.S., I was curious about the district labs and the attentiveness of the staff to the issue and wanted to see have they begun to develop their own best practices?

Are they developing mechanisms where they taking the initiative in this and coming up with their own criteria, or are they waiting for that to be handed to them from Washington? So are they taking the lead, and what is their attitude? Are they adjusting their work-

load so that they are responding to the increase of imports? Or are they frustrated with it?

Mr. NELSON. There is a lot of frustration. We visited two labs that are not proposed to be closed, Atlanta and New York. So it is not just the labs that are going down. One of the things that we learned is that an awful lot of methods for analysis for important things like melamine and fish are developed by the FDA labs, by the experts in the labs. They determine how you find what is food, and I suppose that other methods are developed in Washington by the Center for Food Safety and Applied Nutrition, but we weren't told that. It is an assumption on my part.

The work plans for the labs though, what the labs are supposed to look at and which labs look at what things are dictated in Washington. They don't have an ability to independently determine what they look at, what kind of samples are there to analyze. It has to fit into a work plan that is sent to them on an annual basis, and their performance is rated entirely upon how close to that work plan they come.

Mrs. BLACKBURN. OK, so they are functioning under a top down?

Mr. NELSON. Yes.

Mrs. BLACKBURN. Or a deductive approach to this, if you will. So their criteria is coming from Washington. The methods they are to use to evaluate the product is coming from Washington, and so are their work plans. And as they have things making their way into the offices, they don't have the flexibility. The bureaucracy doesn't allow them the flexibility to turn on a dime and say let us try this or this or this?

Mr. NELSON. Well, the bureaucracy from time to time tells them to turn on a dime, and they have done a pretty good job of it. The Kansas City lab, for example, in a matter of 6 weeks, was able to process 400 samples of wheat gluten and pet food. The direction is entirely from Washington.

Mrs. BLACKBURN. OK, thank you. One other thing. You mentioned in your testimony that primarily the products are coming from China and that they are for a group of stores. And you gave the name of the stores, but I couldn't find where you had that in writing. Is it the Dollar Store? Is that what you said?

Mr. NELSON. Yes, I am taking that from press accounts.

Mrs. BLACKBURN. OK, so these are products that are being produced specifically for a chain of stores?

Mr. NELSON. I don't know the answer to that question.

Mrs. BLACKBURN. OK, all right. And so are our district staffs developing the ability to look at products coming from certain provinces in China and developing an awareness there? Or are they using that to red flag any of these products that are coming in?

Mr. NELSON. I don't think there is a single answer to that.

Mrs. BLACKBURN. OK.

Mr. NELSON. It depends on the product and depends on the district, but the national prerogatives, the national priorities established—

Mrs. BLACKBURN. OK. So basically what we need is more flexibility given to those in district offices so that they can begin to make some determinations about what is coming from where and what they think may be the potential dangers within that consumption

item. And I think my time is about out, so I will reserve those questions. But thank you very much.

Mr. NELSON. Surely.

Mr. STUPAK. The gentlewoman from Illinois, Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. Mr. Nelson, first I want to thank you and the staff for the good work that you did on these investigations. I wanted to get a sense—Ms. DeGette was talking about the lack of response from the FDA when she has written letters, and Members of Congress. What was the response from the FDA in terms of responding to your questions and your inquiries? It sounded like you still don't have all the information that you had asked for?

Mr. NELSON. Well, the committee's document request, it is like pulling teeth to get FDA to respond. Actually, they have responded very, very well in the last 5 days as the hearing approached. But generally the delays are substantial. The document production is usually incomplete and often not identified as incomplete, or what is missing is not identified. That is the way to put it.

In terms of the interviews in the field with the staff, they have been incredibly cooperative. Just about everywhere we went, the local district offices assembled the people that were doing the work in the areas that we have asked for, seafood or wheat gluten or whatever, and the field people were entirely candid.

Ms. SCHAKOWSKY. But it sounds like there is a real disconnect that what they see as important to do, what they would like to do, they are either prohibited because of some bureaucratic rule that they don't have the authority to do it.

Let me ask a couple of specific questions about the laboratories. You have in your testimony only a minute fraction of the 25,000 daily food shipments are ever tested by a Government laboratory. What percentage is that?

Mr. NELSON. Far under 1 percent.

Ms. SCHAKOWSKY. Under 1 percent. So what are those laboratories doing? And is that the excuse then for shutting them down?

Mr. NELSON. The laboratory system is divided by caste. So for example, Puerto Rico, San Juan, Philadelphia, and Detroit aren't really food labs at all. They are entirely drug labs, and drugs from all over the country are sent to those labs for analysis. Likewise, the heavy food labs, Denver, Kansas City, that are being shut down get food from all of—Kansas City does an awful lot of the food analysis stuff coming across the southern border from Mexico. They have larger labs in Los Angeles and New York that, in fact, do both, I think. But for the labs that we looked at, there is a lot of specialization. Atlanta is almost all food, for example, not drugs.

Ms. SCHAKOWSKY. But not among their functions is to do these inspections of food shipments that are coming from many other places?

Mr. NELSON. Yes, the work plan, the national work plan, designates the number of samples that will be tested in FDA labs for the year, and it specifies them by labs and by kind of food. And except for emergency situations, like the wheat gluten situation, those work plans are expected to be followed pretty precisely. So it is Washington that decides what will be sampled. The labs do

the analysis of that minute fraction of 1 percent of the food coming in that is determined to need sampling.

Ms. SCHAKOWSKY. I want to ask you about the Oasis system. Is that what you are really referring to? Because you say that only 20 percent of food imports appear in the FDA's computer system, which is called Oasis, right?

Mr. NELSON. Right.

Ms. SCHAKOWSKY. For a review by the field inspection force. So there is just this huge category of foods that aren't even included for inspection?

Mr. NELSON. That is right. FDA-regulated products, not just foods. And it is a risk-based system. And when you have got limited resources and a big problem out there, you have to do some sort of risk-based analysis.

Ms. SCHAKOWSKY. But obviously that risk has not been properly calculated because we are at risk.

Mr. NELSON. Well, the wheat gluten sort of drew a road map for anybody that wanted to attack our food supply maliciously. You don't go to milk and water and the things that are fairly obvious targets. You find stuff that is not being reviewed at all. There was no wheat gluten ever—

Ms. SCHAKOWSKY. And that is in the 80 percent?

Mr. NELSON. Yes, that is in the 80 percent. Also in that 80 percent are exporters that are sending food into the United States subject to an import alert that have those five consecutive positive tests. So while the product and the country of origin may still be on import alert, as the exporters get out from underneath, they drop into that 80 percent.

Ms. SCHAKOWSKY. Thank you very much.

Mr. STUPAK. Next Mr. Burgess for questioning.

Mr. BURGESS. Thank you, Mr. Chairman. And I appreciate that I am relatively new here, but I just have to say this is kind of an unusual situation for me to be asking questions of a panel that is composed entirely of staff from the other side. Structurally, was our side involved in this at some level?

Mr. NELSON. Yes, sir, and they were invited to testify.

Mr. BURGESS. OK, and our staff was present at these inspections?

Mr. NELSON. Most of them, yes.

Mr. BURGESS. OK, and again this is just, Mr. Chairman, strictly housekeeping and structural. Perhaps my general knowledge should be better than it is, but are Members ever involved in this type of field hearing or field questioning?

Mr. NELSON. They have been in the past. There was an intense investigation by this committee while you guys were in the Majority that involved the import of drugs, personal importation, and Members went out with the staff to look at the international mail facilities, to look what the postal authorities were doing.

Mr. BURGESS. I don't want to use all my time on this, but I just would say for the future that this Member would be interested in this type of activity if time and scheduling would permit if future activity is planned.

Mr. STUPAK. We plan on sending these guys to China and probably to India over the August break.

Mr. BURGESS. Well, that would actually be the other part of my question, Mr. Chairman. As I look at this, and clearly we have a system that was designed for the world as it existed 50 or 60 years ago. And now we have the world as it exists today, and it doesn't seem like the system has kept pace.

First off, is there ambiguity between who is in charge here between the FDA, Department of Commerce, the USDA? Do all of those three agencies mesh seamlessly in this process?

Mr. NELSON. Most of the time I would think so. Their responsibilities are distinct. Their statutes are distinct. They all ultimately rely on Customs and Border Patrol to enforce the enforcement actions, the detentions, the denial of entry, the destruction of goods, that sort of thing.

Mr. BURGESS. Well, because I remember Tommy Thompson's comments as he was leaving as the Secretary of HHS, and he alluded to the food supply in the country. And I don't know that I really appreciated at that point how significant the problem was.

I will just tell you in my district, I had a veterinarian in who was up for a social visit last week, and I asked him about the pet food problem. And I did not appreciate that even in my little district in north central Texas how severe the problem was. And, of course, now looking back on animal records of animals that came in with kidney disease during that time span, he suspects that that problem was significantly more widespread than was appreciated at the time and probably involved pet food brands that weren't those that were the subject of the recall because there was a spike in otherwise unassociated kidney disease in the pets that he was seeing or that were brought into his office during that time.

Do we have to get wheat gluten from China? Can't we get it anywhere else? We grow some in Texas, I know, and I think they do in other States.

Mr. NELSON. Actually, yes, Canada supplies wheat gluten to us. Russia supplies wheat gluten to us.

Mr. BURGESS. Is there still wheat gluten coming in from China at this point?

Mr. NELSON. I presume so.

Mr. BURGESS. Why don't we just stop any importation of wheat gluten from the People's Republic of China until we ascertain that it is safe?

Mr. NELSON. Well, that is a question for the FDA. I will say that—

Mr. BURGESS. I thought this was an FDA hearing, Mr. Chairman.

Mr. STUPAK. They are our employees, not FDA's—

Mr. BURGESS. All right, I will ask the commissioner. I will reserve the question.

Mr. NELSON. I will say that FDA did a lot of testing, and except for the melamine in the Chem Nutra imports that went into the pet food, they found very little other batches of wheat gluten or any of the vegetable proteins as containing melamine. As I understand it, even the animal feed where it was found came indirectly from the discards of the pet food company that had imported the melamine-laced—

Mr. BURGESS. So it was just one rogue operator that was injecting this poison into the pet food supply or the wheat gluten supply?

Mr. NELSON. That is what their testing, I think, showed. The reports that we have heard from China though suggests that it is a much more widespread problem over there. And sooner or later, there will be another one.

Mr. BURGESS. Well, again this was a scientific study, but talking to this one veterinarian who happened to be up showing his kids the Washington Monument. And I just asked him about this, and he didn't have any data for me. But his impression was it was a much more widespread problem than was initially reported because of the number of cases of kidney disease and otherwise previously healthy animals that he was seeing during the winter and spring of last year.

But thank you, Mr. Chairman. Are we going to have a second round, or can I press on for a while?

Mr. STUPAK. Yes, we will.

Mr. BURGESS. OK, I yield back.

Mr. STUPAK. Thanks. Ms. DeGette from Colorado please.

Ms. DEGETTE. Thank you very much, Mr. Chairman. Mr. Nelson, you had testified in response to Mr. Inslee's question that the FDA employees that you and your staff talked to in general supported mandatory guidelines. I'm wondering if you can describe for the committee what kinds of guidelines you mean when you say mandatory guidelines?

Mr. NELSON. Well, the agricultural practices are voluntary. They are voluntary guidelines that the industry is supposed to abide by, but there is no standard to test against. One of the things they were most concerned about was that even in the voluntary guidelines, there were no testing protocols, there were four possible sources of contamination in the spinach that were identified in the CalFerd's. CalFerd being FDA and the State of California together, their report back in March.

But the FDA investigations that we talked to, and we talked to them all. They were all there. All seemed to think that the real problem was water. It could have been some of the other sources, but it was most likely water. And what they say would actually solve the problem or come close to—what they thought was the best solution to the problem was mandating that field that supply vegetables that are not cooked.

Ms. DEGETTE. So it is really mandating certain testing protocols and also certain agricultural practices?

Mr. NELSON. That is right, yes.

Ms. DEGETTE. OK, I am wondering if the FDA presented you or your committee with evidence that showed cost savings for closing these field labs particularly the Denver lab?

Mr. NELSON. We were shown no numbers, no solid cost numbers in all of the documents that they produced to us. There was one early analysis that was sort of back of the envelope. It was exhibit 40 in your exhibit books. That was the sum total of the cost analysis, and it is, as you can see, filled with assumptions that are assumptions and undocumented assertions as to cost.

Ms. DEGETTE. And you didn't receive the supporting documentation to this?

Mr. NELSON. There is no supporting documentation.

Ms. DEGETTE. Were you given any information by the FDA in your investigation about the impact of shutting the Denver lab and other field labs on food safety?

Mr. NELSON. They did no such analysis. But they supplied us—mind you, they are still supplying—they supplied documents as late as 4:30 yesterday afternoon that we haven't been able to go through entirely.

Ms. DEGETTE. Did they give some reason for their delay in supplying these documents to the committee?

Mr. NELSON. Every time we asked about the documents—the first letter was written in February requesting these documents. And every time that we would say look, this can't be a full production. There is nothing from the field here. There is nothing critical of your plans here. There is no substantive cost analysis here. There is no saving analysis here. We would get another batch of documents that were also non-responsive until—

Ms. DEGETTE. But did they give reasons why they have not produced these? I understand you haven't been given them. Did they tell you why they haven't been giving them?

Mr. NELSON. Not formally.

Ms. DEGETTE. OK, now the Denver lab in particular, according to your report, does a number of things like it has a lot of responsibility for food research and animal research, correct?

Mr. BARSTOW. That is correct.

Ms. DEGETTE. Mr. Barstow, you are the one that visited the Denver lab?

Mr. BARSTOW. Yes.

Ms. DEGETTE. Now, the Denver lab is the only FDA lab to have a section for testing animal feeds and the only lab to test milk for antibiotics. Correct?

Mr. BARSTOW. That is correct.

Ms. DEGETTE. And the Denver lab is the lab that developed the test for melamine in fish, and they did it pretty quickly, didn't they?

Mr. BARSTOW. They did. I believe they did it in 3 or 4 days. And it is an animal drug research center, and it is three analytical chemists. They all have Ph.Ds, and they are in charge of developing methods that are used agency-wide and by States and by even other countries to test food.

Ms. DEGETTE. Now, when you visited the Denver lab, Mr. Barstow, did you get a sense that it was antiquated and run down?

Mr. BARSTOW. No, not at all.

Ms. DEGETTE. Were there problems with staff morale there?

Mr. BARSTOW. Morale at every laboratory we visited was very low.

Ms. DEGETTE. I imagine it was particularly low at the labs slated to be closed.

Mr. BARSTOW. Exactly.

Ms. DEGETTE. Did those scientists tell you that they were going to transfer to the other labs?

Mr. BARSTOW. No, very few did. I believe the numbers were two in San Francisco, two in Denver, six in Kansas City, and two at the Winchester lab.

Ms. DEGETTE. Two that planned to transfer, and all the rest were not going to?

Mr. BARSTOW. That is correct.

Ms. DEGETTE. That is experience we would just lose if we closed those labs?

Mr. BARSTOW. Probably thousands of years.

Ms. DEGETTE. Thank you. Thank you, Mr. Chairman.

Mr. STUPAK. Mr. Murphy for questions please.

Mr. MURPHY. Thank you, Mr. Chairman. A couple things I want to know about. In your statement, you talked about how the FDA relies heavily on some labs, these private labs. But I think you are saying we don't have a list of unapproved labs or things like that. What kinds of problems are there with some of these labs in terms of equipment or procedures? Are they substandard, or are there some actions that you are finding exist at those places which is of concern?

Mr. NELSON. FDA doesn't inspect the labs.

Mr. MURPHY. They do not?

Mr. NELSON. And we certainly didn't. The complaints from FDA laboratory employees were improper methods of analysis and shoddy work in terms of recording the information that was then sent to FDA. And then there was a general complaint that we had at a couple of labs that essentially they believed there were labs—not all private labs mind you, but there were labs in each of the districts were importers knew the results were not going to be positive on their shipments. And FDA had no power to not accept those laboratory results. All they could do was send an inspector out to take a sample from the same shipment and have it analyzed in FDA labs. And when that happened, often is what we were told, the results were different.

Mr. MURPHY. So you are saying the importers know how to maneuver around FDA? What are some examples of how do they do that?

Mr. NELSON. Yes. Well, one of the examples is fish, large fish, tuna, swordfish, the like. Fish that grow to that size accumulate chemical toxins, mercury, arsenic, cadmium, heavy metals from the pollution in the ocean waters where they swim. And the older the fish, the larger the fish, the higher the toxin level. So because the FDA policy permits an exporter into the United States to come off of an import alert for, say, mercury and tuna if they have shown five consecutive private laboratory analyses of five different shipments, consecutive analyses, that they can be removed from the alert all together. So the game that is played is that they ship in the first five samples of small fish, fish that haven't grown, haven't been around long enough to accumulate the toxins. And then once they are off the import alert, then they don't have to worry about the size of the fish that they are importing.

Mr. MURPHY. Are there any kind of other things they use besides avoiding the big fish? I am just curious. This is important to know these kind of things. I just wonder what other kind of techniques they use to get around the system.

Mr. BARSTOW. Well, they know what ports to go into. They know where the FDA does not have an inspector or where they don't have a lab. Often those foods will not be tested either by the FDA.

They also, as we said earlier, they know what private labs to go to. One FDA employee told me that with the private labs, the bottom line is money so—

Mr. MURPHY. Do we have statements or responses from these private labs to these accusations?

Mr. BARSTOW. I spoke with one owner of a private lab, and he says that his lab is good but that he can point to numerous private labs that will guarantee you good test results.

Mr. MURPHY. Well, who pays the private labs? Is it the importer that pays them?

Mr. NELSON. The importer pays. The theory is that once a product is detained at the importer's premises, it is the importer's responsibility to prove to the FDA that the import is safe. And so the importer pays for the private lab test.

Mr. MURPHY. So just to make sure I understand, these are not labs that contract under the FDA. They are ones that contract with the importers who present some sort of a documentation that say our products are clean. The FDA accepts those documents then, and that is all that is needed?

Mr. NELSON. They have to accept those documents unless they are going to try and take a duplicate sample. And they have a limited capacity to do that.

Mr. MURPHY. And then you are saying the FDA does not inspect these private labs?

Mr. NELSON. They don't inspect the labs themselves.

Mr. MURPHY. But they accept the documents from the labs?

Mr. NELSON. They have to.

Mr. MURPHY. Why?

Mr. NELSON. I don't know. I don't know whether it is a function of the regulations or a function of guidelines, but it is FDA policy.

Mr. MURPHY. Thank you very much. Thank you, Mr. Chairman.

Mr. STUPAK. Thank the gentleman. Next will be Mr. Melancon for questions please.

Mr. MELANCON. Thank you, Mr. Chairman. First let me apologize for being late. Seems like we are still doing hurricane stuff in my office.

Mr. STUPAK. That hearing will be August 1.

Mr. MELANCON. Thank you. I appreciate that. And let me maybe not change so much as to try and expand. We were talking about the lead in the fish and the small fish being brought in. How many ports of entry are there where USDA checks products coming into the country as opposed to FDA checking the products coming into the country?

Mr. NELSON. USDA restricts the imported meat to 10 ports. There is no such restriction for FDA. So all 326 ports of entry—these are ports where there are Customs personnel, but in very, very few are there FDA personnel.

Mr. MELANCON. So if I were an importer, I could send it almost any place I wanted to and specifically if I was gaming the system, send it in a place where I knew there weren't any. FDA has seafood, and, of course, that is one of the things I am concerned about because of the shrimp contamination and the basa and such. How many FDA facilities do we have, and at what ports do we have them, or what is the number that are available?

Mr. NELSON. I don't know. You should ask the FDA that question.

Mr. MELANCON. OK.

Mr. NELSON. I don't have an answer to that.

Mr. MELANCON. At any of these ports where they have the physical facility as well as the scientist that could do the testing, do they do any of that?

Mr. NELSON. Well, there are only 13 labs right now throughout the whole United States that are FDA labs. Customs has labs. USDA has labs. So there is more than 13 Government labs. There are only 13 FDA labs, and they are proposing to reduce it to six. In terms of where there are FDA inspectors, at relatively few of those 326 ports. I don't know whether the number is 50 or 70 or 80, but it is certainly not 300 of the 326.

They do have arrangements with Customs. When an airplane comes in to one of these smaller airports, or right now, for example, there is no FDA presence in the Virgin Islands. There hasn't been since last October. They are trying to fill the position, but they haven't filled it yet. So Customs in the Virgin Islands is tasked to alert the FDA officials in San Juan, Puerto Rico of any shipments that Customs thinks might be problematic. And then a phone conversation occurs, and FDA asks them to let the goods go through or to hold them up for FDA to get a sample.

Mr. MELANCON. Or then the importer gets a private company that he pays to come test it and sends the result to the FDA, and they have to accept it?

Mr. NELSON. That is when there is an import alert, yes.

Mr. MELANCON. OK.

Mr. NELSON. Like there is now on farm-raised fish from China, certain fish and shrimp.

Mr. MELANCON. Is there some reason why crawfish didn't get included in this list of fish?

Mr. NELSON. That is a good question for FDA. I don't know. Maybe no crawfish comes in from China, but I don't know.

Mr. MELANCON. I think China and Vietnam, I think, send crawfish if I remember correctly.

Mr. NELSON. Yes, they have had problems. San Francisco told us a lot about seafood problems from Vietnam, not just China.

Mr. MELANCON. Yes, and as I understand it, that as soon as they crack down on them either for the dumping or because they have product that is contaminated, whoever it is over in the foreign country just started putting them in a different manufactured name bags and sending them through somebody else or sending them through another port.

Mr. NELSON. That is certainly a common method of avoiding, of shopping for ports. But we didn't have any specific evidence of that. We didn't ask those question.

Mr. MELANCON. OK, let me just ask because I came in late. I apologize for that. You all talked about detention and what exactly detention was?

Mr. NELSON. Yes, sir.

Mr. MELANCON. And it is not really detention in the sense of being the dunce in the corner if you get caught. The question was

asked of me yesterday, and it was about how is beer and booze and wine handled coming into this country?

Mr. NELSON. There is a different agency than FDA deals with.

Mr. MELANCON. And is there some testing or validation, or is it restricted to certain importers who are regulated? How do we do that?

Mr. NELSON. I have idea. That wasn't part of our inquiry.

Mr. MELANCON. And the reason I asked that is, I mean, booze, which of course all the generations and still some people believe is the evil spirit. In Louisiana, we don't look at it that way. We look at it as the fun spirit. Yet at the same time, we get this product in, or alcohol products, and we don't seem to have any problem with it. But food that is part of everyday nourishment that is part of what we need to survive, we are not checking.

Mr. NELSON. Very, very little.

Mr. MELANCON. Most people run around worrying about booze. I think that is all I have for right now. Thank you, Mr. Chairman.

Mr. STUPAK. Thank you. We have gone through one round, and we will go through a second round. I know Mr. Burgess has other questions. So we will be recognized for 5 minutes, those Members who would like to ask other questions. Mr. Barstow, you indicated you were in the San Francisco area. I understand that you had the opportunity to visit Customs and Border Patrol and a centralized examination station. Is that correct?

Mr. BARSTOW. Yes, at the port of Oakland.

Mr. STUPAK. OK, what was the focus? Why did you go there?

Mr. BARSTOW. They had pulled shipments of wheat gluten, and we were going to go there and watch them pull samples from the base.

Mr. STUPAK. OK, and what did you observe when you were there at Oakland?

Mr. BARSTOW. That is where we observed the wheat gluten.

Mr. STUPAK. Well, go to exhibit No. 16 in the main binder there. If we can have that photograph up.

Mr. BARSTOW. That is what we observed.

Mr. STUPAK. OK, these bags don't appear to have any markings on which would indicate the country of origin. When you were doing wheat gluten, were you looking for Chinese wheat gluten?

Mr. BARSTOW. Yes, we were.

Mr. STUPAK. OK. Well, if they don't have any writing on and you have a windmill. You have wheat gluten. You have melamine, whatever it is there. You have Amsterdam pollen it says on there. Why would you believe that this came from China?

Mr. BARSTOW. We had the opportunity to view the entry documents.

Mr. STUPAK. So is this just another way of getting around the import alerts that you spoke about earlier?

Mr. BARSTOW. I don't know if it is a way to get around the import alerts, but—

Mr. STUPAK. These bags have no markings whatsoever to indicate they are from China, right?

Mr. BARSTOW. None whatsoever.

Mr. STUPAK. But there is no doubt in your mind or to Customs Border Patrol that this was from China wheat gluten?

Mr. BARSTOW. That is correct.

Mr. STUPAK. OK, San Francisco has quite a reputation of being very good at detecting problems with seafood, the FDA inspection team there, correct?

Mr. BARSTOW. That is correct.

Mr. STUPAK. Did I read somewhere in report that to avoid San Francisco they now go to Las Vegas?

Mr. BARSTOW. Yes.

Mr. STUPAK. You mean imported seafood instead of going to San Francisco, which is our best lab, they go to a different point of entry?

Mr. BARSTOW. Right, they know the expertise in San Francisco is so good, and there are inspectors there that are looking for these kind of problems. Instead, they import into Las Vegas.

Mr. STUPAK. We mentioned the quality of the work done in San Francisco. In the report, it indicated that—Mr. Nelson, your answer is that—what is all the stuff that comes through San Francisco? A lot of food, medical, drugs?

Mr. NELSON. A lot of food. Basically San Francisco, Seattle, and Los Angeles get the imports from the Far East.

Mr. STUPAK. OK, but I read somewhere in your report that they only have like 30 seconds to take a look at a shipment or documents of a shipment?

Mr. NELSON. They only have an average of 30 seconds. For most entry reviews, it is a lot less than 30 seconds because if they take any action on one, it cuts down on their time. They have got about 30 seconds to look at a computer screen and decide whether or not to recommend the inspection of that entry or not.

Mr. STUPAK. Now, the FDA put out—we have been talking about these voluntary guidelines, and these guidelines relate to the use of pesticides, chemicals, sanitation, handling of food, food products, packaging, irrigation. And that is strictly a voluntary guidelines.

Mr. NELSON. As I understand it, yes.

Mr. STUPAK. And that applies to U.S. producers and manufacturers?

Mr. NELSON. Yes, also Mexican producers.

Mr. STUPAK. And also Chinese producers?

Mr. NELSON. And Chinese products.

Mr. STUPAK. Chile, I think, was another country mentioned today, those voluntary guidelines, Chilean producers?

Mr. NELSON. Yes, they are voluntary. They don't bind anyone.

Mr. STUPAK. OK, in this country it might be a little easier, but are there any FDA inspectors in China or Chile or any other countries that ship food?

Mr. NELSON. Very food foreign food processors are inspected, and they are almost all low-acid canned food plants.

Mr. STUPAK. At canned food plants?

Mr. NELSON. Low-acid canned food plants.

Mr. STUPAK. OK, you mentioned wheat gluten at the Kansas City lab, but I thought I read in the report that while the Kansas City lab did a good job on wheat gluten, a lot of this work to detect the wheat gluten is also turned over to private labs?

Mr. NELSON. They were turned over to university labs that are part of the FERN Network. What was remarkable about—

Mr. STUPAK. FERN is Federal Emergency Response—

Mr. NELSON. Response Network. I am sorry, yes. And what was remarkable is that none of the labs except Kansas City, which is right there where the Menu Foods plant was, none of the rest of the labs that were being closed were allowed to do the analysis on this emergency basis. Instead, they contracted out work to university labs, and we were told that there are often, maybe always—I am not sure—chain of evidence issues with university labs. State labs and FDA labs know how to handle samples from a legal standpoint, but not university labs.

Mr. STUPAK. OK, there are 326 ports of entry for food in the United States. Is that correct?

Mr. NELSON. Yes, there is 326.

Mr. STUPAK. Do you know how many of them have an FDA inspector at?

Mr. NELSON. No, but I would be surprised if it was more than a quarter of them.

Mr. STUPAK. So you would anticipate maybe one-fourth of them have a FDA inspector?

Mr. NELSON. Right.

Mr. STUPAK. OK.

Mr. NELSON. The rest are very small.

Mr. STUPAK. The USDA now—and they deal mostly with meat, correct?

Mr. NELSON. Yes.

Mr. STUPAK. The Agriculture Department, they only allow food to come in to 10 sites in the country, right, not 326?

Mr. NELSON. That is my understanding. Yes, sir.

Mr. STUPAK. OK, my time has expired. Mr. Burgess for questions.

Mr. BURGESS. Now, Mr. Nelson, did you and your group go to the place where they inspect fish in Los Angeles?

Mr. NELSON. No, we went to Los Angeles, to the port of Los Angeles, and we spent some time in the Customs area, discussing wheat gluten imports with Customs. We then went to the port of Los Angeles, but we were only in their offices and only met with officials of the district there. We did not talk to any inspectors or compliance people or laboratory people in Los Angeles.

Mr. BURGESS. My understanding is that at Los Angeles for fish inspection, they have a prototype or a demonstration project of the new way forward that truly does have an automated system, a risk-based analysis of the imports as opposed to just inputting economic data, a system that can take into account perhaps the local conditions where the product was obtained, a very dry year or a very wet year or something that might affect the overall quality of the product coming into the country.

Is this type of concept—you talked about an inspector having to pass on a specimen on a 30-second time interval. Someone said they have got great noses, but my wife does too. But even she need more than a 30-second break in between assessing things at the meat market.

Are we getting to a point where again we have the 21st century of food stuffs coming into this country from around the world, and we are dealing with a system that was set up after the Second

World War, as far as dealing with imports. We have to do one of two things, either close the borders, which some of us might favor, no more imports from the People's Republic of China. I am told that is not feasible so we are going to have to be much smarter about the way forward from this. From your observations in all of these labs, did you get any sense of the way forward, the way out of this conundrum in which we find ourselves?

Mr. NELSON. One of the principle caveats to the testimony today is that we have not done extensive examination of the possible technological solutions to some of these problems. It is one of the deficiencies of the investigation to date that will correct as we go along.

Mr. BURGESS. And yet, if I may interrupt, that is one of the most critical things ahead of us. I see in the testimony here a comment about user fees, and we just went through a big that the FDA doesn't collect user fees from the food importers, and perhaps that is something we should consider. But remember we just went through an agonizing several weeks with reauthorization of the prescription drug user fee and the medical device user fee. And on the floor of the House, Members from the other side were coming to the floor saying user fees are wrong because the people that want to get the stuff in the country are the ones that are going to be paying them.

In this case, the drug companies are paying the fees. So inherently there is a conflict of interest that cannot be overcome. Well, do we want to develop that same system with our food importation? I am not saying whether it is right or wrong. It seems to work, in my opinion, fairly well for prescription drugs and medical devices. And maybe this is something we need to explore if funding is an issue and the speed, the rapidity with which we are able to get inspection sites and labs up until the 21st century, maybe that is something that needs to be evaluated.

But I think a part of it may be inspectors and analysts and numbers of square feet that we have in labs. But part of it also is going to have to be capturing the innovation of the technology that we all know is out there and likely could cut some of the problems off the list for us if we would embrace that and explore that. I hope that you all will continue, as you continue to make these inspections and make these analyses of the labs—and I am grateful that you do it. And I do hope we have more budget space from the minority side in the future. But I hope you will keep in mind about some of the changes that are taking place.

In my opinion, we have to get to some sort of risk-based management of this problem. We cannot just simply input economic data and trade data from the countries that expect to be able to overcome it. We could hire inspectors from now until doomsday and still not be able to—just the sheer volume of stuff that is coming in now. Again if we don't have the institutional courage to close the border, which some people would say would solve the problem for us as well, then we are going to have to be much smarter about the way we do this process.

Thank you, Mr. Chairman. I will yield back my time.

Mr. STUPAK. Second round of questions, Mr. Inslee. If I may before you start. Mr. Burgess, you mentioned a couple times about

minority, and every time we have a hearing, every time we have an interview, every time we have done anything on this committee, especially in this panel, the minority staff was always welcome to attend. Sometimes they chose to. Sometimes they chose not. This has been a bipartisan investigation. It will continue to be bipartisan with that great cooperation. Please don't make any kind of reference that somehow the minority was excluded from all this. They were with these gentlemen on some of the trips. Some of them, they chose not to. Sure, go ahead if you want to respond.

Mr. BURGESS. I think the comment I made was that I hope the minority would participate in the future. And if there is a question, I will be glad to participate in the future because this issue is that important, then we should assume it can't be left to just business as usual here in Congress. We have to be able to get on top of this issue.

Mr. STUPAK. Great. Talk to the minority staff. Urge them to participate fully with us. And with that, I will turn to Mr. Inslee please.

Mr. INSLEE. Thank you. The staff report suggests that a lack of aggressiveness may have had some role in the peanut butter salmonella issue, and it makes reference to a disclosure on April 24—excuse me. I have the wrong date. Anyway, there was a disclosure of some potential salmonella toxicity in some peanut butter associated with ConAgra. And then there was in the report a description of the FDA not obtaining the microbiological testing by the producer because they had not issued a written request. Apparently the producer said we won't give it to you unless you give us a written request, and the FDA would not give them a written request. Could you illuminate what is going on there? Is this a policy of the FDA? Is it confusion between FDA and producers? What is going on?

Mr. NELSON. Well, it is apparently a policy. Let me be clear. First of all, the inspector that did the February 2005 investigation based on the informant's information that there were microbiological tests showing salmonella in October of 2004 did not recall being told that they could have the records upon a written request. But he said it was not extraordinary that they would do that. That is sort of standard operating procedure for large food companies because they know that in almost all cases FDA will never ask for the documents in writing.

And the rationale dates back to section 703 of the Act. It provides, with legal interpretations that courts have made, that manufacturers provide records in response to written requests, they can't be held criminally liable. And so no written request is made. But in the case of this peanut butter and a whole lot of other things, we talked to people in Atlanta and San Francisco as well as—talked to people in Kansas City and San Francisco as well as Atlanta. And we are told that written requests simply aren't made. And it is amazing to me that where you have an allegation from a credible informant, somebody that worked for the company, that the company found a toxin pathogen in their product and refused to voluntarily give you the records, that you wouldn't write for them just as a matter of the agency's responsibility to protect the public health whether you could prosecute them or not.

Mr. INSLEE. Even after going through Katrina and everything, I still have a hard time understanding why the Government would not do that. Is there some rational, like if they would not issue written requests? Unless it was they don't want to shield the producer from the community? But that seems shortsighted to me. What is the reason?

Mr. NELSON. We were not provided a reason except that it is not policy. One inspector told us that it had happened once in his 33 years on the job. Another thought that they had heard of it happening two other times, but they weren't directly involved in their 20 years on the job. The field instruction manual only says that if a company insists on written records, that the inspector has to go to a supervisor.

But apparently at minimum, this raises to the level of the district director because nobody below a district director writes for records. And district directors, it just doesn't go up there. The agency just doesn't do it, and it is one of the simple things that the agency could commit to correct today that would make things a little bit safer.

Mr. INSLEE. Is it a lack of aggressiveness or is it concern about liability, or what is the rationale that was offered?

Mr. NELSON. Well, the inspectors don't have any liability. I mean the Act, as interpreted, says they can't get a criminal conviction based on those records. But it doesn't say anything about not being able to get a seizure or an injunction or a voluntary compliance from the company on a better testing program. To me, it was nonsensical that the records weren't asked for in writing in the case of ConAgra—

Mr. INSLEE. Was it your sense, at least in that case, had there been a written request, the records would have been provided?

Mr. NELSON. The manual that was entered into the record in the last hearing, I believe, said that they would make an evaluation at their headquarters about responding to it. There is nothing in the law that requires them to provide those records.

Mr. INSLEE. Of course, we haven't had a lot of luck getting written answers to our written questions either, but that is another matter. Thank you.

Mr. STUPAK. Mr. Murphy, questions? Ms. Schakowsky, please questions?

Ms. SCHAKOWSKY. I wanted to ask about the country-of-origin regulations. In terms of processed foods in particular, how can we protect ourselves if ingredients within those products that may come from the Netherlands or wherever, like wheat gluten, whether it would come from China? Are country-of-origin regulations potentially misleading and provide false comfort if we don't know where the component parts come from?

Mr. NELSON. It is my understanding that no one has to label ingredients as to country of origin.

Ms. SCHAKOWSKY. Right.

Mr. NELSON. We label them with regard to grams of this, that, or the other. But we don't label them with regard to country of origin, and—

Ms. SCHAKOWSKY. So was it just chance that we are able to find out that the windmill product came from China or at least parts of it came from China?

Mr. NELSON. Well, what Customs told us is that under the country-of-origin rules that exist, the importer of that wheat gluten, as the distributor, importer, would have to tell the next guy he sells it to that it was Chinese. He couldn't sell it to them without telling them it is Chinese. And presumably, they have an obligation up until it reaches the final processor who puts it into the food.

Ms. SCHAKOWSKY. Right.

Mr. NELSON. Then there is no obligation any further, but Customs also told us that this is the kind of situation where they could require—I don't know whether they did or not, but they could require the bag to be marked as a product of China because almost certainly in that procession of trade, the identity of the true source of the wheat gluten would be masked by this packaging which suggests that it comes from Holland.

Ms. SCHAKOWSKY. So they could, on their own initiative, require that it be identified?

Mr. NELSON. Customs has that discretion to require that bag to be marked. Once it is out of that bag, even then there is no requirement that consumers be notified of where the ingredients in the food comes from.

Ms. SCHAKOWSKY. In looking at your testimony, it sounds as if that the CBP, Customs and Border Protection actually did act on its own initiative and detained all imports in 10 specific tariff codes. But was there not coordination with the FDA? I wonder if you could talk to us a little bit more about that and how those agencies do or don't work together to protect our food supply.

Mr. NELSON. In almost every case, Customs defers to FDA to make the decisions on what is entered into the commerce of the United States because FDA has the responsibility to determine whether it is safe or not, not Customs. But I think because of the publicity—I don't know—Customs exercised the authority it always has to stop a shipment and test it in their own labs. And that is what they did at Oakland when we were there.

Ms. SCHAKOWSKY. Do you know had they requested the FDA to act, or did they just act on their own initiative?

Mr. NELSON. In the case of San Francisco when we were there, clearly FDA had not been notified of what Customs was doing. And I mean within 2 or 3 days, they coordinated it.

Ms. SCHAKOWSKY. So is there any problem that we have in assuring that kind of coordination?

Mr. NELSON. It is just a very rare event that Customs would act without FDA's request to detain something. When Customs detains something, they detain it in their control. When FDA detains it, they ship it on to—they let the supplier hold it.

Ms. SCHAKOWSKY. Yes.

Mr. NELSON. The importer hold it.

Ms. SCHAKOWSKY. I am just about out of time. I thank you very much.

Mr. NELSON. Sure.

Mr. STUPAK. I thank the gentlelady. Mr. Melancon, any further questions?

Mr. MELANCON. Thank you, Mr. Chairman. Do we have any idea of the total budget and the total employees of FDA and the total budget and the total number of employees that are within FDA just for testing and purposes of checking imports?

Mr. NELSON. We have that data. I don't have it at the top of my head.

Mr. MELANCON. If we could get that information, I would be interested in seeing. We talked about the ability to check all the products. What has happened in America, and a lot of people don't realize it, but about 2 years ago for the first time in the history of this country, we became a net importer of agricultural products, of foodstuffs. For the history before that, 200 plus years, we were producing more food than we consumed and a net exporter.

And when I look at what has gotten us to where we are not checking the food, I guess the question is when you analyze the reasons for FDA looking at closures, is it just dollars? It is budget cuts that have caused this?

Mr. NELSON. I actually don't think it is dollars because I don't think they are going to save anything with these closures. It is really more consolidation of power, centralization of power away from the districts and the inspectors and into Washington and into regional centers. Part of the reorganization plan that receives the most derision in the field is their plan to take those entry reviewers we talked about that are in each district, that they are sort of the last line of local control over inspections, and put them into six regional offices. So the inspectors in the field at that point will be entirely reactive to the instructions of people miles and miles away.

Mr. MELANCON. So they don't have any authority to speak of whatsoever?

Mr. NELSON. Under the proposal, the inspectors in the field will just be sort of soldiers going out in response to whatever Washington or the regional centers that are doing the entry review determine they should do. As far as I can see, there are no lines of import of the information back in. Sort of like it is consolidation—when I say consolidation of power, I am really talking about consolidation of policy so that the policy that is established, good, bad, or indifferent, the policy established in Washington is the sole source of activity in the field.

And most people in law enforcement will tell you that the key to effective detection in information. And so essentially what this plan does is remove from the agency its principle source of information about what is going on in the marketplace.

Mr. MELANCON. In other words, taking eyes and ears on the ground out of the circulation.

Mr. NELSON. Right.

Mr. MELANCON. One of the statements about closing the borders, we do that, then we close off food, oil, gas and everything else. So I have a problem with that, but as I have noted, when I look at the trade agreements that we have done, which ought to be a place that we could put some teeth into enforcement of food stuffs particularly coming to this country.

Is there any logic why none of the trade negotiators, USTR, ever wants to discuss or put in country of origin or sanitary regulations or any of these things? Is there something out there that I don't

understand? Is it the major corporations, or is it just the small guys? I don't understand why we wouldn't ask for that.

We make our domestic producers abide by very strict standards for sanitary purposes, for what they put in their products and labeling. And yet you saw the bag. I have no clue where it came from other than I thought maybe Holland.

Mr. NELSON. The question you are asking is way beyond our investigation.

Mr. MELANCON. OK.

Mr. NELSON. It is an interesting question, but it is beyond what this specific investigation is about.

Mr. MELANCON. I guess that my curiosity got peaked because I used to be in the sugar business in Mexico, which has a NAFTA agreement. Most years can't produce all the sugar it needs for its own domestic use yet. When they run their final numbers in the year, they have hundreds of thousands of tons of sugar extra. Guatemala just happens to be a border, and the bags come across maybe and change labels. But anyway that is a whole other issue that we have.

And I would like if we could just for the staff to check and see number of people employed by the agency, the budget, and the budget specifically on those agencies that are affected by the labs and on the ground at the ports.

And I guess the last thing real quick is do you have any specific recommendations of things that we ought to be looking at consolidating, like USDA, the number of ports that certain imports can come through, putting the labs maybe at those particular ports of entry? As attention rules being changed or tightened up, is anything that you all might suggest?

Mr. NELSON. The investigation really isn't at that stage yet. It is still preliminary, but I am sure that Mr. Dingell and everyone on the panel will be asking us questions as they begin to draft the food safety legislation.

Mr. MELANCON. Thank you. I appreciate it.

Mr. STUPAK. OK, all time has expired for questioning of this panel. We will excuse this panel. Thank you, gentlemen, for the work you have done and also the minority staff for helping you with this investigation, and we look forward to your continued work. And you are excused for now. Thank you.

We will call up our second panel of witnesses to come forward. On our second panel, we have Ms. Caroline Smith DeWaal, director of food safety at the Center for Science in the Public Interest; Mr. William Hubbard, former associate commissioner of the FDA; Mr. Charles Clavet, microbiologist at the Winchester, MA FDA Engineering and Analytical Center; Ms. Belinda Collins, director of the FDA's Denver District; Mr. Richard Jacobs, chemist and toxic element specialist at the FDA San Francisco District Lab; Dr. Ann Adams, director of the FDA's Kansas City District Lab; and Ms. Carol Heppel, director of the FDA's Cincinnati District.

It is the policy of this subcommittee to take all testimony under oath. Please be advised that witnesses have the right, under the rules of the House, be advised by counsel during their testimony. Do any of you wish to be represented by counsel? Everybody indi-

cated no. I will ask you to rise. You all have. Please raise your right hand to take the oath.

[Witnesses sworn]

Mr. STUPAK. Let the record reflect all witnesses answered in the affirmative. They are now under oath.

We will begin with opening statements. We will start with Ms. DeWaal if you could limit to 5 minutes. If your testimony is longer than that, it will be submitted for the record. Thank you. Ms. DeWaal, if you would please.

TESTIMONY OF CAROLINE SMITH DEWAAL, DIRECTOR, FOOD SAFETY, THE CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Ms. DEWAAL. Thank you very much, Mr. Chairman. I am director of food safety for the Center for Science in the Public Interest. CSPI is a non-profit organization representing over 900,000 consumers.

The CDC estimates that 76 million Americans get sick and 5,000 die from food-borne hazards each year in the United States. And today, over 10 percent of the average American diet is imported food products. For certain commodities like seafood, imported products form the bulk of the American diet. But recent events have really increased consumer concern about imported food coming from China. In fact, over 80 percent of consumers believe that “made in China” equates to “may be contaminated.”

The Food and Drug Administration and the U.S. Department of Agriculture each manage food import programs. USDA’s Food Safety and Inspection Service is responsible for ensuring the safety of imported meat and poultry products, but they use very different tools than FDA.

Foreign countries wishing to export to the U.S. must undergo two levels of in-country review before they can ship products: an evaluation of the food safety program followed by an on-site review of all aspects of the food system, including plant facilities, laboratories, training programs, and in-plant inspection operations.

Upon arrival at the U.S. port of entry, this same meat that is subject to inspection in the country has to be approved by FSIS before it can be allowed into the U.S. Every lot is visually inspected, and then FSIS conducts random statistical sampling of lots. These more stringent inspections could include sampling of the product for microbial analysis, physical examination for visible defects, sampling for drug and chemical residues, and food chemistry analysis. An average of 15 percent of products presented for importation are physically examined or sampled by USDA.

Compare this to the program at the FDA, which is responsible for all other foods, including produce and seafood. Its import inspection program is anything but comprehensive. FDA does not evaluate national programs to determine equivalents or visit foreign countries to verify compliance with food safety procedures. Instead, FDA relies on border inspections but inspects less than 1 percent of the food crossing the border. While these products can enter any of many hundreds of U.S. ports, the vast majority of these ports have no FDA inspectors on site. And products come in with only nominal record checks.

The failure of FDA's import program has been demonstrated with the recent outbreaks related to imported food items. First the deaths and illnesses among American pets caused the largest ever pet food recall. Next, lethal pufferfish imported under the label of monkfish from China caused several illnesses from a severe marine toxin, one of the most severe toxins known in the human food supply. And most recently, FDA took action to ban five species of fish from China for illegal antibiotic residues, a problem the agency said it had been watching since 2001.

Throughout the years there have been many other outbreaks linked to imported food, proving the FDA cannot rely on other countries to ensure the safety of imports to the U.S. The gaps in protection from this system are indeed alarming, particularly as imports in some commodities and from some regions grow.

In recent years, China, for example, has become the third leading foreign supplier of agriculture and seafood products to the U.S. CSPI is supporting a number of bills which have been recently introduced, but the bottom line here is the U.S. food safety laws are more than 100 years old. And they were not designed to deal with these modern problems such as escalating imports, bioterrorism, and tainted produce.

It is critical that Congress take action this year to develop a comprehensive modern law, one that can encompass all the problems, produce, imports, peanut butter. Consumers would like you to take action this year. Thank you.

[The prepared statement of Ms. DeWaal follows:]

**Import Inspection Failures and What Must Be Done
Testimony of Caroline Smith DeWaal
Director of Food Safety
Center for Science in the Public Interest
before the
United States House of Representatives
Energy and Commerce Committee's Subcommittee on
Oversight and Investigations**

**Washington, DC
July 17, 2007**

My name is Caroline Smith DeWaal, and I am director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 900,000 subscribers to its *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

The Centers for Disease Control and Prevention (CDC) estimates that 76 million Americans get sick, 325,000 are hospitalized, and 5,000 die from foodborne hazards each year in the United States. Since September, we have had three significant nationwide outbreaks and recalls that amply demonstrate holes in the web of protection from contaminated food. Spinach contaminated with a deadly strain of *E. coli*; peanut butter with *Salmonella*; pet food with toxic chemicals – each of these tragedies has demonstrated a different problem with our system of regulating the food supply. It is time for Congress to take action to better ensure food safety and to protect Americans from these preventable illnesses and deaths.

Each year the average American eats about 260 pounds of imported foods, accounting for about 13 percent of our annual diet.¹ U.S. imports for 2006 reached a record value of \$65.3 billion, roughly \$6 billion higher than the year before.² Twelve federal agencies share responsibility for inspecting food imports, resulting in a chaotic and inefficient system. The two principal agencies, FDA and USDA, each control import programs purportedly responsible for ensuring the safety of those imported foods, but the programs are not comparable, not adequate,

¹ Bridges, A, "Imported food rarely inspected," *Washington Post*, April 16, 2007.

² U.S. Agricultural Trade Update, *Electronic Outlook Report from the Economic Research Service*, Feb. 15, 2007.

and, in many ways, not reliable. Further, import programs sometimes overlap but resources are not shared. For example, USDA and FDA inspect food imports at 18 ports, but they do not share inspection resources at these locations. In fact, according to a recent GAO report, some USDA-approved import inspection facilities store FDA-regulated products, and although USDA maintains a daily presence at these facilities, FDA products can languish at the port waiting for FDA inspectors.³ The distinctions between the two import systems are not limited to actual inspection performance, however; the structure of import procedures is also vastly different.

USDA's Food Safety and Inspection Service (FSIS) is responsible for ensuring that imported meat, poultry, and egg products are safe, wholesome, and accurately labeled. According to FSIS's mandate, foreign countries wishing to export to the U.S. must undergo two levels of review to determine eligibility to import. USDA must first perform an evaluation of the foreign country's food system, reviewing the laws and regulations of that country as they pertain to five risk areas: sanitation controls, animal disease controls, slaughter and processing controls, residue controls, and enforcement controls.

If that evaluation shows the country's system to be equivalent to the U.S., a USDA technical team then conducts an in-country assessment, which involves an on-site review of the five risk areas as well as other aspects of the food system, including plant facilities and equipment, laboratories, training programs, and in-plant inspection operations. According to FSIS, these on-site audits are used to verify that a country has in fact implemented the programs described in the document review, and if not, to clarify and resolve any differences. It is only after the completion of both prongs of the review that a country is deemed eligible for import consideration. After appropriate notice-and-comment rulemaking, the foreign country is granted importation status and is subject to annual re-certification documentation and review.⁴

³ GAO, *Federal Oversight of Food Safety: High-Risk Designation Can Bring Needed Attention to Fragmented System*, Statement of David M. Walker (GAO-07-449T)(Washington, D.C.: Feb. 8, 2007).

⁴ Special circumstances may result in a country's import status being suspended. FSIS offers three examples of special circumstances: (1) if an emergency sanitary measure is implemented by FSIS to address a hazard that is so severe that no product can enter the marketplace from a foreign establishment until the control is in place; (2) if an exporting country does not provide satisfactory documentation of an equivalent sanitary measure; (3) if a system audit reveals that an exporting country is not implementing a public health sanitary measure in the manner that FSIS initially determined to be equivalent.

Permanent withdrawal of eligibility, like initial approval of eligibility, can only be accomplished by rulemaking. FSIS may, however, take action to ensure that products from a particular country are not admitted into the United States if they are adulterated or misbranded based on specific findings during on-site audits, because of port-of-entry reinspection failures, or other means.

This application process does not guarantee that all products from a certified country will enter the U.S., however. After certification, foreign products must pass through U.S. Customs, where appropriate documentation and bonds are required. Upon arrival at a U.S. port, 100% of meat and poultry shipments must be approved by FSIS before they are allowed into the country. Every lot is visually inspected for general condition, proper labeling, proper certification, and accurate count. In addition, the Automated Import Information System (AIIS)—implemented in 2002—conducts random statistical sampling of the lots and assigns other types of inspection based on an algorithm of risk and volume. These more stringent inspections could include sampling of the product for microbiological analysis, physical examination for visible defects, sampling for drug and chemical residues, and food chemistry analysis.

According to the FSIS Quarterly Enforcement Report from FY 2006, an average of 15% of products presented for importation were physically examined or sampled by USDA.⁵ In 2006, a total of 3.88 billion pounds of meat, poultry, and egg products were presented, and 598 million pounds were reinspected (physical inspection after visual inspection is called reinspection). Of those, 12 million were rejected. In the first quarter of FY 2007 (Oct- Dec 2006), over 935 million pounds were presented, 11.8% (110 million pounds) reinspected, and 2.7 million pounds rejected.

While USDA has a fairly intensive program for ensuring the safety of imported meat and poultry products, the FDA program is anything but comprehensive. FDA's procedures are much less stringent and much less effective. FDA does not evaluate national programs to determine equivalence or visit foreign countries to verify compliance with food safety procedures. FDA's Import Program System Information website does not delineate an audit system for imported product, but rather directs users to U.S. Customs for inspection and enforcement procedure information.

The shoddy state of U.S. inspection procedures has not gone unnoticed, even within the ranks of those tasked with creating and implementing the policies. In 2004, Tommy G. Thompson, the former secretary of health and human services, expressed deep concern about the

USDA Food Safety and Inspection Service, *Equivalence Process*, referenced July 13, 2007 at http://www.fsis.usda.gov/regulations_&_policies/equivalence_process/index.asp.

⁵ Canada may account for as much as 43% of meat and poultry imports.

nation's food supply, saying that he was "shocked" that terrorists had not struck the nation's food supply "because it is so easy to do," and that he "worried every single night" about food safety.⁶

It is currently estimated that FDA only inspects 1% of food at the U.S. border, so it is frankly surprising that catastrophes like the recent pet food contamination haven't happened more often. Although imports of FDA-regulated foods have more than doubled in the last 7 years—from 4 million shipments in 2000 to approximately 9 million shipments in 2006—the rate of inspections has remained woefully low.⁷ Of these 9 million shipments, only 0.2% were analyzed in a laboratory as part of their inspection process.⁸

Although products enter the U.S. through 361 ports, at the peak of its funding, FDA had inspectors on-site at only 90 of these ports. Today the agency likely covers half that number. To increase inspections of FDA-regulated imports to 10% (still a strikingly low figure) would require an additional 1600 full-time inspectors. To double that figure to 20% import inspection would require 3200 full-time inspectors and \$540 million, according to FDA estimates given to the House Agriculture Appropriations Subcommittee in 2001.

The gaps in protection from this system are indeed alarming, particularly as imports in some commodities grow. Overall, U.S. imports of agricultural and seafood products from all countries have increased by nearly 50% over the last decade, and certain countries and commodities are showing exponentially greater increases. U.S. imports of Chinese agricultural and seafood products, for example, have increased almost 350% in the same time period—an increase in value from \$880 million in 1996 to over \$4 billion in 2006.⁹ China is the sixth leading foreign supplier of agricultural products to the U.S. when seafood imports are not considered. Adding seafood, however, raises China to the third ranking supplier of all food products to this country.

Late last month, FDA announced import detention of five fish species routinely imported from China due to the presence of illegal and potentially dangerous antibiotics.¹⁰ Farm-raised catfish, shrimp, eel, basa, and dace were contaminated with the antimicrobials nitrofurans,

⁶ "Tommy Thompson Resigns From HHS," *The Washington Post*, December 3, 2004.

⁷ "Food Imports Often Escape Scrutiny," *The New York Times*, May 1, 2007.

⁸ *Ibid.*

⁹ CRS Memorandum, *Food and Agricultural Imports from China*, June 6, 2007.

¹⁰ U.S. Food and Drug Administration Press Release, *FDA Detains Imports of Farm-Raised Chinese Seafood*, June 28, 2007.

malachite green, gentian violet, and fluoroquinolones, presumably in an effort to combat increasing levels of illness among aquatic populations. In humans, however, these substances may be carcinogenic, and can create antibiotic resistance in a critically important class of antibiotics.

In May, FDA issued a consumer warning for pufferfish, mislabeled as monkfish, from China.¹¹ After two people in Chicago were sickened after eating fish soup made with the purported monkfish, laboratory testing confirmed that the fish contained life-threatening levels of tetrodotoxin, one of the most hazardous toxins found in food. According to FDA's *Bad Bug Book*, poisoning by tetrodotoxin is one of the most violent intoxications from marine species. Pufferfish can contain levels of tetrodotoxin sufficient to produce rapid and violent death, as quickly as 20 minutes after consumption.¹² It appears that lethal pufferfish were illegally imported to the U.S. from China mislabeled as monkfish.

FDA cannot rely on other countries to ensure the safety of imports, because in many parts of the world, under-funded food safety agencies do not have the ability to regulate food entering the global market.¹³

A Failure of Import Inspections in the Pet Food Scandal

For the thousands of people whose cherished pets became ill or died during the recent recall of contaminated pet food, FDA's lapse in protecting our food supply was a tragedy. In March 2007, pet food manufacturers recalled more than 100 brands of cat and dog food after receiving complaints about cats and dogs that developed kidney failure from eating pet food. For weeks after, new brands were pulled from shelves as processors tracked the tainted wheat gluten.

FDA investigations revealed that the pet food that sickened so many pets was contaminated with melamine and cyanuric acid, two industrial chemicals. These toxins were found in wheat gluten imported from China and used in many pet food and animal feed products manufactured in the U.S. Chinese wheat gluten producers are thought to have intentionally contaminated the product with melamine to give the appearance of increased protein content.

¹¹ U.S. Food and Drug Administration Press Release, *FDA Warning on Mislabeled Monkfish*, May 24, 2007.

¹² U.S. Food and Drug Administration *Bad Bug Book*, referenced June 11, 2007, <<http://www.cfsan.fda.gov/~mow/chap39.html>>.

¹³ World Health Organization, *Healthy Food Markets*, (2006).

According to an investigation by the *New York Times*, cutting grain products with melamine to fool protein tests is apparently common practice among producers in China, yet the contaminated wheat gluten passed across our borders without being found or stopped by the FDA.¹⁴

Melamine was also found in imported rice protein concentrate that was identified as an ingredient in hog and chicken feed. After melamine was found in the urine of hogs fed with this feed, the hogs were quarantined. However, some hogs may have already entered the human food supply. Thousands of chickens fed contaminated feed have also already entered the food supply. The breadth of the pet food and animal feed scandal is a troubling signal of FDA's innate weaknesses.

Melamine-tainted feed is the latest example of gaps in FDA's oversight of imports. Many more human illnesses have been linked to imports as well, particularly from imported produce. Americans seek a variety of fresh fruits and vegetables year-round, and supplying this demand is done by importing produce from around the world. In fact, one-quarter of our fruit, both fresh and frozen, is imported. But lack of adequate border controls has led to numerous large and occasionally deadly outbreaks linked to imported food. Here are some examples:

- In Fall 2003, a major Hepatitis A outbreak linked to raw green onions used in restaurant salsa sickened 555 people in Pennsylvania, killing three of them. Preliminary traceback by FDA indicated that green onions supplied to the restaurant were grown in Mexico under conditions where contamination with human waste was likely. Green onions from this area were also linked to outbreaks in Georgia, Tennessee, and North Carolina that occurred earlier that fall.¹⁵
- Three multistate outbreaks of *Salmonella* serotype Poona infections associated with eating cantaloupe imported from Mexico occurred in the spring of consecutive years during 2000-2002. FDA conducted traceback investigations and determined that the cantaloupes were from farms in Mexico. FDA conducted on-farm investigations in Mexico and found many possible sources of contamination, including sewage-contaminated irrigation water; processing (cleaning and cooling) with *Salmonella*-contaminated water; poor hygienic practices of handlers; pests in packing facilities; and

¹⁴ Barboza D and Barrionuevo A. "Filler in Animal Feed Is Open Secret in China." *NY Times*, April 30, 2007.

¹⁵ V Dato *et al.*, (2003) "Hepatitis A Outbreak Associated with Green Onions at a Restaurant—Monaca, Pennsylvania, 2003," *MMWR*, 52(47): 1155-1157.

inadequate cleaning and sanitizing of equipment that came in contact with the cantaloupe.¹⁶

- In 1997, over 256 cases of Hepatitis A were associated with the consumption of frozen strawberries. The strawberries were harvested in Mexico and processed and frozen in southern California before they were distributed by U.S. Department of Agriculture (USDA) to school lunch programs in several states, including Michigan, Wisconsin, Louisiana, Maine and Arizona.¹⁷
- In 1996 and 1997, thousands of people became ill in both the U.S. and Canada from a parasite, *Cyclospora*, on raspberries grown in Guatemala.¹⁸ Illness associated with *Cyclospora* includes watery diarrhea and persistent fatigue, which can persist for a month or longer if untreated.¹⁹ *Cyclospora* is chlorine-resistant and can be transmitted through water or from infected handlers.

Modernizing the Law: The Safe Food Act

Following September 11, 2001, Congress enacted the Bioterrorism Act of 2002 but left the most frequent traveler across U.S. borders — imported food — under the supervision of a bifurcated federal system of food regulation. According to the National Academy of Sciences, “[a]t least a dozen federal agencies implementing more than 35 statutes make up the federal part of the food safety system.”²⁰ In a post-September 11 world, with risks of bioterrorism and ongoing natural hazards such as *E. coli* O157:H7, the U.S. food safety system has become an issue of national security. The existing regulatory framework is simply insufficient to handle these challenges. Several bills propose modernizing import inspection.

¹⁶ SM Anderson *et al.*, (2002) “Multistate Outbreaks of Salmonella serotype Poona Infections Associated with Eating Cantaloupe from Mexico—United States and Canada, 2000-2002,” November 22, 2002, *MMWR*, 51(46):1044-1047.

¹⁷ Centers for Disease Control (1997), “Hepatitis A Associated with Consumption of Frozen Strawberries—Michigan, March 1997,” *MMWR*, 46(13): 288-295.

¹⁸ J Hoffman *et al* (1996). “Update: Outbreaks of *Cyclospora cayetanensis* Infection – United States and Canada, 1996,” July 19, 1996, *MMWR* 45(28): 611-612.

¹⁹ CDC Division of Parasitic Diseases (2004). “*Fact Sheet: Cyclospora Infection—Information for Healthcare Providers*,” April 19, 2004, March 5, 2007. <http://www.cdc.gov/ncidod/dpd/parasites/cyclospora/healthcare_cyclospora.htm>.

²⁰ Institute of Medicine, National Research Council, *Ensuring Safe Food from Production to Consumption*. (Washington, DC: National Academy Press, 1998)

The Imported Food Security Act of 2007, introduced by Senator Richard Durbin (D-IL), is the most recent in a spate of legislation being considered to address the import problem.²¹ Designed to bolster FDA resources—particularly in the areas of import inspection—the bill directs FDA to create and implement more rigorous import controls. The bill also creates a new user fee program at FDA and directs the agency to devote part of the user fee revenue to research efforts on promising testing technologies that would rapidly detect the presence of food contaminants.

The Human and Pet Food Safety Act, introduced May 2, 2007 by Senator Durbin (D-IL) and Representative Rosa DeLauro (D-CT), is another strong legislative attempt to stem the tide of alarming imports.²² The Act would help regulate the industry by establishing mandatory processing and ingredient standards (both domestically and internationally) and requiring more inspections of pet food processing plants. Further, the Act would create an early warning system to help identify possible contaminants earlier and penalize companies that don't report possible contamination. In an important step, the Act would also ensure that any future recalls are conducted quickly by giving the Food and Drug Administration the power to order mandatory recalls of tainted food.

Yet another, more comprehensive, approach is the Safe Food Act, introduced February 15, 2007, also by Senator Durbin and Representative DeLauro.²³ The Act would streamline food safety at the federal level by consolidating the FDA, USDA, Center for Veterinary Medicine (CVM), EPA, and several other key food agencies to create a unified, science-based Food Safety Administration. In addition, the bill would modernize the outdated inspection system and give clear authority for on-farm programs. It relies on preventative control systems implemented by the industry and performance standards monitored and enforced by the government.

²¹ United States Senate, 110th Congress, 1st Session. S.1776, *The Imported Food Security Act of 2007*. [introduced in the Senate 12 July 2007]. 110th Congress.

²² United States Senate, 110th Congress, 1st Session. S. 1274, *The Human and Pet Food Safety Act of 2007*. [introduced in the Senate 2 May 2007]. 110th Congress. Accessed <http://thomas.loc.gov/cgi-bin/query/D?c110:1:./temp/~c110amOnGS::>

²³ United States. Congress. House of Representatives. 110th Congress, 1st Session. *H.R. 1148, The Safe Food Act of 2007*. [introduced in the House of Representatives 16 February 2007]. 110th Congress. Congressional Bills, GPO Access. <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h1148ih.txt.pdf>

The Safe Food Act gives the Food Safety Administration the authority to evaluate and certify a country's food safety program to ensure that it is "at least equivalent to the food safety program in the United States."²⁴ The Administration would have the authority to audit the certified countries and would ensure continued compliance at least every five years.²⁵ The proposed law also requires routine inspections of foreign food imports to ensure that the food is safe and properly labeled. Under the Safe Food Act, foods would no longer have an "open visa" to enter the U.S. without inspection or regulation.

The Safe Food Act further mandates the establishment of a national system for "tracing food and food producing animals from point of origin to retail sale."²⁶ The Act would allow companies to issue voluntary recalls should their product be deemed unsafe, but also grants authority for the Food Safety Administration to issue a mandatory recall if the company fails to do so. This will ensure quick removal of contaminated products from the market and increase consumer confidence in the food supply.

The Safe Food Act creates a single food agency with the necessary authority to fulfill its mission to put safe food on America's tables, a recommendation made by the National Academy of Sciences in 1998. The new agency could detain imported food and recall tainted food from the market. It provides the necessary authority to penalize persons or organizations for violating food safety laws, allowing both civil and criminal penalties, and also provides whistleblower protection for individuals who disclose food safety violations.

The Act would work to prevent foodborne illness and bioterrorism without grand schemes or an inflated budget. Instead, it ensures a strong national program, outbreak surveillance, and effective, honest public communication. The food industry remains the first line of defense, but the Act recognizes that effective industry programs require government monitoring and oversight.

U.S. food safety laws are more than a century old and were not designed to deal with modern issues such as escalating imports, bioterrorism, or tainted produce. The September 11,

²⁴Id.

²⁵ Id.

²⁶ Id.

2001 terrorist attacks demonstrated the need for enhanced national security, and the recent outbreaks serve as a reminder that much more must be done to protect the food supply. The Safe Food Act draws from these recommendations and creates a program that puts public health at the forefront of food safety in America. We urge Congress to take action this year to modernize food safety laws in the U.S. and to fully fund federal food safety programs.

Mr. STUPAK. Thank you for your testimony. Mr. Hubbard please, 5 minutes.

**TESTIMONY OF WILLIAM HUBBARD, FORMER ASSOCIATE
COMMISSIONER, FOOD AND DRUG ADMINISTRATION**

Mr. HUBBARD. Thank you, Mr. Chairman. I have extensive written comments, but I will just make a few remarks if I may. I am William Hubbard. I served at the FDA for 27 years before my retirement in 2005, and there are many, many food safety issues to talk about. But I would like to focus just on a couple today, particularly on imports.

I believe we are at a critical point in FDA's history in terms of their ability to protect the food supply, and I think that we are at a point where we need to make some serious decisions. Please forgive for using a well-worn cliché, but I think we are approaching a perfect storm risk for American citizens in which you have a flood of imports from other countries, more and more threats to food, and an ever-weakening FDA. And I believe that.

In fact, what I am seeing is a hollowing out of the FDA's food program. That really underlies all of the issues we are talking about today. And the horror stories we are hearing from China and other developing countries are of no surprise to me and I am sure not to my former colleagues at the FDA. Gross violations of sanitation, widespread use of industrial chemicals and pesticides in food. There are fish and other animals fed drugs not allowed in the United States. Many more examples of practices that were common in this country in the 1880s or early 1900s but not today.

But trade from these countries is a reality, and we have no hope that these developing countries, in my view, will adopt and enforce the kinds of safety standards that we expect any time soon. So our citizens must depend on one mechanism to protect them, and that is the FDA. But when we provide that agency with only 450 inspectors to screen almost 20 million imports of foods and drugs, the situation approaches hopelessness in my view.

There are many ideas that you will hear mentioned today for improving the FDA. Better management, new legislation, more regulations, better training all may be good ideas. But in my view, unless you deal with the basic fact that the FDA needs people to do these things, we are not going to fix this problem.

Please understand that FDA's food program has undergone a decade of budget cuts. The current budget does it again. Let me give you a couple of examples. The administration's fiscal year 2008 request for the Department of Agriculture request \$163 million of new money to protect farms against bioterrorism, zero for the FDA. That same budget request seeks \$131 million in new money for food safety research at the Department of Agriculture and cuts food safety at the FDA. In total, the agency has lost an appropriated staff, 1,000 people in the last decade. Most of those have come out of the food safety program. This just has to stop in my view.

The empty desks among the FDA's food scientists are a stark testimony that things aren't getting done, the imports are not being inspected, and the risky food is not being excluded from our country. So I urge you to make strengthening the FDA a priority. This

committee has come to the FDA's rescue many times in the past with dangerous drugs and foods and medical devices. And I certainly hope that you will do that again in this case because that agency needs help, and you may be the only ones that can provide it. Thank you.

[The prepared statement of Mr. Hubbard follows:]

STATEMENT OF WILLIAM K. HUBBARD

Mr. Chairman and members of the committee, I am William K. Hubbard. Before my retirement after 33 years of Federal service, I served for many years with the U.S. Food and Drug Administration, and for my last 14 years was an FDA Associate Commissioner responsible for, among other things, FDA's regulations and policy development. Although I have remained retired since my departure from FDA in 2005, I have agreed to provide advice to a remarkable group of patient, public interest, and industry groups that have recently formed themselves into a Coalition for a Stronger FDA (whose mission is to urge that FDA's appropriations be increased). Throughout my career at FDA, I was deeply involved in seeking improvements in one of FDA's most important functions: the safety of our food supply, with particular concern for the massive increase in foods being imported into the United States from around the world. Accordingly, I wish to thank the committee for inviting me to testify on that subject today.

BACKGROUND

As you know, Congress established the Food and Drug Administration in 1906 as a result of concerns about the safety of our food supply. In those days, it was common for foods to be subjected to all manner of problematic practices: filthy, unsanitary conditions were common in food processing facilities; talcum powder, sawdust and many other contaminants were added to deceptively increase the weight or value of foods; and chemical preservatives were used in food that were untested and often highly toxic. As the 20th Century progressed, FDA's scientists and those in the emerging food processing industry slowly built a food safety infrastructure for the United States that enabled us to claim that we had the safest food supply in the world. And the standards established by the FDA for the production of safe foods became the model for protection around the globe. But I believe those accomplishments are at great risk today, and I would like to use my testimony at this hearing to describe why I think FDA is no longer able to provide the assurances of safe food that were once taken for granted in this country. While food safety domestically is a major concern, I will focus my comments today on the problems posed by foods imported from other countries.

FDA'S STATUTORY CONSTRUCT FOR IMPORTS

FDA's authority over imported foods actually pre-dates the agency, as the original statutory construct was created in 1896, and allowed Federal inspectors to examine foods as they passed through U.S. ports. That authority was included in the Pure Food and Drug Act of 1906, which established the FDA, and again authorized port inspectors to open food cargo containers and examine their contents. In those early days, it was a fairly simple process. Most imported foods were staple goods, such as flour and molasses, and a visual inspection was often the appropriate means to assure that the food did not contain mold, insect parts, or other visible contaminants. When Congress radically revised FDA's authorizing statute in 1938 to create the modern FDA, it discarded all of the provisions of the 1906 Act, which it concluded were inadequate, except for the import provision, which appeared to have worked well up to that date. Thus, FDA's statutory authority over imported foods remains essentially the same as it was in that much earlier, simpler day. The authority, embodied in Section 801 of the Food, Drug and Cosmetic Act, permits FDA to examine foods, drugs, and other FDA-regulated products when they arrive for entry into the United States. If the product appears to be in violation of U.S. standards, it can be refused admission. Unlike the Department of Agriculture's meat inspection program, FDA cannot require the exporting country to make assurances that it applies an equivalent safety standard to exported foods, cannot pre-certify foreign food processors, cannot designate the U.S. ports at which the food can be entered, and cannot remove the exporting country from a list of authorized exporters if it fails to maintain U.S. standards. So, the burden is primarily on the FDA to find a problem in an imported food and deny its admission into this country. .

And, as I will discuss later, the agency has few resources with which to effectuate that authority.

GLOBALIZATION AND THE FDA

As I have noted, FDA's import screening process was designed for an earlier era, and there is ample evidence that it is not adequate in today's world. The changes wrought by a globalized economy are stark, and even alarming, in the context of FDA's responsibility to assure the safety of our food:

- First and foremost, there is the matter of volume. Whereas imports of FDA-regulated products from other countries were about 10,000 in 1920, by 1993 they were up to 2 million, to 9 million only a decade later, and are approaching 20 million today. In any given year, about 65 percent of such imports are food; but, of course, FDA is responsible as well for screening the millions of shipments from abroad of pharmaceuticals, medical devices, dietary supplements, cosmetics, animal feeds, microwave ovens, and other consumer goods under its regulatory purview.

- Second, the nature of imports has changed. The staple goods of a century ago have expanded to every conceivable commodity—fresh fruits and vegetables, canned and other processed foods, food preservatives, emulsifiers and stabilizers, seafood, apple juice, cheeses and many more.

- Third, the threats to food have increased greatly since the turn of the century. Pesticides, industrial chemicals and heavy metals often contaminate imported foods, either as result of intentional acts, such as appears to be the case with the recent melamine contamination, or via environmental pollution that is commonplace in some exporting countries. Also, disease-causing pathogens, such as E Coli 0157:H7, which were unknown in nature a century or even a few years ago, can infect food and present life-threatening risks, especially to children and the elderly.

- And finally, so much of our food is coming today from developing countries, which have weak regulatory systems and that simply cannot assure the safety of food exported from producers within their borders.

FOODS FROM CHINA AND THE DEVELOPING WORLD

The exporting country most in the public eye today in relation to contaminated food is, of course, China. FDA has long identified problems with food imported from China, but in the past it was often with "ethnic" foods and other low-volume commodities, many of which would seem strange to the average American's palate. A favorite example of mine was a product known as Gecko-On-A-Stick, a dried lizard impaled on a wooden skewer that one would dip into hot water to make a presumably flavorful tea. It was heavily infested with mold and bacteria and, of course, denied admission to the United States.

But today, products from China fill our supermarkets. Whole foods such as apple juice, garlic, honey, mushrooms and several types of seafood frequently are of Chinese derivation. And it appears that many, in some cases a majority, of the ingredients American food manufacturers use to make our processed foods are purchased from China—constituents such as wheat and corn gluten, rice protein concentrate, soy lecithin, ascorbic and citric acid, and xanthan gum. In fact, U.S. food processors report difficulties in even identifying sources of some ingredients outside of China.

Chinese food imports are increasing at a rate exceeding the rapid increase in imports generally. In 2002, 82,000 food shipments were presented to FDA inspectors, yet last year the number was 199,000, and it will likely be at 300,000 in another year or two. The foods appear to be coming from an enormous network of food producers across China, a large percent of which are farmers deep in the Chinese provinces. Indeed, estimates of the number of Chinese food producers are as high as 1.5 million, and the Chinese Government has acknowledged its difficulties in reaching into their country's hinterlands to regulate such a vast cottage industry.

With such a huge, fragmented food production system, in a nation rapidly developing, it is no surprise that we see examples of food processing mistakes that border on horror stories—poultry cages suspended over fish farm tanks, so that the fish will consume the bird droppings; substitutions of safe and approved pesticides and food additives with chemicals known in the West to be hazardous; polluted water used in food production; and reports of filthy processing conditions that would be alien to most American food manufacturers. I recall an FDA inspector's story of his visit to a Chinese herbal tea manufacturer, where the normal process for drying the leaves was laying them out in the sun. But the firm's desire to speed production caused them to spread the leaves out on the concrete floor of a huge warehouse, over which large trucks would be driven, using the exhaust to hasten drying. The trucks

used leaded gasoline and did not have catalytic converters, so lead and other heavy metals were being spewed directly onto the leaves.

These concerns are not just our view of the problems. Chinese food safety officials have publicly acknowledged that the reports of substandard foods and improper processing methods are “not isolated cases,” to quote a Chinese food safety official, and that 75 percent of that nation’s food processors are small, privately-owned entities over which the central government has exerted little regulatory control. Chinese regulators announced in late June that a recent investigation of processing facilities had found 23,000 food safety violations, including the use of industrial chemicals, banned dyes, and other illegal ingredients in food.

Despite the widespread publicity associated with Chinese imports, it should be recognized that FDA commonly finds problems with foods from many other countries as well, especially less developed nations. Raspberries from Guatemala, catfish from Vietnam, melons from Mexico, and other products from countries such as India, Malaysia, Thailand, Pakistan, the Dominican Republic and the Philippines have often been found in violation of FDA’s food safety standards. Indeed, Mr. Chairman, one of our most common confectionary and soft drink ingredients, gum Arabic, comes often from Sudan and Somalia, countries with arguably no functioning government, and thus no discernible food safety system.

In a world in which global trade is an acknowledged fact, I believe we must accept the reality that foods will be imported into the United States from countries that simply do not have the regulatory infrastructure, industry resources or scientific expertise to be a model of safe food production. One recent study, for example, concluded that China alone must invest \$100 billion in its food safety system in order to bring it up to Western standards. That analysis, by the global management consulting firm A.T. Kearney, noted, for instance, that China must insure against food spoilage by better refrigerating products during shipment, but found that the entire country possessed only 30,000 refrigerated trucks and 250 million cubic feet of cold storage (yet that it would need 365,000 such trucks and 5 billion cubic feet of cold storage). For its part, the Chinese Government has said it intends to improve its food safety procedures and has suggested that it may be able to have better functioning rules in place by 2012.

FDA’S CAPACITY TO OVERSEE IMPORTED FOOD

Although it has become somewhat of a cliché, let me describe the emerging problems with food imports as a “perfect storm”—a scenario in which the United States is flooded with an enormous volume of food from abroad, where the risks to food are greater than ever before, and at a time in which FDA’s ability to protect our food supply is growing ever weaker. I have described the first two parts of that scenario; now, let me elaborate on the third.

When I began service in the Federal Government, in 1971, FDA’s food program comprised almost half of the agency’s total budget. Today, it is about a quarter. During the intervening years, there has been a dramatic drop in FDA’s oversight of the food supply. One stark example domestically is the drop in FDA inspections of food processing facilities, from 35,000 in the early 1970s, to fewer than 8,000 today.

More recently, FDA’s budgets have been particularly alarming for their effects on food safety. On first blush, it appears that FDA’s budget has been rising, but that is due to increased user fees paid principally by drug firms for the review of new drugs. Those funds cannot be used for programs such as food safety. The appropriations for FDA have been inadequate to fund even the staffing level that the agency had in the early 1990s. Thus, the agency has lost 1,000 people over the last decade in non-user fee programs such as the food program. [The attached graph illustrates the drop in non-user fee staffing.] Why has this severe drop in staff occurred?

In most FDA budgets since the mid-1990s, the administration’s annual budget request for appropriations for FDA has not included the inflation “catch up” that Federal agencies routinely expect. Thus, the agency must absorb each year’s inflation-driven costs, and if any new funds are requested, they must go to offset the additional costs of employee pay, building rent, and other expenses—which for FDA have averaged about 6 percent in recent years. This means that the food program, in particular, has undergone steady budget cuts: the staff of FDA’s headquarters food program has been reduced from almost a 1000 scientists to fewer than 800 in just five years; and FDA’s field force, which includes its inspectors and import staff, has dropped during that period from over 4000 to about 3300 today. Of course, this is at a time in which the problems are growing and food imports are skyrocketing. The current budget request for Fiscal Year 2008 is a good example of the recent trends. Although the official budget request states that it includes an “additional” \$10 million for food safety, the food program’s inflation needs are not covered by

the request, so the practical effect of that budget is a 3 percent (or \$14 million) decrease (even with the \$10 million “increase”).

How does this affect FDA’s import coverage? This year, FDA has 450 inspectors to cover more than 400 ports at which imported foods can enter the United States. With those 450 inspectors, they are asked to screen almost 20 million imports of food, drugs, and other products, which average a staggering 44,000 shipments per inspector. I suggest to you, Mr. Chairman, that no “efficiencies,” “better management” or “working smarter”—all solutions suggested for FDA—will significantly improve this picture. The agency needs to open and examine a significant portion of these food containers, send samples to laboratories for analysis, and refuse entry to those foods deemed unsafe—and only people can do that.

Perhaps another China example will be helpful in understanding the workload dilemma. Last year, 199,000 food imports from China arrived at U.S. ports. Also last year, FDA was able to take 19,000 samples of imported food for laboratory analysis. So, if the agency had sampled only Chinese food imports—and none from more than 130 other countries—it would have been able to sample and test only 10 percent of those imports. And, of course, one could easily argue that, given the large number of Chinese imports turned away for violations, far more than 10 percent should be analyzed.

A HISTORY OF FAILURE

It has been suggested, Mr. Chairman, that FDA’s inability to protect our citizens from contaminated imports is a failure on FDA’s part. That may be true, but I suggest that there is ample evidence that the cause of that failure lies beyond that agency. Let me support that contention that by describing a recent pattern of events:

- In the mid-1990s, FDA, USDA, and EPA began a major initiative to identify threats to our food supply, improve our scientific knowledge of foodborne threats, and act against them in a coordinated, aggressive fashion. It was called a “Farm to Table” approach intended to “fix” food safety both domestically and in terms of imported foods. Despite a promising beginning, it eventually withered away due to lack of funding.

- In 1999, with no prospect for additional funds for food imports and a rising tide of incoming products, the agency drafted a legislative proposal that would have given FDA authority to require foreign countries to take more responsibility for the foods they send to us. It would have allowed FDA to embargo a given food from a given country if there were repeated instances of that food being found contaminated when it arrived here. Countries that sent safe food would have no reason to be concerned, as they would be unaffected. But countries that demonstrated a pattern of disregard of U.S. safety standards would have to step up their oversight of food exported from their country. Congress did not accept the recommendation; indeed, no hearings were ever scheduled.

- In 2002, with statutory change and funding denied, the agency formulated a thorough reinvention of its import program to rely more on modern risk assessment procedures, to develop better intelligence about foreign food processing practices, and to design a sophisticated computer data base to make the few inspections that could be done more targeted and thus more effective. Result: denied due to even the fairly minimal funding it would have required.

- Just this year, FDA’s food safety scientists proposed to the administration new rules for fresh fruit and vegetable production that promised perhaps a 50 percent reduction in foodborne disease from domestic and imported produce. Despite the support of such rules from the produce and food manufacturing industries, the proposal was denied.

- And during this entire period, FDA officials repeatedly pointed out to officials in the Clinton and Bush Administrations that food safety should be a priority, that imports were reaching alarming dimensions, and that the agency’s food safety program was severely under funded. FDA has seen the problem, proposed several different solutions, tried to raise an alarm, and been met with relative indifference at higher levels. Therefore, Mr. Chairman, I believe that it is fair to conclude that FDA has not failed us so much as we have failed the FDA.

OPTIONS FOR THE FUTURE

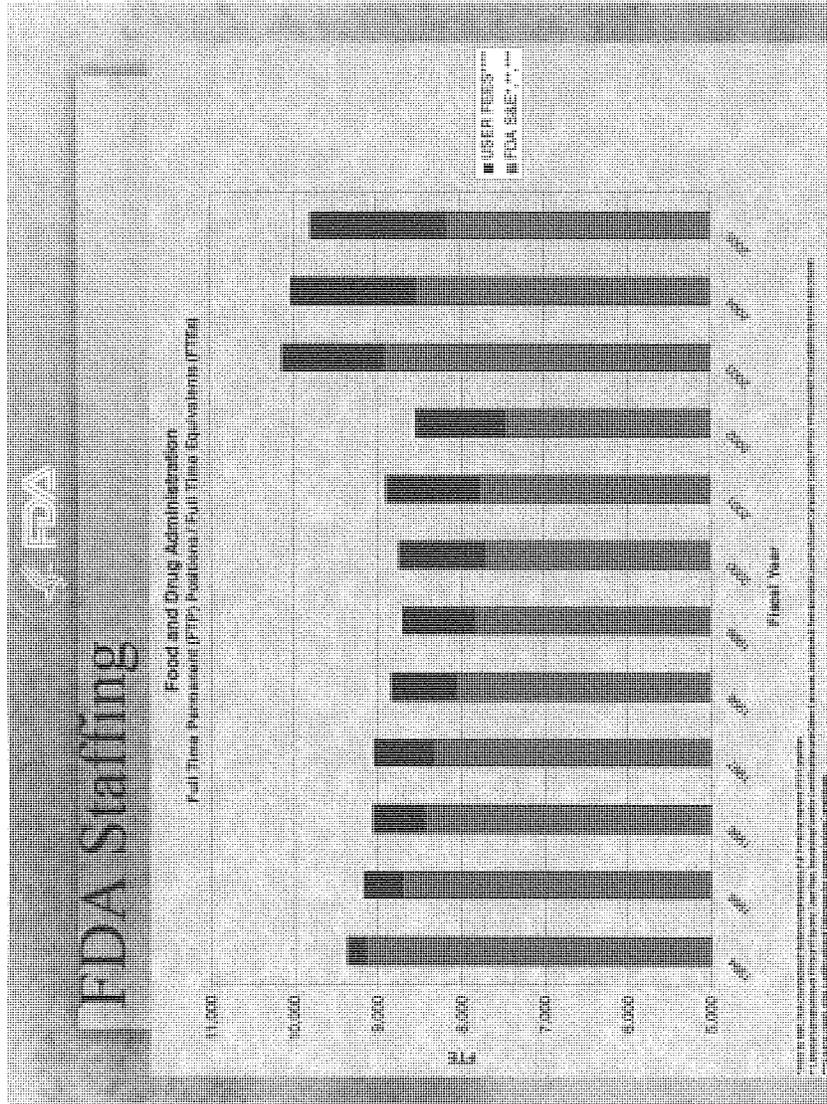
We have all heard the story of the English livery stable owner, Mr. Hobson, who gave everyone who hired a horse his option of whichever horse he wished, so long as it was the one nearest the door. Unfortunately I believe that we are faced with a series of Hobson’s choices in the case of food safety—in other words, no real choice at all. Banning food importation is obviously not a serious option, nor is authorizing

FDA to implement a USDA-like program that would require the agency to certify hundreds of countries and hundreds of thousands of food processors. Demanding that FDA “do better” and solve the problem without new resources sets vastly unrealistic expectations. And country of origin labeling is, in my opinion, neither practical nor a substitute for safe food. I suggest to the committee that the only effective option is to give FDA the resources to design and implement an effective food safety program. The Coalition for a Stronger FDA is recommending an initial increase of at least \$450 million, but it is likely that more would be needed to be truly successful.

The default, of course, is to do nothing, which means that imports will continue to soar, foreign exporters will believe they can send food of any quality to our nation’s dinner tables with impunity, we will continue to blame FDA for problems they cannot fix, U.S. food processors will bear an ever larger burden of concern and liability for food ingredients they purchase on the world market, and Americans’ confidence in our food supply—and in their government’s willingness to protect them—will deteriorate further.

I urge the committee to find ways to help the agency solve this dilemma. When similar problems have occurred in the past—drug deaths in 1937 and 1962, pesticide fears in 1955, medical device failures in 1975, counterfeit drugs in 1985, and many other times—this committee has come to FDA’s rescue. I hope that this will be another of those times when you bring to bear your determination to correct a problem that threatens us all.

Thank you for inviting me to give my views on this subject.



Mr. STUPAK. Thank you, Mr. Hubbard. Ms. Heppe. We are going to have votes here, but let us get your testimony and Ms. Collins before we have to break. In 1 second. It is going to ring here for 1 second.

Ms. HEPPE. I am glad you understand those signals.

Mr. STUPAK. I guessed. Ms. Heppe, go ahead. Five minutes please.

TESTIMONY OF CAROL HEPPE, DIRECTOR, CINCINNATI DISTRICT, FOOD AND DRUG ADMINISTRATION

Ms. HEPPE. Thank you, Mr. Chairman, for inviting me to testify at this hearing, and I request that my formal statement be made part of the hearing record. I am Carol A. Heppe, District Director in FDA's Cincinnati District Office. I have almost 35 years of service with FDA in both the field and headquarters offices.

On February 6, 2007, some information about the Office of Regulatory Affairs Field or Reorganization was provided at an Office of Regulatory Affairs senior staff meeting, which includes all the senior managers of the field operations. Along with lab closures, it was announced that a number of the district offices in the field would be reduced from 20 to 16. Also, some district boundaries would be realigned.

The plan given us was this: Cincinnati would merge with Detroit, New Jersey with Philadelphia, Denver with Kansas City, San Juan, Puerto with Florida. And there would be a realignment of the district of Kansas City to put the States of Missouri and Iowa with the Chicago district.

We were not given any information on how they reached this new structure, and quite honestly, I still don't know how they came up with it. However, I did learn through the grapevine that there was a goal to have no districts with fewer than 50 investigators. I don't know why 50 was selected.

At this meeting, we were asked to do evaluations at the end of each day. A common complaint reported from the evaluations was that communication on the reorganization has not been done well in the last year. We had been told the previous year in February 2006 there would be a reorganization, but in the field and probably headquarters too, we did not know what was going to happen.

It is true that we have received several e-mails from associate commissioner for regulatory affairs, Ms. Glavin, and have a transformation leadership team Web site that we can go to for information. These have provided broad goals ORA attempts to achieve with the reorganization and other information; however, there is nothing to tie these broad goals and intentions with the newly planned reorganization.

In other words, field employees have not been given a justification or criteria that has been used by those developing this reorganization to indicate this reorganization will result in achieving these goals. We were also told that the reorganization included reducing the number of compliance branches from 20 to 10, which meant that several of the districts would not have a compliance branch, 6 of them out of the 16.

For a better understanding of the compliance branches, I would like to explain them a little, what they have to do. There are two

branches in the district offices. One is compliance, and one is investigations. Investigations develops evidence if they find a violation at a firm through inspections, investigations, and sample collections. They write a report tying all this evidence together, and then they submit it to the compliance branch.

The compliance branch takes all this information along with the lab results from the FDA laboratories and decides whether they want to do a recommendation for an enforcement submission to headquarters.

As you can see, this could be quite problematic under the new compliance branch merger because the district director is the one that normally makes the decision on whether we will go forward or not if there is a disagreement between investigations and compliance.

And at this point, if we do not have a compliance branch at some of these districts, the district without the compliance branch will have to go to the compliance branch at another district and try to get them to go along with their decision whether to take the case or not.

Unfortunately, the group devising this plan has not consulted the people who have the most knowledge of their districts, the district directors who manage the districts and their staff before proposing this reorganization. Now that we have been told of the plan, we see inefficiencies related to it and many concerns if it is implemented. I have included some of those inefficiencies in my formal statement.

Some of these concerns are it appears to be threatening our relationships with the States with which we often leverage resources. It is disrupting important cultural and long-term working relationships with the States that the States have with the district they have been in. There has been no clarification of duties for managers in these structures. And given the restructure, it is likely that many of the positions are not supportable under OPM rules.

Headquarters' staffs appear to be building at the expense of the field forces, which do the core functions of inspections, investigation, sampling, and analysis. Lines of authorities will be muddled due to the cross servicing of compliance units and also related to the imports where they want to have the import entry reviewers report to headquarters.

Districts and compliance branches still vary greatly in size under this plan. Some directors of compliance branches will have as many as 17 to 18 employees reporting to them, while others will have as few as 10. Currently they now have on an average of eight. However, like most of the decisions on this reorganization, there has been no discussion of their basis and ultimate direction. And we are concerned that their final plan may be that we will go down to 10 districts because there are 10 compliance branches.

The current proposal could reduce our effectiveness at regulating an ever-expanding and growing industry. ORA needs solid and effective leadership at all levels in the organization. We need managers and leaders who are well informed and conversant on the issues and compliance profile of forms around the country. Each State has its own way of doing business. Each industry has its characteristics.

It is not the number of 50 investigators that should dictate the size of a district. Factors to use are industry concentration, number of States, population centers, border coverage and type, cultural similarities of the States within the district, size of the various industries, travel distances, and industry startup plans, and States prone to national emergencies, such as hurricanes.

I believe it would be impossible to understand the implications of these factors from headquarters since they do not work with these factors on a daily basis. And it is not just about making decisions for a one-time reorganization. It is about the daily decisions that need to be made in the field every day. There is nothing to indicate that this proposal will result in our better serving our constituents——

Mr. STUPAK. Would you please summarize? We are way over.

Ms. HEPPE. I have a concern that when we increase the number of these districts to as big as they are, we will have a more difficult time managing emergencies locally. And we will have more cases to review, more personnel issues and union issues to resolve. The managers in the field would be spread very thin with these much bigger districts, and I just want to point out that a lot of employees are so unhappy that we are hearing we could have a mass loss of institutional knowledge in the field with this reorganization, which would hurt us at a time when we are trying to be proactive in emergencies and do something about them before they happen. And we are now going through a big hire, and we need those people to mentor them.

Thank you, and I will be happy to answer any questions.

[The prepared statement of Ms. Heppe follows:]

TESTIMONY OF CAROL A. HEPPE

Mr. Chairman, I want to thank you for inviting me to testify at this hearing on the reorganization of the Food and Drug Administration's (FDA) field offices.

I am Carol A. Heppe, District Director of FDA's Cincinnati District Office (CIN-DO). I have almost 35 years of service in FDA. My first 12 years were as an investigator in four field offices: Minneapolis; Portland, Oregon; Boise, Idaho; and Los Angeles. The next 14 years were in headquarters' Center for Food Safety and Applied Nutrition, Office of Legislative Affairs, and Office of Executive Secretariat. In 1999, I went back to the field as CIN-DO Director of Investigations Branch and later went into my current position.

In the afternoon of February 2, 2007, I received a call telling me that my job as District Director in CIN-DO was being eliminated due to the field reorganization.

On February 6, 2007, some information about the Office of Regulatory Affairs (ORA) field reorganization was provided at an ORA Senior Staff meeting in Maryland. Along with the lab closures, it was announced that the number of district offices in the field would be reduced from 20 to 16. Also, some district boundaries would be realigned. The plan given us was this: Cincinnati District (CIN-DO) would merge with Detroit District (DET-DO) with Detroit being the district office. New Jersey District (NWJ-DO) would merge with Philadelphia District (PHI-DO) with Philadelphia being the district office. Denver District (DEN-DO) would merge with Kansas City District (KAN-DO) with Kansas City being the district office. San Juan, Puerto Rico (SJN-DO) would merge with Florida District (FLA-DO) with Florida being the district office. The realignment of district boundaries was: the states of Missouri and Iowa would be moved from KAN-DO to Chicago District (CHI-DO). Although I don't remember this being announced at the Senior Staff meeting, I later learned that the state of New Mexico was being moved from DEN-DO to Dallas District (DAL-DO).

We were not given information on how they reached this new structure. The one criterion I saw in a draft document and heard mentioned by a couple of managers was a goal of no district under 50 investigators. I did not hear any reason why 50

or more is the correct number for a district. It should be noted that with the hiring of investigators we are being authorized to do now, few to no districts will be under 50 investigators in the next year.

At this meeting, we were asked to do evaluations at the end of each day. A common complaint reported from the evaluations was that the communication on the reorganization has not been done well in the past year.

It is true that we have received several emails from the Associate Commissioner for Regulatory Affairs (ACRA) and have a Transformation Leadership Team (TLT) web site that we can go to for information. These have provided the broad goals ORA intends to achieve with the reorganization. However, there is nothing to tie these broad goals and intentions with the planned reorganization. In other words, field employees have not been given a justification or criteria, which have been used by those developing this reorganization, to indicate that this reorganization will result in achieving those goals.

We were also told that the reorganization included reducing the number of compliance branches from 20 to ten. We were not told where these compliance branches (CBs) would reside but were told which ones were merging. PHI-DO CB (containing NWJ-DO CB) and Baltimore District's (BLT-DO) would merge. DET-DO CB (containing CIN-DO CB) and CHI-DO's would merge. KAN-DO CB (containing DEN-DO CB) and Minneapolis District's (MIN-DO) would merge. DAL-DO CB and SW Import District's (SWID) would merge. Seattle District (SEA-DO) CB and San Francisco's (SAN-DO) would merge. Atlanta District (ATL-DO) CB and New Orleans District's (NOL) would merge. FLA-DO CB having merged with SJN-DO would have the CB. New York District (NYK-DO), New England District (NWE-DO), and Los Angeles District (LOS-DO) CBs would remain the same. We were told it had not been decided where the CBs would reside when merged.

For a better understanding of CBs, the compliance branch is one of two branches that have (at least during my time in FDA) been in an FDA district office. The other is investigations branch (IB). IB develops evidence for the enforcement cases through inspections, investigations, and sample collections. IB then writes a report tying the evidence together. The report is given to CB along with any sample results from an FDA lab to decide whether there is a viable case for writing an enforcement recommendation. Sometimes IB and CB disagree on whether there is a viable case. The District Director (DD) is ultimately responsible for deciding whether the recommendation for submission to HQ should move forward. As you can see, this could be quite problematic under the CB merger when there is a disagreement about a case between a district office that no longer has a compliance branch and the CB within another district.

In April 2007, ORA TLT Inspection Compliance Directorate implementation three member team (ICD) asked, in writing and during a teleconference, the district directors of the merging districts to develop and write a report to identify issues to be addressed in the merger/realignment, propose strategies and time lines to address those issues to make implementation successful, and ensure uniformity and minimize negative impacts on meeting core mission objectives during planning and implementation.

This implementation group, in writing and during a teleconference, also asked all Directors of the Compliance Branches (DCBs) and DDs to discuss obstacles and opportunities that need to be addressed for the new CB structure, propose strategies and solutions and timelines for implementation, effect a uniform transformation with minimum disruption of core functions, and keep the ICD in the loop. We were told that this new organization would save 80 FTE although it was not clear whether this was just from the CB reorganization or the whole field reorganization. We were not given any charts to demonstrate how these FTE would be saved.

The ICD gave an approximate June 1, 2007 due date for a finished report from both projects.

I actively worked in both groups. I was specifically on the compliance merger committee personnel and resource management workgroup, which reviewed the impact of the merger on personnel and ways to operate the new structure. This was one of seven groups in the compliance merger committee. It was around that time that we learned where the ten CBs would be located: PHI-DO, DET-DO, SEA-DO, KAN-DO, DAL-DO, ATL-DO, FLA-DO, NYK-DO, NWE-DO, and LOS-DO. We were not told the reason for locating the CBs in these district offices.

Our work on the district merging document indicated problems with the proposed new structure. We understood we were to work with the structure proposed because it had already been agreed to by ACRA Glavin. However, in reviewing the plan, there were some glaring issues with the boundaries and locations of the main offices. For example, it was clear to our group of DDs that KAN-DO should not be the district office site because it was on the extreme eastern edge of the new merged

over 1000 mile across district that stretched through Utah; with Missouri going to CHI-DO, the split of the Kansas City inventory left little to be covered in the new DEN/KAN merged district, and inventory and case work shifted west making Denver the logical site for a district office.

Other questions came to mind:

- How would CHI-DO cover western Missouri firms with the current major office located and staffed in Lenexa?
- Should CHI-DO and KAN-DO have a partnership for KAN-DO to do the work for CHI-DO because it would save resources?
- Should CHI-DO have a small group of employees housed in the same office with the KAN-DO employees to do the work?

The complications and loss of efficiency in trying to make a border between Missouri and Kansas begged the question, why was Missouri put in CHI-DO and not kept with KAN-DO?

This led to a concern that there may be other unknown efficiencies related to the reorganization because we had not had time to look at all the issues. The problem we found may have been avoided and possibly a better reorganization proposed if the group devising this plan had consulted the people who have the most knowledge of their districts—the DDs who manage them and their staff—before proposing the reorganization.

In the compliance merger committee meeting, which consisted of DCBs and DDs, we found it was difficult to proceed because our project was related to the results of other groups' projects such as the import group project. Our concern was we could be making decisions in a vacuum that may not coincide with another groups' decisions. The leader of our committee mentioned this concern to the ICD team. He reported back to us that we were just to continue our work.

Because of these concerns, the compliance merger committee's personnel and resource management work group, of which I was a member, submitted a document recommending that the reorganization be implemented by sequencing. We recommended that HQ be reorganized first, the districts next, with the compliance branches last. We questioned whether this proposal was the best fit and suggested a CB in each district to avoid conflicts with dual district management structures. We were concerned that having a CB reporting to one DD but doing work for up to three districts could create conflicts in case management. Who ultimately decides which cases have priority and which cases will go forward? We noted that the reorganization did not resolve the issue of the disparity of district and CB size, which we had been told at the February Senior Staff meeting, was the driving factor. Districts and CBs still varied greatly in size. Under the reorganization plan, some DCBs have as many as 17-18 employees reporting to them while others have as few as 10. Currently, on an average, eight employees report to a DCB. I am not aware that our document was addressed by the ICD team although I was told at least two of the three ICD members saw it.

Furthermore, geographic dispersion of such a large supervisory group would only complicate matters. Managing this many employees would be difficult because they would be located in up to three offices, separated by hundreds of miles with the increased geographical area resulting from the mergers. This was noted as a grave concern in compliance merger committee discussions. Their report noted that employee morale is already being affected by the proposed reorganization because employees do not know where or what their next job is or will be.

In addition, ORA headquarters has expressed concern about the decrease in ORA's enforcement actions. Most of the field managers believe the CB merger will result in a further decrease. The DCB will have more employees' work to review and they may be located in up to three offices separated by wide geographical distances. It will also make interacting with firms much more difficult because they will be located further from the DCB (and DD where the districts have merged).

My discussions with other DDs and DCBs confirm widespread belief that these are major concerns for the workability of the CB merger. Furthermore, the role of the DCB has not been defined relative to ORA headquarters Office of Enforcement.

Regarding the field reorganization plan as a whole, I have the following concerns:

- It appears to be threatening our relationships with the states with which we often leverage resources.
- I understand that one of the states moving into CHI-DO has threatened to discontinue their inspection contracts with FDA unless they can continue to work with the KAN-DO employee. Loss of these vital inspections from any state places even more pressure on our districts.
- After the Association of American Feed Control Officials Board of Directors was briefed on the reorganization in the spring, concern was expressed about the dis-

tance they would be from FDA employees they need to work with on a continuous basis.

- Both Kentucky and Ohio State officials have told me that they prefer to have the district office remain in the much closer Cincinnati, OH.

- This is resulting in a disruption of important cultural and long term working ties the states have with the district they have been in.

- There has been no clarification of duties for the managers of these structures, and given the restructure, it is likely that many of the positions are not supportable under Office of Personnel Management (OPM) rules.

- Headquarters staffs appear to be building at the expense of the field forces which do the core functions of inspections, investigations, sampling and analysis.

- Lines of authority will be muddled due to cross servicing of the compliance units and integration of directions from headquarters in the import programs. Daily activities at the field level cannot wait for decisions and directions out of distant units, be they a consolidated compliance function or an import entry review unit directed by HQ.

- There is speculation that the development of only ten CBs is a prelude to reducing district offices further to ten. However, like most of the decisions on this reorganization, there is no open discussion on their basis and ultimate direction. We were told the plan would go until 2011 so other changes must be under consideration.

- The current proposal could reduce our effectiveness at regulating an ever expanding and growing industry. ORA needs solid and effective leadership at all levels in the organization. We need managers and leaders who are well informed and conversant on the issues and compliance profile of firms around the country. Each state has its way of doing business; each industry has its characteristics. It is not the number of 50 investigators that should dictate the size of a district. Factors to use are industry concentrations; number of states; population centers; border coverage and type; cultural similarities of the states within the district; size of the various industries; travel distances; industry start up plans; and states prone to natural emergencies such as hurricanes. I believe it would be impossible to understand the implications of these factors from headquarters. And, it is not just about making decisions for a one-time reorganization. It is about the daily decisions that need to be made to manage our regulatory operations.

- The proposed reorganization will create confusion of direction, delay in implementation of programs, and sever many of our current working relationships with critical state and local governments and industry groups. Oversight of daily work will be difficult if not unachievable due to the overly wide span of control of the remaining managers. Concerns for quality of work do not appear to be addressed with this reorganization. We should not be making district offices larger and then correcting any problems with quality of work by adding more FTE in headquarters to review and correct it. We should address work quality issues where they originate.

- There is nothing to indicate that this proposal will result in our better serving our constituencies--the states, the industry, the broker and importer community and, ultimately, the consumer.

Furthermore, I am concerned that there is no indication that this reorganization will strengthen the way we regulate industry. As our emergencies have shown, we need to do a better job of regulating industry. I have not seen that any revisions made in the plan to strengthen our regulation of industry to prevent emergencies. Instead the reorganization continues as told to us in February--several districts will be increased in size and the number of CBs will be reduced. Those, who will be managing the emergencies locally, will have more industry to cover and thus greater potential for multiple emergencies and recalls, more cases to review and more personnel issues and union issues to resolve. They will be spread very thin, resulting in their having less time to concentrate on the work of consumer protection.

I am also concerned that many employees (managers and non managers) will retire or leave ORA because they disagree with the reorganization. This will result in a mass loss of institutional knowledge and expertise at a time when the agency is trying to be proactive in our operations to prevent more emergencies. Then, couple that with a current increase in hiring and not having these experts to mentor and train the new hires while we carry on the daily business of consumer health protection.

These issues must be considered if FDA's public health mission is to be sustained. This concludes my formal statement.

Mr. STUPAK. Thank you. For Members, we are going to try to get Ms. Collins' testimony in before we break for a vote. We have three

votes on the floor. Ms. Collins, if you would for 5 minutes please, and your full statement will be entered in the record.

TESTIMONY OF B. BELINDA COLLINS, DIRECTOR, DENVER DISTRICT, FOOD AND DRUG ADMINISTRATION

Ms. COLLINS. Mr. Chairman, distinguished members of the committee, I am the director of the Denver district office of the Food and Drug Administration, which includes the Denver district laboratory. I have been responsible for the operations of this office for a little over 5 years.

I would like this committee to know that the Denver district employees are dedicated to the public health mission of the agency for the good of all American consumers. The work we do for the agency begins when our investigators conduct investigations regulated industry to determine their compliance with the regulations we enforce.

The Denver district investigations branch has been operating with approximately 50 percent of the investigators needed to get the work done, and that is mandated by the agency. Despite that diminished staffing, Denver district has consistently met and even exceeded those goals based on their employees' determination and dedication.

They have worked tirelessly to get the job done. They put their personal lives in abeyance to respond to national emergencies, such as the recent findings of melamine in pet food. During the melamine emergency, Denver district's animal drug research center developed a scientific method for detecting the presence of melamine and its analogs in animal tissue. Within 72 hours from the start of that process, the method was validated and shared with other FDA and private laboratories and was distributed internationally. This technology was not available prior to its development in the Denver district.

Mr. Chairman, I am very proud to be working with this very dedicated and talented staff of investigators, scientists, and managers. As part of the proposed FDA reorganization, the Denver district office is scheduled to merge with Kansas City district on October 1 of this year. This reorganization will affect employees who work in the investigations branch, the laboratory branch, and those in my immediate office, and will include the reassignment of job functions.

The next milestone in the reorganization will be the closure of the Denver district laboratory. The approximately 50 employees of the laboratory have told me they will not leave the Denver area. The loss of the laboratory staff will result in a significant shortage of expertise and skill. The same can be said for the other district employees who will be reassigned to other positions.

The result of such a reorganization will result in a brain drain within the FDA field organization. The work that the Denver district laboratory does cannot be successfully accomplished with novice employees that will be hired to replace our scientists, as has been proposed. It is important to note that it takes a minimum of 3 years for an analyst or an investigator to become trained to conduct the complex work that we do. At a time when our baby boomers are retiring from Federal service in record numbers, it

would be a travesty to lose the institutional knowledge of the seasoned and experienced field staff members that we do have.

The Denver laboratory is a go-to laboratory in this agency. We are efficient, cost-effective, and scientifically solid. We were the leader in laboratory accreditation for FDA laboratories. And once accredited, the Denver district laboratory served as the gold standard of accreditation for all other laboratories in the agency.

I am confident that without the Denver laboratory, the food we eat as well as the human and animal drugs we use would be much less safe. Thank you, Mr. Chairman.

[The prepared statement of Ms. Collins follows:]

TESTIMONY OF B. BELINDA COLLINS

I am the Director of the Denver District Office of the Food and Drug Administration, which includes the Denver District Laboratory. I have been responsible for the operations of this office for over five years.

I would like this Committee to know that the Denver District employees are dedicated to the public health mission of this agency, for the good of all American consumers.

The work we do for the agency begins when our investigators conduct inspections of regulated industry to determine their compliance with the regulations we enforce. The Denver District Investigations Branch has been operating with approximately 50 percent of the investigators needed to meet the performance goals mandated by the Agency.

Despite that diminished staffing, Denver District has consistently met and even exceeded those goals, based on their employees' determination and dedication. They have worked tirelessly to get the job done. They put their personal lives in abeyance to respond to national emergencies such as the recent findings of melamine in pet food.

During the melamine emergency, Denver District's Animal Drug Research Center (ADRC) developed a scientific method for detecting the presence of melamine and its analogs in animal tissue. Within 72 hours from the start of that process, the method was validated and shared with other FDA and private laboratories, and was distributed internationally. This technology was not available prior to its development in the Denver District.

Mr. Chairman, I am very proud to be working with this very dedicated and talented staff of investigators, scientists and managers. As part of the proposed FDA reorganization, the Denver District Office is scheduled to merge with the Kansas City District on October 1 of this year. This reorganization will affect employees who work in the Investigations Branch, Laboratory Branch, and those in my immediate office, and will include the reassignment of job functions.

The next milestone in the reorganization will be the closure of the Denver District Laboratory. The approximately 50 employees of the laboratory have told me that they will not leave the Denver area. The loss of the laboratory staff will result in a significant shortage of expertise and skill. The same can be said for the other district employees who will be reassigned to other positions. The result of such a reorganization will result in a brain drain within the FDA field organization.

The work that the Denver District Laboratory does cannot be successfully accomplished with novice employees who will be hired to replace our scientists, as has been proposed. It is important to note that it takes a minimum of three years to for an analyst or investigator to become trained to conduct the complex work that we do. At a time when our baby boomers are retiring from Federal service in record numbers, it would be a travesty to lose the institutional knowledge of the seasoned and experienced field staff members.

The Denver Laboratory is a "Go To" lab in this agency. We are efficient, cost effective and scientifically solid. We were the leader in laboratory accreditation for FDA laboratories. Once accredited, the Denver District Laboratory served as the "gold standard" of accreditation for all other laboratories in the Agency.

I am confident that without the Denver laboratory, the food we eat as well as the human and animal drugs we use would be much less safe.

Thank you, Mr. Chairman and Distinguished Committee Members.

Mr. STUPAK. Well, thank you, and thank you for your brief statement. We are going to recess probably about 20 minutes. We have three votes on the floor. We will be back in about 20 minutes. Thank you.

[Recess.]

Mr. STUPAK. Sorry about the interruption. We will get back to it. We are not supposed to have votes for a couple hours, so hopefully we can move right along. Let us see, Ms. Collins. Dr. Adams, you will be next for your opening statement. I remind the witnesses you are still under oath. Dr. Adams, if you would please your opening statement.

**TESTIMONY OF ANN M. ADAMS, DIRECTOR, KANSAS CITY
DISTRICT LAB, FOOD AND DRUG ADMINISTRATION**

Ms. ADAMS. Mr. Chairman and distinguished members of the committee, I am Dr. Ann Adams, director of the Kansas City district laboratory located in Lenexa, KS. The lab and district office is centrally located in our country. In addition to many drug firms and agricultural industries, the Kansas City area is home to an international railroad center and two more smart ports under development, both within an hour's drive from the lab.

These centers are intended to unload and distribute imports which will be directly shipped to the KC area from San Diego and the west coast Mexico prior to their introduction to the domestic commerce. The largest FedEx trucking center is about 10 miles from the lab. We are about 35 miles from the Kansas City International Airport, which is also developing a large distribution center.

My lab relocated to its present location in 1992 and was remodeled in 2001. We are well equipped with numerous scientific instruments, including approximately \$2 million worth of equipment purchased in 2002. A large portion of that equipment expanded and enhanced our ability to respond to emergencies and to terrorist events. We are the sixth largest lab in ORA with about 56 employees in the lab branch with three chemists and a total diet research center.

We are a full service chemistry lab, analyzing both human and animal drugs and foods. We are ISO-17025 accredited for numerous programs, including drugs, dioxins, micotoxins, elemental analysis, pesticide residues, industrial chemicals such as acrylamide, perchlorates and now melamine, and the total diet study.

My lab also provides chemists for participation in both foreign and domestic drug inspections and for the deployment of FDA's chemistry mobile lab. We are the national center for the total diet study, coordinating, processing, and analyzing four collections a year, each containing about 280 separate food items from around the country for volatile organic compounds, over 350 pesticide, herbicide, and fungicide residues, toxic elements, such as lead, cadmium, arsenic, and mercury and nutritional elements including iodine, calcium, sodium, and magnesium.

We have also analyzed samples for acrylamide and perchlorates. We provide total diet samples to three other ORA labs for analysis of folic acid, dioxins, and radiological elements. The total diet study began in 1961 and has become a complex and unique program by

which the actual consumption of residues and elements from common foods in the American diet can be monitored. Foods are purchased from grocery stores and prepared as if they are to be consumed by the public.

Each year, we analyze over 1,100 samples and report over 45,000 data points in this program alone. These data are used by toxicologists, nutritionists, and other scientists in FDA, USDA, academia, and other organizations for their studies. Our program is recognized by the WHO as the standard for other countries to model their programs. We have regularly participated in the International Total Diet meetings sponsored by WHO, providing guidance and instruction to numerous countries in various stages of developing their own programs. Many countries have sent their analysts to our lab for training, including Australia, Canada, Kuwait, New Zealand, Pakistan, Sweden, the Philippines, and Saudi Arabia.

We also have a research center with a primary mission to develop or improve methods for the total diet study. Many of these methods have been published, validated, and incorporated into other FDA State and national programs in addition to the total diet.

Our lab is one of two ORA labs which analyzes for dioxins. We have four chemists working our dioxin program analyzing for dioxins, furans and PCBs in fish and shellfish. Our analysis group tests regulatory samples of human and animal foods and ceramicware for toxic elements.

Our micotoxin group analyzes 800 to 1,000 samples a year of various grains, nuts, apples, and finished products for toxins produced by molds. And lastly, our drug lab analyzes a wide variety of human and veterinary pharmaceutical products and participates in FDA's drug survey program. We participate in both foreign and domestic drug inspections providing expertise for the evaluation of labs in drug firms. Thank you very much.

[The prepared statement of Ms. Adams follows:]

STATEMENT OF ANN M. ADAMS

Good Morning. I'm Dr. Ann Adams, Director of the Kansas City District Laboratory located in Lenexa, Kansas. The lab and district office is centrally located in our country. The Kansas City area is home to an international railroad center and 2 more Smart Ports under development—both within an hour's drive from the lab. These centers are intended to unload and distribute imports which will be directly shipped to the KC area from San Diego and the west coast of Mexico. The largest FedEx trucking center is about 10 miles from the lab. We're also about 35 miles from the Kansas City international airport which is also developing a large distribution center.

My lab relocated to its present location in 1992 and was remodeled in 2001. We are well equipped with numerous scientific instruments including approximately \$2 million worth of new equipment in 2002. A large portion of that equipment expanded and enhanced our ability to respond to emergencies or terrorist events.

We are the sixth largest lab in ORA with about 56 employees in the lab branch and three chemists in the Total Diet Research Center. We are a full service chemistry lab, analyzing both human and animal foods and drugs. We are ISO 17025 accredited for numerous programs including drugs, dioxins, mycotoxins, elemental analysis, pesticide residues, industrial chemicals (such as acrylamide, perchlorates and melamine), and the Total Diet Study. My lab also provides chemists for participation in both foreign and domestic drug inspections, and for the deployment of FDA's mobile chemistry lab.

We are the national center for the Total Diet Study—coordinating, processing, and analyzing four collections a year, each containing about 280 separate food items from around the country for volatile organic compounds; over 350 pesticide, herbicide, and fungicide residues; toxic elements such as lead, cadmium, arsenic, and mercury; and nutritional elements including iodine, calcium, sodium, and magnesium. We have also analyzed samples for acrylamide and perchlorates. We provide Total Diet samples to three other ORA labs for analysis of folic acid, dioxins, and radiological elements.

The Total Diet Study began in 1961 and has become a complex and unique program by which the actual consumption of residues and elements from common foods in the American diet can be monitored. Foods are purchased from grocery stores and prepared as if they are to be consumed by the public. Each year we analyze over 1100 samples and report over 45,000 data points in this program. These data are used by toxicologists and nutritionists in FDA, USDA, in academia, and other organizations in their exposure studies.

Our program is recognized by the WHO as the standard for other countries to model their programs. We have regularly participated in the international Total Diet meetings sponsored by WHO, providing guidance and instruction to numerous countries in various stages of developing their own programs. Many countries have sent their analysts to our lab for training, including Australia, Canada, Kuwait, New Zealand, Pakistan, Sweden, the Philippines, and Saudi Arabia.

We also have a research center with a primary mission to develop or improve methods for the Total Diet Study. Many of these methods have been published, validated and incorporated into other FDA, state and national programs in addition to the Total Diet.

Our lab is one of two in ORA which analyzes for dioxins. We have 4 chemists working in our dioxin program analyzing for dioxins, furans, and PCBs in fish and shellfish. They also analyze dietary supplements and vitamins that contain fish oil for these contaminants. With these data, FDA can perform risk assessments comparing the benefits versus the exposure levels. This program is important to FDA and the American public because even at low levels, these chemicals can increase rates for cancer and birth defects.

In addition to Total Diet samples, our elemental analysis group tests regulatory samples of human and animal foods and ceramic ware for toxic elements. We are one of the primary servicing labs for metals for FDA's import district. We analyze many samples of imported products including seafood, candies, snacks, seasonings, and juices for toxic elements, particularly lead and mercury.

Our mycotoxin group analyzes 800 to 1,000 samples a year of various grains, nuts, apples and finished products for toxins produced by molds. Mycotoxins can cause cancer, liver damage, reproductive failure, and even death. Our lab is currently the only lab in ORA analyzing for fumonisins in cereal products. These mycotoxins can cause neurotoxic effects in animals, particularly in horses.

Lastly, our drug lab analyzes a wide variety of human and veterinary pharmaceutical products and participates in FDA's drug survey program. We participate in both foreign and domestic drug inspections, providing expertise for the evaluation of labs within drug firms.

Mr. STUPAK. Thank you. Dr. Jacobs, do you have an opening statement, sir?

Mr. JACOBS. Yes.

TESTIMONY OF RICHARD JACOBS, CHEMIST AND TOXIC ELEMENT SPECIALIST, SAN FRANCISCO DISTRICT LAB, FOOD AND DRUG ADMINISTRATION

Mr. JACOBS. Good afternoon. My name is Richard Jacobs. I am a chemist with the laboratory branch of the San Francisco district. I have 44 years of Government service, 40 of which were spent with the FDA. I was located at Su San for 19 years and in the field activities since that time. Thank you for this opportunity to bring to your attention those critical capabilities and functions that the San Francisco district laboratory provides, not only the agency but our partners in public health to the public in general and to our commercial industry.

Our lab is 17025 accredited. Our scientific staff include 10 chemists, 14 microbiologists, and 3 biologists, and 1 technician. Many of our scientists have advanced degrees. Some have doctoral degrees. While our laboratory management staff includes a science director supervising analysts and a district quality assurance manager, the laboratory lacks a sample custodian and safety officer, glassware, dishwasher, and two media prep technicians. And those duties are presently being performed by scientific staff.

Additionally, we have lost several journeymen scientists in the last year that haven't been replaced. With the exception of filth analysis, drug analysis, and micotoxin and pesticide analysis, our lab covers the rest of the program in field program areas.

Our lab houses two specialty functions for the Pacific region: toxic elements and food and color additives. I believe that the closure of our laboratory facility will lead to a critical loss of expertise, functionality, and capacity in certain programs, some of which will never be regained. Critical relationships with the State of California that will be lost without having FDA analytical experts nearby are also critical. Our laboratory has been a pioneer in introducing many technologies to the field. Examples include elemental analysis techniques such as ICP mass spec, XRF, which is x-ray fluorescence spectrometry, and methods to actually measure mercury and methyl mercury in seafood.

Our laboratory is piloting the use of x-ray fluorescence devised by investigators in field examination of hazardous levels of toxic elements in food, Asian, herbal, and patent medicines. This device can detect certain elements in a matter of seconds with little or no preparation of the sample.

Together with State of California, our group was instrumental in developing information to support new policy with regard to lead in candy. The laboratory performs seafood sensory analysis, widely used for detection of spoilage in imported seafood as well as analyzing for histamine and indull, two compounds that are indicative of microbiological spoilage.

Our local analytical presence and the participation of analysts and inspections are essential for having impact on the local and import seafood industry. San Francisco district also has a unique expertise in interric viral analyses, especially norwal virus and hepatitis A. Analytical methods for these two viruses are in preparation for in-laboratory validation.

Over recent years, numerous outbreaks of norwal virus indicate a need for sensitive method for detection of this virus on foods and in food handling environments. The San Francisco district laboratory contribute very importantly to the detection of *E. coli* 015787 in last year's investigation of spinach and later on an outbreak found to be in lettuce.

This laboratory performed approximately half of the 900 samples analyzed by Bay area laboratories and found several strains that were linked to clinical cases using PULSENET. Outbreak investigations would be severely hampered by not having analysts and analytical activity available locally. Moreover, many microorganisms, for example *E. coli* 015787 can be negatively affected by shipping practices. So having a nearby lab where samples can be delivered in a few hours is critical.

Our microbiology section is capable of handling all food-related pathogen detections and is the only laboratory in the Pacific region able to analyze drugs and medical devices for sterility and mematoxin. The laboratory is well-equipped for many analytical programs and state of the art for microbiology and toxic elements. Aside from the typical equipment, we have clean facilities for sterility testing of drugs and medical devices and toxic element testing.

We also have special sample preparation rooms, equipment, rooms specifically designed for viral analytical methods and a BSL2 suite illustrates its CDC standards for working with several select agents. We possess a number of other analytical equipment that gives us flexibility such as responding to the recent melamine related compound outbreak in pet foods.

As a member of FERN and the CDC's laboratory response network, our laboratory heavily contributes to the national trading programs, and most of our analysts are very well trained. The laboratory collaborates and maintains contacts with the California Department of Health Services and their subservient agencies, the USDA and the Lawrence Livermore National Laboratory and the University of California at Davis. Thank you.

[The prepared statement of Mr. Jacobs follows:]

TESTIMONY OF RICHARD M. JACOBS

Good morning. My name is Richard Jacobs, and I am a chemist with the Laboratory Branch of the San Francisco District. I have 44 years of Government service, 40 of those have been with the FDA. Most of my career has involved the work with the essential and non-essential elements.

Thank you this opportunity to bring to your attention those critical capabilities and functions that the San Francisco District Laboratory Branch provides not only the agency, but to our partners in public health, to the public in general, and to our local commercial industry.

The San Francisco lab is: Q03

- ISO 17025 accredited.
- Lab scientific staff includes 10 chemists, 14 microbiologists, 3 biologists, and 1 technician. Many of our scientists have advanced degrees. Some have doctorates.
- While laboratory management staff includes a Science Branch Director, 3 supervisory analysts, and a district quality assurance manager, the laboratory is currently lacking a sample custodian, a safety officer, glassware washer, and 2 media preparation technicians. Those duties are presently being performed by scientific staff. Additionally, we have lost several journeyman scientists in the last year that haven't been replaced.
- With the exception of filth analysis, drug analysis, mycotoxin analysis, and pesticide analysis our lab covers the rest of the field program areas.
- Our lab houses two specialty functions for the Pacific Region: Toxic Elements (in foods and ceramicware) and Food and Color Additives.

I believe that the closure of our laboratory facility will lead to a loss of critical expertise, functionality, and capacity in certain critical programs, some of which may never be regained. Critical relationships with the State of California will be lost without having certain FDA analytical experts nearby:

- Our lab has been a pioneer in introducing many new technologies to the field. Examples include elemental analysis techniques such as ICP-MS, XRF techniques, and methods to accurately measure mercury and methylmercury in seafood.
- Our group is piloting the use of X-Ray Fluorescence by investigators in the field to detect potentially hazardous levels of toxic elements in foods and Asian herbal and patent medicines. This device can detect certain elements in a matter of seconds with little or no preparation of the product.
- Together with the State of California our group was instrumental in developing information to support new policy regarding lead in candy.
- The laboratory performs seafood sensory analysis, widely used for detection of spoilage in imported seafood, as well as analyzing for histamine and indole, two compounds indicative of microbial spoilage. A local analytical presence and the par-

ticipation of analysts in inspections are essential for having impact on the local domestic and the import seafood industry.

- San Francisco district laboratory also has unique expertise in enteric viral analyses, especially Norwalk Virus and Hepatitis A. Analytical methods for these two viruses are in preparation for inter-laboratory validation. Over recent years, numerous outbreaks of Norwalk Virus indicate a need for a sensitive analytical method for detection of this virus on foods and in food handling environments.

- The San Francisco district laboratory contributed very importantly to the detection of *Escherichia coli* O157:H7 in last year's investigation of the incidence of clinical infections due to this organism traced to spinach, and later, in a different outbreak, to lettuce. This laboratory performed about half of the approximately 900 samples analyzed in the San Francisco Bay Area and found several strains which were linked to clinical cases using PULSENET. Indeed, one isolate matched about 63 clinical cases that had not previously been identified by the CDC as an outbreak and which occurred during the previous summer. Outbreak investigations would be severely hampered by not having analysts and an analytical activity available, locally. Moreover, many microorganisms, e.g. *E. coli* O157:H7, can be negatively affected by commercial shipping practices. So having a nearby lab where the samples can be delivered in a few hours is critical.

- The Microbiology section is capable of handling all food related pathogen detections and it is the only laboratory in the Pacific Region able to analyze drugs and medical devices for sterility and endotoxins.

The laboratory is well equipped for many analytical programs. It is "state of the art" equipped for Microbiology and Toxic Elements:

Aside from the typical equipment the lab is equipped with:

- Clean room facilities for sterility testing for drugs and medical devices and toxic element testing.
- Specialized sample preparation rooms and equipment.
- Room for specifically studying viral analytical methods
- A BSL2+ suite and ten analysts trained to CDC standards for work with several select agents.
- Possession of analytical chemistry equipment allowing flexibility in adapting to novel analytes, such as, currently, melamine and related compounds (cyanuric acid, ammeline and ammeline).

The lab is a member of FERN (microbiology, toxic elements) and CDC's Laboratory Response Network. San Francisco analysts have participated in training elemental analysis, *E. coli* O157:H7, FERN (Food Emergency Response Network) methods, Select Agent analytical methods, basic microbiology FDA analytical methods and Mobile Laboratory Training.

The laboratory actively collaborates or maintains contacts with the California Department of Health Services, USDA, the Lawrence Livermore National Laboratory and the University of California at Davis.

Thank you again Mr. Chairman for this opportunity, I will be glad to answer any questions that you or the other committee member might have.

Mr. STUPAK. Thank you, Dr. Jacobs. Mr. Clavet, opening statement please.

TESTIMONY OF CHARLES CLAVET, MICROBIOLOGIST, WINCHESTER ENGINEERING AND ANALYTICAL CENTER, FOOD AND DRUG ADMINISTRATION, WINCHESTER, MA

Mr. CLAVET. Good afternoon, Chairman Stupak, Ranking Member Whitfield, and members of the subcommittee. I thank you for your interest in allowing me this valuable opportunity to speak on behalf of my friends and colleagues at the Winchester Engineering and Analytical Center and the citizens of the Nation at this critical juncture, at a time when the Office of Regulatory Affairs is redefining its commitment to its mandated public health mission.

My name is Charles Clavet, and I have worked for the past 16 years as a microbiologist at the Winchester Engineering and Analytical Center, which is located in Winchester, MA. I would like to take this time to briefly describe many of the unique public health

functions and capabilities WEAC possesses and to discuss openly our concerns and questions regarding the impending laboratory closures.

The closing of WEAC and subsequent loss of virtually all analysts will have an impact on ORA's ability to continue to fulfill its public health mission. In order to comprehend the full impact of losing this facility and personnel, it is imperative that the wide range of WEAC's capabilities be made known. In fact, the list of capabilities and interactions is so extensive and impossible to cover in the time allotted that I would like to submit for the record several documents that elaborate upon WEAC's immense contribution to ORA's mission.

WEAC is a truly unique laboratory asset with many experienced, motivated scientists, radio chemists, chemists, biologists, microbiologists and engineers working in harmony to provide specialized analytical capabilities utilizing their respective disciplines. We are an American Association of Laboratory Accreditation, 82L8, certified ORA field laboratory that specializes in regulatory testing of foods for radionuclides and the analysis of medical devices for safety and efficacy. This accreditation would not easily be transferable to another location without the associated movement of the personnel currently performing this work.

WEAC Laboratory provides services to the Center for Food Safety and Applied Nutrition, the Office of Criminal Investigation, the Center for Devices and Radiological Health, States and local governments with a legacy of proven performance in fulfilling ORA's public health mission while continuously enduring budget constraints.

WEAC is the only facility that has full analytical capability and expertise for the analysis of foods for the detection of gamma, beta, and alpha contamination. WEAC holds the only Nuclear Regulatory Commission license and handles radiation equipment, calibration, and radiation safety training for all ORA field personnel. WEAC is the sole laboratory providing food expertise to the CDC, the EPA, the Department of Defense, the USDA, and the Department of Homeland Security under the Interagency of Consortium of Laboratory Networks.

WEAC has a memorandum of understanding with USDA Food Safety Inspection Service for the radionuclide analysis of USDA-regulated products in case of an emergency. WEAC also has an MOU with the United States Department of State and Department of Energy. If WEAC closes, the NRC license will have to be reestablished, and all current radiological arrangements and agreements will be cancelled.

In addition to our radionuclide specialty, WEAC is the servicing lab for the Center for Devices and Radiological Health, providing a wide range of engineering and analytical capabilities—microbiological, biological, and chemical—for medical device evaluation. Historically, CDRH has relied heavily on the scientific and regulatory expertise of WEAC and anticipates both continuing and growing needs into the foreseeable future. For this reason, CDRH has requested that ORA commit a single physical laboratory site to the CRH work plan and method development goals.

We are confused. The continuous flow of rhetoric does not agree with the actions. On one hand, we have been praised for our commitment, our dedication, and knowledge and skills that we possess. There is talk about the need for retention and recruitment, yet when 100 new positions were recently made available, personnel at the affected laboratories were excluded from applying for these jobs. One high level ORA manager from the TLT committee States that we are committed to going outside the agency. An FDA spokesperson says ultimately we want new people and new equipment.

Why was this done? I can tell you, Mr. Chairman, the puzzlement I have expressed is not solely mine but is shared by my colleagues and peers at WEAC. I have discussed this with the elected leaders of NTEU, our union at WEAC, and with many of the dedicated professionals I work with. None of us see any merit in the lab closure proposal. NTEU officers have been in communication with employees at other labs proposed for closure, and their views are the same.

In conclusion, as I prepared this testimony, I began to realize that it was going to be very difficult to articulate and convey the complete picture of WEAC and its personnel in 5 minutes. I came to the realization that I could only highlight some of its responsibilities, contributions, and interactions that occur on a daily basis as this group of dedicated scientists carry out ORA's public health mission. The more time I spent on trying to condense the information, the more puzzled I became. Why would anyone want to close this facility? At this point in time, Mr. Chairman and members of this subcommittee, WEAC's fate is in your hands. I hope you can find a way to allow WEAC to continue its vital public health service to the citizens of this Nation, and I would be happy to answer any questions members of the committee may have. Thank you.

[The prepared statement of Mr. Clavet follows:]

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Statement of

Charles R. Clavet

Microbiologist/IVD Specialist
Winchester Engineering and Analytical Center
Office of Regulatory Affairs
United States Food and Drug Administration

Before

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Rayburn House Office Building

Good morning Chairman Stupak, Ranking Member Whitfield, Chairman Dingell and members of the Subcommittee. I thank you for your interest and allowing me this valuable opportunity to speak on behalf of my friends and colleagues at the Winchester Engineering and Analytical Center (WEAC) and the citizens of this nation at this critical juncture at a time when the Office of Regulatory Affairs (ORA) is redefining its commitment to its mandated public health mission. My name is Charles Clavet, and I have worked for the past 16 years as a microbiologist at the Winchester Engineering and Analytical Center which is located in Winchester, Massachusetts and is one of thirteen field laboratories operated by the Office of Regulatory Affairs (ORA). It is an FDA owned facility that costs nothing in terms of rent or lease payments. I would like to take this time to briefly describe the many unique public health functions and capabilities WEAC possesses and to discuss openly our concerns and questions regarding the impending laboratory closures.

The closing of WEAC and subsequent loss of virtually all analysts will have an impact on ORA's ability to continue to fulfill its public health mission. In order to comprehend the full impact of losing this facility and personnel it is imperative that the wide range of WEAC's capabilities be made known. In fact, the list of capabilities and interactions is so extensive, and impossible to cover in the time allotted, that I would like to submit for the record several documents that elaborate upon WEAC's immense contribution to ORA's mission.

WEAC is a truly unique laboratory asset with many experienced, motivated scientists (radiochemists, chemists, biologists, microbiologists and engineers) working in harmony to provide specialized analytical capabilities utilizing their respective disciplines. We are an American Association for Laboratory Accreditation (A2LA) certified ORA field laboratory that specializes in regulatory testing of foods for radionuclides and the analyses of medical devices for safety and efficacy. This accreditation would not be easily transferable to another location without the associated movement of the personnel currently performing this work. WEAC's laboratory provides services to the Center for Food Safety and Applied Nutrition (CFSAN), the Office of Criminal Investigations (OCI), the Center for Devices and Radiological Health (CDRH), states and local governments with a legacy of proven performance in fulfilling ORA's public health mission while continuously enduring budget constraints.

Radiochemical Capabilities/Responsibilities

- WEAC is the only FDA facility that has full analytical capability and expertise for the analysis of foods for the detection of gamma, beta and alpha contamination.

- WEAC holds FDA's only Nuclear Regulatory Commission (NRC) license and handles the radiation equipment, calibration and radiation safety training for all ORA field personnel.
- WEAC's radionuclide laboratory has state-of-the-art equipment and personnel. Our site and processes are A2LA accredited and significant quality systems are in place to ensure that they are legally defensible.
- WEAC is the sole laboratory providing food expertise to the CDC, EPA, DOD, USDA and the Department of Homeland Security under the Interagency Consortium of Lab Networks agreement (ICLN).
- WEAC has Memorandum of Understanding (MOU) with USDA/FSIS for the radionuclide analysis of USDA regulated products in case of emergency.
- WEAC also has a MOU with the United States Department of the State and the Department of Energy.
- If WEAC closes the NRC license will have to be reestablished and all current radiological arrangements and agreements will be canceled.
- WEAC radionuclide laboratory has effectively responded to food emergencies resulting from Chernobyl, Three Mile Island, Mass. Bay Foul Area Survey, polonium (Po)-210 static eliminators in pharmaceutical products, nuclear reactor scares and the recent polonium (Po)-210 poisoning in the UK that quickly became worldwide in scope.
- In the recent polonium (Po)-210 incident, CDC asked WEAC for assistance in development of a food method for Po-210 sample analysis.

- WEAC was the only US regulatory lab that participated in the International Atomic Energy Agency (IAEA) polonium (Po)-210 proficiency to assess laboratory readiness and passed all acceptance criteria.
- WEAC is the lead laboratory for the Food Emergency Response Network (FERN) laboratories in response to radiological emergencies and is actively expanding its capabilities for detecting all radionuclides of greatest concern through research and method development.
- WEAC prepares proficiency samples and provides methods and training to the various FERN laboratories.

Microbiological Method Development- FERN

- ❖ WEAC conducts research at the University of New Hampshire Biosafety Level-3 facility in support of ORA's Microbiological FERN program.
- ❖ WEAC's research has contributed to the development of a method for the detection of *Yersinia pestis* (the plague bacterium) in foods and participated in a collaborative study for the automated detection of *Yersinia pestis*.
- ❖ The lab is currently preparing to conduct studies with *Francisella tularensis*, another select agent, for the food defense workgroup.

WEAC Laboratory Support for CDRH Programs

In addition to our radionuclide specialty, WEAC is the servicing laboratory for the Center for Devices and Radiological Health (CDRH) providing a wide range of

engineering and analytical capabilities (microbiological, biological and chemical) for medical device evaluation. WEAC is the only laboratory that employs engineers and regularly sends them to China to inspect production facilities of non-ionizing radiation emitting products (lasers, microwave ovens and televisions. No other ORA laboratory provides this unique combination of scientific disciplines working in concert. WEAC engineers have conducted numerous research projects for CDRH and the results have been used to set international standards and methods.

Historically, CDRH has relied heavily on the scientific and regulatory expertise of WEAC and anticipates both continuing and growing needs into the foreseeable future. For this reason, CDRH has requested that ORA commit a single physical laboratory site to the CDRH work plan and method development goals.

It appears that ORA has determined that the condition of the WEAC facility is the reason for closing the building. Incredibly, during the whole ORA transformation process no member of the Transformation Leadership Team (TLT) has surveyed the physical WEAC facility to examine the equipment and its environment. Within the last year the Associate Commissioner of Regulatory Affairs (ACRA) came to Boston and never visited WEAC. Yet, the decision has been made in Rockville, MD, and ORA continually sites an outdated study as the evidence for the closure. There have been major improvements to the facility over the past three to four years. Has this been considered?

We are confused. The continuous flow of rhetoric does not agree with the concomitant actions. On one hand we have been praised for our commitment, our dedication, and the knowledge and skills that we possess. There is talk about the need for retention and recruitment. Yet, when 100 new positions were recently made available

personnel at the affected labs were excluded from applying for these jobs. One high level ORA manager from the TLT committee states that, “we are committed to going outside the agency”, and the FDA spokesperson says, “Ultimately we want new people and new equipment”. Why was this done? I can tell you Mr. Chairman, the puzzlement I have expressed is not solely mine but is shared by my colleagues and peers at WEAC. I have discussed this with the elected leaders of NTEU, our union at WEAC, and with many of the dedicated professionals I work with. None of us see any merit in the lab closure proposal. NTEU officers have been in communication with employees at the other labs proposed for closure, and their views are the same.

In conclusion, as I prepared this testimony I began to realize that it was going to be very difficult to articulate and convey the complete picture of WEAC and its personnel in five minutes. I came to the realization that I could only highlight some of its responsibilities, contributions and interactions that occur on a daily basis as this group of dedicated scientist carry out ORA’s public health mission. The more time that I spent on trying to condense the information the more puzzled I became. Why would anyone want to close this facility? At this point in time Mr. Chairman and members of this subcommittee, WEAC’s fate is in your hands. I hope that you can find a way to allow WEAC to continue its vital public health service to the citizens of this nation. I would be happy to answer any questions members of the committee may have.

Mr. STUPAK. Thank you, and thank you all for your testimony. We will begin questioning. Ms. DeWaal, you indicated that China is one of the leading suppliers of U.S. agricultural and seafood imports. In fact, Canada is No. 1, Mexico is No. 2, and China is No. 3. But then you are talking about the rejections and food problems. I find that Mexico, which is No. 1 in rejections, but India is No. 2. Why India?

Ms. DEWAAL. India probably for the same reason that China is having so many problems. They don't have regulatory structures nationally that would help to ensure that the food products they are shipping to us are of a quality that meets the standards for U.S. consumers.

Mr. STUPAK. But if the quality is voluntary, the standards are voluntary, what basis do you reject it then? There has to be something more than just voluntary standards.

Ms. DEWAAL. They can find problems, for example, with filth. If products are coming in with visible filth, clearly they can reject for that matter.

Mr. STUPAK. Is it salmonella in Indian spices?

Ms. DEWAAL. Yes, sometimes they find problems with salmonella, which again for ready-to-eat product shouldn't be there. So even without those mandatory standards, but really the best thing, the best system would be one where we had mandatory standards and on-site, in-country review.

Mr. STUPAK. Correct. To the lab directors, Ms. Heppe, Ms. Collins, Dr. Adams, Dr. Jacobs, Ms. Clavet, any reasons given why your lab was chosen to close? Can anyone articulate a reason? I didn't hear any in the testimony.

You are all silent, so I take it no one has an answer. Dr. Adams, it has been mentioned to me that Kansas City lab played a prominent role in the wheat gluten case. Correct?

Ms. ADAMS. That is correct.

Mr. STUPAK. How did your role, the samples analyzed by Kansas City lab, compare to those wheat gluten sent to other labs?

Ms. ADAMS. Our laboratory is an hour and a half away from Emporia, KS where the firm was located, so when this first occurred, it was investigators from our district that went down there. And it was very easy for them to bring samples up to our laboratory. As a result, we received a lot of samples, which pertained to the actual components of the foods being produced in addition to the finished product. So we have got the wheat gluten, the rice proteins, the amino acids, all the different components for us to test.

Mr. STUPAK. Was the test going to other labs, like university labs, also did testing on wheat gluten, did they follow your lead. Did they develop their own standards or testing? How did that occur?

Ms. ADAMS. I wasn't involved in that assignment.

Mr. STUPAK. OK.

Ms. ADAMS. I am assuming that was through a FERN program, and if that is the case, then they should be following the same methodology that we used.

Mr. STUPAK. How many of your employees at the Kansas City lab would be willing to transfer to another lab if you were to close?

Ms. ADAMS. Right now, I have about six employees who said that they would consider moving. However, that was contingent on their being able to move to the laboratory of their choice.

Mr. STUPAK. I see.

Ms. ADAMS. And also you have to remember that most of these people who are willing to move are fairly new employees. They don't have the same kind of ties to the community that other employees have, and they just don't have the level of experience.

Mr. STUPAK. You mentioned the total diet study. That program would be relocated then if your lab is closed, right?

Ms. ADAMS. Correct.

Mr. STUPAK. And how many of those employees are willing to leave?

Ms. ADAMS. Right now, I know about three of the people who would be willing to move.

Mr. STUPAK. OK, thanks. Dr. Jacobs, we have held hearings on the spinach. It was our first hearing on April 24, and you are located probably the closest proximity to Salinas Valley, correct?

Mr. JACOBS. Yes.

Mr. STUPAK. The Salad Bowl of America they call it?

Mr. JACOBS. Yes, that is true.

Mr. STUPAK. Dr. Adams mentioned it, but why is the close proximity? Is there an advantage to having the lab close to, let us say, like fresh produce or wheat gluten, whatever it might be?

Mr. JACOBS. First thing is getting the samples into the lab as fast as possible so you can get results. In the follow-up investigation we had water samples, we had fecal material, we had spinach samples and other samples that needed to get to the lab very quickly. We relied on, say, FedEx to send them out the next day. Many of those would not have been worth analyzing so—

Mr. STUPAK. Why? Because it—

Mr. JACOBS. The organisms are fairly—

Mr. STUPAK. Fragile?

Mr. JACOBS. Yes. And you may cause an enhancement in other organism, or it may not reflect what actually occurred in that particular sample. So having a lab nearby is very critical.

Mr. STUPAK. The last panel mentioned the California food emergency response team. Now, sort of like the primary investigative lead. But they work very closely with you, and I think CalFerd said that they would not want to see your lab close down.

Mr. JACOBS. Yes, I am sure that CalFerd doesn't want to see us close down. We make up half the investigators and people who participate in that.

Mr. STUPAK. Do you work well with CalFerd?

Mr. JACOBS. I am not personally involved, but as I understand, they work quite well with CalFerd and the food and drug branches in the State of California.

Mr. STUPAK. Well, besides proximity to Salinas Valley, why would the closing of the San Francisco lab be of great loss to this country?

Mr. JACOBS. Well, we do approximately half of the samples. The California food and drug branch has five employees. They did half of the samples also or approximately half. I am not exactly sure of the numbers, but we give them no surge control. We have a lot of

people who are analysts who work as partial investigators and go out in the field and try to develop a sharpening of what samples are collected and how they are tested. So having somebody nearby that has analytical expertise is really critical.

Mr. STUPAK. I have more questions, but my time is up. Before I turn to the gentleman from Kentucky for questioning, Mr. Laurel from Connecticut is very interested in food safety and has a number of pieces of legislation. But more importantly, she is also chair of the appropriations committee, which deals with the FDA. And I think you—I know she is trying very hard to put forth language or the money to make sure these labs don't close but no results yet. We are working on it. Don't lose heart in it yet.

Mr. Whitfield.

Mr. WHITFIELD. Thank you, Mr. Stupak. I want to thank all of you for being with us today as we look at this very serious issue. And, of course, we welcome your testimony because all of you have valuable experience at FDA and have insights that certainly we do not have. And, Mr. Hubbard, you had mentioned, I believe in your testimony, that USDA had been plussed up for food safety and plussed up for some other programs. I think you mentioned \$163 million and \$130 million, and yet FDA had been reduced.

Now, in fact, any of you can answer this question, but if it true that FDA is responsible for 80 percent of food safety in America and only has 20 percent of the budget, and USDA is responsible for 20 percent and has 80 percent of the dollars, what is the rationale for that? And is it defensible?

Mr. HUBBARD. It boils down to the way Congress set up the meat inspection program back in 1906, which requires meat to be continuously inspected. In other words, if a meat packing plant operates, it must have USDA inspectors in the plant, inspecting the meat at all times. So that essentially requires Congress to provide full funding for that program every year plus inflation because if the meat inspectors aren't there, the plant can't legally operate. So even though they only have 20 percent of the food supply, the paradigm forces Congress to be given 80 percent of the money.

And so I don't think anyone is suggesting that money be taken away necessarily from USDA but that the FDA part, which is so underfunded, be strengthened.

Mr. WHITFIELD. OK, and, of course, when this program was first set up, the situation was certainly a lot different because today we have all these imports coming in of fish and seafood and so forth. So do all of you agree that FDA does not have sufficient money to inspect these food items the way they should be inspected? Do all of you agree with that or—OK, and when I listen to this testimony today, it really is sort of scary because of the amount of contaminated food that we see coming in from China and other countries. And all of you have been quite straightforward and even critical in your opening statements. But if we put this on a scale of 1 to 10 and 10 being a perfect job of inspecting food for the American people, where would you on a range of 1 to 10 put the FDA today in protecting the American people in guaranteeing food safety. Would you assign a number for that, Ms. DeWaal?

Ms. DEWAAL. I assume 1 is low and 10 is high?

Mr. WHITFIELD. One is low, and 10 is high.

Ms. DEWAAL. I feel bad having to do this, but we are in the range of 1 because FDA isn't preventing problems.

Mr. WHITFIELD. OK.

Ms. DEWAAL. They are acting as a fire department running around putting out fires.

Mr. WHITFIELD. OK, so on 1 to 10, you would put FDA at 1 right now? OK.

Mr. HUBBARD. Well, I would divide it, Mr. Whitfield, I would say that if you look at the scientific expertise, the credibility, the global reputation, and the dedication of the employees, I would put it at 9 or 10. But if you are looking at capacity, the capability, I would be down here with Ms. DeWaal.

Mr. WHITFIELD. And I don't think anyone is questioning the dedication, the expertise, the commitment of the people that work there. But looking at the totality, what is the job that is being done for the American people in providing safe food? So both of you said 1 maybe. What about you, Ms. Heppe?

Ms. HEPPE. I would probably give it a 5 because we do not have enough resources, but we try to do the best we can with what we have.

Mr. WHITFIELD. OK.

Ms. HEPPE. We try to concentrate on the areas we need to.

Mr. WHITFIELD. Ms. Collins?

Ms. COLLINS. I would probably give it a 3 or a 4.

Mr. WHITFIELD. OK.

Ms. COLLINS. However, if we lose the expertise that we have in the field right now, I would give it probably a minus 2.

Mr. WHITFIELD. OK. Dr. Adams?

Ms. ADAMS. I would probably divide it up. I would give a 7 to the drugs and devices, parts that have much more personnel and much more income. And I would probably lower food to a 4 or a 5.

Mr. WHITFIELD. OK, Dr. Jacobs, do you have any thoughts?

Mr. JACOBS. I would give a low number, but I can't give you a quantitative—

Mr. WHITFIELD. Mr. Clavet?

Mr. CLAVET. Two or 3.

Mr. WHITFIELD. OK. Well, that is pretty astounding because we are the leading nation in the world. We talk about our food safety. We talk about our institutions, and yet for you experts who work in this area who have the responsibility of doing this, to give that kind of rating certainly does not speak well for where we are. And we have a lot of work to do. So thank you very much.

Mr. STUPAK. Thank you, Mr. Whitfield. Mr. Burgess for questions.

Mr. BURGESS. Thank you, Mr. Chairman. Dr. Jacobs, I apologize. I hadn't made it back from the vote when you gave your testimony, and I don't see written testimony in the stuff in front of me. But I would like to ask you a question, if I could, just for my general knowledge. I get the part about using the carbon monoxide on beef because cosmetically it improves its color. What is the rationale for treating fish with carbon monoxide?

Mr. JACOBS. It turns the hemoglobin bright red, or the myoglobin, in the sample.

Mr. BURGESS. Most of the fish I buy is white though, so I don't get—

Mr. JACOBS. It wouldn't help in those fish.

Mr. BURGESS. So it is the salmon in particular?

Mr. JACOBS. Yes.

Mr. BURGESS. OK. Mr. Hubbard, I really appreciate you being here, having your perspective over—you were at the FDA, I guess, starting right after the earth cooled and have been there—

Mr. HUBBARD. Not quite that far.

Mr. BURGESS. But it is an amazing length of time that your career spans at the FDA. So you have seen it all through various administrations, through various iterations of Congress. And I am really struck by your comments in your written testimony about how perhaps it is not the FDA that has failed, but the body responsible for funding the FDA has been the failure. And I suspect that point is one that you would want to make fairly strongly. Is that correct?

Mr. HUBBARD. Well, I do feel that way, Mr. Burgess. I think that the agency scientists have identified these problems for years. They have brought forth suggestions for regulation, for legislation, and for funding. And they have been denied, and now for them to be criticized and be told that you are the problem I don't think is entirely fair.

I won't say the FDA is perfect by any means, but I do believe that they have been denied the opportunities to fix some of these problems when they have identified them, brought them forward for solution, and then told no, you can't do that. You can't have that regulation. You can't have that legislation. You can't have that funding. And so they are to some extent as much victims of this as, I think, we all are. And that is why I hope this committee will be looking at a broad range of issues and understanding there may be management issues and deal with that, but also understand there are some of these other issues about authority and resources that need a look.

Mr. BURGESS. And these are not entirely new problems.

Mr. HUBBARD. No, I think the FDA folks have been raising the alarm about this for years, and import flares up about every 2 or 3 years, and it dies down. And I hope that doesn't happen this time. I hope this time Congress acts.

Mr. BURGESS. I hope so too. Now, you think it is an inability of the FDA to articulate the problem and the funding requirements, or is it indifference on the part of the particular Congress or particular administration?

Mr. HUBBARD. No, this is not a partisan issue. The problems cross political parties and political administrations. I think that priorities have been shifted in the 1980s and 1990s toward some of the drug issues. Money needed to be found for biotechnology, for blood safety, for AIDS. And commissioners and secretaries essentially shifted money out of food. I think if they had been able to see to the future that one day food would be biting us back, that these imports would skyrocket, maybe decisions would have been made differently. But they weren't. Now, we are at a point where the food program has essentially been taken down, and I think unless we build it back up, all of these other ideas we have are not

going to be very meaningful. You can't implement a regulation without people. You can't implement legislation without people. You can't manage better without people.

Mr. BURGESS. Now, I seem to recall—I was just a regular guy back in the 1990s, but I seem to recall—well maybe 1993 or 1994—a bad outbreak of *E. coli* at some fair or something. A big push was made to fix this problem. And in fact, I remember the administration signing a bill and making a big deal out of the fact that finally at long last our food safety is now in the right hands and going forward. We won't have this problem to deal with any longer. What happened there?

Mr. HUBBARD. Well, you are absolutely right. FDA took the lead first with seafood and doing preventative controls and largely addressed that. Then they did it with juice after, I guess, there. The meat program at the USDA essentially followed FDA's lead and did it for meat, and meat outbreaks have dropped precipitously. And so meat is a much safer product now. But FDA recently tried to do that with fresh fruits and vegetables, and reports are they were denied the ability to do that. And so I think those are the kinds of things you need to look at. Where do the scientists think the fixes are? And can you help them get them?

Mr. BURGESS. And let me just ask you one other thing before my time expires. We heard some comments about country-of-origin labeling and how that would be an improvement, but in your testimony, you cast some doubt on the fact that the country-of-origin labeling will actually get us where we want to be. I got to tell you I got people in my district who are very suspicious. They are suspicious of the Government anyway, but they have the feeling that this is a way to get the small farmer to pay for the sins of the big agricultural conglomerate.

Mr. HUBBARD. I do not think country-of-origin labeling works. I think it should not be, first of all, a substitute for safe food. No matter where the food comes from, it should be safe. And Canada has country-of-origin labeling, and I saw a bottle of olive oil the other day. It said "product of Canada". I don't think you are going to find many olive trees in Canada or in a hothouse, because in Canada, they allow the final value to go into what country is labeled. And so 51 percent of the value of that bottle of olive oil is Canadian, so it says product of Canada. And there are lots of other examples around the world.

And the other issue is that if you had country-of-origin labeling, I think that would be an administrative nightmare for Customs or FDA or whomever to enforce it. Because you would be wasting resources chasing all these labels around. As you saw from the wheat gluten, very easy to change a label or fake a label.

In fact, one of the big problems with these Chinese product is the difficulty tracing back because they find counterfeit labeling, counterfeit shipping invoices. And that is true in the drug world as well. So I don't see labeling being an answer. We need safe food, not better labels, in my view.

Mr. BURGESS. Well, I appreciate your testimony, and I know I am over my time. If they are growing olive trees in Canada, that global warming thing may be worse than we thought. I will yield back my time.

Mr. STUPAK. Mr. Walden for questions please.

Mr. WALDEN. Thank you, Dr. Burgess. I want to thank all of you for being here today. Mr. Hubbard, you mentioned in your testimony the FDA-regulated food imports are approaching 13 million entries a year, I believe. What percent of our American food supply does that represent?

Mr. HUBBARD. I think about 15 percent of our total food supply is imported from other countries.

Mr. WALDEN. One-five?

Mr. HUBBARD. One-five.

Mr. WALDEN. Fifteen percent?

Mr. HUBBARD. Yes, 15.

Mr. WALDEN. OK, how many of the food illness outbreaks are related to imported food?

Mr. HUBBARD. There is no decent data on that. CDC generally can only identify about 5 percent of food-borne outbreaks to their source. I think certainly FDA has found examples of raspberries and mushrooms from China, or raspberries from Guatemala, mushrooms from China, seafood from Asia where there have been specific illnesses. But I don't think anyone has a decent database that says food from this source or this source are more or less dangerous.

Mr. WALDEN. Do you think that the meat products we are exporting to China represent a food threat?

Mr. HUBBARD. I certainly wouldn't think. The American beef industry would say so, and I think that the meat industry in this country meets these regulations. USDA requires Cohassa which are state-of-the-art controls for ensuring safe meat. So, no, I think that our exports are very safe.

Mr. WALDEN. This is probably out of your realm, but I read a story today that China has now stopped allowing the importation of certain meat products. So do you think that is maybe more in retaliation of our concerns over the poisoning of the dog and cat food and—

Mr. HUBBARD. Well, there certainly has been speculation to that effect. It is very clear the Chinese have been stung by this, and they did mix messages. Some officials in their health industry have acknowledged there are lots of problems with their food. Others have said wait a minute, our food is not so bad either. And that implies that they are going to be looking at more American food. These trade issues do get thorny as you know.

Mr. WALDEN. I am aware of that. I actually have supported country-of-origin labeling, and I appreciate what you had to say in opposition to that. But I will tell you as a consumer, it does affect my purchases where it is labeled. I do a second look. Maybe I shouldn't, but I do because I think about well, what are the food safety requirements of that country? What do their ag producers do versus what we do? And who is inspecting this stuff coming in? And you all have sat here today and basically said our food supply safety is in peril if you are relying on imported foods.

So I am at a loss how you can sit here and tell us that we are not going a good job, that we are 1 or minus depending on where you are at, and then say but don't worry to the consumer. You don't need to know where it is coming from, and I am not trying

to throw a big rock at any particular country. But it just strikes me that, as consumers put a lot of pressure on a country too. And I understand China has some pretty tough laws, regulations, but they don't have enforcement mechanisms. Is that an accurate assumption?

Mr. HUBBARD. I have talked to trade officials who tell me that the central government is woefully incapable of regulating out in the hinterlands.

Mr. WALDEN. Right.

Mr. HUBBARD. You know an estimated one-half million small producers of food in China, some of which export to other countries, and then the central government simply cannot reach to these small farmers. Said in some cases, it might be someone who might produce four or five bags of wheat gluten a week. We are talking about essentially a farmer making something in a shed behind his house that gets rallied into a larger distribution point. And so to try to regulate an entity like that efficiently for sanitation and other means is just an enormous task.

Mr. WALDEN. And so to whom should that task fall, the United States taxpayers through FDA to inspect these coming in or not, Ms. DeWaal?

Ms. DEWAAL. Thank you. First of all, I did participate in an export consultation with the Chinese Government. Their food law is in the process of being modernized, but what Mr. Hubbard said is all accurate about the failure to regulate.

What U.S. consumers though are looking for is a system whereby they can trust the food that is coming here. So that has got to start at the country of origin, and we can't rely on the Chinese Government or the Indian Government. So it has really got to be through a certification program where either governments, like for example Australia or New Zealand have very up-to-date food systems. They could certify for the whole country potentially. Or individual plants might get certified to ship product in. And there is legislation currently that has been introduced that Congress is currently considering to do that.

Mr. WALDEN. Because I know I have talked to some food processors in my State who say we have to track everything clear back—if it is peaches or pears or something, back to the box it came from in the orchard. And they make the thing that goes into various food items that are manufactured, and they have told me look, we already have to have these data available to us. And other countries require us to label everything as the country of origin and document everything. And it always sort of confused me that if our producers have to do that to get into many industrialized countries, why wouldn't we protect our consumers coming this way.

How big does FDA need to be to guarantee safety and move up that chart? You have all told us that you are at a 1 or minus 1 or 2 or 3 or 4 in terms of safety. So how big do you have to be, and how many more labs do you need?

Mr. HUBBARD. Well, I will begin the answer, which is a few years ago we did do an analysis and well, what would the ideal food safety system look like? How many inspectors would you do? How many scanners would you have? How many imports would you look at? And that suggests that about a doubling of the agency. That is

out of date now, but clearly it is a big number. If you really want to fix it I am afraid, there is going to have to be a substantial increase in staff and other scientists to fix the problem. And that includes lots of inspectors.

Ms. DEWAAL. And it is not just the number that is important; although, the number is important.

Mr. WALDEN. Sure.

Ms. DEWAAL. It is also modern mandates, and the work of this committee is very important to ensure the FDA is actually working off of a law, off of legal structures that are more modern. And so it is going to require both authorizing and appropriation.

Mr. WALDEN. It just seems to me we are working off a 1906 strategy to protect American-raised meats. That worked great, cleaned up the problem, gave us safety and security. And now we are importing this enormous amount of food from countries that may not have anything close to what we had back in 1906 even today. And now all of a sudden we are at peril when we go into local groceries store potentially or buy dog food for our animals. And I think most Americans are going what happened? How did this get to this point? I have way overshot my time, Mr. Chairman. Thanks for your indulgence. Thank you.

Mr. STUPAK. The gentleman from Oregon, Mr. Melancon, for questions.

Mr. MELANCON. Thank you, Mr. Chairman. And I guess I might go back and visit what I had asked Mr. Hubbard if you can maybe help me with this. I heard your explanation about the country of labeling concern that you have. Would that be for all products or could you at least find the ability to police bulk products or for instance the gluten was brought in large sacks. If you had to go look at every bottle of olive oil, I think it would be tough.

Mr. HUBBARD. First of all, there is absolute validity to the concept of the bulk product that the shipping invoice says as they come through Customs into the FDA should show country of origin. I fully agree with that. I think the question really is should the consumer see it on the label. There is some country-of-origin labeling for seafood. But with all of these ingredients in foods, it is very difficult to do that.

Plus the manufacturers bring all these products from different sources. I saw a country-of-origin labeling on a jar of apple juice the other day, and it said apple juice from Turkey, Greece, Germany, United States, China, and a couple of other countries. So what that meant was they were buying from all those sources, mixing it all together.

And I think to tell the food industry that they would have to separate all that and label each bottle differently would just be a logistical nightmare for manufacturers. Plus you have got to understand the ingredients. Soft drinks contain something called gum araby which comes from places like the Sudan and Somalia. Are you going to put product of Sudan on there? I don't think you are going to see the soft drink guys wanting to do that, but there are these products in soft drinks.

Mr. MELANCON. Well, the soft drinks guys didn't want to put fructose and/or sugar. They wanted to leave you believe it was sugar, but they were selling you fructose for a bunch of years. But

all that took was a change in the computer program. It is easy enough. And I agree. Maybe that is where people like yourself can help us find some remedies to some of this to where there is documentation by the importers and exporters, the product manufacturers where there is a trail. When we get a tag on a cow that came from Canada, we know where to go look for the disease and to track it where it came from. So it has got to be—if it can be done on a cow, it can be done on products.

But the other thing that has always bothered me in international trade is vital sanitary. Why does our country walk away from that issue and doesn't want to put it in any agreement? Or so it appears to me.

Mr. HUBBARD. Well, there are trade agreements that set vital sanitary standards and—

Mr. MELANCON. But the Europeans are not using those with the same standards that we have in America.

Mr. HUBBARD. I think the problem is, as Ms. DeWaal said, the current law doesn't give FDA authority to impose its standards on the exporter. The paradigm is that FDA can open the container, examine the food, and refuse it if it is unsafe or contaminated or appears to be unsafe. It doesn't allow FDA to go to those other countries and say here are the standards you must meet. We can do that for meat, but we cannot do that for the FDA-regulated products.

Mr. MELANCON. And I think that is why we are here today to talk about what we need to do to bring these standards up to modern times if you would and try and make sure that our food supply is safe. And from a standpoint of dealing with other countries, and you obviously have had some of that experience, is there some way to put the mandates on there, to have laboratories that are either accredited or some way or another controlled by FDA to make sure that there is not collusion, that we are not getting fish that has actually been shipped around the world three times before it finally lands somewhere because they are trying to avoid inspection? Anybody want to address that? Mr. Hubbard, if you have some thoughts.

Mr. HUBBARD. Well, obviously certifying labs would a good thing. If the facts are accurate that these laboratories are not up to snuff, that certainly needs to be fixed.

Ms. DEWAAL. Can I just add I mean we have a different model for import inspection at USDA. And while that model may not completely fit all FDA-regulated products, it is certainly that, I think, this committee should look at as they move forward. There are different models than the one FDA is using, and I think it is just a matter of putting those pieces together.

Mr. MELANCON. Is there someone in the—probably not in the agency because they have got their own model that they are designing. Can we look to someone that can give us an objective viewpoint, past experience, seeing what was good, seeing what was bad, maybe giving us some insight views on why we need to do things? My personal feeling is we need to constrain the number of ports that we have of entry for different products or confine entry of certain products to certain ports so that we can have expertise on the ground there.

This thing of backing off, if we are going to back off, just bring everybody back to Washington, let them sit in an ivory tower surrounded by the Beltway. And we will never know what is going on out there at the ports. Of course, that speaks something for what DHS does sometimes, but that is a whole other issue. Now, I see my time is running out, but thank you for your input. I hope that maybe we could look to some of you to help us with devising the mechanisms legislatively that will protect America's food in the future. Thank you, Mr. Chairman.

Mr. STUPAK. I thank the gentleman. We will go for a second round of questioning if anyone has further questions. Mr. Hubbard, if I may, you are the associate commissioner of policy, planning, and legislation. In the mid 1990s, Mr. Dingell, myself, we all had legislation on trying to strengthen these laws to give the FDA the authority that the USDA has to impose inspection fees, to make sure the countries have same standards we have in this country. But yet you always opposed that legislation. Why was that? Now you are saying we should have this stuff. When you were in the position to do something as associate commissioner, you opposed us.

Mr. HUBBARD. Well, certainly there were provisions that the administration opposed, and as the administration official, I needed to support those. But I think we agree with you on a number of—

Mr. STUPAK. Well, are you testifying now as concerned citizen or if you were still associate commissioner, you would not be here today?

Mr. HUBBARD. I think I worked with your staff on a number of items of legislation in this area that we absolutely agree with you on. The most important one, you may recall, was one that was often dubbed USDA Light, which say that FDA could, if it found repeated instances of contaminated food from a given country, it could then say to that country you have now earned your right into further regulation. You can't send any more of that food that we found to be contaminated until you have shown that you would fix the problem at your end.

Mr. STUPAK. Sure, why should we accept food from countries that don't have the same standards as us?

Mr. HUBBARD. And I thought that was a very reasonable concept.

Mr. STUPAK. But you didn't support it.

Mr. HUBBARD. Well, no we absolutely supported it, but Congress didn't—

Mr. STUPAK. Let me ask you this. Do you support inspection fees where the USDA gets their money to do this inspection system? Do you support inspection fees?

Mr. HUBBARD. Speaking for the Coalition for a Stronger FDA, I don't have a position. But personally, yes, I think anything that can get the FDA the resources it needs to do more inspectors is a good idea.

Mr. STUPAK. No, on your testimony—you don't have it numbered, but fifth to last page, you talk about the current budget request for fiscal year 2008 as a good example of recent trends. Although the official budget request states it includes an additional \$10 million for food safety, the food program's inflation needs are not covered by this request. But if we did \$10 million, what good is that if the

FDA is going to give away \$9.5 million in bonuses to drug approval process? So the money that should be going into food safety is going for bonuses in another part of the FDA without some control over that money. So what is an extra \$10 million going to do if they are going to give it away anyways like has happened in 2006?

Mr. HUBBARD. So the \$10 million in inadequate to fix food safety. In fact, it doesn't even offset their inflation at cost.

Mr. STUPAK. Well, during your tenure as associate commissioner, you approved retention bonuses for some FDA employees, didn't you?

Mr. HUBBARD. I don't recall approving any. I received one my last year or so, but I—

Mr. STUPAK. Well, don't you remember approving the retention bonuses for Margaret Glavin, director of FDA's Office of Regulatory Affairs?

Mr. HUBBARD. I may well have.

Mr. STUPAK. In 2003, you signed off on a retention bonus of Ms. Glavin. That amounted to more than 12 percent of all the top bonuses of ORA. Is that correct?

Mr. HUBBARD. I don't recall. I didn't have any control over ORA, but the retention bonuses were intended to try to induce people to stay that might have retired or otherwise left the agency.

Mr. STUPAK. OK. Well, look at tab 59 there in that big book right there. We have it all there where you approved those bonuses, and your logic for that for Ms. Glavin was that you were signed off on her bonus, and the justification was it indicated that she would seek employment in a private sector if the FDA could not provide a salary comparable to a top Government affairs executive. In other words, Ms. Glavin, the way to retain her was to give her this bonus, and it was calculated not based upon top Government affairs executive, but based upon the average income of a lobbyist in Washington, DC. It is in tab No. 59. You want to look at that and answer that one for me?

Mr. HUBBARD. Would you like me to take a moment to look at it now?

Mr. STUPAK. Sure.

Mr. HUBBARD. Hand me the book.

Mr. STUPAK. Third page in, under tab 59, page 3 you will see your signature on there about Ms. Glavin's bonus.

Mr. HUBBARD. Before I read this, we had recruited Ms. Glavin from the Department of Agriculture where she had been a senior official, and we felt she could be a tremendous benefit in the bio-terrorism area. But one of the inducements was to—obviously when she was freemarketable outside the agency, the law allows an agency to give people a thing called a retention bonus which says if you will stay and then you agree to a certain amount of time to stay, you will receive this \$10,000 or \$20,000 bonus.

Mr. STUPAK. Correct, but Congress did not intend \$10 million for a food safety program that would turn around and be used for \$9.5 million in bonuses for drug approval. That is completely separate divisions. That is what happened in the last year.

Mr. HUBBARD. I can't link the food safety request to Ms. Glavin's retention bonus but—

Mr. STUPAK. Well, if you go on to read that there, you said you based it upon what a lobbyist would make, so therefore are we now basing retention bonuses not on value but on where a lobbyist is because we don't have an exact description of a top executive—

Mr. HUBBARD. The principle was to try to get people a slight bump up in pay to induce them to stay yet another year or another year and not retire at that point.

Mr. STUPAK. Let us go on to country of labeling. You said you are not in favor of that, but the 2002 farm bill actually had country-of-origin labeling and a schedule to be implemented in 2004. For 5 years, that COOL, as they call it, country-of-origin labeling for meat, produce, and peanuts have been blocked. In fact, in fiscal year 2004, House agriculture appropriations included the language to prohibit implementation.

And then we brought a bipartisan amendment to strike the provision failed 193 to 208. And then again in June 2004, House Agriculture Committee Chairman Goodlatte introduced legislation H.R. 4576 to repeal the mandatory COOL and make it voluntary. Yet 92 percent of the people in the country want country-of-origin labeling. They want to know where their food comes from. Don't you think the American people have a right to know where their food comes from?

Mr. HUBBARD. You are absolutely correct if people say they do want that, and the seafood provision in COOL went into effect.

Mr. STUPAK. Yes, it did.

Mr. HUBBARD. The others have not, and I—

Mr. STUPAK. There hasn't been these problems that you complained about with COOL under seafood, has it? It worked pretty well.

Mr. HUBBARD. That is a whole food, and I think it probably worked reasonably well for a whole food.

Mr. STUPAK. My time is up. Mr. Whitfield, any questions?

Mr. WHITFIELD. No, sir.

Mr. STUPAK. Mr. Burgess, any questions?

Mr. BURGESS. Yes. First, Mr. Chairman, may I ask unanimous consent that my opening statement be made part of the record? I wasn't here when you—

Mr. STUPAK. Absolutely. And also Senator Durbin who also wanted to testify today has submitted his statement. So I will put that in the record also at the same time. Thank you.

Mr. BURGESS. OK, and there is no particular relevance, but since it is in the evidence binder, if everyone can turn to tab 70 and see the insightful letter that I wrote to you, Mr. Chairman, I think that would be instructive about Tommy the Train. That is not a food item, but we are concerned about imports from China.

Mr. Hubbard, I have one last thing to follow up on your testimony. In 1999 with no prospect for additional funds for food imports and a rising tide of incoming products, the agency drafted a legislative proposal. It would have given the FDA authority to require foreign countries to take more responsibility. I really think that is a key point here. If there were some way to hold accountable those countries who are guilty of the most egregious behavior, perhaps they would have an incentive to not behave in that way. As you say in your testimony, countries have demonstrated a pat-

tern of disregard of U.S. safety standards would have to step up their oversight of food exported from their country. Congress did not accept the recommendation, and indeed no hearings were ever scheduled.

Would you include this as a hearing on that matter?

Mr. HUBBARD. I sure hope so. I sure hope you take a look at it. The concept was that a country that had no problems would have no problem, would do nothing additional. But a country that kept sending bad food here would be told you are going on essentially an embargo list until you fix the problems at your end. So don't put the food on the boat to send to us until you have shown us that you have corrected the problem over at your end.

And they would essentially earn their way into a stricter regulatory regime, which I thought made a lot of sense at a time.

Mr. BURGESS. But if you couple that with a risk-based assessment here in our country, as opposed to simply trying to cover—assuming everything is bad and trying to cover every eventuality. One last thing I just wanted to ask about since you and Mr. Stupak were talking about numbers. You had mentioned the number of \$131 million for food safety research centers, which I believe is in this year USDA appropriation.

Mr. HUBBARD. It is in the President's budget request to Congress. \$131 million for food safety research that would go to the Department of Agriculture.

Mr. BURGESS. OK, and in the Department of Agricultural appropriation bill, my understanding is that number is pretty close to the President's request.

Mr. HUBBARD. I understand that to be the case too, yes.

Mr. BURGESS. And the actual number reported out of committee for food inspection is a little bit lower than that. Is that not correct?

Mr. HUBBARD. It is \$28 million, and then if you subtract the inflation cost the program will have, which is \$14 million, under the subcommittee action, the food safety program will get an increase, as I understand it, of \$14 million, which is not a lot, but it sure helps.

Mr. BURGESS. But does that reflect an imbalance then of putting this money toward the food safety centers? Why would there be more of an effort to fund that activity as opposed to the inspectors?

We heard the other side talking about needing cops on the beat, and it would seem to me you don't need the precinct house if you don't have enough cops on the beat to further that analogy. Well, we are going to be voting on that bill, and again I think these are numbers that are reported on committee. So it is important to bring it up, and it is important for Members to understand exactly what they are voting on. Do you think is there any opportunity to try to—on the appropriations bill, is it open rule? We can amend these things as they come through? Would you like to see some of the money perhaps moved from the food safety research centers to the food inspectors?

Mr. HUBBARD. Speaking personally, absolutely. I think that food safety research is important. But when the crisis is facing us, that FDA doesn't have a strong food safety program. Anywhere you can

find funds to beef that up, in my view, is a good idea. But I think you will get push back from the USDA folks.

Mr. BURGESS. From the USDA? Are these food safety research centers in any way, are they part of the earmark process? Do Members ask for those in their district?

Mr. HUBBARD. I don't know. I am not familiar with their process.

Mr. BURGESS. Well, again I really appreciate you being here. I appreciate your valuable insight. You have been at this problem a long time, and I think you brought a lot to this hearing. I thank you for being here. I will yield back, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Burgess. Mr. Markey, a member of the full committee, wishes to ask questions, I think, of Mr. Clavet. You can state your objection. Wait a minute. I want to hear from Commissioner von Eschenbach as much as anybody because I have a lot of questions for him, but it is a courtesy given to anyone who is a member of the full committee, they are not allowed to give opening statements, but they are allowed to ask questions. I certainly would wish that Members would come from the opening bell to the last bell so we could do it in an orderly process. Unfortunately, that is the way it goes. OK, objection overruled. Go ahead, Mr. Markey.

Mr. MARKEY. I thank the gentleman very much, and I hope everyone appreciates that I am not allowed to speak until the very last moment so it makes no difference if I arrive in the beginning. I can only speak at this moment after everyone else is done. So that is the courtesy I, as the subcommittee chairman, give to every Member as well.

What is unique, Mr. Clavet, about the Winchester Engineering and Analytical Center? Can you move the microphone over please?

Mr. CLAVET. It is unique because it is the only FDA regulatory lab that does analysis for foods and for radionuclides. It is the only laboratory that does it, and besides that, we are also the only laboratory—there is no other—that does medical devices from an engineering, chemical, biological, microbiological perspective.

Mr. MARKEY. Now, when I was a boy and I had no scientific ability at all and I wanted to do a science fair project as an over-achieving sophomore, I went over to the Hood Milk Company where my father drove a truck. And they explained to me that because the United States and Soviet Union were exploding these nuclear bombs that Linus Pauling and others said that the stronskium 90 was being carried by clouds, going down into the grass, cows were eating the grass, and children were now drinking the milk with stronskium 90. So in addition to homogenization and pasteurization, we needed also a stronskium 90 remover.

And I did the science fair project with my father's help, of course, because I had no mechanical abilities either, but I got honorary mention. I was only a sophomore, and this was actually a chemistry thing for the juniors. So I was quite proud of myself, and I am not saying it is exactly because of me, but 1 year later, the United States and Soviet Union signed the Atmospheric Nuclear Test Ban. I am not taking full credit for it, but I think it is related.

And so here now we have a new threat from Al Qaeda, new threats of dirty bombs, new threats of potential nuclear meltdowns, and what is the FDA doing? The FDA is actually shutting down,

by the way 2 miles from my house, the very facility, the only facility in the country that has the capacity for doing the testing for radiological impacts on children across the country.

It seems so, Mark Twain used to say that history doesn't repeat itself, but it does tend to rhyme. And so this rhymes a lot with the people who really did not understand how important that danger was back in the late 1950s and early 1960s. Can you give the committee some examples of when the Winchester lab has tested food for radiological contamination?

Mr. CLAVET. Well, during the Chernobyl incident, the WEAC laboratory insured that the food in this country coming from that area was safe. During the Three Mile Island incident, the Mass Bay foul area survey, we participated in that. And the recent outbreak—not the recent, UK poisoning of the Soviet KGB agent, the CDC asked us to participate and stand ready to assist them and to help them develop a method for food analysis for polonium 210.

Mr. MARKEY. Great. So the same kind of partnership that Kennedy constructed with Khrushchev you have with the former Soviet Union as well; although, we are not sure who actually gave that polonium over but—who used it on who, but who utilizes the capabilities of Winchester?

Mr. CLAVET. Well, State and local governments, ORA, all the field laboratories, the inspectors using TLD badges utilizes WEAC's capabilities, the CDC, the Department of Defense, USDA FSIS, Food Safety Inspection Service. We have an agreement with them to analyze food in case of an emergency. One of the important things is we have a lead lab in the FERN, which is the Food Emergency Response Network for radiological and terrorist acts. We are the lead laboratory.

Mr. MARKEY. What do we lose, Mr. Clavet, if this laboratory shuts down?

Mr. CLAVET. You will lose the ability to oversee the FERN for one thing. You will lose our radiological component of the FDA.

Mr. MARKEY. Have they given you a reasonable explanation yet from the FDA why they are going to shut it down?

Mr. CLAVET. I can't say. No one has really told us why we are closing.

Mr. MARKEY. Mr. Clavet, I sincerely appreciate your willingness to come forward and to testify today at a time when the FDA has been struggling and in many occasions, failing to keep the Nation's food supply safe from contamination. It is totally unacceptable to further weaken the FDA's field operation and inspection system by closing this critical field lab. I am very concerned about the FDA's proposed plans and look forward to getting answers from the commissioner as to why he thinks it is a good idea to shut down the Winchester laboratory when it serves such an important and unique public health function. Mr. Chairman, I thank you for your graciousness, and I yield back the balance of my time.

Mr. STUPAK. Thank you for your questions. Ms. DeGette, your questions.

Ms. DEGETTE. Thank you, Mr. Chairman. I apologize for my absence. I was downtown speaking about an issue that everyone here would care about, which is conflicts of interests. And I was speaking to high-level researchers who I suggested they might perfect

the cloning technique so that we could all be both in the hearing and making speeches and on the floor.

I want to extend another welcome to Ms. Collins for being here today, and I want to follow up on Mr. Markey's question about the Massachusetts firm lab because the Denver lab is also a member of the FERN network. Correct, Ms. Collins?

Ms. COLLINS. That is correct.

Ms. DEGETTE. And tell me about the kind of work that the Denver lab does with the FERN network.

Ms. COLLINS. We do both microbiological as well as chemistry. We test foods. We test feeds. We have an extensive amount of work that we do to help with the FERN capabilities.

Ms. DEGETTE. And so that is a different type of FERN work than the Massachusetts lab does, correct?

Ms. COLLINS. A little, yes.

Ms. DEGETTE. And, as I understand it, Denver will be the only full-service FERN lab that would be closed under the current plan?

Ms. COLLINS. I believe that San Francisco is also FERN laboratory.

Ms. DEGETTE. But that lab is not scheduled to be closed.

Ms. COLLINS. Yes.

Ms. DEGETTE. It is? OK. Now, after the recent food safety outbreaks, did the Denver lab have any involvement with those outbreaks?

Ms. COLLINS. Yes, absolutely we did.

Ms. DEGETTE. Could you describe that for me, Ms. Collins?

Ms. COLLINS. Well, of course, we had a lot of work to do with melamine. We had facilities within our district that had contaminated products with melamine that we had to go out and inspect and collect samples. Additionally, one of the most important things that we did was in the Animal Drug Research Center or ADRC. We developed the methodology to test for melamine in animal tissue, and the remarkable thing about that was when we were able to do that within 72 hours after we started on the project so that we could test immediately what was in animal tissue, fish tissue, in order so that there would be a method out there for our laboratories, for international laboratories, State laboratories, and even private labs.

Ms. DEGETTE. And why do you think that you were able to develop that method within 72 hours?

Ms. COLLINS. Several reasons. One is the dedication of the staff to get the job done. Second was the amount of expertise that we had from the three Ph.Ds that work in ADRC, and the fact that one of those Ph.Ds has been with us for a long number of years and is very experienced in developing these kind of processes.

Ms. DEGETTE. Now, how many employees are located at the FDA's Denver lab?

Ms. COLLINS. We have anywhere from I think it is about 47 or 48 right now.

Ms. DEGETTE. And how many of them are experienced Ph.Ds like the one you have been talking about?

Ms. COLLINS. We only have three Ph.Ds. We do have several specialists that are at the GS-13 level pay grade. We have quite a bit

of experience just in our chemistry section alone. Most people have an average of 22 years experience.

Ms. DEGETTE. Of all those experienced folks, how many of those are going to be willing to relocate to other parts of the country after the closure of the FDA's Denver lab?

Ms. COLLINS. Personally, I have only heard one person within that group that said that they would be willing to move.

Ms. DEGETTE. And so in your opinion if the Denver lab is closed and that one person moves and everybody else leaves or finds something else to do, what impact is that going to have on our ability to research these different issues?

Ms. COLLINS. It will be tremendous.

Ms. DEGETTE. Can you give me a couple of examples of things that people do who have said that they won't relocate?

Ms. COLLINS. Well, we have the drug residue testing. We have antibiotic resistance testing. Antibiotic resistance testing is only done in Denver district. We have seriology testing. There is only one other lab that does that.

We have several things like that that will be lost, and so when you move those processes to other laboratories, you are going to have to train the people that are either there, or you are going to have to bring in new people. And if you bring in novice employees, chemists, microbiologists like we have, then you have got to train them. And that is going to take approximately 3 years to get them at what we consider the journeyman level to be able to do this work.

It is very complex. It requires experience, and you can't pull someone off the street to start doing this in any less than 3 years with confidence.

Ms. DEGETTE. Thank you. That is about all I need to know. I appreciate you coming today.

Mr. STUPAK. That is all the questions for this panel. Thank you all very much, and thank you for your expertise in the field you testified on today. Thank you. I will now call our third panel of witnesses to come forward.

On our third panel, we have the Honorable Andrew von Eschenbach, Commissioner of the Food and Drug Administration, Mr. Stephen Mason, Acting Assistant Commissioner for Legislation at the FDA; Margaret Glavin, Associate Commissioner for Regulatory Affairs at the FDA; and Dr. Robert Brackett, Director of the FDA's Center for Food Safety and Applied Nutrition.

It is the policy of this subcommittee to take all testimony under oath. Please be advised all witnesses have the right under rules of House to be advised by counsel during their testimony. Do any of you wish to be represented by counsel? Everyone is saying no. Please take the oath.

[Witnesses sworn]

Mr. STUPAK. Let the record reflect all witnesses answered affirmatively. They are now under oath.

Commissioner von Eschenbach, I understand you are going to take the opening statement for all. Is that right?

Dr. VON ESCHENBACH. Yes, sir.

Mr. STUPAK. Did you want to give an opening? But first before you do, thanks for being here today. I know you stayed through the

whole thing. Hopefully you learned a few things. Hopefully we all learned a few things, and I am sure with your testimony we will learn a few more things. And I know you had to be at the Senate at 2 o'clock, and you moved it back for an hour. We appreciate that. Hopefully we can get this in. There are a series votes to be coming up here fairly soon. So if you would want to begin with your opening statement, sir. Thank you again.

TESTIMONY OF ANDREW C. VON ESCHENBACH, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY STEPHEN MASON, ACTING ASSISTANT COMMISSIONER, LEGISLATION; MARGARET O'K GLAVIN, ASSOCIATE COMMISSIONER, REGULATORY AFFAIRS; AND ROBERT E. BRACKETT, DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

Dr. VON ESCHENBACH. Thank you very much, Mr. Chairman, and I do appreciate the fact that this has been a very long day for everyone, and it is testimony to the importance of this hearing. I want to thank you and all the members of the committee for your attention. And I do also want to express my gratitude for your consideration of my prior commitment to testify at the Senate, and the fact that I will be able to leave at 3 o'clock

With regard to my statement on behalf of the Food and Drug Administration, I am very pleased to be joined at the table by Margaret Glavin, our FDA's associate commissioner for regulatory affairs, and Dr. Bob Brackett, the director of FDA's Center for Food Safety and Applied Nutrition because I think they are very critical and key to many of the questions and issues that have been raised today. And they will actively participate on behalf of FDA to provide the committee with insight into these very important issues. And Mr. Mason has also joined us.

The Food and Drug Administration came into existence in this country 100 years ago, in fact, because of critical problems in the safety of our Nation's food supply. And over that past 100 years, the agency has had to constantly adapt and respond to emerging challenges, but I am here today very proud to lead an agency that is, in fact, recognized around the world as the gold standard for ensuring the health of our food and our medical products.

But I am not here today, Mr. Chairman, to defend the FDA of the past but to continue the discussion with you as to how to create an FDA of the future. Because once again, FDA is facing challenges that have been brought on by recent changes in the production, distribution, and consumption of food.

Today, we no longer bring home spinach to be washed multiple times and cooked before we eat it. But rather we purchase a bag off the shelf, take it home, open it, turn it over, and dump out the fresh cut spinach or lettuce along with the salad dressing and immediately eat it raw. We have become accustomed to being able to walk into a supermarket 365 days a year and purchase fresh fruit and watermelon, even though they are not grown in this country during the winter months.

The American people will not go back to previous practices. And, in fact, given the importance of fresh fruits and vegetables in our nutrition and diet, nor should they. Recent events have riveted our

Nation's attention on the fact that the modern production, distribution and consumption techniques and patterns have created not only unique health benefits but also unique risks. And once again, FDA is challenged to rapidly and effectively respond to this changing reality around us.

How does an agency like FDA respond to these recent events while continuing to maintain an exceptional record of promoting and protecting the public health? Well, in short, Mr. Chairman, we also, the FDA, must radically and rapidly change. But change is difficult and requires meticulous planning, and it is also painful to implement. Let me just mention some of the changes that we have engaged in to attempt to respond to these challenges.

You reflected on the fact that I created within the Office of the Commissioner the new role for coordinating food safety work across the entire agency by appointing Dr. David Acheson to the newly created position of assistant commissioner for food protection. This is not simply window dressing, but Dr. Acheson's role is to provide leadership to create an agency-wide strategic planning protection plan that builds on the excellence that already exists in our centers, like CFSAN, like the Center for Veterinary Medicine, ORA and all of the rest.

This plan will enable FDA to be engaged in quality assurance through the total life cycle of food from its very production all the way through to consumption. If you will, FDA's commitment is to be engaged from farm to fork. And to do that in the context of a comprehensive, well-developed plan that includes prevention so that we can eliminate food safety problems by building quality into our very production of food, intervention strategies that will preempt problems by virtue of enhanced inspections and detection, and certainly enhancing our response to any outbreak. This plan will also address domestic as well as imported foods.

And we clearly must build on the quality not only of production but also in strengthening our surveillance and detection, particularly by paying very close attention to our ability to have a modern, well-equipped field force of the 21st century.

Much is being discussed today about FDA's proposal to modernize our laboratory capabilities. These are intended for the sole purpose of strengthening our capability to increase and enhance our frontline inspections, giving our inspectors modern tools of science and detection along with better systems of communication, while streamlining and enhancing and modernizing our backup laboratory facilities so that we can serve this entire Nation with an infrastructure that is now modern and adequate.

We recognize in this planning process not only the need to come forward with an importantly well-developed strategy, but we recognize that these will require additional resources. We have been persistent in requesting additional resources and have received such in 2007. We are grateful for Congress's consideration of our 2008 increases, and we are working with the department and the administration to prepare our 2009 implementation plan and additional resources.

Let me be clear that we are also examining our legal authorities. We recognize that we must explore ways to use our current exist-

ing authorities more efficiently, more effectively, and with greater clarity.

Second, we must work collaboratively and cooperatively with other agencies and their opportunities and their resources, and it is not our intention to work and function in a vacuum. This is particularly true with our ability to address food imports.

Last May when we held the strategic economic dialog with China here in Washington, DC, Secretary of Health and Human Services Michael Leavitt, Secretary of Agriculture Michael Johanns and myself met simultaneously with all the Chinese leaders and counterparts to begin to address the important problems that have been referred to today with regard to our increasing awareness of imports of food and other products from China.

FDA is working with the Department of Health and Human Services towards creating a memorandum of understanding with China to enhance ability to build quality into these products before they are shipped to this country. Secretary Leavitt will be going to China in December. I am going to be there in October. We recently last week had a meeting here of our bilateral counterparts in China.

And third, we are in fact examining whether we need new authorities that will enhance our ability to oversee our food supply. Current authorities that make it possible for us to be more effective with regard to being adapted to our food defense activities for imported food, being able to look at issues as to whether voluntary recall structure provides sufficient incentives in a global marketplace, and what we need to do to help to continue to enhance the prevention aspects of our effort by building quality at the outset.

We are working very hard at a comprehensive food protection plan, and it is a process that is iterative and underway as we speak. And I look forward to continuing to work with you and other Members of Congress and other stakeholders, and especially the staff of the Food and Drug Administration to further refine, develop, and implement these comprehensive plans.

I look forward to continuing to even more effectively dialog with this committee by providing documentation immediately upon being requested. I have changed the policy within the agency so that we respond immediately to requests for documents even if we are not able to provide the full complements of the documents requested.

I have appointed Matthew Lyons in our Office of Legislation to specifically oversee and take responsibility for an accelerated effort in our oversight activities. I have created an agency taskforce that will bring components of the agency together to specifically focus on the preparation and rapid dissemination of these documents.

And most recently, I was able to procure additional resources on a temporary basis from the Department of Health and Human Services that quite frankly enabled us to be able to meet more recent demands without further deploying people from their daily commitments to the overwhelming mission of responsibilities that you have heard about today.

We at the FDA must and will radically change and will do that in an ongoing dialog in consideration to do the right thing and to do it in the right way. Thank you, Mr. Chairman.

[The prepared statement of Dr. von Eschenbach follows:]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF
ANDREW C. von ESCHENBACH, M.D.
COMMISSONER OF FOOD AND DRUGS
FOOD AND DRUG ADMINISTRATION
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

JULY 17, 2007

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning, Chairman Stupak and Members of the Subcommittee. I am Dr. Andrew von Eschenbach, Commissioner of Food and Drugs at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). I am pleased to be joined here today by my Agency colleagues Dr. Robert Brackett, Director of the Center for Food Safety and Applied Nutrition (CFSAN), Ms. Margaret Glavin, Associate Commissioner for Regulatory Affairs, and Mr. Stephen Mason, Acting Assistant Commissioner for Legislation. We appreciate the opportunity to discuss FDA's food safety activities and the transformation initiative underway in FDA's Office of Regulatory Affairs (ORA), which will enhance FDA's ability to prevent and respond to food safety problems.

In my testimony today, I will describe FDA's role in food safety and some of the efforts we have underway to help prevent future outbreaks. I will also describe how ORA's proposed transformation will support and enhance our food safety programs.

The Office of Management and Budget (OMB) and the relevant food safety agencies are collaborating on ways to most effectively address issues raised in the General Accountability Office's (GAO) designation of Federal Oversight of Food Safety as a high-risk item in February 2007.

FDA is committed to ensuring that America's food supply continues to be among the safest in the world. In recent years, we have done a great deal to protect the food supply from both unintentional and deliberate contamination. We have made significant progress, but the 2006

and 2007 outbreaks of foodborne illness in humans due to contaminated fresh produce and peanut butter and the illnesses in pets due to contaminated animal food, as well as the problem of potentially harmful drug residues in farm-raised Chinese seafood, underscore the need to develop new multidisciplinary and integrated food safety strategies at FDA. These new strategies are necessary to meet the challenges created by changes in the global food supply; changes in farming, manufacturing, and processing practices; and changes in consumer demographics and needs.

Because I am committed to ensuring that the U.S. food supply remains safe and secure, I recently created the new position of Assistant Commissioner for Food Protection. I have appointed Dr. David Acheson to that position. Dr. Acheson's first priority is to develop a new strategy for food safety and food defense that will address changes in the global food safety and defense system, identify our most critical needs, and serve as a framework to help us address the challenges we face. Our goal is to augment our current comprehensive and robust food protection program in a way that is tailored to meet the risks posed by the types of foods we regulate. I expect the plan to focus on efforts by industry to prevent food problems, and FDA interventions that provide the tools and science necessary not only to head off outbreaks of foodborne illness but address intentional contamination as well, and also to ensure compliance with preventive controls that are designed to stop problems before they arise. The result should be a stronger preventive national food protection infrastructure capable of rapid response when contaminated food or feed is detected, or when there is harm to human or animal health.

Although the outbreaks since last summer presented challenges to FDA, they also demonstrated FDA's ability to respond quickly and effectively to protect consumers. Upon becoming aware

of a foodborne illness outbreak associated with FDA-regulated products, FDA's Emergency Operations Center (EOC) coordinates the Agency response, providing a central point in the Agency for managing the early phases of an emergency so that crucial information can be shared and acted upon immediately by appropriate FDA offices. This enables FDA to initiate investigations quickly; often the same day as developing information is obtained. The EOC coordination also enables FDA to base public health messages on real-time up-to-date information. It provides technical experts within FDA with access to both investigational and analytical data to facilitate their ongoing evaluations with the goal of making appropriate recommendations to prevent further illness and adverse impact to human and animal health. EOC staff are available on an around-the-clock basis. As appropriate, FDA works closely with our sister public health agency in HHS—the Centers for Disease Control and Prevention (CDC)—the states, and other agencies, in any emergency response.

During last fall's foodborne illness outbreak of *Escherichia coli* (*E. coli*) O157:H7 associated with fresh spinach, FDA investigators were in spinach processing facilities in California the day after CDC notified us of the outbreak. Similarly, when CDC informed FDA of a multi-state outbreak of *Salmonella tennessee* apparently associated with Peter Pan peanut butter, FDA sent investigators into the ConAgra peanut butter plant the next day. The Agency warned consumers the day after CDC notified us of these outbreaks. When Menu Foods, a pet food manufacturer, notified FDA that it was conducting a recall of certain pet food due to illnesses and deaths of cats and dogs, FDA initiated an inspection of the Menu Foods manufacturing facility the next day and notified consumers within 48 hours.

Although FDA has demonstrated its ability to respond quickly to protect public health, the outbreaks have shown that a great deal more needs to be done to enhance prevention of problems at the source.

FDA'S ROLE IN FOOD SAFETY

FDA's mission is to promote and protect the public health. Ensuring that FDA-regulated products are safe and secure is a vital part of that mission. FDA is the Federal agency that regulates everything we eat except for meat, poultry, and processed egg products, which are regulated by our partners at the United States Department of Agriculture (USDA).

Although FDA has the lead responsibility within HHS for ensuring the safety of food products, CDC has an important complementary and non-regulatory public health role. CDC is the lead Federal agency for conducting disease surveillance and outbreak investigations and routinely monitors the occurrence of specific illnesses in the U.S. attributable to contaminated foods within the food supply. The disease surveillance systems coordinated by CDC, in collaboration with states, provide an essential early-information network to detect and minimize the impact of foodborne illness outbreaks.

In addition to working closely with CDC, FDA has many other food safety partners – Federal, state, and local agencies; international food safety partners; consumers, academia; and industry.

FOOD SAFETY FROM FARM TO FORK

To reduce the risk of foodborne illness at all points in the food chain, FDA has adopted a “farm-to-fork” approach to food safety. This approach systematically applies risk management principles at each step as food moves from growers and producers to consumers.

FDA has focused its food safety efforts in three key areas:

- strengthening the scientific basis for FDA’s food safety program with a focus on prevention;
- enhancing effective partnerships, both domestic and international; and
- improving risk-based targeting of inspection resources.

I will elaborate on these below.

Strengthening the Scientific Base for FDA’s Program to Improve Food Safety

Improving the effectiveness of FDA’s food safety program requires strengthening the science base that supports FDA’s food protection work. FDA’s food safety science program involves a number of intramural and extramural efforts, which can play a major role in reducing levels of foodborne illness. For example, FDA has conducted research focused on: (1) identifying mechanisms of contamination of fresh produce with pathogens and preventing contamination; (2) identifying effective interventions to address contamination that has occurred; and (3) developing fast and sensitive analytical methods for the detection of pathogens on fresh produce. The results of FDA’s research help the Agency develop, implement, and evaluate policies designed to improve food safety. They also help maintain FDA’s awareness of emerging issues and enable the Agency to respond rapidly to emergencies.

Extramural collaborations allow FDA to make its resources go further and use those resources more efficiently to address food-related safety concerns, and to prepare for new and emerging issues. For example, for the past decade, FDA has worked closely with USDA's Agricultural Research Service (ARS) and Cooperative State Research, Education, and Extension Service (CSREES) to coordinate and mutually support our respective science efforts related to produce safety. This relationship allows FDA to augment its resources and scientific laboratory expertise. During the outbreak of illness associated with spinach last fall, we were able to capitalize on that ongoing relationship by collaborating with ARS and CSREES to analyze water samples from the Salinas watershed for *E. coli* O157:H7 and to relate the location of bacteria to geographical, seasonal, or rainfall variation. An extension of this research will look for sources of *E. coli* O157:H7 in California's Salinas Valley. As part of our plan to be more proactive about food safety, we will use information obtained from this study to inform produce growers about strategies to prevent pre-harvest microbial contamination.

We strengthen the scientific base for our program through collaborations and also by participating in many scientific and technical meetings on food safety. In February, for example, we participated in a forum sponsored by the Western Institute for Food Safety and Security to share information on assessing industry approaches to address the safety of lettuce and leafy greens on the farm and at packing, cooling, and processing facilities. Also in February, the FDA-affiliated Joint Institute for Food Safety and Applied Nutrition and the University of Florida sponsored a workshop to improve understanding of how tomatoes become contaminated with *Salmonella* and other pathogens. And on May 30 and 31, FDA, the National Center for Food Safety and Technology, and the University of Georgia's Center for Food Safety

co-sponsored a workshop on microbial testing to reach a consensus on the role of microbial testing to ensure the safety of produce.

In response to the recent outbreaks associated with fresh produce, FDA held two public hearings on March 20 and April 13 of this year. The purpose of these hearings was for FDA to share information about the recent outbreaks of foodborne illness related to fresh produce and to solicit comments, data, and additional scientific information on this issue. We are soliciting input from all our stakeholders on ways to improve the safety of fresh produce and the Agency is currently evaluating the comments we received in response to these hearings.

Enhancing Effective Partnerships

To succeed in our science-based efforts to promote food safety, we need to enhance our collaborations with stakeholders interested in food safety. For example, fresh produce is produced on tens of thousands of farms, and contamination at one step in the growing and processing chain can be amplified at the next step. One of the key elements of FDA's 2004 Produce Safety Action Plan calls for efforts to improve communication and collaboration with all our food safety stakeholders. FDA has worked with the public and private sector to encourage industry to follow the recommendations and standards contained in FDA guidance documents. After enlisting the help of the scientific community and the industry, FDA published the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." This guide, published in 1998, recommends good agricultural practices and good manufacturing practices which growers, packers, and shippers can take to address common risk factors in their operations. FDA and USDA issued the guidance in several languages and have

conducted significant outreach, both domestically and internationally, to encourage its implementation. In addition, FDA has assisted industry in developing a number of commodity-specific food safety guidelines for the commodities most often associated with foodborne illness outbreaks. These include guidelines for lettuce and leafy greens, melons, and tomatoes. Industry is currently working on similar guidance for herbs and green onions, for which FDA is providing technical input.

The following example of fresh alfalfa sprouts illustrates how successful these efforts can be. In 1999, there were 390 reported illnesses associated with eating contaminated fresh sprouts. FDA published two guidance documents for sprouts that year. In 2004, only 33 illnesses were reported associated with fresh sprouts and, in 2005 and 2006, there were none. We believe that the subsequent decline in sprout-associated illnesses was in large part due to the industry's adherence to the recommendations FDA provided in those guidance documents through our outreach, inspection, and sampling efforts. In addition, maintaining this low incidence requires FDA's continued outreach and industry vigilance. Although no set of actions can be expected to prevent all outbreaks, we believe that adherence to this guidance will likewise reduce the risk of future outbreaks.

FDA's efforts in this area are ongoing. In March, FDA issued a draft final version of its "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" (the Fresh-cut Guide). This guidance is intended for all fresh-cut produce firms, including, among others, those that process fresh-cut spinach and lettuce/leafy greens, to enhance the safety of fresh-cut produce by minimizing the microbial food safety hazards. In addition, because food safety is truly an international public health issue, the FDA-led Delegation of the United States to the

Codex Committee on Food Hygiene spear-headed the request from the Codex Alimentarius Commission (the international food safety standards body) to the Food and Agriculture Organization/World Health Organization (FAO/WHO) for an expert consultation on the microbiological safety of fresh produce to support the development of commodity-specific annexes to the hygienic code. FAO/WHO just announced that this consultation will occur during 2007 and early 2008.

In August 2006, FDA launched its "Lettuce and Leafy Greens Initiative," which assesses practices and conditions at select farms and facilities in California, in collaboration with California's Department of Health Services and its Department of Food and Agriculture. FDA launched a similar Tomato Safety Initiative in Virginia and Florida on June 12 of this year. We will continue to work with Federal, state, local and international food safety partners and with industry to develop guidance, conduct research, develop educational outreach materials, and initiate other commodity- or region-specific programs to enhance the safety of fresh produce.

In response to the contamination of pet food and animal feed, FDA has worked closely with a broad partnership that includes scientists in government, industry, and academia and with 50 state departments of agriculture, health authorities, veterinarians, and the Association of American Feed Control Officials. We are utilizing data from Banfield Pet Hospital (a nationwide network of veterinary hospitals), the Veterinary Information Network, Poison Control Centers, universities, and other organizations to assess the extent of the outbreak of cat and dog illnesses and deaths.

FDA scientists recently worked with the Food Safety and Inspection Service of USDA, CDC, the Environmental Protection Agency (EPA), and the Department of Homeland Security (DHS) to develop a risk assessment to evaluate the risk to human health from consuming pork, chicken, fish, and eggs from animals inadvertently fed animal feed containing pet food that contained melamine and melamine-related compounds. The assessment found that this consumption is very unlikely to pose a human health risk. The risk assessment is an important new science-based component of the continuing federal joint investigation into imported wheat gluten and rice protein concentrate from China that contained melamine and melamine-related compounds. On June 14 the Science Board, which is an FDA Advisory Committee, met to review and discuss the risk assessment and its subsequent peer-review. The Board concurred with the findings in the report, including the low probability of risk to humans, analysis of risk to the food supply and methods used in the assessments. The Science Board also made recommendations for additional research for future assessments.

In addition, the FDA/USDA Food Emergency Response Network (FERN) has continued to grow and enhance the nation's food testing capacity. FERN is a network of Federal, state, and local laboratories capable of testing food samples for microbiological, chemical, and radiological threat agents. This partnership provides essential analytical expertise and surge capacity during emergencies. The FERN network proved to be a critical asset in the *E. coli* O157:H7 outbreak associated with fresh spinach. FERN analysts worked closely with CDC's Laboratory Response Network personnel to harmonize and approve a modified FERN method for detecting *E. coli* O157:H7 in spinach. This method allowed for substantially improved testing of spinach samples as it allowed for the detection of *E. coli* O157:H7 at lower levels.

FDA is also a significant participant in international food safety standards organizations such as the Codex Alimentarius, assisting in the development of international standards that reflect the level of food safety protection equivalent to domestic standards. These international standards are vital to the safety of foods imported into the U.S. FDA also provides foreign countries with training in all aspects of food production, technology, transportation and consumer advice.

Recently, concerns have been elevated about the quality and safety of products imported from China. HHS and FDA are currently planning negotiation of a Memorandum of Understanding (MoU) with relevant regulators in China to address food and feed safety as well as a separate MoU on medical product safety.

Office of Regulatory Affairs's (ORA's) Transformation: Improving Risk-Based Targeting of Inspection Resources

ORA is the lead organization within FDA responsible for enforcing FDA's public health laws and regulations. ORA supports FDA's public health mission by maximizing compliance of FDA-regulated products and minimizing risks associated with those products. ORA's activities include conducting inspections, collecting and analyzing samples, initiating investigations, overseeing recalls, taking enforcement actions, and monitoring the entry of regulated products at our nation's borders.

Today ORA faces significant challenges in carrying out its public health mission. In the 21st Century, we are confronted with increasingly complex products manufactured through highly technical processes and requiring stringent controls. These products are no longer produced

exclusively in America; there is an increasing volume of products from overseas, often from countries with emerging regulatory systems. New food pathogens and counterterrorism responsibilities place an additional burden on our traditional regulatory process. And the challenges arising from these changes promise to become even more complex and difficult to address.

ORA's field organizational structure and the methods and tools it employs date back 40 years -- to a time that pre-dates the tissue transplant industry, pre-dates computerized implantable medical devices such as defibrillators, and pre-dates the year-round availability of fresh produce and other products from all over the world. ORA is at an historic crossroads -- with unprecedented challenges and opportunities before it. The volume and complexity of our work has never been greater. In order to continue to meet today's challenges successfully and to respond swiftly and effectively to new threats and public health emergencies, we must adapt and become a more dynamic, flexible, and responsive organization. This means transforming ORA, adapting and improving its tools, methods and technologies to meet the expanding and ever-changing aspects of its mission to protect the health of the American people.

Enhancing risk-based approaches, as a systematic means of prioritizing our work to maximize public health impact, is a key element to meeting the challenges of today and tomorrow. ORA, together with CFSAN, have made great strides in focusing our food safety work where it has the greatest impact on protecting the public. But there continue to be significant opportunities to enhance our risk-based approaches. We must develop more flexible, mobile and adaptable approaches to getting the job done, including approaches that improve our efforts to target high risk products to protect the American public, and approaches that leverage our resources through

enhanced collaboration with domestic and foreign regulatory counterparts. New tools must include the use of risk management analyses to refine and focus inspection strategies; increasing data mining for more effective monitoring of imports; increasing the number of foreign establishment inspections; updating the capabilities and efficiency of our regulatory laboratories; and expanding partnerships with states and other regulatory bodies to augment existing inspection capabilities.

Our transformation proposal calls for streamlining management in the field. Doing this will reduce management and overhead costs, while allowing us to support the same, or even greater, number of inspections and to invest in assuring that our employees have the skills, tools and training they need to do their jobs. Our proposal will significantly enhance our capability to assess and rank risks in order to improve the targeting of our inspection, enforcement, and analytical resources. The need to increase the use of risk-based approaches is especially acute for imports. And because responding to public health emergencies will continue to be a priority for ORA, our plan will enhance our capacity to work with state and Federal partners to better manage and coordinate FDA's emergency response activities. Our plan will multiply the impact of all of our resources by enhancing partnerships with our regulatory counterparts and stakeholders, both domestically and abroad. In 2003, FDA worked with state counterparts to create the California Food Emergency Response Team (CALFERT), which includes inspectors and analysts from ORA's San Francisco and Los Angeles District Offices and the California Department of Health Services' Food and Drug Branch. Because this model was so successful during the *E. coli* O157:H7 outbreak associated with fresh spinach, we are pursuing ways to expand this concept.

ORA's transformation proposal, if implemented, will improve our analytical capacity and capability by creating from our existing thirteen field laboratories a strengthened, enhanced network of six centrally managed state-of-the-art regulatory laboratories. Because the Committee has expressed particular interest in the laboratory consolidation, I would like to provide some additional information about this component of our transformation.

As I have already stated, ORA must have well-equipped and well-maintained state-of-the-art regulatory laboratories that can quickly and effectively analyze a high volume of regulatory samples and that can adapt swiftly to emerging threats and challenges. With rapid package delivery services widely available, these laboratories do not need to be near every sample collection site. Indeed, given that we collect samples in literally thousands of locations, it is not possible to have a laboratory in close proximity to every collection site. FDA's mobile labs have been an extremely valuable resource to this Agency, and have proven their effectiveness in responding to emergencies. They complement FDA's traditional laboratories and provide flexibility for emergency response.

The six enhanced laboratories are dispersed geographically throughout the country. They have sufficient space to accommodate all of our analysts and equipment, including those from the seven labs from which people, work, and equipment will be transferred. Currently, FDA pays costs associated with approximately forty percent more laboratory space than is needed to conduct all of the laboratory work performed in support of all of FDA's field programs and activities. In some cases, the existing laboratories are housed in older buildings that require higher-than-average maintenance and repair costs. Reducing the number of laboratories for which FDA pays utilities, maintenance, and security costs will enable us to invest in up-to-date

equipment and the maintenance of that equipment; high efficiency sample throughput technologies to increase analytical speed and capacity; development of new methods to detect emerging threats; better training for our laboratory analysts; and the development of rapid screening methodologies for use at ports of entry and elsewhere. Consolidating our work into six laboratories whose capacity will meet and even exceed the capacity of FDA's 13 existing field laboratories will strengthen and increase ORA's analytical capabilities to meet the challenges of the 21st Century.

FDA values its dedicated workforce, and every analyst from a closing laboratory will be offered a job in the laboratory to which his or her work is transferred. Although we realize that some employees will choose not to relocate, there may be opportunities for them to compete for positions in the same or nearby locations, in other high priority and currently under-resourced program areas such as inspections and import review work. The laboratory consolidation will be implemented over a two-year period, and we are now developing detailed implementation plans designed to limit any adverse impact on our analytical work. These plans will allow us to adjust for changes in workflow and laboratory efficiency as the process moves forward so that we will be able to meet our obligations and continue laboratory operations in a seamless manner.

CONCLUSION

FDA is working hard to ensure the safety and security of food, in collaboration with our Federal, state, local, and international food safety partners, and with consumers, industry, and academia. As a result of this effective collaboration, the American food supply continues to be among the safest in the world. Although we have made progress, much remains to be done. The recent

incidents of contaminated food and animal feed demonstrate the challenges we face and the need to move toward a food safety and security system that is even more proactive and strategic, with a field force that is trained and equipped to focus on the challenges of today and tomorrow.

Mr. Chairman, as a firm believer in continuous improvement, I can assure you that FDA will be up to the challenge. I appreciate the opportunity to discuss FDA's food safety activities and the ORA Transformation Initiative today. My colleagues and I would be happy to answer any questions.

Mr. STUPAK. Thank you. Anyone else care to give an opening statement at this time? OK, we will go right to questions.

Mr. Commissioner, you indicated you are going to China in the fall. I would suggest maybe you want to go August 17 with our investigators. They are going to China to work just on food safety and also drug safety. Could some of your people accompany them on this trip or yourself?

Dr. VON ESCHENBACH. Yes, sir. I would be happy to entertain it. I mentioned my own participation, but there is other participation that is underway as well. And we would be happy to work with you and the committee staff to accommodate that.

Mr. STUPAK. OK, the other thing that you heard today Members are—I have a whole series of questions on documents we have not received. Ms. DeGette has mentioned documents she has not received. I think most of us have mentioned documents we have not received. So this individual you have selected to provide documents is not providing documents.

Dr. VON ESCHENBACH. I was concerned when I heard Ms. DeGette's comments, and I must confess it was my understanding that the particular documents I thought she referred to had been provided to you. But I will double check on that to be certain.

Mr. STUPAK. Well, we are still looking for documents from the peanut butter case, ConAgra. We are looking for documents from Ketek. There are numerous documents I am looking for with Accutane. There are a number of things we are looking for, not just all food safety, but there is a number of them

Ms. DEGETTE. And if the chairman will yield. It is not even just documents. I sent the FDA a letter on the 24th of January with Senator Salazar and Congressmen Udall and Perlmutter about the Denver lab closure that I never received a response to. On June 12, 2007, there was a hearing on medical devices, and I asked if I could submit questions. And the FDA representative said that they would respond to them, and I have never since then received that information. And at that same hearing then, I was talking about a May 16, 2007 hearing, and that was post-market surveillance for medical devices relating to children and other kinds of things relating to children. And frankly, sir, I haven't received any responses to any of those requests.

Dr. VON ESCHENBACH. Well, Congresswoman, please accept at this point that it is my intent and absolute commitment that we be completely responsive to the appropriate requests of this committee and every other appropriate request by committees in Congress. And we have, as I indicated in my opening remarks, recognized that the very intensive effort that is currently underway has placed great strain on us, and I am attempting to respond to that as rapidly and as quickly as possible.

One letter that is unresponsive to is one letter too many, and I want this agency to be responsive to your appropriate requests, and I am working towards that. And I will certainly look into those specific issues personally, but I am anticipating that we will get this down to zero defects.

Ms. DEGETTE. I appreciate my chairman yielding, and I yield you some of my time. Thanks.

Mr. STUPAK. Mr. Commissioner, there are 12 agencies that we know of that deal with food safety. Have you been coordinating your efforts with these 12 agencies?

Dr. VON ESCHENBACH. We have been working very extensively, for example, with USDA to continue that relationship, and I think that was very apparent—

Mr. STUPAK. USDA. Who else have you been—

Dr. VON ESCHENBACH. One of the other important elements has been CDC as it relates to outbreaks and illnesses. That is another important part. So we have continued to look at various opportunities. A lot of discussion has—

Mr. STUPAK. Have you asked these 12 agencies about your reorganization plan, about whether these labs should be closed? You started off talking about spinach, but yet the lab that is responsible for the spinach by Salinas Valley is one you want to close.

Dr. VON ESCHENBACH. One other point was raised earlier today, and I want to emphasize. We are working very closely with the Department of Homeland Security because of the issues that were discussed earlier about Customs and border protection.

Mr. STUPAK. Right, so why do you want to close the West Chester lab?

Dr. VON ESCHENBACH. With regard to reorganization, I know a great deal has been raised today about that reorganization proposal, and I want to make it very clear that this is intended for one purpose and one purpose only. And that is to bring FDA's laboratory infrastructure into the 21st century. I personally went to a laboratory in New York when I first took over this position and asked them how did they inspect seafood for its freshness. And I was told that we use taxpayer dollars. Somebody goes out to the docks and goes around and buys seafood, shrimp, brings it back to the laboratory, and then we have an expert there who smells it and determines whether it is fresh or not.

That, Mr. Chairman, is not my view of the FDA of the 21st century.

Mr. STUPAK. That is why Mr. Dingell and all of us had legislation after legislation in the 1990s trying to bring the FDA into the 100th year of it, not 1906 standards. And FDA has always fought us on those. You wouldn't even comment on our legislation. It was a non-starter.

Dr. VON ESCHENBACH. May I give you one example as to some of the misconceptions that I think have occurred in today's testimony about what we are trying to do?

Mr. STUPAK. I don't think—

Dr. VON ESCHENBACH. This is not to eliminate laboratories or eliminate the ability to test products. It is to be able to consolidate science in a way that our laboratories are much more effective, but at the same time to increase our inspection force out there on the cutting edge and to do it by giving them the modern tools of science and technology with which they can actually do these analyses—

Mr. STUPAK. By closing these labs, how are you going to increase your inspection field?

Dr. VON ESCHENBACH. Let me give you a specific example.

Mr. STUPAK. Sure.

Dr. VON ESCHENBACH. Today, this bottle of water—and we have recently had a problem with a concern of arsenic contamination of water being imported from another country. The way it happens today is an inspector seizes or takes a bottle of water. It has to be sent to a laboratory and undergoes laboratory analysis that takes hours, and then finally there is a report. We have a modern tool of science and technology that we can deploy to inspectors in the field and by simply pointing this instrument at this bottle, it can register whether there are any heavy metals like arsenic, possibly strontium, and do that rapidly and efficiently in the field. That doesn't require a laboratory.

Mr. STUPAK. That is great, but my question is how many employees or inspection people will have those little handguns so you can go do his thing by closing these labs?

Dr. VON ESCHENBACH. My expectation and intent with regard to the strategy that we are employing, which is to create state-of-the-art, multidisciplinary, well-staffed laboratories with modern robotic technologies. And then deploy many, many more investigators and inspectors than we currently have at all of the ports where we never could have that opportunity.

Mr. STUPAK. What number? That is what I am looking for.

Dr. VON ESCHENBACH. Well, we have talked—

Mr. STUPAK. I won't have to ask you all these questions because if the FDA would have provided the information we asked on our reorganization plan, we wouldn't have had to have all these questions. They provided us zero information because it is pre-decisional. So we have no information on your reorganization plan even though we have been promised time and time and time again we will have the information before this hearing. It will be timely. It will be worthwhile. It was pathetic, to say the least, what we received.

Dr. VON ESCHENBACH. Well, Mr. Chairman, as I indicated in my opening statement, our reorganization and our strategic plan is a proposal. It is in process. It is being developed. There are parts and pieces of it that have become public, for which we have been looking at response and reaction, and quite frankly, this hearing has been a very important part of that giving us impact and insight from the inspections that occurred that your staff carried out.

These plans will need to be further refined and developed, but the expectation is although the changes may be painful, we cannot depend on the current laboratory system that exists today to carry out the responsibilities of tomorrow. And this will require change, consolidation, reorganization, but not loss of function.

Mr. STUPAK. My time is up, but when you have these plans, give them to the committee. And most of all, give it to your lab people so they know what is happening. There is probably nothing worse than FDA employees not knowing what their future is and no one knows why they are being let go. In fact, in your testimony, you said these were backup labs that could be duplicated elsewhere, done elsewhere. Watch that word. I don't think West Chester or some of these others would consider themselves a backup lab. With that, I will turn to Mr. Barton.

Mr. BARTON. Thank you, Chairman Stupak. Welcome, Commissioner.

Dr. VON ESCHENBACH. Thank you, sir.

Mr. BARTON. I have a series of questions on the issue at hand, but I want to first pile on a little bit with Ms. DeGette and Mr. Stupak on non-response to letters. Back on April 18, Mr. Whitfield and myself wrote you about the issue of FDA warning letters and what the appeal process is, how many companies have appealed an FDA warning letter. We asked you a series of, I think, three or four questions. I have to get in line with Congresswoman DeGette and Congressman Stupak. We have not received a response either. Could you check into that? This is an April 18 letter from Mr. Whitfield and myself, and I assure you that we are asking for factual information in this letter. But there is no hidden agenda. We are not trying to "got you" the agency.

Dr. VON ESCHENBACH. Thank you, sir. May I apologize to you and the committee. It is not our intention to withhold information. It is not our intention to be delinquent in immediate response to you, to every member of this committee, and to the entire Congress.

In defense of what has occurred at FDA, we happen to be in an extremely intensive period of time with regard to the request for documents and information from the agency. And at the same time we have been engaged in many significant legislative changes like for our FDARA et cetera, our appropriations.

Mr. BARTON. We may complain once we get your answer, but we are darn sure going to complain if we get no answer.

Dr. VON ESCHENBACH. Well, and I am attempting within that context, without diverting people from missioncritical activities day in and day out, to shift resources, find resources, find systems and processes so that we are not delinquent in response.

Mr. BARTON. We are the committee of jurisdiction, and this is the subcommittee of oversight. And any reasonable response effort in your office would prioritize responses to members of this subcommittee and which Congresswoman DeGette is a senior member, Mr. Stupak is the chairman, Mr. Whitfield is the ranking Republican, and I am the ranking Republican on the full committee. So we ought to be somewhere up in the hierarchy of you get an answer to us even if it is an answer that is going to upset us.

Dr. VON ESCHENBACH. Mr. Barton, I fully respect and appreciate the authority that this committee exercises, and it is not my intention to, in any way, shape, or form—

Mr. BARTON. I don't want to belabor it, but we will get you a copy of the letter before you leave. And we hope you will reply. My policy questions are dealing with how to modernize the FDA process for inspecting and overseeing the food imports. In my opening statement, I listed four points that I wanted the FDA and the committee to consider if we decided to move in a legislative approach. In a nutshell, I suggested that we do something to make our good manufacturing processes information more available internationally. We do something to help profile the foreign food control agencies and their processes for food safety inspections before it leaves their country. And third—this is one that I think is very important—that you consider separating the foreign inspection activities and setting up a separate office just for foreign inspections. And then fourth, that you consider issuing a rule on the import alert

program and specifically make a determination if you need congressional legislation, can the FDA detain shipments from overseas without physical examination. Do you care to comment on any of those ideas?

Dr. VON ESCHENBACH. Yes, sir. I took notes during your opening statement, and we will be happy to address those in great detail. Let me just say at the outset I recognize the importance of really strengthening our ability to build quality into the products that are being produced outside of our borders but that ultimately come to us.

I was in Belgium and met with the European Union and the European Commission, signed a memorandum of understanding with our counterparts there with regard to food safety and food protection so that we will be mutually sharing and interacting with regard to information.

I indicated earlier about the important role we will be playing in developing relationships with our counterparts in China to contribute to their ability to put a system in place that will assure the quality of what comes to our borders, as we also strengthen the protection at our borders. So I am committed to increasing foreign inspections, to increasing our foreign presence, and our interaction with our foreign counterparts to build quality in at the outset.

Mr. BARTON. My time has expired. I just want to ask one final question on the closure program or the reorganization program that there have been some questions about. Three or 4 months ago, you and your staff came by and briefed me on that, and I think you also briefed Mr. Whitfield. I suggested that you brief Mr. Dingell and Mr. Stupak. I know you attempted to set those meetings up. Were those meetings ever successfully set up, and have the majority also received a briefing that you gave to myself and, I think, Mr. Whitfield?

Dr. VON ESCHENBACH. I have not had the opportunity personally to be able to brief Chairman Dingell or Chairman Stupak, but I have continuously encouraged our staff to find opportunities to do that at a staff-to-staff level. But, no, I have not had an opportunity.

Mr. BARTON. All right, is there a reorganization formal proposal that is in written form, or is this still an internal concept within the agency?

Dr. VON ESCHENBACH. The reorganization is still very much an internal document in terms of its development, and I call it a proposal. We have crystallized it to the point where we have specific initiatives that we are now presenting as options and opportunities, and there clearly have been discussion about each of those in terms of its own unique features.

I think what is important to point out is this is not a workforce reduction plan. This is not being done simply to save money. Just the opposite. It is being done to sort of enhance our ability to respond to the challenges that we now are facing.

Mr. BARTON. Well, I think Mr. Stupak's comment is well taken. If you are really going to try to implement it, the sooner you formalize it and let the people know what it is, the greater the potential for having it accepted and having less kickback from the political system. When it is a great unknown, everybody is going to oppose because there is no certainty. It is just normal for Congress-

men to try to protect projects and facilities in their district, but it is also quite possible that if there is a coherent, well-organized plan that makes sense, you can get a majority of the committee to support it.

Dr. VON ESCHENBACH. Well, I very much appreciate that advice and wisdom, and we will continue to follow that principle. I would also add, of course, that one of the other things I want to be clear about is that we are not closing laboratories with the idea of eliminating functionality. This is not the case, and I think that just occurred with the discussion of our ability to address radionuclear materials and health.

It is to be able to consolidate our assets in a way, enhance our assets in a way that gets the maximum impact, but that will require change. And it may require movement and shifts of those resources so that we have a national network, not a regional or local network. And when Ms. DeGette related to the issues, for example, in Denver, clearly it is not a factor that that laboratory is inadequate or the people have not been exceptional. In fact, they have been.

But as you pointed out, there are three Ph.Ds in that laboratory, and quite candidly, that is not necessarily critical mass for the kinds of things that we need to be able to analyze and do at these reference laboratories as we move forward into the future. So how do we create that kind of modern, multi-disciplinary infrastructure is very difficult and very painful, and I welcome critical input as well as reinforcement when it is appropriate.

We are also looking at asking independent organizational management experts to look at this and view this and give us the benefit of their perspective as well before we carry this forward as a concrete proposal to Congress to be implemented.

Mr. STUPAK. Ms. DeGette for questions.

Ms. DEGETTE. Thank you very much, Mr. Stupak. I think that we have beat the lack of response issue to death, and I am really serious, Dr. von Eschenbach. We just need to get this resolved. I think you have that message.

I want to ask you some questions about the topic of the hearing. The first thing I want to ask you, one thing you said that I agreed a lot with what you said is that the FDA is reviewing its current levels of authority, particularly with respect to food safety to decide whether it needs more authority. As you may know, I have been working on a bill for several years to give the FDA mandatory recall authority with respect to meat. But now I am actually getting ready to reintroduce the bill, giving broader authority for mandatory recall of all food.

Do you think that kind of authority would help maybe prevent some bad actors from trying to sell contaminated food?

Dr. VON ESCHENBACH. This is precisely one of the areas that I was referring to, and I do agree with you that this is an area of the impact of a mandatory recall authority for FDA and its ability to take care of the bad actors, if you will, is one of those explicit things that I am hoping to pursue.

Ms. DEGETTE. When I talk to people about how the FDA doesn't currently have mandatory recall authority, they are shocked because they are thinking about the Consumer Products Safety Com-

missioner. And it seems like if we can recall child safety seats, we should be able to recall food. Would you agree with that?

Dr. VON ESCHENBACH. I do, and we have been fortunate in that the voluntary system has worked exceedingly well, and voluntary recalls by the manufacturers and producers of food have worked well. We just recently had one with baby food where Gerber, without any intervention on our part, voluntarily took the initiative to remove a product they were concerned about.

The issue I would like to pursue is exactly the one that you raised, which is if there are “bad actors.” Those are the ones we want to focus on.

Ms. DEGETTE. But even with legitimate actors, at the peanut butter hearing we had, while it is true that the company voluntarily eventually recalled the peanut butter, if the FDA had mandatory recall authority, I bet you there would have been much faster cooperation.

Dr. VON ESCHENBACH. Possibly so.

Ms. DEGETTE. I want to talk to you for a minute about—I know you will be shocked—the Denver lab closure, and you talked to several members about this is a modern era, we need to look and see whether we are working the most effectively.

The thing is though, as I understand it, these regional labs don’t all do the same thing. Is that correct? The Denver lab does some different things than San Francisco or Massachusetts or the other labs, correct?

Dr. VON ESCHENBACH. That is correct.

Ms. DEGETTE. And at least in looking at, you know, I live in a State where everybody wants to live there in Colorado, which is part of the reason you are having a hard time getting your senior scientists to be willing to relocate. But the way that private business is operating is with the advent of electronic communications and computers, people are more and more working from remote locations. It seems to be, if you want to look at a modern era of working, oftentimes you can effectively and efficiently use smaller locations that network together. And I am wondering if the FDA has looked at that kind of alternative for some of these labs where you have scientists who have years and years of experience?

Dr. VON ESCHENBACH. Yes, if I may with your permission, I would like to turn the microphone over to Ms. Glavin who has, for the past 2 years, really been working through this in a layer-by-layer fashion. And the answer to your question is yes, we have looked at it, and I would like her to give you the detail.

Ms. GLAVIN. Certainly some of the proposals to have some districts remain in place but report into another district are exactly what you are talking about so that we don’t need as many managers, and we can have more cops on the beat I think was the term you used earlier.

With respect to labs, of course, working at home isn’t really an issue.

Ms. DEGETTE. Well, I am not talking working at home.

Ms. GLAVIN. Right.

Ms. DEGETTE. The Denver lab is at the Denver Federal Center, which is a secured facility with a number of Federal agencies there.

Ms. GLAVIN. Right.

Ms. DEGETTE. And my question is if you have the expertise there, if you have senior scientists who have been there for 20, 25 years and put down their roots, why wouldn't you want to try to find a way to help them do that job and reporting in and working with other agencies, which they are apparently doing very effectively now?

Ms. GLAVIN. Well, and I agree that that can be done from a variety of locations, but as the commissioner has said, we have labs in 13 locations at this point. And that makes it very hard to have a coordinated approach, and we would like to see if we can bring people together, provide them with the tools and the technology that they need and deserve to do 21st century science.

Ms. DEGETTE. And just one last question. Has the FDA considered the balance of the hope of bringing people together doing 21st century science with the deep loss of expertise that the FDA is going to suffer when it closes these offices?

Dr. VON ESCHENBACH. Yes, we have, and can I just add specifically, I think your point about there being three Ph.Ds in that laboratory in Denver, and the question we have to ask is would they benefit by being nested with a lot of other Ph.Ds with other kinds of disciplines that would enhance their impact, and at what loss? What would we give up in that regard? And I think that the other side of that is can we give them an infrastructure that is adequate? Can we give them modern facilities that have robotics so that they could high throughput analyses and things of that sort?

It is the people, and they are the most important. But then it is also the infrastructure that we provide for them.

Ms. DEGETTE. But there—

Dr. VON ESCHENBACH. It is a little bit of all of that.

Ms. DEGETTE. There is nobody else that does what—

Mr. STUPAK. OK, got to go now. Other Members have to ask questions.

Ms. DEGETTE. I would ask unanimous consent for just 15 additional—

Mr. STUPAK. Seconds. I am counting.

Ms. DEGETTE. There are only three people that do that job, and those are those three Ph.Ds in Denver. Has anybody talked to them about whether they are going to leave and become nested in the robotic area?

Dr. VON ESCHENBACH. I can't speak specifically to a conversation with those three people. We would want those three people to move if that was what was necessary because we don't want to lose those people. This is not about losing expertise or eliminating function.

On the other hand, if they don't, we have to believe that there are at least in this country three other Ph.Ds that we could attract and recruit to the modern, sophisticated, 21st century environment. That is the strategy that we are applying.

The chairman asked me about our reorganization plan and other agencies. Well, we talked a lot about the USDA with all of its array of inspectors, and yet it only has three laboratories. And we are talking about going from 13 to 6.

Ms. DEGETTE. Thank you.

Dr. VON ESCHENBACH. USDA has three.

Mr. STUPAK. Mr. Burgess for questions.

Mr. BURGESS. Thank you, Mr. Chairman. Dr. von Eschenbach, too let me commend you for being here through this entire day, and I know we have kept you a very long period of time. I cannot recall having ever seen the head of a Federal agency who has been made to sit through three panels, and it is a testament to your abilities and willingness to get this problem solved. And I appreciate so much you being here and listening to the testimony today. If I could, it is on my mind because I heard—it was either CNN or NPR this weekend—the two little girls who ate the contaminated spinach from out in Salinas, CA year. And it kind of brought home to me again that there was actually a problem that was sort of identified earlier before that outbreak had occurred. And somewhere along the line, we sort of lacked the follow-through to make certain that that was taken care of. Do I remember that correctly?

Dr. VON ESCHENBACH. I quite honestly can't recall to testify that that is a correct recollection.

Mr. BURGESS. But we had in testimony that we had when we did the first series of hearings on this last spring. Said in November 2005, the FDA sent letters to growers, packers, and processors and shippers, warning them to improve safety in view of continuing outbreaks. The agency wrote we encourage firms to consider modifying your operations accordingly to ensure that they are taking the appropriate measures to provide a safe product to the consumer something we would all be in favor of. What can we learn from that experience? How can we make sure that those products are indeed safe? Are there other tools that you need that you need us to give you so that going forward, we can be certain that that doesn't happen?

Dr. VON ESCHENBACH. Well, as I indicated in my opening statement, in addressing this radical change that has occurred in production and consumption and distribution of food, the fact that there is no such thing anymore as made in America, made in China. It is more assembled, and even the products we are talking about have ingredients that come from all over the place. We have to look at this in a comprehensive way, and that is why I talk about production to consumption or farm to fork.

So that we have a multipronged strategy to address this across that entire continuum. One of the things FDA has not in the past is really emphasize the front end of that, emphasize prevention. And so prevention is going to be an extremely important part of the plan that Dr. Acheson will be bringing forward.

And part of that prevention is to work with the producers in terms of these good agricultural practices based on science that Dr. Brackett is formulating so that we can assure that we are enhancing the quality before it actually even comes into our system.

And I would like to turn the microphone to him to talk a little bit about how we could really enhance the front end using modern science.

Mr. BURGESS. Very quickly.

Mr. BRACKETT. Thank you, Dr. von Eschenbach.

Mr. BURGESS. The chairman has a sharp gavel when it comes to me.

Mr. BRACKETT. Yes, Mr. Burgess. I think one of the things that we have learned a lot from that is the impact that one small tiny

mistake that can happen on the front end, as Dr. von Eschenbach, can have radical change and disastrous consequences that you mentioned before with the young children that became ill.

I think some of this has been addressed from the research needs that have come from this. We have learned a lot in that particular instance about how produce can become contaminated, what the results are, and getting some ideas of where to best test.

From that, what we are looking for are devices, as Dr. von Eschenbach mentioned earlier, with the x-ray fluorescence detector, to do the same sort of things with microbial contamination, to have indicators to try to find out where are the hot spots because we know that the vast majority of the fields are fine. But whenever you have contamination in a concentrated area, that is where the trouble starts.

And we need to have the scientific basis on which to develop techniques and methods but also for our regulatory strategies as well. It doesn't do any good to have guidance and regulatory strategies aimed at things that are not actually going to improve public health.

Mr. BURGESS. Would part of that regulatory strategy be to beef up the recall process so that FDA has the ability to issue mandatory recalls?

Mr. BRACKETT. Well, I think that fits right in it, and also encouraging such things as perhaps a more modernized traceback system so that we can trace these things back much faster, minimize the damage to the patients and to the consumers as well as to the industry as a whole.

Mr. BURGESS. Now, part of the bioterrorism or mitigating the threat of bioterrorism is syndromic surveillance where products that are bought over the counter at drugstores, for example cold medications, cough medications, medications to treat an upset stomach, if there is a sudden spike in the purchase of those products, the emergency rooms and public health sectors are notified that there may be something going on and to watch out for it. Are you keyed into that syndromic surveillance so that the FDA knows to look at perhaps a foodborn source as well and perhaps get a day or two's lead time on that?

Dr. VON ESCHENBACH. Dr. Burgess, very recently, Dr. Gerberdin, head of the CDC, and I have put together an interagency effort to specifically link our ability to be more effective at data sharing, information sharing because CDC is that first line of defense that you just talked about in recognition of a foodborn illness. And then when it becomes obvious, as it did with the spinach, that it is an outbreak by virtue of the fact it is the same organism causing these problems in multiple places, then it becomes FDA.

We need to be much more seamless in that recognition, detection, identification continuum, and we are working on that as we speak with CDC to enhance our data information sharing systems.

Mr. BURGESS. Do you have the—

Mr. STUPAK. Gentleman's time. We want to get to, Mr. Burgess, we are going to have votes here in a few minutes.

Mr. BURGESS. Thank you.

Mr. STUPAK. Trying to get everybody in. If we have time, we will come back again. Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you. Commissioner, I really do appreciate the fact that you have been here the whole time. Had you checked with the San Francisco district office, as our investigators did, they would tell you that in the last 10 years, there have been 10 outbreaks in leafy green vegetables in the Salinas Valley. So Dr. Burgess is right, and that is an important fact. And to a person, our investigators said that your staff there believe that voluntary guidelines have not worked and that concrete rules for both the farm and processing operation are necessary. Do you agree?

Dr. VON ESCHENBACH. Let me be clear because this is an important issue of the distinction between a mandatory regulation and a guidance, which is voluntary.

I have discussed this at great length with the experts, and I consider Dr. Brackett to be my most important expert, in which there are areas, quite frankly, where the science is not mature enough for us to be able to define a regulation that is mandatory for everyone all the time. And so what we have pursued is use of guidances in good agricultural practices.

Ms. SCHAKOWSKY. There are no instances where you think you have enough information to introduce mandatory rules as opposed to voluntary guidelines? The science just isn't there anywhere?

Dr. VON ESCHENBACH. I am not going to say the science isn't there anywhere. I think in large part we heard earlier today in one of the testimonies that someone thought it might have been the water. I have heard other people think it might have been wild pigs running through those spinach fields. And the science is going to have to decide what is the source of that contamination with *E. coli*, and then we can put in place a regulation that would address that.

In the meantime, what we are using are guidances that will enable us to be flexible as the science continues to evolve before we lock into something.

Ms. SCHAKOWSKY. OK, but there is certainly a lack of confidence right now that the FDA is doing all that it can and the Government is doing all it can. I wanted to ask you about water. Does the FDA need congressional authority to regulate water quality and other controls for the farm that supplies spinach and lettuce for our grocery stores?

Mr. BRACKETT. Well, certainly the water, that surface water and others, there is EPA authority to look at the quality of that water. And I guess what you are asking is should agricultural water be regulated as such. At this point, water quality is one of the things that is addressed in good agricultural practices. That was introduced in 1998 to make sure that the water is not looked to be contaminated, such as, perhaps outwash from rivers. And so that is one of the things that the producers are actually supposed to be looking at is the water quality—are you sure of the water quality.

Ms. SCHAKOWSKY. The producers are supposed to be looking at that.

Mr. BRACKETT. The producer.

Ms. SCHAKOWSKY. But what is the role of Government? Does FDA need congressional authority to regulate water quality when it comes to it being involved in our food production?

Mr. BRACKETT. Well, again EPA has that for total water quality. Whether we would need it on the food production side of it, that is one of the things we are considering in looking at that. It wouldn't do any good to go requesting authority if we found out that it wasn't, in fact, going to be the problem or was duplicative of what is already out there.

Ms. SCHAKOWSKY. So you are examining whether or not you need that authority?

Mr. BRACKETT. Yes, we are.

Ms. SCHAKOWSKY. And are you also looking at voluntary versus mandatory?

Mr. BRACKETT. Well, yes. Already water quality is part of good agricultural practices, which is the voluntary part of it. And that states that one must use water of acceptable sanitary quality. So that is already there, and that is something that we do.

Ms. SCHAKOWSKY. That is a guideline?

Mr. BRACKETT. It is a guidance, yes.

Ms. SCHAKOWSKY. OK, and so none of this is mandatory?

Mr. BRACKETT. Not at this point.

Ms. SCHAKOWSKY. Are you examining that in your reorganization and looking at your authorities?

Dr. VON ESCHENBACH. We are reexamining that in the food protection plan that I alluded to earlier, which the reorganization is a part and separate.

Ms. SCHAKOWSKY. Right.

Dr. VON ESCHENBACH. There is a larger, more strategic agenda that is agency-wide, and our reassessment of authorities is a part of that.

Ms. SCHAKOWSKY. I think it is really important that you communicate with the committee about that because we may act anyway, and so it would be a really good thing.

Dr. VON ESCHENBACH. Agreed.

Ms. SCHAKOWSKY. The other thing I want to say is that you looked annoyed when another example was given of not answering a letter, but it looks to me from what we heard from our investigators that there is a systematic withholding of information. When our investigators say it is like pulling teeth to get information, we have a responsibility too. Our responsibility is oversight. We don't want to have to fight with you. We don't want to have to wait. We want to be able to get the information that is needed for us to do our job which is equally mandated as your job is.

Dr. VON ESCHENBACH. I apologize if my nonverbals appeared that I was annoyed.

Ms. SCHAKOWSKY. No, you should be annoyed.

Dr. VON ESCHENBACH. I am frustrated.

Ms. SCHAKOWSKY. You should be annoyed and frustrated that Members of Congress didn't get an answer.

Dr. VON ESCHENBACH. I agree.

Ms. SCHAKOWSKY. But it is not some sort of unique oversight. What we are finding is that it is systematically, when we ask questions and our investigators, who we give authority to ask questions, aren't given the answers that we need. So this is a more pervasive problem. That is all I am saying. It is not like we messed up again,

again and again and again and again. And I thank you, Mr. Chairman.

Dr. VON ESCHENBACH. Thank you. And I am committed to addressing that.

Mr. STUPAK. We have a series of votes, but I think it is only fair to ask you about the bonuses. I want to ask you a couple questions about that. I mentioned it publicly. We are perplexed as to why we put in fiscal year 2006 \$10 million for bonuses, and what we can determine from data collector for HHS, just on employees who receive \$5,000 more, you gave out \$9.5 million in bonuses. Seems like the extra money for food safety and food inspection went to bonuses and then not to personnel.

Dr. VON ESCHENBACH. May I take a few moments to put that into perspective? First of all, when I arrived at the FDA, I quickly came to the realization that our most precious asset at FDA is our people.

Mr. STUPAK. Then why don't you ask for the bonus money and retention things in salaries and not in food safety money?

Dr. VON ESCHENBACH. Well, we haven't quite done that the way I think it has been perceived.

Mr. STUPAK. Well, members are—

Dr. VON ESCHENBACH. But the bonus dollars that are being allocated are coming from each individual allocation. We have not transferred dollars from drugs to some place else to pay bonuses. The bonuses that are applied, are applied out of each center's individual allocation.

Mr. STUPAK. So then you have to cut back food safety money in order to get the bonuses to your people?

Dr. VON ESCHENBACH. No, sir.

Mr. STUPAK. Where are you getting the money then for the bonus?

Dr. VON ESCHENBACH. The bonuses that have been paid for people who are in, for example, the Center for Food Safety and Applied Nutrition come out of Dr. Brackett's budget. The dollars that are paid for bonuses for people who are—

Mr. STUPAK. Then how come we can't find that extra \$10 million that Congress put in for food safety and inspection? We can't find where that money went. We just have this bonus money that shows up—

Dr. VON ESCHENBACH. It wouldn't go to bonuses in somebody else's center, I can assure you that.

Mr. STUPAK. Well, the part that bothered us was if you take a look at employees in your office, OK, Office of the Commissioner, collected more than 30 percent of all the top FDA cash awards in 2004, 2005, 2006. And the Office of Regulatory Affairs only received 19 percent of all the FDA's top cash awards, yet they have 35 percent of all the FDA employees. So if you take a look at it, cash bonuses in your office these last few years went up 80 percent, where in the same Office of Regulatory Affairs only went up 30 percent.

So as imports have increased, the FDA's workload to do more and more with fewer resources, the field employees' cash awards have actually gone down, where your office, Office of Commissioner, the executive level, has gone way up. How do you explain that?

Dr. VON ESCHENBACH. Well, I need to look at that specific data to give you detail as to where those dollars are going, but I will tell you in principle we have put in place across the agency now a committee to look at bonuses so that we are certain that the criteria that are being used are uniform and applicable across the agency. But it is individual centers that use their own individual budget as a percentage of that to use for bonuses within that center. We don't take money from one center and give it to another to be used for bonuses.

Mr. STUPAK. Well, we have asked for that criteria, and we can't seem to find the purpose of it because it bothers some of us that the FDA's inspector of the year received a \$1,000 bonus. And I don't think that is fair to your best investigator to get only \$1,000 bonus while your management team gets like 20 times more in bonuses each year. How is that fair to that inspector who is doing the legwork on food safety?

Dr. VON ESCHENBACH. You have performance bonuses. There are retention bonuses, and there are different mechanisms for giving bonuses.

Mr. STUPAK. But back to the same point. Get us the information so we can ask the questions because from this perspective, you get \$10 million for extra in food safety in 2006, and you got \$9.5 million in bonuses. It looks like all the money that went to food safety went there. We wouldn't be asking the questions if we have the information.

Dr. VON ESCHENBACH. I will provide you the—

Mr. STUPAK. Damned if you do and damned if you don't. That is basically what it comes down to.

Dr. VON ESCHENBACH. I will be happy to provide that to you.

Mr. STUPAK. All right, let me ask you—I have 55 seconds. Does USDA get bonuses?

Dr. VON ESCHENBACH. I am assuming that other Government agencies give bonuses.

Mr. STUPAK. Don't assume.

Dr. VON ESCHENBACH. Certainly it is true at NIH.

Mr. STUPAK. USDA requires certification from a foreign country that their safety regulations are at least as strong as ours in order for them to export to the United States. Do you support a similar certification for imports under FDA's jurisdiction?

Dr. VON ESCHENBACH. I support working with foreign sources to be able to continuously enhance their ability to assure the quality of product of foods that are coming to our borders.

Mr. STUPAK. So the answer is no?

Dr. VON ESCHENBACH. At this point, I don't have enough information to answer whether that should be mandatory across the board. I think it is something that, as we have looked at imports, we need to address.

Mr. STUPAK. Let me ask you this. USDA restricts imports of products under their jurisdiction to 10 ports of entry. You have somewhere between 326 to 361. We are still trying to get the exact number of your ports of entry. Would you be in favor of bringing it down to the 91 ports where you have FDA inspectors?

Dr. VON ESCHENBACH. At this point, Mr. Chairman, I could not be in favor of that because I don't have a careful analysis of what that might imply. To decide to take all of our—

Mr. STUPAK. Don't you think that should be in your reorganization plan?

Dr. VON ESCHENBACH. Not from a perspective of forcing producers in foreign countries to only send their food to certain ports.

Mr. STUPAK. How else are you going to get it inspected?

Dr. VON ESCHENBACH. That is not part of our reorganization plan.

Mr. STUPAK. How else are you going to get them inspected?

Dr. VON ESCHENBACH. By having inspectors with modern tools of science deployed at the ports of entry—

Mr. STUPAK. But if you only have 91 ports of entry covered. You only have 91 covered out of 326.

Dr. VON ESCHENBACH. Today.

Mr. STUPAK. Today.

Dr. VON ESCHENBACH. And we will look forward to continuing to expand that as we make this transition into the FDA of the 21st century.

Mr. STUPAK. All right, if Congress puts in reports language that you do not close these labs until we have approved a reorganization level, will you follow that in the report language?

Dr. VON ESCHENBACH. Well, obviously, I will always follow the dictates of Congress, but I will—

Mr. STUPAK. But will you do it? You always say you are going to provide information, and you don't. But will you do it?

Dr. VON ESCHENBACH. I would hope that we would have the opportunity to further dialog on the rationale behind the proposal and allow us to go forward with the reorganization, modernization of FDA. We may have differences about unique features of it, but I don't think we should have a difference that if we continue the way we are today we will be inadequate to address the problems we have been talking about throughout this entire day.

Mr. STUPAK. I will bet you you will have your reorganization done before we get the information we requested. Mr. Burgess had a question.

Mr. BURGESS. Thank you, Mr. Chairman. And I would just like to offer the observation—I haven't been here that long, but it is hard to keep and train and retain good people. So I have no problem at all with you offering retention bonuses. Just don't tell my staff that I said that, and we will all be in good shape.

On the FDA's reorganization, you said that you think you can do that without disrupting the functionality of the FDA, and yet one of the reasons for the reorganization or one of the consequences will be reduction in staff by perhaps several hundred full-time employees. How is that going to keep from disrupting the functionality?

Dr. VON ESCHENBACH. May I first correct that particular issue? This is not intended to reduce FTEs. There may be a shift in the nature of that FTE. For example, a shift from someone who happens to be a technician in a laboratory perhaps to shift to someone who is a field-deployed inspector using the modern technical devices I alluded to. There may be a shift but not a reduction. So I

hope that this is not viewed as a workforce reduction plan because it is not that.

Mr. BURGESS. So it is redeployment of existing forces?

Dr. VON ESCHENBACH. It is very much redeployment, in certain cases, consolidation, modernization. It is more than just simply we need to do something to save money. That is not the point.

Mr. BURGESS. So going forward in this process during the reorganization, can I ask that you keep the committee updated as to how this is going and demonstrating that functionality is not being impaired or lost as employees are being reassigned within the organization?

Dr. VON ESCHENBACH. We are not going to allow a loss of functionality, and we will phase this in over years. This is not something that will happen precipitously. It is expected it may take 3 years to do whatever ultimately comes out of this plan.

The other thing I want to make absolutely clear is the people who have testified earlier today from these laboratories are FDA's finest. The people in these laboratories are working extraordinarily hard, and they are superb people. I had the privilege of giving someone in Denver an award very recently, and I have seen the pain that they have of facing the possibility of a relocation.

This is not about our people not having done a good job or being inadequate or these laboratories having been failures. Just the opposite is true. These laboratories and this work force is something I am extraordinarily proud of, but the world has radically changed around us. And we must radically change in order to adapt and adjust to that. And we would like to do that in a deliberative thoughtful fashion so that we serve the American people to protect and promote their health. And that is the whole purpose of this.

Mr. BURGESS. Very well. Just one last thought, Mr. —

Mr. STUPAK. Quickly. We have 2 minutes left to vote.

Mr. BURGESS. You are fast. Mr. Hubbard, when he testified put forward the concept that we need to have some way of holding countries that export to the United States accountable for the stuff that they send to this country. Would you be in favor of that type of process?

Dr. VON ESCHENBACH. That is also one of the authorities that we are exploring so that we have much better security in protecting what is coming into our borders, if we are unable to get the kind of quality built in on the front end that we want. And we will be coming back to Congress through the appropriate channels as we further mature this protection plan.

Mr. BURGESS. I want you to have that. I hope you do come back and ask us if you need—when I address additional tools, that would be one I would be very happy to put in your hands.

Dr. VON ESCHENBACH. And we are also working, as the chairman indicated, in close coordination with the Department of Health and Human Services and all of its agencies as well as counterparts outside of the agency as we address this protection of our borders and homeland security.

Mr. BURGESS. Thank you, Mr. Chairman. I will yield back.

Dr. VON ESCHENBACH. Mr. Chairman, I will leave my colleagues with your permission.

Mr. STUPAK. We have seven votes. I don't think it would be fair for your colleagues to sit for another hour unless Mr. Burgess has questions of other. So we will excuse this panel and thank you very much for coming.

Dr. VON ESCHENBACH. Thank you, Mr. Chairman, and thank you, all the members of the committee, for your commitment to the FDA.

Mr. STUPAK. That concludes our questioning. I want to thank all of our witnesses for coming today and for your testimony. I ask unanimous consent that the hearing will remain open for 30 days for additional questions for the record. No objection. The record will remain open. I ask unanimous consent the contents of our document binder be entered in the record. I will also note that the documents provided by the FDA to justify the bonuses in exhibits 47 through 56 are included in the binder, but the volume of supporting documents, several boxes, will be retained in the subcommittee files for access and review. No objection. Documents will be entered into the record. That concludes our hearing. Without objection, this meeting of the subcommittee is adjourned.

[Whereupon, at 3:10 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

STATEMENT HON. RICHARD J. DURBIN, A SENATOR FROM THE STATE OF ILLINOIS

Mr. Chairman, I want to begin by commending you for calling this hearing and to thank you very much for the opportunity to present written testimony.

The issue of food safety has been one of my top legislative priorities for more than 10 years. I am disappointed to report that the recent string of food recalls does not surprise me. Unfortunately, Mr. Chairman, we have an antiquated food safety system that is in desperate need of additional resources and updated statutory authority. While the United States continues to have the safest food supply in the world, our food safety standards and practices have been eclipsed by some of our major competitors.

Our food safety system is particularly deficient in the area of food imports. The recent recalls of contaminated pet food, seafood, toothpaste, and other imported food products have demonstrated that we need to make changes in this area.

The volume of food that the United States imports has increased significantly in recent years, from \$45.6 billion in 2003 to \$64 billion in 2006. According to the USDA, imported food accounts for 13 percent of the average American's diet, including 31 percent of fruits, juices, and nuts; 9.5 percent of red meat; and 78.6 percent of fish and shellfish.

This upward trend in imported food has been accompanied by an increasing number of health and safety incidents related to imported food products. In the past 6 months, we have seen what appears to be the intentional contamination of wheat gluten and rice protein concentrate with melamine, which is an industrial product that should never find its way into food products. In addition, we recently learned that a significant volume of imported seafood products from China have been contaminated with chemicals and residues, including Malachine green and Nitrofurans. We have found imported Chinese toothpaste in the U.S. that was contaminated with diethylene glycol, which is a toxic component used in antifreeze.

Unfortunately, the FDA currently lacks the resources and authority to adequately determine the quality and safety of food imports, inspect an adequate volume of imported food, and rapidly detect and respond to incidents of contaminated imports.

What has been made clear by the pet food recall and other outbreaks of food borne illnesses is that the FDA is a severely under funded and understaffed agency. Much of the responsibility for overseeing and inspecting the safety of imported food rests with the FDA. However, due to flat budgets and increasing responsibilities, the number of inspectors looking at these shipments has actually decreased from more than 3,000 inspectors in 2003 to the present level of around 2,700 inspectors.

The Centers for Disease Control, CDC, estimates that 76 million Americans become sick from food borne illnesses each year. More than 300,000 are hospitalized

and 5,000 die each year. Less than 1.5 percent of imported food is inspected by the FDA and the FDA lacks the resources and authorities to certify the standards of our trading partners. This situation presents an economic, public health, and bio-terrorism risk to the U.S.

The FDA office that is responsible for regulating more than \$60 billion of imported food, the Center for Food Safety and Nutrition, CFSAN, is also responsible for regulating \$417 billion worth of domestic food and \$59 billion in cosmetics. All of this activity is regulated by an office for which the President requested \$467 million in fiscal year 2008. Only \$312 million of that amount would be for inspectors. We clearly need to review FDA's funding to make sure that it has the resources necessary to safeguard the 80 percent of our food supply that it is responsible for regulating. For this reason, a group of my colleagues and I sent a letter earlier this year to the Agriculture Appropriations Subcommittee, which funds the FDA, asking for a significant increase in the level of funding for the FDA foods program.

In addition to working for increased appropriations for the FDA foods program, I recently introduced legislation in the U.S. Senate, the Imported Food Security Act of 2007 (S. 1776), that is designed to close the gaps in FDA's imports program and improve the standards for imported food.

The legislation does three things. First, the bill would impose a fee for the FDA's oversight of imported food products. These fees would generate revenues to be used for increased inspections of imported food and critical food safety research. The legislation would also establish a food importer certification program that would require foreign firms and governments to demonstrate that their food safety systems are equivalent to ours.

Imports present a special challenge to the FDA. It may cost more to ensure the safety of food produced in other countries, and the logistical challenges are greater. It is important that we supplement the FDA's budget with additional funding streams to make sure that it has the resources necessary to safeguard our food supply from contaminated imports.

This legislation would direct the FDA to collect a user fee on imported food products, for the administrative review, processing, and inspection costs borne by the FDA. The legislation directs the FDA to use some of this funding to perform cutting-edge research to develop testing technologies and methods that would quickly and accurately detect the presence of pervasive contaminants such as *E. coli* and listeria.

In addition, the legislation would use this funding stream to bolster FDA's import inspection program, which currently inspects less than 1.5 percent of all imports. My hope is that this legislation would give the FDA the resources it needs to double or triple the percentage of shipments that are inspected each year and focus its limited resources on the shipments that present the greatest risk to human health.

Lastly, this bill would establish an imported food certification program. Today, any country and any company can export food products to the United States as long as they inform regulators of the shipment. No checks are performed to ensure that the producer has adequate sanitary standards. The FDA does not ensure that trading partners have equivalent regulatory systems or inspect overseas plants when problems arise.

When the FDA does want to investigate an outbreak, it can be delayed by uncooperative foreign governments. For example, during the pet food recall, U.S. regulators were delayed three weeks in their request for visas to inspect facilities.

This new program would mark a watershed change in the food import safety posture of the U.S. This bill says that if you want a slice of the lucrative U.S. market, you have to comply with the same common-sense standards that apply to U.S. food producers. You have to have equivalent food safety systems and processes in place to those of the United States. You need to give U.S. regulators access to your facilities and records so they can check your safety record without unnecessary delay. In addition, U.S. regulators would have the power to revoke the certification of a company or country that fails to comply, and to detain products that fail to meet U.S. standards.

For too long, we have gone without a solid safety standard for imported foods. Instead, our regulators jump from alert to alert and recall to recall. This legislation would close these loopholes that allow dangerous imports into our country and put a solid, proactive system in place to protect our food supply.

In addition, Mr. Chairman, I would like to mention one other issue that I believe would significantly improve the food safety system we have in place today. Because the FDA lacks the authority to order recalls, we depend on a system of voluntary or cooperative recalls, in which the FDA works with companies to pull products from shelves and notify consumers and retailers of defective products.

In most instances, this system functions well because food companies have a concerted interest in protecting their brands and taking aggressive action to ensure the

health and safety of their customers. However, in some instances, food companies do not fully cooperate with the FDA—they delay in sharing information or implement recalls slowly and unevenly. Part of the reason why these situations occur is because there is no requirement in statute, regulation, or even guidance that informs companies of when they are required to report serious adulterations of food and what notifications they are required to make.

The net effect of this is that human health is put at risk, consumer confidence in food decreases, and companies find themselves in uncertain situations about when and how to conduct recalls. It is inevitable that at least once a year, we see slow, uneven, and ineffective recalls that don't remove product from shelves and that need to be expanded.

The Senate-passed Prescription Drug User Fee Act of 2007 (PDUFA) contains language that I co-authored with Chairman Kennedy that would fix this shortfall in our regulatory environment. The language creates a reporting system for significant adulterations of food that clarifies when food companies are required to report adulterations of food to the FDA and what they are then required to do to notify retailers, suppliers, and consumers of these health risks. It is a non-controversial approach that clarifies the legal requirements of food companies and improves the FDA's ability to protect consumers from adulterated food.

In the next couple of weeks, the House and Senate will go to conference on PDUFA. I believe that including the language from the Senate bill would make a significant step toward improving our food safety system.

Thank you again, Mr. Chairman for allowing me to present testimony at this hearing and I look forward to continuing to work with you on this issue.

STATEMENT OF HON. ED PERLMUTTER, A REPRESENTATIVE IN
CONGRESS FROM THE STATE OF COLORADO

I would like to go on record to voice my strong opposition to the proposed closure of seven of the 13 FDA field laboratories, including the Denver District Laboratory, located in the Seventh Congressional District, in Lakewood, Colorado. The Denver District Laboratory, located at the Denver Federal Center, a GSA owned and operated facility, is an award winning lab. Many of the employees at this facility have vast experience and an invaluable research knowledge base. Furthermore it is doubtful these same employees would move to any of the consolidated laboratories, which under the proposed consolidation would be in Arkansas.

The FDA has yet to provide any evidence supporting that the proposed closures and consolidation would lead to better safety standards for our Nation's food supply, pharmaceutical products, medical equipment, cosmetics and other health-related products for safety and effectiveness and ensuring that the products are labeled properly.

The fact of the matter is these FDA lab closures are purely economic in nature and do not take into account the safety of our citizens. I understand the need to be good stewards of our tax dollars, but we must not risk or compromise the health and safety of our Nation. As a proud member of the House Homeland Security Committee, I understand the importance and responsibility entrusted to Members of Congress to ensure the safety of our Nation and the FDA's closure of these laboratories is contrary to that duty.

Time and again the Denver District Laboratory has performed critical research for our Nation. Recently, the FDA asked the Denver laboratory to assist in evaluating the levels of the contaminant melamine in animal feed used to raise food for human consumption. The FDA asked the Denver laboratory to quickly develop a methodology to quantify melamine residues in fish tissues. Because melamine has not been approved as a food additive, no published types of analysis were available for its determination in fish. In less than 2 weeks, the lab developed, validated and submitted the method for publication, and made it available for national distribution to all state and Federal laboratories. As of June, the Denver District Laboratory continues to be the only FDA laboratory capable of testing seafood samples for the presence of melamine.

The FDA failed to address several key components for their rationale for justifying the closure of seven field laboratories including how they are going to fund the laboratory closures. The agency has yet to reveal a plan to recover the loss of experience, knowledge and scientific expertise resulting due to potential FDA laboratory consolidation. Additionally, the FDA has yet to explain why they are displacing their more senior employees while hiring new employees.

The closing and consolidation of the Denver District Laboratory would leave a large geographic gap in the Nation's ability to monitor and maintain food and drug safety and research. Under the FDA's closure plan, the closest lab to the two on the west coast (Seattle and Los Angeles) would be in Arkansas. This would leave the entire Rocky Mountain region and large parts of the Midwest without a close field lab. Denver is a major transportation and commerce hub with major links to a vast portion of our country. I believe these lab closures will compromise the safety and security of our nation.

In light of the increased contaminants found in both domestic and imported food sources, and in particular recent contaminations of both pet and human food from China, I fail to see how the closures of seven FDA field laboratories will assist in making our Nation safer. The FDA has failed to provide adequate reasons for justifying these closures.

In conclusion, I would like to reiterate my opposition to closing these field labs and in particular the Denver District Laboratory in the Denver Federal Center in Lakewood, CO, in Colorado's Seventh Congressional District.



Written Statement for the Record

Submitted August 2007 by the American Society for Quality to the
 Subcommittee on Oversight and Investigations
 Committee on Energy and Commerce
 United States House of Representatives

Subsequent to the Subcommittee's hearings entitled "***Diminished Capacity:
 Can the FDA Assure the Safety and Security of the Nation's Food
 Supply?***"

The American Society for Quality thanks the Chairman of the Subcommittee for the opportunity to submit a written statement which we hope will be included in the record of the series of food safety hearings titled, "*Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?*"

We have been following these hearings with a great deal of interest, and our purpose in this commentary is to offer perspectives on the topic from the quality assurance professions that we believe will be useful to the Subcommittee, to the FDA, and to the food processing industry.

The principal advice we could offer to the Subcommittee is to be wary of the drumbeat calling for more inspection as the way to address current food safety problems, as this represents a simplistic solution to a complex situation and an expensive approach that cannot work. The rationale behind this position is explained in more detail in the ASQ Quarterly Quality Report titled "*Food Safety: A Quality Management Systems Approach*," which is attached to this filing as Appendix A.

The Quarterly Quality Report raises several main points that are relevant to the questions currently before your Subcommittee:

- More inspection is not the answer to improving food safety; however, more effective inspection and assessment pinpointed to high-risk areas can go a long way toward plugging gaps in the current food-safety framework.
- More widespread adoption of HACCP practices and the ISO 22000 food safety management international standard are needed to raise performance worldwide to best practice levels and prevent occurrences of foodborne illness.

In addition, we believe the Subcommittee should focus on several other areas in its

assessment of the FDA's ability to ensure safe food, such as:

System and process focus. Today's food safety challenges demand less focus on end-item testing and more push onto the process and as far back into the supply chain as possible.

Supply Chain Management. Much of the inspection effort has been concentrated at particular points close to the ends of the food chain, specifically at import and processors. However, what is needed is more focus on the links of the food supply chain. Supporting the "one-up-one-down" mechanism of the members of the chain by finding innovative methods of evaluating the passing of the product between the links may yield better results.

Joint Agency Activities. As these Subcommittee hearings have pointed out, Federal food safety oversight is a fragmented undertaking, with multiple agencies playing a role. These agencies are not necessarily working together to meet common food safety or public health goals, as a number of GAO studies have emphasized.¹ Joint agency activities carried out in overlapping and complementary fields could obviate some of the need for additional inspectors and permit more thorough oversight with existing personnel resources. In addition, FDA has a long history of collaboration with state departments of agriculture for inspection of food processing plants using uniform FDA guidelines and procedures—a practice which could be expanded. Rather than continuing to feed the old inspection-based process that was designed for century-old conditions, FDA and Congress should devote energies to re-engineering the process and only then determining what personnel resources are required.

Government/Industry Partnerships. There will never be enough inspectors no matter what the design ends up being. What is also necessary is for the agencies to focus on the weak areas. This requires more reliance upon activities that strengthen the food chain, such as the involvement of industry trade groups who are attempting to police their members. Supporting such activities permits the agency to spend time and resources where needed most—on the participants who are not complying.

International Data System for Traceability. Food safety professionals are talking more and more about the extreme need to share data internationally in order to have true traceability. This means we must all use common data entry means such as common IUU codes to better trace the transfer of the product throughout the supply chain. This is especially important for highly traded commodities such as seafood where over 80% of the seafood consumed in the US is imported. Countries such as Australia and the EU are very interested in implementing these more sophisticated data systems, even though the percentage of imported seafood is lower there than it is in the United States.

Footnotes

- 1.) See the following GAO reports: GAO 01-204: *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers* and GAO 04-246 *Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements Are Needed*

APPENDIX A**The Quarterly Quality Report****June 2007**

The ASQ Quarterly Quality Report provides a detailed look at a variety of quality-related topics and issues. The report is developed by the American Society for Quality in keeping with its role as the steward of the quality profession—to promote the use of quality as a global priority, an organizational imperative and a personal ethic, and to promote quality concepts, technology and tools to make the world a better place.

Food Safety – A Quality Management Systems Approach

Public attention has been focused as perhaps never before on the safety of the food supply as a result of recent high-profile outbreaks of illness linked to various foods.

According to the United States Centers for Disease Control and Prevention (CDC), a rare strain of *Salmonella* in peanut butter produced at a plant in Georgia between August 2006 and January 2007 sickened 628 people in 47 states. California fresh spinach contaminated with a pathogenic form of the bacterium *E. coli* killed three people and sickened more than 200 people in 26 states in late summer 2006. There were two multi-state outbreaks of pathogenic *E. coli* associated with lettuce used in fast-food restaurants and two multi-state salmonella infections associated with tomatoes in 2006. And while the glare of widespread media attention was focused on these human food incidents, at least 16 pets died from the effects of tainted wheat gluten processed in China and blended into pet foods that were sold in the United States, Canada, and Mexico under more than 100 brand names.

The resultant calls by the media, the public, consumer groups and legislators for more oversight of the food supply almost invariably include a clamoring for more inspectors and more inspection.

"The problem is, the science of quality has told us that more inspection is not going to inspect the defect out of the product," says Steve Wilson, chief quality officer for the U.S. Commerce Department's Seafood Inspection Program. "Asking, 'Do we need more inspectors?' is a loaded question, because usually you do need more inspectors—but only because of the way the current system is designed," states Wilson, who is also on the board of directors of the American Society for Quality (ASQ).

"If you're going to have a glitch, the problem is major and can affect a large number of individuals," Surak says. "When we had more locally produced food processed in smaller, more localized plants, a glitch may not have appeared on the national media radar screen because not very many people got sick," he adds.

Today's health-conscious consumers want fresh fruits and vegetables all year round. They also demand foods that are essentially ready to eat. The fresh-cut sector is the fastest-growing segment of the produce industry. For example, fresh spinach consumption per capita has increased 180 percent since 1992. When these fresh, ready-to-eat foods do become contaminated, the likelihood they will produce a foodborne illness is quite high, since unlike meat and poultry they are not cooked prior to being consumed. Fresh produce has now surpassed beef as the leading source of illness caused by pathogenic *E. coli* in the United States.

This consumer demand has created new opportunities in the way we grow, harvest, and process fresh fruits and vegetables. From a food safety perspective, it has allowed the development of Good Agricultural Practices—a set of food safety principles that can be applied in the farm field, such as controlling animal wastes that originate in feedlots. They are designed to prevent contamination from microorganisms that are naturally present in the agricultural environment. Complementing the Good Agricultural Practices are Good Manufacturing Practices (GMP) which prevent further contamination of fresh fruits and vegetables after harvest.

Elements of a preventive approach to food safety

Some of the elements of a prevention-based approach to food safety are already well established within industry and within the regulatory framework, while other elements are in various stages of development or have been proposed in the past but not implemented. These include:

Going back to the basics

"One of the things I emphasize day in and day out when I work with industry is that you have to do the basics well, and you repeat it time and time again," states Surak. "I see problems in companies where they tend to forget about doing the basics."

An FDA report on causes of food recalls occurring between 1999 and 2003 revealed that 83 percent of the two most serious classes of recalls could be attributed to failure to control GMP issues or to breakdowns in prerequisite programs—in other words, failing to do the basics correctly.

Some of these basics include strictly following good manufacturing practices at the plant level and good agriculture practices at the producer or farm level. These GMPs and GAPs are some of the prerequisites that are the foundation for implementing HACCP.

HACCP (hazard analysis and critical control point) is a quality management system for effectively and efficiently ensuring farm-to-table food safety by controlling microbial, chemical, and physical hazards associated with food

versus what our gut is telling us to do—what the perception is telling us to do,” says Wilson. “And then you work on the process versus the product, and you work on the system versus the process. If you do it that way you have a better chance of having stronger product than if you’re simply inspecting the product.”

For that reason, Wilson, Surak, and others who have studied ISO 22000:2005 say it is a very strong standard that deserves to be widely implemented. Both Surak and Wilson served on the committee that developed the standard.

“So far, those who have implemented it seem to think it’s working quite well,” Wilson states. “Inspectors and plants who really look at it like the standard.”

As of February 2007, more than 250 companies had sites registered to the ISO 22000:2005 standard. The bulk of these, about 75 percent, are in Europe.

Raddatz says her company is investigating ISO 22000:2005. “We’re doing a gap analysis right now, comparing what we have under our HACCP based system with what ISO 22000 is asking for. If we’re missing anything, can we close the gap? So, if there becomes a competitive advantage—if our customers start to say, ‘We will not do business with you unless you become 22000 registered’—then we’re poised for that.”

What can be done now

Food safety in the United States is better today than ever. Still, there remains huge opportunity for improvement in preventing illness from known food pathogens and in responding to new and emerging foodborne illnesses and threats.

Here are some steps that can be taken now that would have high impact, are do-able, and are consistent with established quality practices.

- **No let-up on the basics.** In the food processing environment, constant reinforcement on the food safety basics is necessary. These basics include such procedures as personnel hygiene practices and training programs, cleaning, sanitation, and maintenance procedures, effective product recall programs, provisions for safe water supply, and procedures for handling product throughout the entire manufacturing and distribution processes.
- **Continuing consumer education.** Once food leaves the processor, there is also a role for consumers and others to play in maintaining basic food safety precautions. Improper food handling in the home and at retail food establishments accounts for more reported cases of foodborne illness than does failure at the food processing level.
- **Greater use of risk-based criteria and greater flexibility in directing regulatory resources quickly and efficiently to high-risk areas.** Massive restructuring of the nation’s food regulatory agencies may not be

- **Globally applicable tools for a global food chain.** Sourcing of food and food ingredients is now a global business, so it makes sense to tackle food safety issues with internationally accepted and globally applicable tools such as the ISO 22000:2005 standard.
- **More effective inspection—not more inspection.** Federal and combined federal-state inspection resources are limited and workload is growing, so these resources need to be targeted where they are needed most. Food producers and processors—domestic or foreign—that do not show evidence of compliance with HACCP and/or ISO 22000:2005 and those dealing in higher-risk foodstuff should be subject to closer surveillance.

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About the American Society for Quality

The American Society for Quality is the world's leading authority on quality. With more than 93,000 individual and organizational members, the professional association advances learning, quality improvement, and knowledge exchange to improve business results and to create better workplaces and communities worldwide. As champion of the quality movement, ASQ offers technologies, concepts, tools, and training to quality professionals, quality practitioners, and everyday consumers, encouraging all to Make Good Great®. ASQ has been the sole administrator of the prestigious Malcolm Baldrige National Quality Award since 1991. Headquartered in Milwaukee, WI, the 61-year-old organization is a founding partner of the American Customer Satisfaction Index (ACSI), a prominent quarterly economic indicator.



July 16, 2007

The Honorable John D. Dingell, Chairman
Committee on Energy and Commerce
2125 Rayburn Office Building
Washington, D.C. 20515-6115

The Honorable Bart Stupak, Chairman
Subcommittee on Investigations and Oversight
2125 Rayburn Office Building
Washington, D.C. 20515-6115

Dear Chairmen Dingell and Stupak:

I am writing in response to your June 26, 2007 correspondence inquiring about the sale of pre-packaged meat packaged in an atmosphere containing carbon monoxide (CO). Your letter also expressed your concern with the Food and Drug Administration's (FDA's) review and "generally recognized as safe" (GRAS) designation of this process.

Our customers and their safety are Safeway's highest priority. We pride ourselves on offering our customers the highest in food quality and wholesomeness and the best in product availability and selection. Likewise, we maintain high food safety standards - in many areas exceeding regulatory and industry standards. We also work with reputable and high quality suppliers and require that they meet all legal regulatory requirements, as well as our own.

Only a limited selection of fresh meat products in our stores are supplied to us utilizing carbon monoxide modified atmospheric packaging (CO MAP). Indeed, the vast majority of our fresh meats are not packaged under such conditions. Safeway neither engages in CO MAP processing of meats, nor does it set code dates for said product.

Our fairly recent decision to try a limited selection of CO MAP items, was based in large part on our commitment to food safety. The FDA-approved CO MAP process afforded our customers meat packaging under strict food processing standards and limited additional handling at critical points of contact.

Both Safeway and its customers rely on the expertise of our federal food safety agencies. We also place a high value on our customers' trust. Because the Committee has expressed concerns - and in so doing may have raised concerns with customers who



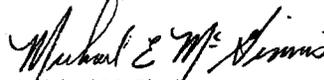
Chairmen Dingell & Stupak
Page 2

do not have the benefit of the background on this process and may be confused – we have elected to discontinue the sale of fresh meat products packaged under CO modified atmospheric packaging conditions.

Safeway has notified its CO MAP fresh meat suppliers of its decision. Likewise, we have ceased ordering and receiving CO MAP fresh meats into our distribution system. We no longer carry these types of products in our distribution inventory and are in the process of phasing out any existing inventory in our retail stores. Specifically, with the exception of two lamb and veal cuts, CO MAP fresh meat products will no longer be sold in our stores as of July 17, 2007. The limited lamb and veal cuts packaged in a CO modified atmospheric process will no longer be available in our stores as of July 27.

We hope that this information addresses any concerns you may have as they relate to Safeway.

Very truly yours,



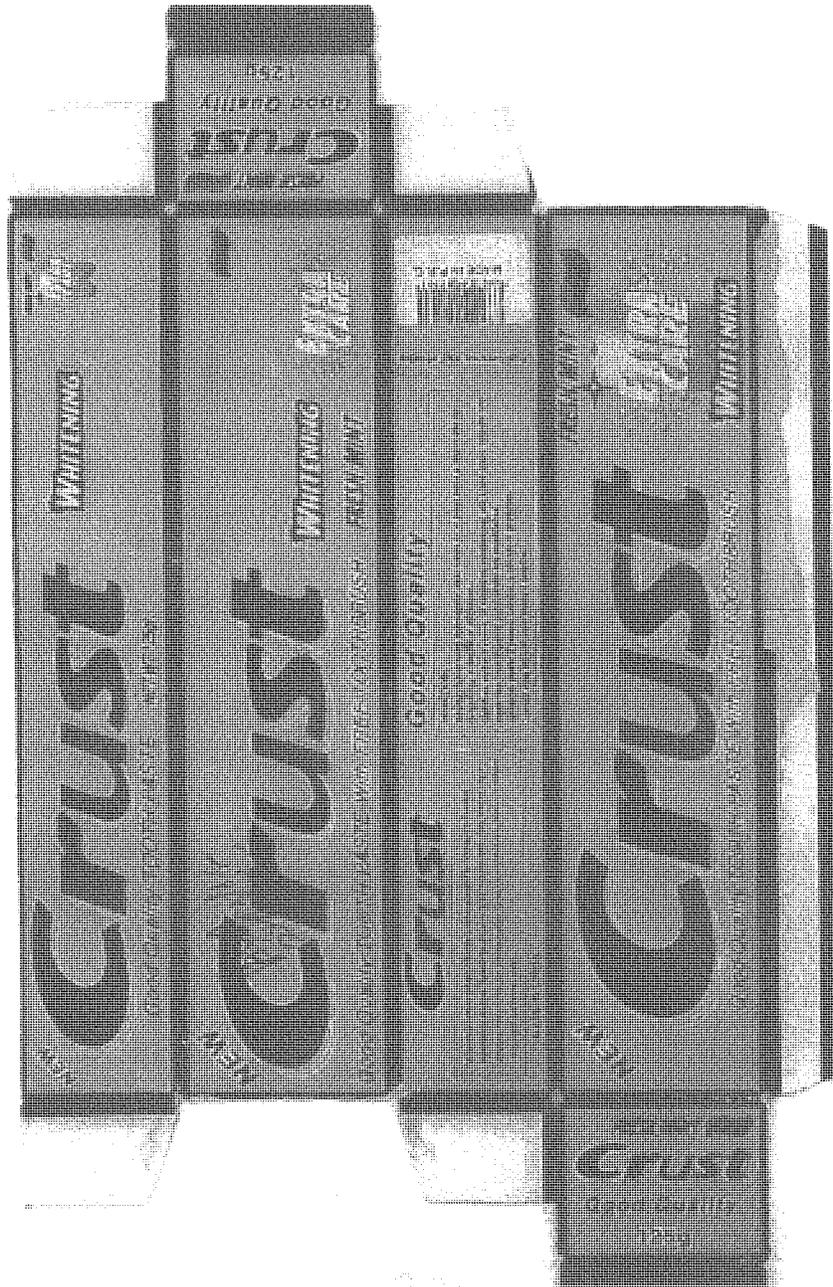
Michael McGinnis
Senior Vice President
Meat & Seafood

cc: Steve A. Burd
Robert A Gordon
Kevin Herglotz
Valerie D. Lewis
Shannon Campagna
Nick Maduros

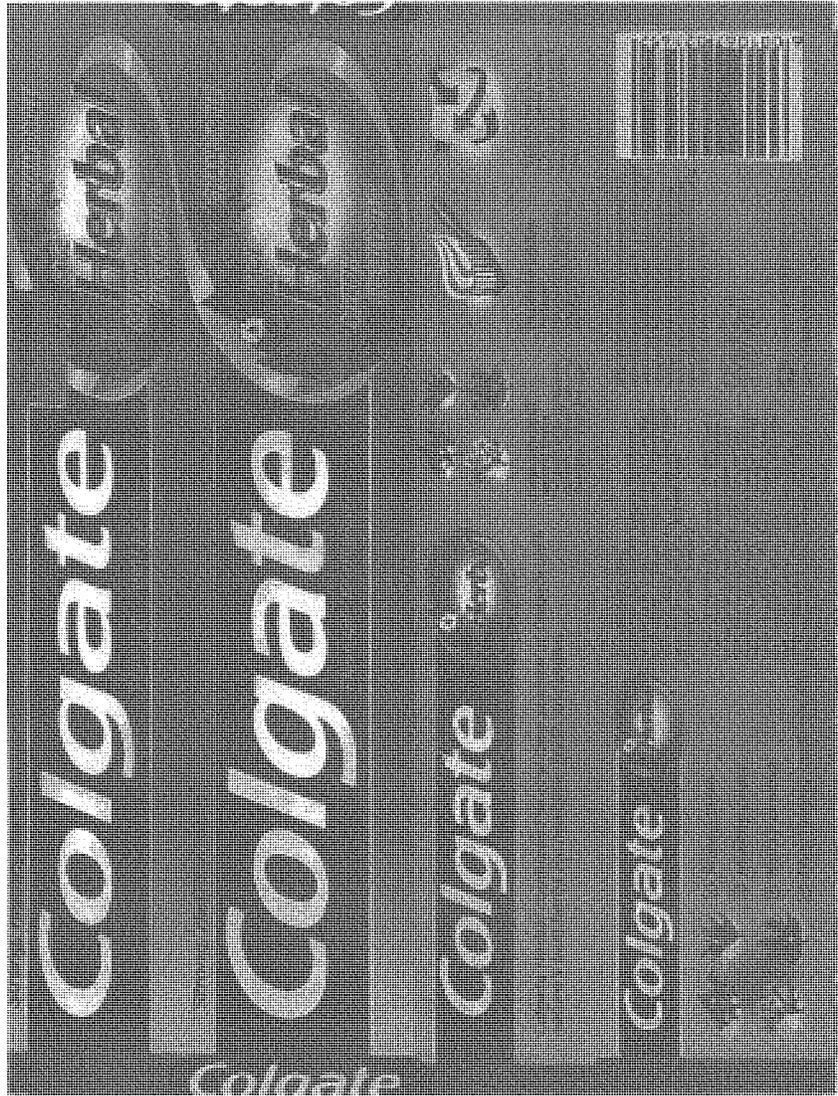


















| Ex. # | Description | Date |
|---|---|--------------|
| 1 | Subcommittee on Oversight and Investigations Witness List | |
| Summary Documents | | |
| 2 | Field Activities - FDA Office of Regulatory Affairs (ORA) | |
| 3 | FY 2007 ORA Workplan | 11/09/06 |
| 4 | FDA Food Import Process Presentation | 03/28/07 |
| 5 | Congressional Research Service article, subject: "Food and Agricultural Import from China" | 06/06/07 |
| 6 | FDA Mission Presentation | |
| 7 | Imported Foods Presentation | |
| Seafood Documents | | |
| 8 | FDA Import Bulletin #16-B95, "Tuna Processed with Tasteless Smoke and/or Carbon Monoxide." | 5/27/99 |
| 9 | Cancellation of FDA Import Bulletin #16-B95 | 6/17/03 |
| 10 | Government Accountability Office (GAO) report, subject: "Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements are Needed." Summary only, full document available within the Subcommittee's files. | January 2004 |
| 11 | Violative Seafood Samples Related to Use of Carbon Monoxide Analyzed by Northern Regional Laboratory (NRL) New York and New England Districts- FY07 | |
| 12 | E&C Committee Letter to FDA re: Chinese importation of contaminated seafood (large focus on seafood) | 06/05/07 |
| 13 | FDA response to 5/05/07 letter | 07/09/07 |
| 14 | FDA News Release, subject: "FDA Detains Imports of Farm-Raised Chinese Seafood." | 06/28/07 |
| Meat Related Documents | | |
| 15 | Packaged beef photographs (2) | |
| Wheat Gluten Documents | | |
| 16 | Wheat gluten photographs (2) | |
| Proposed Lab Closings-Capabilities Documents | | |
| 17 | GAO report, subject: "FDA Laboratories: Magnitude of Benefits Associated with Consolidation is Questionable." | March 1996 |
| 18 | E&C Committee letter to FDA re: lab closures | 02/06/07 |
| 19 | FDA letter re: 2/16/07 response | 03/16/07 |
| 20 | FDA letter re: 2/16/07 response | 05/08/07 |
| 21 | FDA letter re: 2/16/07 response | 05/25/07 |

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|-------------------------------------|---|-------------------|
| 22 | E&C Committee letter to FDA re: lab closures | 06/15/07 |
| 23 | E&C Committee letter to FDA re: lab closures and contaminated vegetables and peanut butter document request | 06/20/07 |
| 24 | E&C Committee letter to FDA re: lab closures and the Winchester Engineering and Analytical Center | 06/26/07 |
| 25 | Memo from Margaret Glavin to ORA Employees, re: "Congressional Requests for Documents." | 06/28/07 |
| 26 | FDA letter re: 6/20/07 response | 07/10/07 |
| 27 | FDA letter re: 6/20/07 response | 07/11/07 |
| 28 | All Closing Labs (Kansas City, San Juan, San Francisco, Winchester, Denver, Detroit, Philadelphia) | |
| 29 | Denver Laboratory | |
| 30 | Kansas City Laboratory | |
| 31 | San Francisco District Laboratory | |
| 32 | San Francisco District Laboratory Overview | |
| 33 | Winchester Engineering and Analytical Center | |
| 34 | Email to Emma Singleton from Michael Chappell; Subject: Laboratory Workgroup | 11/13/2006 |
| 35 | Email to James Strachan and Brenda Holman from Erika Anderson; Subject: Lab Closing Bullets | 1/22/2007 |
| 36 | ORA Laboratory Facilities | |
| 37 | ORA Laboratory Facility Evaluation Tool | |
| 38 | ORA FTE Information | 2001-2007 |
| 39 | What ORA Will Look Like in October 2008 | |
| 40 | Savings and Costs | |
| Peanut Butter Documents | | |
| 41 | Sample Results from ConAgra Inventory | 02/17/07-03/01/07 |
| 42 | ConAgra Foods letter to Rep. Stupak and Rep. Whitfield, re: April 24, 2007 Food Safety Hearing. | 05/11/07 |
| Bonuses and Salary Documents | | |
| 43 | E&C Committee letter to FDA re: FDA compensation | 04/12/07 |
| 44 | FDA response to 4/12/07 letter | 06/11/07 |
| 45 | FDA response to 4/12/07 letter | 06/21/07 |
| 46 | FDA response to 4/12/07 letter | 06/27/07 |
| 47 | Aggregate FDA Bonuses in Excess of \$5000 (per person, per year) | 2002-2007 |
| 48 | FDA Office of the Commissioner Bonuses in Excess of \$5K (per person, per year) | 2002-2007 |
| 49 | FDA Office of Regulatory Affairs Bonuses in Excess of \$5K (per person, per year) | 2002-2007 |
| 50 | FDA Center for Food Safety and Applied Nutrition Bonuses in Excess of \$5K (per person, per year) | 2002-2007 |
| 51 | FDA Center for Biological Evaluation and Research | 2002-2007 |
| 52 | FDA Center for Devices and Radiological Health Bonuses in Excess of \$5K (per person, per year) | 2002-2007 |
| 53 | FDA Center for Veterinary Medicine Bonuses in Excess of \$5K (per person, per year) | 2002-2007 |

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| 54 | FDA National Center for Toxicological Research Bonuses in Excess of \$5K (per person, per year) | 2002-2007 |
| 55 | FDA Center for Drug Evaluation and Research Bonuses in Excess of \$5K (per person, per year) | 2002-2007 |
| 56 | FDA Salaries in Excess of SES / PHS Admiral's pay | 2006 |
| 57 | Correspondence from Casey Hemard, HHS Office of the Asst. Secretary for Legislation, re: "Follow-up Responses to Congressional Questions on Title 42." | 07/11/07 |
| 58 | Terrell L. Vermillion, Director, Office of Criminal Investigations | |
| 59 | Margaret O'K. Glavin, Associate Commissioner for Regulatory Affairs | |
| Toothpaste Documents | | |
| 60 | FDA Import Alert #66-74, "Detention Without Physical Examination of Dentifrice Products Containing Diethylene Glycol (DEG)." | 06/08/07 |
| 61 | Muriella's Corner Blog, "Toothpaste recall in USA culprit diethylene glycol" | 06/18/2007 and 6/28/2007 |
| 62 | Crust toothpaste photograph | |
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| 66 | Correspondence from Micahel Maves, CEO of American Medical Association to Aleta Sindelar, FDA Center for Veterinary Medicine, re: Proposed approval of use of 4th generation cephalosporin in cattle. | 09/22/06 |
| 67 | Correspondence from Micahel Maves, CEO of American Medical Association to FDA Commissioner von Eschenbach, re: AMA's concern of potential FDA approval of use of 4th generation cephalosporin in cattle. | 03/19/07 |
| 68 | Department of Defense Information Paper, subject: "FY206 Financial Summary of the DoD/FDA Shelf-Life Extension Program" | 04/23/07 |
| Lead Contaminated Paint in Toys Documents | | |
| 69 | Consumer Product Safety Commission Press Release, subject: "RC2 Corp. Recalls Various Thomas & Friends Wooden Railway Toys Due to Lead Poisoning Hazard." | 06/13/07 |
| 70 | Letter from Congressmen Burgess and Walden to Congressmen Stupak and Whitfield, re: lead contaminated paint in Thomas & Friends Railway toys. | 07/11/07 |
| Contaminated Snack Food Documents | | |
| 71 | FDA Press Release, subject: "Update on Tainted Veggie Booty Snack Food." | 07/13/07 |

| Contaminated Vegetable Documents | | |
|----------------------------------|--|----------|
| 72 | E&C Committee Letter to FDA re: food recalls | 06/07/07 |
| Media Documents | | |
| 73 | Associated Press article by Andrew Bridges and Seth Borenstein, subject: "FDA Food Safety Inspections Languish." | 02/26/07 |
| 74 | USA Today article by Julie Schmit, subject: "US Food Imports Outrun FDA Resources." | 03/19/07 |
| 75 | New York Times article by Marian Burros, subject: "Who's Watching What We Eat?" | 05/16/07 |
| 76 | Washington Post article by Rick Weiss, subject: "Tainted Chinese Imports Common." | 05/20/07 |
| 77 | Los Angeles Times article by Mark Magnier, subject: "China Sends Message on Food, Drug Scandals." | 05/30/07 |
| 78 | Star-Ledger article by Robert Cohen, subject: "Import Inspections Stress FDA Resources." | 06/10/07 |
| 79 | The Asian Wall Street Journal article, subject: "China Rejects US Foods, Citing Safety Concerns." | 06/11/07 |
| 80 | Wall Street Journal article by Jane Zhang, subject: "FDA Weighs Shift in Safety Checks on Food Imports." | 06/14/07 |
| 81 | Boston Globe interview with David Achenon, FDA Asst. Commission. "His Latest Challenge: Keeping Our Food Supply Safe." | 06/24/07 |
| 82 | Time Magazine article by Jyoti Thottam, subject: "The Growing Dangers of China Trade." | 06/28/07 |
| 83 | Wall Street Journal article by Neil King, Jr., subject: "China Launches Public Response to Safety Outcry." | 06/30/07 |
| 84 | The North Country Gazette article, subject: "Dismal Scorecard for FDA." | 06/30/07 |
| 85 | Wall Street Journal article by Nicholas Zamiska, subject: "China Faces a New Worry: Heavy Metals in the Food." | 06/02/07 |
| 86 | NPR article by Kayla Webley, subject: "List of Problem Chinese Imports Grow;" and "China Executes Ex-Food and Drug Chief." | 06/10/07 |
| 87 | New York Times article by Andrew Martin, subject: "FDA Curbs Sale of 5 Seafoods Farmed in China." | 06/23/07 |
| 88 | Washington Post article by Joel Achenbach, subject: "Do You Know Who Your Next Meal is Coming From?" | 07/15/07 |

FIELD ACTIVITIES - OFFICE OF REGULATORY AFFAIRS

Introduction

FDA's Field Activities – Office of Regulatory Affairs (ORA) Program summarizes the budget program requirements that justify a \$546,232,000 request for FY 2008. The Field Activities program narrative has four sections:

- summary of FDA's program resources, historical funding and FTE levels
- description of the Office of Regulatory Affairs program functions
- effects of the full year FY 2007 Continuing Resolution on the Office of Regulatory Affairs
- description of the program resources changes, base resource activities, program accomplishments, program activity data, and performance plan analysis.

The Field Activities funding table shows a three year span of program level resources, budget authority resources, and proposed user fees enacted in FY 2006, displayed in the FY 2007 President's Budget and FY 2007 Continuing Resolution, and proposed in the FY 2008 budget request.

| | FY 2006 Actuals | FY 2007 Continuing Resolution | FY 2007 Pres. Budget | FY 2008 Pres. Budget | Increase or Decrease |
|---|----------------------|-------------------------------------|-------------------------|-------------------------|-------------------------|
| Program Level | \$499,853,000 | \$501,373,000 | \$527,018,000 | \$546,232,000 | \$19,214,000 |
| FTE | 3,460 | 3,242 | 3,460 | 3,472 | 12 |
| Budget Authority | \$482,361,000 | \$482,435,000 | \$504,029,000 | \$520,567,000 | \$16,538,000 |
| <i>Foods</i> | <i>\$285,251,000</i> | <i>\$285,153,000</i> | <i>\$301,324,000</i> | <i>\$312,138,000</i> | <i>\$10,814,000</i> |
| <i>Human Drugs</i> | <i>\$79,923,000</i> | <i>\$79,919,000</i> | <i>\$79,794,000</i> | <i>\$81,488,000</i> | <i>\$1,694,000</i> |
| <i>Biologics</i> | <i>\$27,075,000</i> | <i>\$27,161,000</i> | <i>\$28,776,000</i> | <i>\$29,310,000</i> | <i>\$534,000</i> |
| <i>Animal Drugs and Feeds</i> | <i>\$34,756,000</i> | <i>\$34,842,000</i> | <i>\$35,778,000</i> | <i>\$35,774,000</i> | <i>(\$4,000)</i> |
| <i>Medical Devices</i> | <i>\$55,356,000</i> | <i>\$55,360,000</i> | <i>\$58,357,000</i> | <i>\$61,857,000</i> | <i>\$3,500,000</i> |
| <i>Pay Increases</i> | – | – | – | <i>\$9,210,000</i> | <i>\$9,210,000</i> |
| <i>Strengthening Food Safety</i> | – | – | – | <i>\$5,500,000</i> | <i>\$5,500,000</i> |
| <i>MDUFMA Trigger</i> | – | – | – | <i>\$2,421,000</i> | <i>\$2,421,000</i> |
| <i>Outreach, Coordination, Research Reduction</i> | – | – | – | <i>(\$593,000)</i> | <i>(\$593,000)</i> |
| Total FTE | 3,400 | 3,191 | 3,397 | 3,403 | 6 |
| User Fees | \$17,492,000 | \$18,938,000 | \$22,989,000 | \$25,665,000 | \$2,676,000 |
| <i>PDUFA</i> | <i>\$7,389,000</i> | <i>\$7,077,000</i> | <i>\$9,833,000</i> | <i>\$9,169,000</i> | <i>-\$664,000</i> |
| <i>MDUFMA</i> | <i>\$1,123,000</i> | <i>\$0</i> | <i>\$1,295,000</i> | <i>\$1,406,000</i> | <i>\$111,000</i> |
| <i>MQSA</i> | <i>\$8,980,000</i> | <i>\$11,861,000</i> | <i>\$11,861,000</i> | <i>\$12,454,000</i> | <i>\$593,000</i> |
| <i>Proposed Generic Drugs</i> | – | – | – | <i>\$2,636,000</i> | <i>\$2,636,000</i> |
| Total FTE | 60 | 51 | 63 | 69 | 6 |

EY2

The historical funding and FTE levels table shows a five year history of program level funding, budget authority funding, user fee funding, and program level FTE.

Historical Funding and FTE Levels

| Fiscal Year | Program Level | Budget Authority | User Fees | Program Level FTE |
|----------------------------|---------------|------------------|--------------|-------------------|
| 2004 Actuals | \$528,853,000 | \$513,906,000 | \$14,947,000 | 3,872 |
| 2005 Actuals | \$493,258,000 | \$315,562,000 | \$15,690,000 | 3,633 |
| 2006 Actuals | \$499,853,000 | \$482,361,000 | \$17,492,000 | 3,460 |
| 2007 Continuing Resolution | \$501,373,000 | \$482,435,000 | \$18,938,000 | 3,242 |
| 2007 President's Budget | \$527,018,000 | \$504,029,000 | \$22,989,000 | 3,460 |
| 2008 President's Budget | \$546,232,000 | \$520,567,000 | \$25,665,000 | 3,472 |

Statement of the Budget Request

The ORA Field Activities is requesting \$546,232,000 in program level resources for accomplishing its mission activities:

- conducting investigational, inspectional, and laboratory functions to ensure that FDA-regulated products comply with the laws and regulations that FDA is charged with enforcing
- responding rapidly to emergencies and redirecting field efforts, as necessary, to respond to unforeseen events
- managing and conducting criminal investigations within the Agency's jurisdiction, including advising and assisting the Commissioner and other key officials on legislation and policy involving criminal justice matters
- monitoring clinical research and conducting inspections of FDA-regulated products before they are marketed to ensure that manufactured products will be safe and effective
- performing prior notice import security reviews on food and animal feed imports considered to be at risk for bioterrorism and field examinations of all types of imported products to determine compliance with FDA regulations

- serving as FDA's primary liaison with consumers, health professionals, the media, States, and the regulated industry and trade associations to disseminate information on the products the Agency regulates.

Program Description

Please note: The Office of Regulatory Affairs supports the Foods, Human Drugs, Biologics, Animal Drugs and Feeds, and Devices and Radiological Health Programs. The narratives for these programs include a Field component.

ORA is the lead office for all FDA field activities. ORA supports five FDA Centers (CFSAN, CDER, CBER, CDRH and CVM) by inspecting regulated products and manufacturers, conducting sample analysis on regulated products, reviewing imported products offered for entry into the United States, and advising key officials on regulatory and compliance-oriented matters that have an impact on policy development and execution, and on long-range program goals. ORA protects consumers and enhances public health by maximizing the compliance of FDA-regulated products and minimizing the risks associated with those products.

ORA staff is dispersed throughout the United States. Over 85 percent of ORA's staff works in five Regional Offices, 20 District Offices, 13 Laboratories, and 157 Resident Posts and Border Stations. The Office of Criminal Investigations (OCI) personnel are located throughout the field organization in Field Offices, Resident Offices, and Domiciles, which are located in 25 cities throughout the U.S. FDA maintains offices and staff in Washington, D.C., the U.S. Virgin Islands, Puerto Rico, and in all States except Wyoming. FDA also monitors imported products traveling through 12 international mail facilities and 20 courier ports.

ORA's work involves conducting foreign and domestic pre-market and post-market inspections. Pre-market activities include bioresearch monitoring of clinical research, pre-approval inspections and laboratory method validations needed for premarket application decisions, and inspections of manufacturing facilities to determine if the factory is able to manufacture the product to the specifications stated in their application. The largest portion of ORA's work involves post-market inspections of foods, human drugs, biologics, animal drugs and feeds, and medical device manufacturers. These post-market inspections assess the manufacturers' compliance with Good Manufacturing Practice (GMP) requirements. ORA's radiological health activities include inspecting certified mammography facilities for compliance with the Mammography Quality Standards Act (MQSA). ORA also inspects radiological health products such as lasers, sunlamps, and x-ray equipment to ensure they are in compliance with performance standards. In addition, ORA monitors and samples imports to ensure the safety of the food supply and medical products.

ORA works with its State counterparts on safety activities. ORA funds grants and cooperative agreements to perform State inspections, and to provide technical

assistance to the States in such areas as milk safety, food safety, and shellfish safety. State inspection staffs attend and participate in ORA-sponsored training courses.

In addition to overseeing regulated products on a surveillance or “for cause” basis, ORA staff also respond to emergencies and investigate incidents of product tampering, as well as terrorist events or natural disasters that may impact FDA regulated goods. To complement the regular field force, the Office of Criminal Investigation (OCI) investigates instances of criminal activity in FDA-regulated industries.

FDA relies heavily on ORA’s post-market investigation, inspection, and compliance activities to assure the safety and quality of the products the Agency regulates. ORA’s Counter Terrorism (CT) program role includes ensuring the safety and security of the food and feed supply; supporting the development and manufacturing of vaccines and medical counter measures; assessment of drugs and other medical products included in the Strategic National Stockpile Program; and participation in and support for exercises and security preparations for public events such as the Olympics and National political conventions. FDA’s responsibilities for radiation safety and health requires assessing x-rays used for security screening of packages and other radiation emitting products with medical or CT uses. ORA provides emergency responses to illness and injury potentially linked to FDA-regulated products and coordinates its activities with the Centers for Disease Control and Prevention (CDC). In addition, ORA inspections and investigations are essential to human tissue safety; BSE feed contamination prevention; counterfeit drug, infant formula, and other product investigations; and dietary supplement safety enforcement.

ORA coordinates import activities with the Department of Homeland Security’s Customs and Border Protection (CBP) Agency. The number of FDA-regulated imported products is increasing exponentially. Even if security concerns were not taking an ever increasing role, this would challenge FDA’s ability to provide an appropriate response. In FY 2008, FDA projects a total of 17.9 million import lines, which will be comprised of 52 percent food products, 11 percent cosmetic products, 2 percent human drugs and biologic products, 2 percent animal drugs and feeds products, and 33 percent medical device and radiological health products. ORA uses a combination of electronic information technology for risk-based screening and staff intensive surveillance, physical examinations, and laboratory analysis to make import entry decisions. ORA’s information technology systems allow Field personnel to respond to an ever increasing number of imports through electronic screening. ORA also uses information technology to track domestic inspections and allocate resources to identify and inspect the highest risk program areas.

Effects of Full Year FY 2007 Continuing Resolution

The analysis in this section assumes funding levels for FY 2007 based on the enactment of the President’s FY 2007 budget for the Fields Program. For comparison purposes, the FDA budget tables include a column that reflects the FY 2007 Continuing

Resolution (CR) funding level in the event that Congress enacts this level of appropriations for the remainder of FY 2007.

If FDA receives the CR rather than the FY 2007 President's budget request, this will have a significant impact on FY 2007 performance for ORA and each of the field program areas.

All ORA Program Areas will be affected by the FY 2007 Continuing Resolution:

- ORA will have to modify normal operations to cope with reduced operating funds by instituting a hiring freeze, reducing FTE, and reducing operating expenses to cover the payroll shortfall.
- ORA's investigator vacancies will increase and inspections will be reduced; ORA will not be able to perform its projected number of inspections and other activities, which places the public health at risk.
- With reduced operating funds for travel to high risk inspections, ORA staff will be out of geographical balance with establishment workload; and, districts will be forced to conduct lower risk inspections.
- ORA will not be able to apply modern IT solutions to public health problems or improve risk based targeting, mission accountability or reduce operating costs.
- ORA's reduced training resources will limit specialized training for existing staff, resulting in a gap between the existing staff's skill set and the skill set needed for sophisticated risk based inspections, investigations and laboratory analyses.

Field Foods Program

The FY 2007 Continuing Resolution has six major impacts on the Field Foods Program:

- ORA will limit its Food Emergency Response Network (FERN) funding to the maintenance of the ten State laboratories; FDA's resources to support training, proficiency testing and planned expansions of the FERN system will be limited by reduced operating funds and fewer experienced analytical staff in ORA laboratories.
- The number of high risk foods performance goal inspections planned for FY 2007 will be reduced by almost 20 percent [-1,015 inspections] from the President's budget proposal; firms making high risk products that received annual inspections in previous years will be inspected on a biennial schedule instead.

- Routine Cosmetics inspections will be eliminated and ORA will perform cosmetics inspections only on a “for cause” basis, where a product or firm is suspected of being out of compliance.
- ORA will not be able to fund inflationary increases in State inspection costs and the number of State inspections will decline from the President’s budget level, possibly damaging FDA’s relationships with the States.
- Domestic and Import Laboratory Samples Analyzed will decline by 2,000 samples below the President’s budget level.
- Funding under the continuing resolution causes a loss of 120 FTE for the Field Foods Program.

Field Human Drugs Program

The FY 2007 Continuing Resolution has five major impacts on the Field Human Drugs Program:

- ORA will reduce the number of Good Manufacturing Practice inspections by 277, reducing the inspection interval for moderate risk firms from every three years to every four years.
- Foreign Pre-approval and Good Manufacturing Practice (GMP) inspections will be reduced due to reduced numbers of investigators with the necessary specialized skills and the inability to fund inflationary increases in its foreign travel budget.
- ORA will continue to place a high priority on PEPFAR inspections for foreign establishments preparing to manufacture AIDS drugs for distribution outside the U.S. and will ensure that these inspections receive foreign inspection priority.
- “For Cause” and investigation activities will be limited to the highest risk situations where there is an ongoing risk to public health.
- Funding under the continuing resolution causes a loss of 39 FTE for the Field Human Drugs Program.

Field Biologics Program

The FY 2007 Continuing Resolution has four major impacts on the Field Biologics Program:

- ORA Blood Bank inspections will be reduced by 85 inspections, causing the inspection interval for blood banks to fall below the statutory inspection requirement of inspecting 50 percent of the inventory a year for the first time.

- ORA will only meet the performance goal of 325 Human Tissue establishment inspections allowing for firms in the human tissue industry to continue operating without in-depth ORA oversight.
- ORA will have to decrease the number of Bioresearch Monitoring inspections from 180 to 169, limiting FDA's ability to provide needed research oversight for integrity and the protection of human subjects.
- Funding under the continuing resolution causes a loss of 14 FTE for the Field Biologics Program.

Field Animal Drugs and Feeds Program

The FY 2007 Continuing Resolution has five major impacts on the Field Animal Drugs and Feeds Program:

- The animal drugs and feeds establishments performance goal will decline by 106 establishment inspections with FDA not meeting its statutory inspection requirement of biennial inspections for the first time.
- Domestic and Foreign Pre-approval and Bioresearch Monitoring inspections will be reduced by 75 inspections as a result of reduced travel funds, reduced numbers of investigators, and the elimination of the Animal Drug User Fee Act program.
- Maintaining State funding for BSE inspections will severely limit flexibility in operating funds for travel, training, and coordination with States and industry.
- Resources for investigation of suspect products and firms will be limited to those presenting the highest risk.
- Funding under the continuing rate causes a loss of 13 FTE for the Field Animal Drugs and Feeds Program.

Field Medical Devices and Radiological Health Program

The FY 2007 Continuing Resolution has six major impacts on the Field Medical Devices and Radiological Health Program:

- The medical device Class II and III manufacturers performance goal will decline by the reduction of 258 inspections from the President's budget level.
- Since the MDUFMA program will be eliminated, ORA will reduce Domestic and Foreign Pre-approval Inspections by 119, an 80% reduction in the Pre-Approval Inspection program.
- Foreign Post Market Audit and Good Manufacturing Practice (GMP) inspections will be reduced by 65 inspections because the number of

investigators will be reduced and travel funding will not keep pace with inflationary increases.

- ORA will not be able to fund inflationary increases in State inspection costs and the number of State inspections will decline from the President's budget level, possibly damaging FDA's relationships with the States.
- Funding under the continuing resolution causes a loss of 32 FTE for the Field Medical Device and Radiological Health Program.

If FDA receives the continuing resolution of funding rather than the FY 2007 President's budget request, this will have significant impact on FY 2008 performance for ORA's program:

- Any new hires are unlikely to exceed 25 percent of typical productivity which means that FY 2008 inspection and laboratory analysis targets may not be met and ORA work will include a higher proportion of entry level tasks than in FY 2006.
- Despite ORA's desire to pursue risk based activities, newly hired employees will require intensive coaching and supervision and may need to assist an experienced ORA specialist for several months before assuming responsibility for complex risk based activities.
- Although ORA should be able to award contracts and grants for the increased sums authorized in the FY 2008 budget, reduced staffing will delay activities funded by the contracts and grants.

Program Resources Changes

Budget Authority

Pay Increase: +\$9,210,000

The FDA request for pay inflationary costs is essential to accomplish our public health mission. Eighty percent of FDA's budget authority supports the agency workforce. Of this, payroll costs account for almost sixty percent of our budget authority. The increase will allow FDA to maintain staff levels, including a national cadre of specially trained scientific staff. Maintaining the FDA workforce provides stability for the organization and allows FDA to maintain the current level of coverage for its premarket and postmarket activities. Without these funds, FDA must reduce FTE levels in order to have adequate resources to cover its payroll, which will lead to corresponding reductions in programs that protect public health. The total request for cost of living pay increases in FY 2008 is \$21,773,000. The Office of Regulatory Affairs portion of this increase is \$9,210,000. These resources are vitally important for FDA to fulfill its mission to protect the public health by helping safe and effective

products reach the market in a timely way, and by monitoring products for continued safety after they are used.

Strengthening Food Safety: +\$5,500,000 and +6 FTE

FDA proposes a total of \$10,644,000 for food safety activities, \$5,500,000 of which is for ORA, to enhance FDA's ability to help industry mitigate the risks of increased foodborne outbreaks. The resources would also improve FDA's ability to protect the public health by enhancing our ability to respond to possible foodborne outbreaks. The request would help ORA develop the capacity for more rapid traceback of produce-related outbreaks, and improve the capacity to more quickly determine the root cause of an outbreak. The request would also allow FDA to accelerate the development of an integrated import decision making IT system capable of detecting high-risk shipments of FDA regulated products before they are admitted or released into U.S. commerce. In addition, ORA would begin formal integration of this technology into the Mission Accomplishment and Regulatory Compliance Services (MARCS) system.

Medical Device Safety and Review: +\$2,421,000

The funding request for the Medical Device User Fee and Modernization Act (MDUFMA) Trigger of \$7,164,000 is necessary for FDA to meet the statutory requirements for collecting user fees in FY 2008. The ORA portion of this amount is \$2,421,000. Under the MDUFMA law, a significant feature of this program is the requirement that the Federal government appropriate and spend a minimum amount on the process for reviewing medical devices. The flow of new potentially life saving medical devices will slow, limiting the availability of safe products, including those for untreated conditions. The resources requested allow for program continuation and for FDA to meet its performance commitments under the Act.

Outreach, Coordination, and Research Reduction: -\$593,000

This proposed reduction reallocates resources from lower priority activities to higher priority activities proposed in the FY 2008 budget. FDA must ensure its resources are used for maximum public health impact. This requires FDA to make funding decisions based on risk-based prioritization of needs. FDA diligently assessed research and outreach activities under ORA and proposes a reduction of \$593,000 in FY 2008. This reduction contributes to the FDA's ability to fund cost of living pay increases, medical product and food safety initiatives, and rent increases in FY 2008.

User Fees

Current Law User Fees

Prescription Drug User Fee Act (PDUFA): -\$664,000

In FY 2007, PDUFA collections included a one time increase of \$31,600,000 for the final year adjustment under PDUFA III. For FY 2008, adjustments include increases for inflation and other increases authorized by the PDUFA statute. The net decrease in FY 2008 for the Field program is due to this one-time, non-recurring FY 2007 Final Year adjustment. Because FDA has not completed the public comment period

regarding FDA's proposed recommendations for PDUFA reauthorization, the FY 2008 PDUFA estimate is based on straight reauthorization of PDUFA III with no programmatic enhancements or adjustments.

In the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Congress renewed FDA's authority to collect PDUFA user fees. This authority is effective for five years and directs FDA to strengthen and improve the process for the review of human drugs and to improve risk management for drugs approved under PDUFA. The authority to collect fees under PDUFA expires on September 30, 2007.

Proposals to reauthorize PDUFA are currently under discussion. The PDUFA user fee is expected to bring in \$339,195,000 in FY 2008 collections, with the Field Program request totaling \$9,169,000. These FY 2008 amounts assume that the current authorities in effect for PDUFA III continue in FY 2008. FDA may need to amend its budget request when Congress reauthorizes PDUFA IV and establishes new performance goals and fee levels.

PDUFA user fees allow ORA to perform three activities:

- conduct domestic and foreign pre-market inspections
- ensure compliance with drug manufacturing practices
- monitor and inspect manufacturing facilities to ensure that drug products are safe and effective.

Medical Devices User Fee and Modernization Act (MDUFMA): +\$111,000
Enacted in 2002, MDUFMA improves the quality and timeliness of the medical device review. It authorizes FDA to collect user fees to supplement appropriations for the medical device review program. FDA collects fees from device manufacturers that submit premarket applications and premarket notifications. The authority to collect fees under MDUFMA expires on September 30, 2007.

Proposals to reauthorize MDUFMA are currently under discussion. The MDUFMA user fee is expected to bring in \$47,500,000 in collections, with the Field Program increase being \$111,000, for a total of \$1,406,000. These FY 2008 amounts assume that the current authorities in effect for MDUFMA continue in FY 2008. FDA may need to amend its budget request when Congress reauthorizes MDUFMA and establishes new performance goals and fee levels.

MDUFMA user fees allow Field activities to perform four activities:

- allow establishment inspections to be conducted by third parties
- conduct domestic premarket inspections

- conduct foreign premarket inspections
- conduct Bioresearch Monitoring inspections to inspect the integrity of data and to protect human subjects.

Mammography Quality Standards Act (MQSA): +\$593,000

Breast cancer is the most commonly diagnosed cancer and the second leading cause of cancer deaths among American women. Experts estimate that one in eight women will contract breast cancer during their lifetime. MQSA, which Congress reauthorized in October 2004, addresses the public health need for safe and reliable mammography. MQSA requires that FDA certify mammography facilities by October 1994, and inspect facilities annually to ensure compliance with national quality and safety standards.

MQSA user fees allow ORA to perform two activities:

- fund over 8,000 state contract inspections of mammography facilities annually
- fund FDA conducted foreign inspections to ensure the safety of mammography facilities in foreign countries.

FDA and state inspections combined ensure high quality mammography exams which allow for early breast cancer detection and/or treatment.

Proposed User Fees

Proposed Generic Drugs User Fee: +\$2,636,000 and +6 FTE

Applications to market generic drugs, Abbreviated New Drug Applications (ANDAs), are critical to lowering federal spending on pharmaceuticals. Since 2002, the number of ANDAs has more than doubled.

This proposal is to modify the Food, Drug, and Cosmetic Act to establish user fees for each new application and annually for approved generic products. The additional resources generated by the proposed generic drug user fees would allow FDA to reduce the time to conduct reviews of ANDAs and respond to the growing number of generic drug applications.

Proposed Reinspection User Fee (Mandatory): \$13,014,000 and 102 FTE (Non-Add)

The FY 2008 budget includes \$23,276,000 in budget authority for reinspection related activities. The Budget also proposes a new mandatory user fee to support reinspection activities. Once legislation is enacted, which authorizes FDA to collect this user fee, the Administration will work with Congress to recategorize these fees as discretionary.

FDA conducts follow-up inspections to verify that a firm implements action to correct violations discovered during an inspection or stemming from a warning letter. This

new user fee will amend the Food, Drug, and Cosmetic Act to permit FDA to collect and retain fees to recover from the inspected firm the full cost of reinspections that FDA performs to ensure that their products and facilities comply with current FDA regulations. Under this proposal, FDA reclassifies these activities as mandatory user fees in FY 2008. The total proposed collections for the Agency in FY 2008 are \$23,276,000, with \$13,014,000 of the collections being allocated to the Field program.

Proposed Food and Animal Feed Export Certification User Fee: \$2,716,000 and 17 FTE (Non-Add)

The FY 2008 budget includes \$3,741,000 in budget authority for export certification related activities. The Budget also proposes a new mandatory user fee to support export certification activities. Once legislation is enacted, which authorizes FDA to collect this user fee, the Administration will work with Congress to recategorize these fees as discretionary.

FDA collects user fees of up to \$175 per certificate issued for export certificates for drugs, animal drugs and devices as authorized by Section 801 (e)(4)(B) of the Act. However, there is no similar authority for collecting user fees for export certificates for foods or animal feed. This new user fee will amend the Food, Drug, and Cosmetic Act to permit FDA to collect the cost of food and animal feed export certificate-related activities through user fees. Private sector exporters would bear the cost of the program, but would reap its benefits through the Agency's enhanced ability to facilitate exports of their products. FDA currently funds this activity through discretionary appropriations. The total proposed collections for the Agency in FY 2008 are \$3,741,000, with \$2,716,000 of the collections being allocated to the Field program.

Justification of Base

In FY 2008, FDA will direct its resources to support the highest risk, highest impact, and highest priority initiatives. ORA supported 3,460 FTE, including Office of Shared Services (OSS) FTE in FY 2006. ORA will reallocate resources to recruit a small number of new hires and to move staff around the country to distribute staff relative to the location of its regulated industry and to address evolving Agency priorities. Additional internal resource reallocations will fund travel costs so that foreign and domestic investigational activities, inspections, and sample collections can be based on risk instead of the close proximity to staff locations.

ORA protects consumers and enhances public health by maximizing the compliance of FDA-regulated products and minimizing the risks associated with those products. As the front-line field force supporting the five FDA Centers, ORA reviews imported products being offered for entry into U.S. commerce to ensure their safety and performs laboratory analyses of imported, as well as domestic products. ORA partners with States to increase inspectional coverage of regulated industry and maximize consumer health protection. ORA is also responsible for the enforcement of FDA laws and regulations and the Office of Criminal Investigations is an important part of these

efforts. Along with performing traditional inspections of regulated industry, ORA also responds to public health emergencies, such as foodborne illness outbreaks. Information gathered in traceback investigations is used to identify ways to make produce safer and prevent future outbreaks from occurring. Finally, information technology systems allow ORA to track import, inspectional, and analytical work and more efficiently allocate resources towards the highest risk program areas. The FDA Strategic Goals table below illustrates eight Program Areas that represent the core functions of ORA.

| Program Area | FDA Strategic Goals | | | |
|---|---|---|--|---|
| | Enhance Patient and Consumer Protection and Empower Them With Better Information about Regulated Products | Increase Access to Innovative Products and Technologies to Improve Health | Improve Product Quality, Safety and Availability Through Better Manufacturing and Production Oversight | Transform Administrative Systems and Infrastructure to Support FDA Operations |
| Imports | | | X | |
| Health Fraud | | | X | |
| Office of Criminal Investigations & Enforcement | | | X | |
| Leveraging With the States | | | X | |
| Rapid Response to Emergencies | | | X | |
| Laboratory Capability | | | X | |
| Shelf Life Extension Program (SLEP) | | | X | |
| Information Technology | | | | X |

As illustrated in the table, ORA work provides support to FDA's public health mission. The majority of ORA program areas support the improve product quality, safety, and availability through better manufacturing and production oversight strategic goal.

Imports

The United States is part of an ever increasing global marketplace. FDA processed approximately 15 million import lines in FY 2006, over six times as many as it did in FY 1994. These entries include every type of FDA-regulated product including complex and highly processed goods, and come from more than 230 countries and more than 300,000 manufacturers. This rapid growth, combined with ever present security concerns, has increased the need to assess the status of imported products. FDA electronically screens imports through its Operational and Administrative System for Import Support (OASIS) electronic data system. FDA's electronic screening of

imports will be enhanced by the completion of the Mission Accomplishment and Regulatory Compliance System (MARCS). Imports include other program objectives:

- review more than 17 million import lines for admissibility into domestic commerce by the end of FY 2008
- continue to use information on manufacturer, supplier, source country, and past violations to make enhanced risk-based admissibility decisions
- continue to perform laboratory analysis on products offered for import into the United States
- continue to conduct inspections of foreign establishments as part of the Foods, Human Drugs, Biologics, Animal Drugs and Feeds, and Devices and Radiological Health programs
- perform periodic filer evaluations to ensure that the data being provided to FDA is accurate.

**Prior Notice Security Reviews and
Compliance Actions**

In FY 2006, the Prior Notice Center conducted 89,034 import security reviews. FDA collaborated with Customs and Border Protection to direct field personnel to hold and examine two suspect shipments of imported food; refused 424 lines of food for prior notice violations; conducted 105 informed compliance calls, responded to 29,220 phone and e-mail inquiries; and conducted 89,034 intensive security reviews of Prior Notice submissions out of 9,194,082 submissions in order to intercept contaminated products before they entered the food supply.

Health Fraud

Dietary Supplements: The Consumer Health Information for Better Nutrition initiative is designed to foster two complementary goals concerning the labeling of food and dietary supplements:

- encourage makers of conventional foods and dietary supplements to make accurate, science-based claims about the health benefits of their products
- help to eliminate bogus labeling claims by bringing enforcement actions against those dietary supplement marketers who make false or misleading claims.

The Field will ensure that enforcement activities focus on products with the following marketing strategies: herbal products illegally promoted as alternatives to illicit street drugs; unapproved new drugs containing prosteroids and precursor steroids such as dietary supplements; products which are unapproved new drugs marketed as “natural” treatment for viruses (including the herpes virus), and for cold and flu protection; dietary supplements with unsubstantiated structure function claims (examples include treatments for autism, treatments for mental retardation and epilepsy, sports performance enhancement, and aging); and dietary supplements containing prescription drug ingredients.

Internet Drug Sales: At present, there are an escalating number of new websites marketing FDA-regulated products to the U.S. consumer and medical professionals. FDA currently conducts only minimal levels of web-based oversight. The Office of Criminal Investigations is expanding its efforts to develop cases that address the marketing of counterfeit products:

- continue to monitor potentially fraudulent websites to identify targets for investigation and sampling of products
- conduct “undercover only” purchases of prescription drugs from websites suspected of engaging in illicit drug sales, distribution, and/or marketing
- provide oversight of mail and courier packages entering the U.S. from foreign sources.

Office of Criminal Investigations and Enforcement

A strong, effective, and efficient enforcement of FDA laws and regulations is essential to FDA’s mission of protecting and promoting public health. Enforcement actions also play an important part in ensuring that the American people can have confidence in the safety, quality and integrity of the U.S. food and medical supplies.

The Office of Criminal Investigations (OCI) was established to provide an additional enforcement resource to enhance ORA’s inspectional, compliance, and regulatory efforts. OCI concentrates its resources on investigations of significant violations of the Federal Food, Drug, and Cosmetic Act and Federal Anti-Tampering Act, which pose a danger to the public health and on collecting evidence to support prosecutive actions through the Federal or State court systems as appropriate.

OCI is the FDA office responsible for the conduct and coordination of criminal investigations and, as such, maintains liaison and cooperative investigative efforts with other federal, state, local, and international law enforcement agencies. OCI has primary responsibility and is the primary point of contact for all law enforcement and intelligence issues pertaining to threats or perceived threats against FDA regulated products. OCI participates in numerous law enforcement and intelligence task forces both nationally and internationally to include a full time representative to Interpol.

Drug Safety Activities

In September 2006, an individual from China was arrested by officers of the Hong Kong Customs and Excise Department based on a federal arrest warrant issued by the U.S. District Court for the District of Colorado. The defendant was arrested in Hong Kong after meeting with an undercover OCI agent who posed as a buyer of over 400,000 counterfeit Cialis and Viagra tablets.

This investigation also involved the sale of several thousand counterfeit Tamiflu capsules that were manufactured in China and shipped to the U.S. Information developed by OCI and ICE was shared with Chinese authorities that led to the arrest of four individuals in Hong Kong, China and three defendants plead guilty in the U.S. to counterfeit drug charges.

Leveraging With the States

ORA awards and manages State contract programs that provide resources to States to conduct inspections and report their findings to FDA. These contract programs benefit States with technical training, familiarity with federal requirements, and more uniform enforcement of consumer laws through cooperation and coordination with FDA. The State contract program allows ORA to increase inspectional coverage and redirect resources to other priority activities:

- audit of State contract inspections to ensure consistent application of regulations during FDA and State inspections of food and animal feed establishments
- technical support, monitoring, and evaluation of State programs in milk, shellfish, food service sanitation, and radiation safety
- free training courses to State, local, and tribal regulatory partners.

Rapid Response to Emergencies

Field personnel play a lead role in response to foodborne illness outbreaks by conducting tracebacks of implicated foods. FDA initiates an outbreak investigation when surveillance identifies disease clusters or outbreaks that implicate an FDA regulated product. In foodborne outbreak investigations, ORA has four primary duties:

- investigation and coordination in multistate outbreaks
- tracebacks of implicated foods

- monitoring of recalls of products that are linked to the outbreak
- evaluation of data from investigation findings to identify trends and make recommendations to prevent similar problems.

Information gathered in traceback investigations is used to identify ways to make produce safer and prevent future outbreaks from occurring.

“E. Coli 0157:H7 Outbreak In Raw Spinach”

In September 2006, FDA quickly responded to an outbreak of *E. coli* 0157:H7 associated with contaminated raw spinach. FDA’s efforts focused on the quick removal of the fresh spinach from the marketplace, working with the CDC and state investigators to conduct traceback investigations, and providing consumers with daily updates concerning the outbreak. FDA recall efforts save countless lives every year by causing the swift removal of unsafe foods and medical products from the marketplace and informing the public of the hazards posed by recalled products.

Laboratory Capability

The laboratory analytical function of ORA is conducted in 13 laboratories located throughout the country. The ORA laboratory structure consists of five Regional Labs, four District Labs, and four Specialty Labs. Regional Labs are large general purpose laboratories that participate in most major analytical programs. District Labs participate in several analytical programs and have specialties in specific areas. Specialty labs conduct analyses specific areas of laboratory service:

- Winchester Engineering and Analytical Center (WEAC) focuses on the engineering, biological, and chemical hazards associated with medical devices, electronic products, and radiopharmaceuticals..
- Forensic Chemistry Center (FCC) specializes in forensic analysis of samples related to criminal activities that fall under FDA jurisdiction; including product tampering and drug counterfeiting.

The primary role of field scientists is the analysis of FDA-regulated products. ORA labs facilitate method validation, technical training, inspections, and public outreach. These labs are staffed by a highly-skilled cadre of professional chemists, microbiologists, biologists, entomologists, engineers, physicists, research scientists, quality assurance, and safety/ hazardous waste personnel.

Twelve of the thirteen ORA Laboratories have successfully completed A2LA's final audit assessment for ISO 17025 Laboratory Accreditation. ORA’s FCC is accredited under the American Society of Crime Laboratory Directors/Laboratory Accreditation

Board. The accreditation of all of ORA's laboratories demonstrates ORA's ability to provide work products that fulfill customer needs, meet applicable regulatory requirements, and be able to withstand legal and international scrutiny.

Sample collection and laboratory analysis is a critical part of FDA's regulatory activities. A valid sample is the starting point for most administrative and legal actions. Therefore, the sample must be suitable as evidence to support FDA's charge that there has been a violation of the Act.

The Laboratory Capability includes three additional laboratory activities:

- chemical, microbiological, or physical hazards identification of food source contamination during foodborne illness outbreaks
- engineering, biological, and chemical analysis to prevent the exposure of the public to potentially unsafe or ineffective medical devices, electronic products, radionuclide, and radiopharmaceuticals
- analysis of food samples for pesticides and environmental contaminants.

Shelf Life Extension Program (SLEP)

Shelf Life Extension Program (SLEP) is a cooperative product evaluation program between FDA and the Department of Defense (DOD). It is a key component of the Medical Readiness Strategic Plan in response to Congressional concern over the conservation of military medical resources. To assure preparedness for war or other emergencies, DOD maintains significant pre-positioned stocks or war reserves of critical medical material. All drugs have expiration dates and routine replacement of these stocks can be very costly. To reduce costs, FDA and DOD participate in a cooperative product evaluation program, in which ORA laboratories test product samples, and in cooperation with FDA's Center for Drug Evaluation and Research, determine if the expiration date for the lot of the product can be extended and for how long.

FDA grants extensions to a specific lot number, with an understanding that all lots at all locations have been stored under Current Good Manufacturing Practices, including environmentally controlled storage conditions. The lot is retested annually to confirm extended expiration dating or permit further extension. Products that fail testing at any time are destroyed. All extended SLEP material is relabeled in accordance with FDA regulations. Current testing focuses on military significant pharmaceuticals; drugs that are purchased in very large quantities for specific contingency needs, such as Ciprofloxacin and antivirals, such as Tamiflu. 500 samples were tested in FY 2006 at three ORA laboratories.

SLEP also assures only safe and effective drugs are provided to personnel during war or other contingencies. In 2004, the Strategic National Stockpile, managed by the CDC,

became part of SLEP and in 2005 the Department of Veterans Affairs was added to the program.

Information Technology (IT)

ORA is currently in the midst of a major realignment of its software projects. Burdened with a legacy of stove-piped systems that use outmoded technology, ORA's automated systems cannot provide the support necessary to ensure that FDA can continue to meet its performance goals. ORA's strategy to address this challenge is to combine its IT development efforts into three major programs: Automated Regulatory Management, Data Warehousing and Reporting, and Laboratory Automation. Grouping existing and new IT initiatives into just three areas helps focus resources and managements' attention on ORA's growing business needs. It also ensures that these programs will work together to capture, maintain, and report the information needed to identify and manage health and safety risks, while using resources more effectively.

Automated Regulatory Management - The Automated Regulatory Management program encompasses the Mission Accomplishment and Regulatory Compliance System (MARCS). The MARCS will establish an electronic environment that can dramatically improve the efficiency of FDA Field staff. Benefits include improved import screening, management of foreign inspections, tracking of violative products and BSE firms to improve the safety of the food supply, more sharing of information with States, better integration with FDA laboratories, efficient work-load management, the flexibility to address drug importation if required, and the ability to meet the prior notice requirements for 24/7 support.

Data Warehousing and Reporting - ORA Reporting Analysis and Decision Support System (ORADSS) is a centralized data warehouse that provides integrated decision support to help FDA identify and manage health and safety risks. This will consolidate ORA's reporting functions. When fully implemented, ORADSS will be a comprehensive repository of information about FDA regulated facilities and the enterprises that are part of the supply chain for regulated products. ORADSS' information will allow FDA Centers and management to statistically correlate and analyze multi-year data on geographic areas, firms, products, inspections, and shipments of interest to the FDA.

Laboratory Automation - The Laboratory Automation Program is an emerging ORA program designed to improve the efficiency of the FDA lab staff, the quality of the information the labs provide, and the ability of FDA to share this information with its own centers and other public health labs. In spite of their importance to critical FDA regulatory activities, ORA's laboratories currently depend on manual and semi-automated processes that limit the number and scope of the analyses FDA staff can perform. This program would enable FDA labs to improve chain-of custody tracking, including assignments and sample status, automate collection and processing of analytical data, and track calibration and scheduling to improve the quality of the data produced. The Laboratory Automation Program will also integrate eLEXNET, the

network developed jointly by USDA, CDC, and DoD, to communicate unusual findings from laboratory analyses about food-borne pathogens.

Selected FY 2006 Accomplishments

Imports

Coordination of International Humanitarian Assistance: In the aftermath of Hurricane Katrina, ORA's Prior Notice Center (PNC) worked with the Department of State's U.S. Agency for International Development (USAID), Customs and Border Protection (CBP), the Federal Emergency Management Agency (FEMA) and other federal agencies to develop an International Assistance System (IAS) Manual as part of the National Response Plan. Once the manual is implemented, the PNC will have a system in place to expedite the movement of humanitarian relief shipments to their destinations while ensuring that donated FDA-regulated articles meet regulatory, safety, and security requirements.

Prior Notice Center (PNC) Review and Compliance Actions: FDA received 9,194,082 million prior notice submissions on which the PNC conducted 89,034 import security reviews to identify and intercept potentially contaminated food and animal food/feed products before they entered the U.S. These operations, in cooperation with CBP, actively strengthen the U.S. food supply and provide early warning for potential bioterrorist threats.

Risk-based Screening of Imports: ORA is developing a computerized system that will use known data and artificial intelligence to conduct risk-based screening of imported products. Starting with a system for food imports, FDA and its contractor, New Mexico State University/Physical Science Laboratory (NMSU/PSL), have made substantial progress in the design and proof of concept of the system. Once completed and implemented, this program will help identify imported shipments that pose the greatest risk to public health and will allow ORA to target its resources more effectively.

New Residue Detection Methods Developed: ORA analysts successfully used a new method developed by Canada to detect malachite green in seafood manufactured by 26 different processors. In addition, the State of Florida developed methods to test and measure fluoroquinolones (antibiotic residues) in honey.

New FDA Import Strategy: ORA serves as the lead component within FDA responsible for overseeing the implementation of a new import strategy throughout all product areas. The import strategy provides a framework for re-engineering FDA's agency-wide import operations, policies, and procedures and underscores the importance of applying a risk-based operational approach to the full life-cycle of an imported product. By analyzing data collected throughout the import life cycle, we will be better able to detect risks posed by imported products, as well as key junctures where timely intervention can reduce or eliminate those risks. Once established and emerging risks have been identified and assessed, we can more effectively allocate our resources to manage these risks. Likewise, by employing a more risk-based approach, we can better identify products requiring less FDA scrutiny at the border. This will

help speed the processing of imported products that do meet FDA requirements and free up additional resources for dealing with more risky imports or imports that require further evaluation.

Import Targeting and Intelligence Program (ITIP): OCI has implemented a new initiative intended to enhance and increase our efforts to prevent counterfeit and unapproved pharmaceutical products from entering the U.S. through the various International Mail Facilities (IMF), called the Import Targeting & Intelligence Program (ITIP).

Health Fraud

OCI Liaisons To Combat Fraud Over the Internet: OCI maintains a liaison with the Federation of State Medical Boards and the National Association of Boards of Pharmacy. In addition, OCI maintains a professional liaison with Internet businesses such as Internet Service Providers, GoDaddy, Network Solutions, eBay, and online transaction and financial services PayPal, Mastercard and CENow, and Verisign. OCI provides training and education to internet auction and payment companies.

Development of Alternative Light Source Technology to Fight Counterfeit Drugs: The Forensic Chemistry Center (FCC) developed a new investigative tool utilizing Alternate Light Source (ALS) technology. Once fully implemented, ALS will be a powerful tool to identify potential counterfeit pharmaceuticals.

Warning Letters Issued for Illegal Promotion of Products on Internet: In October 2005, FDA issued Warning Letters to 29 companies that manufacture, market, or distribute products made from cherries or other fruits and which claimed that these products treat or prevent a variety of diseases, including cancer, heart disease, and arthritis. These letters illustrate FDA's vigilance in monitoring the Internet for illegal promotion of fraudulent products targeted to the vulnerable -- those suffering from serious and sometimes fatal illness.

FDA Requested Drug Recall: In February, 2006, FDA requested Cytosol Laboratories of Braintree, MA to conduct a recall of all brands and sizes of its Balanced Salt Solution (BSS), a drug manufactured by the firm to irrigate a patient's eyes, ears, nose and/or throat during a variety of surgical procedures, including cataract surgery. FDA requested this recall because the product was found to have elevated levels of endotoxin. [Endotoxins, also known as pyrogens, are substances found in certain bacteria that cause a wide variety of serious reactions such as fever, shock, changes in blood pressure and in other circulatory functions.] FDA had also received reports of a serious and potentially irreversible eye injury associated with this product called Toxic Anterior Segment Syndrome (TASS) which occurs when a contaminant, such as endotoxin, enters the anterior segment of the eye during surgery and causes an inflammatory reaction. This Class I Recall resulted in the removal of over 1 million units of product from domestic and foreign markets and the firm's subsequent voluntary destruction of over 73,000 units of product.

OCI/Enforcement

Counterfeit Drug Investigation Statistics: In FY 2006, FDA's Office of Criminal Investigations (OCI) initiated 54 counterfeit drug investigations. This resulted in 41 counterfeit drug arrests and 35 convictions in FY 2006, with restitution and fines in excess of \$8,000,000. In FY 2006, OCI continued to coordinate counterfeit drug investigations with several foreign counterparts, especially those in China, Israel, and Canada. These efforts continue to produce positive outcomes for both OCI and its foreign counterparts.

Counterfeit Percocet®, Viagra® and Cialis® Tablets: In September 2006, an individual in Philadelphia who purchased thousands of counterfeit drugs over the Internet from China, including Percocet®, Viagra® and Cialis®, was indicted in the Eastern District of Pennsylvania on charges related to trafficking in counterfeit goods, and other counterfeit prescription drug related charges. This OCI case, worked jointly with U.S. Immigration and Customs Enforcement (ICE), U.S. Drug Enforcement Administration (DEA), U.S. Postal Inspection Service and the Philadelphia Police Department, was part of a much larger OCI-ICE counterfeit drug investigation.

Joint Terrorism Task Force (JTTF) Investigation into Counterfeit Viagra and Stolen Infant Formula: In April 2006, an individual pled guilty in the Eastern District of Virginia to a charge of trafficking in counterfeit Viagra® and was sentenced to 14 months in prison. The defendant in this case distributed or intended to distribute more than 10,000 counterfeit Viagra® tablets to an OCI undercover agent. This case arose out of a Norfolk, Virginia JTTF investigation into stolen infant formula.

OCI Liaisons with Other Agencies: OCI has committed a headquarters agent to serve as a representative to CBP's Office of Anti-Terrorism at CBP headquarters, an office which reports directly to the Commissioner of CBP. OCI also has an agent assigned to the National Counterterrorism Center (NCTC) to serve as a liaison to the Central Intelligence Agency (CIA) and other intelligence agencies. An additional agent is assigned to serve as a liaison to the Department of Homeland Security (DHS) to work on intelligence matters with other DHS agencies, including the Bureau of Immigration and Customs Enforcement (ICE).

Internet Cases: American consumers are increasingly using the internet to purchase their medications. OCI cases involving the internet have risen significantly and represent some of the most egregious threats to the public health. Three cases during FY 2006 illustrate the seriousness of the issue.

Dextromethorphan deaths: On April 12, 2006, two men were sentenced in the Southern District of Indiana Federal Court to 77 months incarceration after pleading guilty to introducing a misbranded drug into interstate commerce. Specifically, they sold dextromethorphan (DXM), a cough suppressant, over the internet through their website. This case started in 2005 after five young people died after ordering and consuming DXM from the defendants' website. DXM is an anti-tussive (cough

suppressant) which is approved for over-the-counter cough medications. The defendants sold the DXM by falsely claiming that DXM was a chemical used for research and development rather than a drug for human consumption. DXM is often abused by some in order to experience a “high.”

Clandestine Drug Manufacturing of Internet Drugs: In 2006, eleven individuals and an Atlanta, Georgia-based company were indicted by a federal grand jury on multiple felony charges relating to a scheme to sell adulterated and unapproved new drugs over the internet. The defendants in this case opened up a pharmaceutical manufacturing facility in Belize, where they made over 24 different prescription medications. The defendants marketed the drugs through “spam” email advertisements where they claimed the drugs were Canadian generic versions of name brand drugs. Some of the drugs the defendants made were unapproved versions of Ambien®, Valium®, Xanax®, Cialis®, Lipitor®, Vioxx® and others. These drugs were then purchased by and shipped to U.S. consumers and to various drug wholesalers.

Fraudulent Avian Flu and Cancer Cures: In 2006, a Florida man was indicted for failing to obey a Temporary Restraining Order (TRO) which directed him to cease and desist marketing non-FDA approved products which he touted as cures for influenza, migraines, cancer, and other ailments. The defendant marketed these products via more than 20 websites that he owned and operated. The TRO issued by the court ordered the defendant to discontinue selling the products and to shut down his websites. Subsequently, the defendant was charged in a superseding indictment for conspiracy, and multiple counts of wire fraud, mail fraud, misbranding, and distributing an unapproved new drug relating to the manufacture and sale of his products.

FDA Flu Statement: ORA/OCI proactively prepared a Press Statement that was cleared at the Agency-level and published on the FDA Website on January 20, 2006 warning the public of the significant threat posed by fraudulent products claiming to prevent/treat seasonal flu or avian flu. As a result of this proactive action, GoDaddy instituted a filtering process to identify and take action against any websites using their services for illegal activity; and made an employee available 24/7 to assist OCI with any problems it uncovers related to the potential flu pandemic.

Leveraging With the States

Electronic State Access to FACTS (eSAF): ORA expanded the number of States that have access to, and can enter data directly into, the electronic State Access to FACTS (eSAF) data system from 17 to 26 in Fiscal Year 2006. This application has conserved resources and allows the States and ORA to share firm and inspection data (including compliance information, consumer complaints, and sample analyses). It also allows ORA to issue inspection assignments directly to the States. With the addition of these nine States, 26 of the 40 states under contract now have access to eSAF.

State Contracts Program: ORA awarded 151 contracts to state and local governments to perform MQSA, feed/BSE, tissue residue, food, and medical device inspections. ORA made its electronic State Access to FACTS (eSAF) database available to 15 state food programs and conducted training for FDA and state personnel to learn the system. ORA began expanding the design of eSAF to include the feed and BSE programs, which will be piloted in FY 2007.

Strategically Manage Human Capital: As part of satisfying the “Green” Standards for Success, the Division of Human Resource and Development (DHRD) developed and implemented a training plan for ORA program staff. Training included 41 classroom courses delivered to 1,400 students, increasing the number of web-based modules to 460 in number; and, delivering 13 satellite/teleconference events. ORA has additional activities to support the strategic management of human capital:

- ORA was authorized by the International Association of Continuing Education and Training to continue to offer continuing education units for ORA courses.
- ORA developed and offered four courses regarding the capabilities of the FERN (Food Emergency Response Network) to 80 students.
- ORA offered eight courses to approximately 280 state and FDA students in response to BSE concerns.
- ORA delivered three import courses focused on risk-based screening of imports to approximately 120 attendees.

Rapid Response to Emergencies (Outbreaks, Recalls)

Hurricanes Katrina and Rita: ORA took the lead in FDA’s emergency response and revitalization efforts following the hurricanes and worked with other federal, state and local officials on many efforts:

- scrutinize more than 500 food service operations in schools, nursing homes, hospitals, shelters and other establishments to make sure the food supply was safe
- inspect 417 pharmacies to ensure that the drugs, medical devices and biologics held and distributed by them continued to be safe and effective
- supervise the reconditioning or destruction of regulated products that were no longer deemed suitable for consumption or their intended use
- identify and examine 53 shipments of humanitarian aid supplies donated by foreign relief agencies to make sure they met FDA requirements

- dispatch two mobile laboratories to Thibodeaux, Louisiana to assist Louisiana health officials in the collection and analysis of 417 water samples so that the quality and safety of shellfish growing waters could be assessed.

Laboratory Capability

Laboratory Accreditation: Twelve of 13 ORA Laboratories have successfully completed A2LA's final audit assessment for ISO 17025 Laboratory Accreditation. ORA's Forensic Chemistry Center (FCC) was accredited under the American Society of Crime Laboratory Directors/Laboratory Accreditation Board, resulting in all ORA laboratories being appropriately accredited. Accreditation against these quality management systems demonstrates ORA's ability to provide work products that fulfill customer needs, meet applicable regulatory requirements, and able to withstand legal and international scrutiny.

Mobile Laboratory Program: In June, 2006, ORA's Mobile Chemistry Lab was deployed to Fort Sam Houston, San Antonio, TX to assist FDA's Southwest Import District in the analysis of samples collected in response to work plan and counterterrorism assignments.

Shelf-Life Extension Program

Shelf Life Extension Program (SLEP): ORA continued its participation in SLEP, a joint FDA/Department of Defense product evaluation program. To reduce replacement costs of critical medical material in war/emergency reserves, ORA laboratories test product samples, and in cooperation with CDER, determine if the expiration date for the lot of the product can be extended and for long. In FY 2006, ORA laboratories tested 500 product samples, including samples of Oseltamivir and Rimantadine. These antiviral drugs are an important component of the federal government's pandemic influenza response.

Information Technology

ORA Web Content Management: ORA implemented the Vignette Web Content Management System and succeeded in standardizing the ORA intranet web site, streamlining more than 6,500 pages of information, making the retrieval of information more user-friendly, and establishing a tool for rapid communication. The Content Management System has facilitated the publication of electronic versions of official ORA reference documents and manuals such as the Investigations Operations Manual, as well as other regulatory information and guidance documents.

ORADSS Upgrades: FDA completed its upgrade of the enforcement data warehouse, the ORA Reporting Analysis and Decision Support System (ORADSS), by consolidating its FACTS reporting system into a single ORADSS user interface. This integration will significantly improve the ability of field, ORA headquarters, and

Center offices to conduct in-depth, customized analyses of compliance programs and enforcement initiatives and to detect patterns of violations.

Mission Accomplishment and Regulatory Compliance System (MARCS): An upgrade of user access capabilities using the Web for the legacy systems, OASIS, FACTS, and Recall Enterprise System was completed in June 2006. In addition the upgrade provides an operational environment and infrastructure in support of the larger MARCS Program strategy. A prototype application to support import examinations at International Mail Facilities was completed and is in use; work to finalize its design and fully implement it is underway.

Prior Notice System Interface (PNSI): During FY 2006, usability and performance was improved by developing features such as personal address books, reusable information from past submissions, and copying and pasting of web entries. With the added benefit of addressing discrepancies related to Section 508 of the U.S. Rehabilitation Act, the process of submitting Prior Notices via the web has been simplified and streamlined.

Electronic Laboratory Exchange Network (eLEXNET): Of the 131 laboratories in the eLEXNET system, 107 are actively submitting data, an increase of 12 laboratories from the previous year. The interface of eLEXNET with the Department of Homeland Security's National Biosurveillance Integration System (DHS/NBIS) facilitates the submission to DHS of bio surveillance reports that could adversely impact the food supply. In addition, the version 5.0 SOA Methods Module was released, improving rapid sharing of validated methods between states, USDA, FDA, and Canada.

Expand Electronic Government: ORA has commitments to expanding electronic government:

- Nearly 8,000 state, local and tribal regulators have now registered with ORA's e-learning source offering 125 technical web-based training modules.
- In collaboration with CDC, ten national food safety associations and others within FDA, developed and delivered a national satellite program on food defense to over 10,000 participants.
- ORA facilitated the development of a web based training tool for state and local food regulatory personnel to initiate discussions with food producers, retailers and service organizations on food defense.
- In collaboration with the Association of Food and Drug Officials and CDC, developed a "course in a box" entitled "The Application of the Basics of Inspection/Investigation FD170" intended to be delivered on site locally to state/local/tribal new hires.

- ORA developed a course for the Shellfish Patrol Officers who police coastal waters for illegal harvesting of shell stock in collaboration with CFSAN and the ISSC (Interstate Shellfish Sanitation Conference)
- ORA developed a new course called "Food Emergency Response FD217" for Commission Corps Officers on rapid deployment teams responding to disasters.
- ORA provided up-to-date training materials on the FDA/ORA internet site for state/local/tribal regulatory employees.
- ORA facilitated the development of the web-based A.L.E.R.T. initiative for FDA, the Centers for Disease Control and Prevention, and USDA to help State and local food regulatory personnel initiate discussions with food producers, retailers, and service organizations on food defense.
- ORA developed and delivered four "eSAF" (electronic State Access to FACTS) courses to approximately 80 students to train State employees who supervise, manage, and/or perform FDA inspections work under State food contracts.

ORA Transformation Leadership Team Support: A customized, interactive website was created to provide FDA personnel with up-to-date information regarding ORA's Transformation Initiative. The site also allows ORA personnel to submit questions, comments and feedback concerning the transformation to ORA management.

**Combined Field Activities – ORA
Program Activity Data**

FOODS FIELD

| PROGRAM OUTPUTS- DOMESTIC INSPECTIONS | FY2006 Actual | FY2007 CR Estimate | FY2007 PB Estimate | FY2008 Estimate |
|--|--------------------------|-------------------------------|-------------------------------|----------------------------|
| Domestic Food Safety Program Inspections | 3,833 | 3,000 | 3,400 | 3,400 |
| Imported and Domestic Cheese Program Inspections | 401 | 200 | 300 | 300 |
| Domestic Low Acid Canned Foods/ Acidified Foods Inspections | 477 | 300 | 400 | 400 |
| Domestic Fish & Fishery Products (HACCP) Inspections | 2,308 | 2,000 | 2,330 | 2,330 |
| Import (Seafood Program Including HACCP) Inspections | 529 | 250 | 500 | 500 |
| Juice HACCP Inspection Program (HACCP) | 441 | 100 | 300 | 375 |
| Interstate Travel Sanitation (ITS) Inspections | 1,175 | 1,000 | 1,550 | 1,550 |
| State Contract Food Safety (Non HACCP) Inspections | 6,680 | 7,780 | 8,400 | 8,400 |
| State Contract Domestic Seafood HACCP Inspections | 1,006 | 1,010 | 1,010 | 1,010 |
| State Contract Juice HAACP | 58 | 47 | 47 | 47 |
| State Partnership Inspections | <u>822</u> | <u>900</u> | <u>900</u> | <u>900</u> |
| Total Above FDA and State Inspections | 17,730 | 16,587 | 19,137 | 19,212 |
| State Contract and Grant Foods Funding | \$6,378,774 | \$6,378,774 | \$6,825,288 | \$7,303,058 |
| Number of FERN State Laboratories | 10 | 10 | 16 | 16 |
| Annual FERN State Cooperative Agreements/Operations Funding | \$7,105,000 | \$7,195,000 | \$12,535,000 | \$10,285,000 |
| Total State & Annual FERN Funding | \$13,483,774 | \$13,573,774 | \$19,360,288 | \$17,588,058 |
| Domestic Field Exams/Tests | 2,455 | 2,500 | 2,500 | 2,500 |
| Domestic Laboratory Samples Analyzed | 11,706 | 9,965 | 10,465 | 10,465 |
| All Foreign Inspections | 125 | 100 | 100 | 100 |
| Import Field Exams/Tests | 94,545 | 71,000 | 71,000 | 71,000 |
| Import Laboratory Samples Analyzed | <u>20,662</u> | <u>26,980</u> | <u>28,480</u> | <u>28,480</u> |
| Import Physical Exam Subtotal | 115,207 | 97,980 | 99,480 | 99,480 |
| Import Line Decisions | 8,883,999 | 9,101,004 | 9,101,004 | 9,323,310 |
| Percent of Import Lines Physically Examined | 1.30% | 1.08% | 1.09% | 1.07% |
| Prior Notice Security Import Reviews (Bioterrorism Act Mandate) | 89,034 | 60,000 | 60,000 | 60,000 |

COSMETICS FIELD

| PROGRAM OUTPUTS- | FY2006 | FY2007 | FY2007 | FY2008 |
|--|----------------------|------------------------|------------------------|------------------------|
| DOMESTIC INSPECTIONS | <u>Actual</u> | <u>CR</u> | <u>PB</u> | <u>Estimate</u> |
| | | <u>Estimate</u> | <u>Estimate</u> | <u>Estimate</u> |
| All Inspections | 151 | 25 | 100 | 100 |
| PROGRAM OUTPUTS- | | | | |
| IMPORT/FOREIGN INSPECTIONS | | | | |
| Import Field Exams/Tests | 2,441 | 2,000 | 2,000 | 2,000 |
| Import Laboratory Samples Analyzed | <u>280</u> | <u>230</u> | <u>230</u> | <u>200</u> |
| Import Physical Exam Subtotal | 2,721 | 2,230 | 2,230 | 2,200 |
| Import Line Decisions | 1,358,918 | 1,611,326 | 1,611,326 | 1,910,616 |
| Percent of Import Lines Physically Examined | 0.20% | 0.14% | 0.14% | 0.12% |

DRUGS FIELD

| PROGRAM OUTPUTS- DOMESTIC INSPECTIONS | FY2006 <u>Actual</u> | FY2007 <u>CR Estimate</u> | FY2007 <u>PB Estimate</u> | FY2008 <u>Estimate</u> |
|--|---------------------------------|--------------------------------------|--------------------------------------|-----------------------------------|
| Pre-Approval Inspections (NDA) | 139 | 112 | 112 | 112 |
| Pre-Approval Inspections (ANDA) | 80 | 110 | 110 | 155 |
| Bioresearch Monitoring Program Inspections | 498 | 555 | 555 | 555 |
| Drug Processing (GMP) Program Inspections | 1,222 | 1,100 | 1,377 | 1,377 |
| Compressed Medical Gas Manufacturers Inspections | 106 | 158 | 158 | 158 |
| Adverse Drug Events Project Inspections | 105 | 133 | 133 | 133 |
| OTC Monograph Project and Health Fraud Project Inspections | 28 | 32 | 32 | 32 |
| State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections | 63 | 110 | 110 | 110 |
| State Partnership Inspections: GMP Inspections | 50 | 50 | 50 | 50 |
| Total Above FDA and State Partnership Inspections | 2,291 | 2,360 | 2,637 | 2,682 |
| Domestic Laboratory Samples Analyzed | 1,706 | 1,587 | 1,587 | 1,587 |
| PROGRAM OUTPUTS- IMPORT/FOREIGN INSPECTIONS | | | | |
| Foreign Pre-Approval Inspections (NDA) incl PEPFAR | 123 | 125 | 190 | 190 |
| Foreign Pre-Approval Inspections (ANDA) incl PEPFAR | 79 | 42 | 42 | 87 |
| Foreign Bioresearch Monitoring Program Inspections incl PEPFAR | 124 | 44 | 44 | 44 |
| Foreign Drug Processing (GMP) Program Inspections | 164 | 134 | 174 | 209 |
| Foreign Adverse Drug Events Project Inspections | 10 | 16 | 16 | 16 |
| Total Above Foreign FDA Inspections | 500 | 361 | 466 | 546 |
| Import Field Exams/Tests | 3,525 | 4,400 | 4,400 | 4,400 |
| Import Laboratory Samples Analyzed | 277 | 275 | 275 | 275 |
| Import Physical Exam Subtotal | 3,802 | 4,675 | 4,675 | 4,675 |
| Import Line Decisions | 279,662 | 295,627 | 295,627 | 312,504 |
| Percent of Import Lines Physically Examined | 1.36% | 1.58% | 1.58% | 1.50% |

Note:

1. The increase in Human Drugs ANDA inspections for FY08 above FY07 are attributed to the Proposed Generic Drugs User Fee.

BIOLOGICS FIELD

| PROGRAM OUTPUTS- | FY2006 | FY2007 | FY2007 | FY2008 |
|--|----------------------|--------------------------------------|--------------------------------------|------------------------|
| DOMESTIC INSPECTIONS | <u>Actual</u> | <u>CR</u> <u>Estimate</u> | <u>PB</u> <u>Estimate</u> | <u>Estimate</u> |
| Bioresearch Monitoring Program Inspections | 88 | 169 | 180 | 180 |
| Blood Bank Inspections | 1,139 | 1,045 | 1,130 | 1,130 |
| Source Plasma Inspections | 145 | 174 | 174 | 190 |
| Pre-License, Pre-Approval (Pre-Market) Inspections | 22 | 6 | 6 | 6 |
| GMP Inspections | 26 | 30 | 30 | 30 |
| GMP (Device) Inspections | 6 | 16 | 16 | 32 |
| Human Tissue Inspections | <u>354</u> | <u>385</u> | <u>484</u> | <u>484</u> |
| Total Above Domestic Inspections | 1,780 | 1,825 | 2,020 | 2,052 |
| PROGRAM OUTPUTS- | | | | |
| IMPORT/FOREIGN INSPECTIONS | | | | |
| Blood Bank Inspections | 0 | 12 | 12 | 24 |
| Pre-License Inspections | 1 | 4 | 4 | 4 |
| GMP Inspections | <u>15</u> | <u>15</u> | <u>15</u> | <u>15</u> |
| Total Above Foreign FDA Inspections | 16 | 31 | 31 | 43 |
| Import Field Exams/Tests | 66 | 100 | 100 | 100 |
| Import Line Decisions | 44,418 | 49,350 | 49,350 | 54,829 |
| Percent of Import Lines Physically Examined | 0.15% | 0.20% | 0.20% | 0.18% |

ANIMAL DRUGS & FEEDS FIELD

| PROGRAM OUTPUTS- | FY2006 | FY2007 | FY2007 | FY2008 |
|--|--------------------|------------------------|--------------------|--------------------|
| | <u>Actual</u> | <u>CR Estimate</u> | <u>PB Estimate</u> | <u>Estimate</u> |
| DOMESTIC INSPECTIONS | | | | |
| Pre-Approval /BIMO Inspections | 64 | 65 | 125 | 125 |
| Drug Process and New ADF Program Inspections | 209 | 168 | 194 | 194 |
| BSE Inspections | 2,510 | 2,594 | 2,594 | 2,844 |
| Feed Contaminant Inspections | 19 | 10 | 10 | 10 |
| Illegal Tissue Residue Program Inspections | 218 | 180 | 233 | 233 |
| Feed Manufacturing Program Inspections | 333 | 170 | 220 | 220 |
| State Contract/Coop Agreement Inspections: BSE | 5,410 | 4,527 | 4,844 | 4,844 |
| State Contract Inspections: Feed Manufacturers | 383 | 314 | 336 | 336 |
| State Contract Inspections: Illegal Tissue Residue | 276 | 285 | 706 | 635 |
| State Partnership Inspections: BSE and Other | <u>1,036</u> | <u>900</u> | <u>900</u> | <u>900</u> |
| Total Above FDA and State Contract Inspections | 10,458 | 9,213 | 10,162 | 10,341 |
| State Contract Animal Drugs/Feeds Funding | \$1,785,384 | \$1,785,384 | \$1,910,361 | \$2,044,086 |
| BSE Cooperative Agreement Funding | \$3,000,000 | \$3,000,000 | \$3,000,000 | \$3,000,000 |
| State Contract Tissue Residue Funding | <u>\$281,031</u> | <u>\$281,031</u> | <u>\$697,500</u> | <u>\$320,375</u> |
| Total State Funding | \$5,066,415 | \$5,066,415 | \$5,607,861 | \$5,364,461 |
| Domestic Laboratory Samples Analyzed | 2,053 | 1,725 | 1,725 | 1,880 |
| PROGRAM OUTPUTS- IMPORT/FOREIGN INSPECTIONS | | | | |
| Foreign Pre-Approval/Bioresearch Monitoring Program Inspections | 31 | 30 | 45 | 45 |
| Foreign Drug Processing and New ADF Program Inspections | <u>11</u> | <u>10</u> | <u>10</u> | <u>10</u> |
| Total Above Foreign FDA Inspections | 42 | 40 | 55 | 55 |
| Import Field Exams/Tests | 4,063 | 4,500 | 4,500 | 4,500 |
| Import Laboratory Samples Analyzed | <u>510</u> | <u>1,075</u> | <u>1,075</u> | <u>1,075</u> |
| Import Physical Exam Subtotal | 4,573 | 5,575 | 5,575 | 5,575 |
| Import Line Decisions | 225,959 | 240,549 | 240,549 | 256,081 |
| Percent of Import Lines Physically Examined | 2.02% | 2.32% | 2.32% | 2.18% |

DEVICES FIELD

| PROGRAM OUTPUTS- | FY 2006 | FY2007 | FY2007 | FY2008 |
|--|--------------------|--------------------|--------------------|---------------------|
| | | CR | | |
| DOMESTIC INSPECTIONS | Actual | Estimate | PB Estimate | Estimate |
| Bioresearch Monitoring Program Inspections | 319 | 300 | 300 | 300 |
| Pre-Approval Inspections | 76 | 20 | 119 | 139 |
| Post-Market Audit Inspections | 50 | 65 | 65 | 65 |
| GMP Inspections (Levels I, II, III and Accredited Persons) | <u>1,472</u> | <u>1,300</u> | <u>1,458</u> | <u>1,558</u> |
| Total Above Domestic Inspections: Non MQSA | 1,917 | 1,685 | 1,942 | 2,062 |
| Inspections (MQSA) FDA Domestic (non-VHA) | 367 | 335 | 335 | 335 |
| Inspections (MQSA) FDA Domestic (VHA) | 31 | 31 | 31 | 31 |
| Inspections (MQSA) by State Contract | 7,620 | 7,838 | 7,838 | 7,838 |
| Inspections (MQSA) by State non-Contract | <u>607</u> | <u>790</u> | <u>790</u> | <u>790</u> |
| Total Above Domestic Inspections: MQSA | 8,625 | 8,994 | 8,994 | 8,994 |
| State Contract Devices Funding | \$225,000 | \$225,000 | \$240,750 | \$257,603 |
| State Contract Mammography Funding | <u>\$8,868,100</u> | <u>\$9,754,910</u> | <u>\$9,754,910</u> | <u>\$10,730,401</u> |
| Total State Funding | \$9,093,100 | \$9,979,910 | \$9,995,660 | \$10,988,004 |
| Domestic Radiological Health Inspections | 85 | 133 | 133 | 133 |
| Domestic Field Exams/Tests | 800 | 1,575 | 1,575 | 1,575 |
| Domestic Laboratory Samples Analyzed | 237 | 173 | 173 | 203 |
| PROGRAM OUTPUTS- | | | | |
| IMPORT/FOREIGN INSPECTIONS | | | | |
| Foreign Bioresearch Monitoring Inspections | 17 | 10 | 10 | 10 |
| Foreign Pre-Approval Inspections | 37 | 12 | 32 | 32 |
| Foreign Post-Market Audit Inspections | 21 | 7 | 27 | 27 |
| Foreign GMP Inspections | 209 | 155 | 200 | 200 |
| Foreign MQSA Inspections | 10 | 15 | 15 | 15 |
| Foreign Radiological Health Inspections | <u>24</u> | <u>19</u> | <u>19</u> | <u>19</u> |
| Total Above Foreign FDA Inspections | 318 | 218 | 303 | 303 |
| Import Field Exams/Tests | 5,063 | 5,000 | 5,000 | 5,000 |
| Import Laboratory Samples Analyzed | <u>1,162</u> | <u>1,340</u> | <u>1,340</u> | <u>1,340</u> |
| Import Physical Exam Subtotal | 6,225 | 6,340 | 6,340 | 6,340 |
| Import Line Decisions | 4,184,839 | 5,026,091 | 5,026,091 | 6,036,455 |
| Percent of Import Lines Physically Examined | 0.15% | 0.13% | 0.13% | 0.11% |

PERFORMANCE ANALYSIS

During FY 2006, which was the latest performance period for which FDA has complete data, ORA successfully achieved or exceeded all 15 targets for its FY 2006 performance goals. For more information about these performance goals and results, please see the Performance Detail section.

For the FY 2007 President's Budget, the Import Food Field Exams goal was decreased by 4,000 exams as a result of redeployment of funds to other food defense priorities. In addition, three additional performance goals were reduced including the high risk foods goal (reduction of 75 inspections); high risk blood banks and source plasma goal (reduction of 37 inspections); and, the medical device Class II and III manufacturers goal (reduction of 75 inspections). The targets for the animal drugs and feeds establishment and BSE inspection performance goals were reduced due to a reduction in firm inventory.

Due to the impact of the FY 2007 Continuing Resolution, four performance goals were reduced. ORA will not have the staff to meet performance commitments made in the FY 2007 President's Budget. Outputs were reduced for the high risk foods goal (reduction of 1,015 inspections); high risk blood banks and source plasma goal (reduction of 85 inspections); animal drugs and feeds establishment goal (reduction of 106 inspections); and, the medical device Class II and II manufacturers goal (reduction of 258 inspections). The FY 2007 Continuing Resolution will also not allow for additional laboratory surge capacity in FY 2008 because ORA will be unable to fund new Food Emergency Response Network (FERN) cooperative agreements in FY 2007.

In FY 2007 and continuing in FY 2008, ORA worked with counterparts in each of the five program Centers to revise performance goals to be more risk-based and outcome oriented. Specifically, five performance goals have been revised to improve the risk-based selection process when determining specific firms to target for performance goal inspections. These include medical device protection of human subjects; foods; human drugs; biologics; and, medical device manufacturing performance goals.

These efforts will continue in FY 2008 as ORA strives to strengthen its risk-based approach and outcome orientation in field performance goals. In FY 2008, the Field will increase performance in the high risk foods goal; high risk blood banks and source plasma goal; and, the medical device Class II and III manufacturers goal.

P.T. 2007 / OPA / VUKR / LAIN November 9, 2006

| 1. PROGRAM ASSIGNMENT TITLE Field Assignments for Chemical Contaminants | | | | 2. PPS PROJECT NAME/NUMBER Pesticides and Chemical Contaminants -04 | | | | |
|--|--|---|---------------------------------------|--|-------------------------------------|--------------------------------|---|--|
| 3. PROGRAM ASSIGNMENT CODE(S) 04F800 | | 4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER | | | 5. OPERATIONAL FTE POSITIONS 8.7 | | | |
| P C I C O N | DISTRICT/ SPECIALIZED LABORATORY | DOC PERCHLORATE IN FOODS | DSA PERCHLORATE IN FOODS *** | | PC CONTAMINANTS IN HONEY | PA CONTAMINANTS IN HONEY | IS/DC/PC PES & TE DIETARY SUPPL. | SA/DA PES & TE DIETARY SUPPL. ** |
| | TOTAL FIELD | 200 | 1000 | | 100 | 100 | 200 | 200 |
| HEADQUARTERS | | | | | | | | |
| REGIONAL STAFF | | | | | | | | |
| NE | NEW ENGLAND | 10 | | | | | | |
| | NEW YORK | 20 | | | 10 | | 40 | |
| | REGIONAL LAB WEAC | | | | | | | 40 |
| | REGIONAL STAFF | | | | | | | |
| CE | BALTIMORE | 10 | | | | | 10 | |
| | CHICAGO | 10 | | | 10 | | 10 | |
| | CINCINNATI | | | | | | | |
| | DETROIT | 10 | | | | | 10 | |
| | MINNEAPOLIS | 10 | | | | | | |
| | NEW JERSEY | | | | | | | |
| SE | PHILADELPHIA | 10 | | | | | 10 | |
| | FORENSIC CHEM. CTR | | | | | | | |
| | REGIONAL STAFF | | | | | | | |
| | ATLANTA | 10 | | | | | | |
| | FLORIDA | 10 | | | 10 | | 10 | |
| | NEW ORLEANS | | | | | | | |
| SW | SAN JUAN | | | | | | | |
| | REGIONAL LAB | | 200 | | | 30 | | 30 |
| | REGIONAL STAFF | | | | | | | |
| | DALLAS | 20 | | | | | 10 | |
| PACIFIC REGIONAL LABORATORY - NW | DENVER | | | | | | 10 | |
| | KANSAS CITY | 10 | 800 | | | | | |
| | SOUTHWEST IMPORT DISTRICT | | | | 30 | | 30 | |
| | REGIONAL LAB | | | | | | 70 | 55 |
| | REGIONAL STAFF | | | | | | | |
| | LOS ANGELES | 30 | | | 20 | | 30 | |
| PACIFIC REGIONAL LABORATORY - SW | SAN FRANCISCO | 30 | | | | | 20 | |
| | SEATTLE | 10 | | | 20 | | 10 | |
| | PACIFIC REGIONAL LABORATORY - SW | | | | | | | 65 |
| HOURS PER OPERATION | | 3.0 | 3.0 | | 3.0 | 6.5 | 3.0 | 24.0 |
| TOTAL HOURS | | 600 | 3000 | | 300 | 850 | 600 | 4800 |
| CONVERSION FACTOR | | .950 | 1.180 | | .950 | 1.180 | .950 | 1.180 |
| TOTAL OPERATIONAL FTEs | | 0.63 | 2.54 | | 0.32 | 0.55 | 0.63 | 4.07 |
| 7. REMARKS *Collection of samples for both Pesticides and Toxic Elements analysis. ** The Analytical module includes resources for both Pesticides and Toxic Elements Collections for Perchlorate and Dietary Supplements will be directed by CFSAN field assignments. Contaminants in honey include chloroamphenicol (See Import Bulletin) and CFSAN assignment. *** 800 perchlorate DSAs for KAN-DO Lab will be collected by EPA. | | | | | | | | |

2x3

| | | | | | | | | | | |
|--|--|-----------------------------|--|------------------|---|---|--|-----------------------------|-----------------------------|------------------|
| 1. PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods | | | | | 2. PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07 | | | | | |
| 3. PROGRAM/ASSIGNMENT CODE(S) 07001 (DOMESTIC) | | | 4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> X ORA <input type="checkbox"/> CENTER | | | 5. OPERATIONAL FTE POSITIONS Total (21.8) 13.9 | | | | |
| G I O N | DISTRICT/ SPECIALIZED LABORATORY | 3 DSCs AFLA- TOXIN | 3 DSCs FUMON- ISON | 3 DSCs DON | 3 DSCs DONRA TOXIN | 3 DSCs PATULIN | 7 ALL DOMESTIC SAMPLE ANALYSES | 7 DSAs AFLA- TOXIN | 7 DSAs FUMON- ISON | 7 DSAs DON |
| | TOTAL FIELD | 800 | 169 | 213 | 274 | 231 | 780 | 800 | 66 | 218 |
| HEADQUARTERS | | | | | | | | | | |
| REGIONAL STAFF | | | | | | | | | | |
| NE | NEW ENGLAND | 24 | 5 | | 3 | 44 | | | | |
| | NEW YORK | 25 | 7 | 18 | 6 | 25 | | | | |
| | REGIONAL LAB | | | | | | 205 | | | 62 |
| | WEAC | | | | | | | | | |
| REGIONAL STAFF | | | | | | | | | | |
| | BALTIMORE | 28 | 11 | 13 | 2 | 9 | | | | |
| | CHICAGO | 81 | 25 | 6 | 11 | 11 | | | | |
| | CINCINNATI | 75 | 23 | 18 | 10 | 7 | | | | |
| CE | DETROIT | 40 | 13 | 13 | 13 | 20 | | | | |
| | MINNEAPOLIS | 30 | 11 | 12 | 8 | 11 | | | | |
| | NEW JERSEY | 21 | 7 | 5 | 2 | 12 | | | | |
| | PHILADELPHIA | 14 | 4 | 8 | 3 | 20 | | | | |
| | FORENSIC CHEM. CTR | | | | | | | | | |
| REGIONAL STAFF | | | | | | | | | | |
| SE | ATLANTA | 79 | 17 | 13 | 2 | 2 | | | | |
| | FLORIDA | 20 | 4 | 5 | | 9 | | | | |
| | NEW ORLEANS | 49 | 13 | 13 | | 5 | | | | |
| | SAN JUAN | 3 | | 6 | | | | | | |
| | REGIONAL LAB | | | | | | 926 | 800 | | 68 |
| REGIONAL STAFF | | | | | | | | | | |
| SW | DALLAS | 105 | 26 | 10 | 6 | 11 | | | | |
| | DENVER | 12 | 3 | 3 | 3 | 3 | | | | |
| | KANSAS CITY | 60 | 13 | 14 | 2 | 25 | 220 | | 108 | 32 |
| | SOUTHWEST IMPORT DISTRICT | | | | | | | | | |
| | REGIONAL LAB | | | | | | | | | |
| REGIONAL STAFF | | | | | | | | | | |
| PA | LOS ANGELES | 54 | 16 | 5 | 8 | 9 | | | | |
| | SAN FRANCISCO | 30 | | 15 | 1 | 4 | | | | |
| | SEATTLE | 52 | 8 | 37 | 9 | 31 | | | | |
| | PACIFIC REGIONAL LAB - SW | | | | | | | | | |
| | PACIFIC REGIONAL LAB - NW | | | | | | 119 | | | 57 |
| HOURS PER OPERATION | | 4.0 | 4.0 | 4.0 | 4.0 | 4.0 | 6.0 | | | |
| TOTAL HOURS | | 3200 | 664 | 876 | 296 | 924 | 8940 | | | |
| CONVERSION FACTOR | | 950 | 950 | 950 | 950 | 950 | 1180 | | | |
| TOTAL OPERATION FTEs | | 3.37 | 0.70 | 0.92 | 0.31 | 0.97 | 7.58 | | | |
| 7. REMARKS Report all Domestic and Import operations under PAC 07001. | | | | | | | | | | |

| 1. PROGRAM/ASSIGNMENT TITLE | | 2. PPS PROJECT NAME/NUMBER | | | | | | | | |
|---|--|---|-----------------|-----------------------|--------------------------|------------------------------|-------------|-------------------------|-----------------|---------------------------|
| Mycotoxin in Domestic and Import Foods PAGE 2 | | Molecular Biology & Natural Toxins - 07 | | | | | | | | |
| 3. PROGRAM/ASSIGNMENT CODE(S) | | 4. WORK ALLOCATION PLANNED BY | | | | 5. OPERATIONAL FTE POSITIONS | | | | |
| 07001 (DSA, ISCs) | | <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER | | | | 2.1 | | | | |
| 6. G I O N | 7 | 7 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | |
| | DISTRICT/ SPECIALIZED LABORATORY | DSAs OCHRAs TOXIN | DSAs PATULIN | ISCs AFLA TOXIN | ISCs PEANUT BUTTER | ISCs FUMON- ISON | ISCs DON | ISCs OCHRAs TOXIN | ISCs PATULIN | ISCs SPECIAL SURVEY |
| | TOTAL FIELD | 24 | 23 | 44 | | 81 | 17 | 59 | 23 | 40 |
| | HEADQUARTERS | | | | | | | | | |
| | REGIONAL STAFF | | | | | | | | | |
| NE | NEW ENGLAND | | | 4 | | | | 1 | 7 | |
| | NEW YORK | | | 148 | (35) | 30 | | 6 | 20 | 91 |
| | REGIONAL LAB | 26 | 117 | | | | | | | |
| | WEAC | | | | | | | | | |
| | REGIONAL STAFF | | | | | | | | | |
| | BALTIMORE | | | 16 | (4) | | 8 | 3 | 5 | 1 |
| | CHICAGO | | | 13 | | | | | 13 | 1 |
| | CINCINNATI | | | 5 | | | | | | |
| CE | DETROIT | | | 66 | (27) | | 14 | 8 | 25 | 3 |
| | MINNEAPOLIS | | | 5 | | | 1 | 1 | 1 | |
| | NEW JERSEY | | | | | | | | | |
| | PHILADELPHIA | | | | | | 6 | | 3 | |
| | FORENSIC CHEM. CTR | | | | | | | | | |
| | REGIONAL STAFF | | | | | | | | | |
| SE | ATLANTA | | | 8 | (3) | | 6 | 1 | 3 | 1 |
| | FLORIDA | | | 20 | | 16 | 3 | | 13 | 4 |
| | NEW ORLEANS | | | 2 | | | | | | |
| | SAN JUAN | | | 2 | | | | 1 | 2 | 1 |
| | REGIONAL LAB | | 58 | | | | | | | |
| | REGIONAL STAFF | | | | | | | | | |
| SW | DALLAS | | | | | | | | | |
| | DENVER | | | | | | | | | |
| | KANSAS CITY | | | 50 | | 12 | | | | |
| | SOUTHWEST IMPORT DISTRICT | | | | | 36 | (3) | 21 | 44 | 4 |
| | REGIONAL LAB | | | | | | | | | 1 |
| | REGIONAL STAFF | | | | | | | | | |
| PA | LOS ANGELES | | | 49 | (6) | | 5 | 11 | 3 | 13 |
| | SAN FRANCISCO | | | 30 | | | 3 | 2 | 6 | 2 |
| | SEATTLE | | | 57 | (27) | | 5 | 16 | 8 | 29 |
| | PACIFIC REGIONAL LAB - SW | | | | | | | | | |
| | PACIFIC REGIONAL LAB - NW | 18 | 44 | | | | | | | |
| | HOURS PER OPERATION | | | 2.0 | | 2.0 | 2.0 | 2.0 | 2.0 | 2.0 |
| | TOTAL HOURS | | | 928 | | 162 | 234 | 118 | 446 | 80 |
| | CONVERSION FACTOR | | | 950 | | 950 | 950 | 950 | 950 | 950 |
| | TOTAL OPERATION FTEs | | | 0.98 | | 0.17 | 0.25 | 0.12 | 0.47 | 0.08 |
| 7. REMARKS | | | | | | | | | | |
| * Peanut Butter ISCs were spread by CFSAN | | | | | | | | | | |

| 1. PROGRAM/ASSIGNMENT TITLE Mycotoxin in Domestic and Import Foods PAGE 3 | | | | 2. PPS PROJECT NAME/NUMBER Molecular Biology & Natural Toxins - 07 | | | | | | |
|--|--|-------------------------------------|--|---|-------------|------------------------|-------------------------------------|---------------------------|--|-------------------------------------|
| 3. PROGRAM/ASSIGNMENT CODE(S) 07001 (ISAs) | | | 4. WORK ALLOCATION PLANNED BY <input checked="" type="checkbox"/> ORA <input type="checkbox"/> CENTER | | | | 5. OPERATIONAL FTE POSITIONS 5.8 | | | |
| R E G I O N | DISTRICT/ SPECIALIZED LABORATORY | ALL IMPORT SAMPLE ANALYSES | ISAs AFLA TOXIN | ISAs FUMON- ISON | ISAs DON | ISAs OCHRA TOXIN | ISAs PATULIN | ISAs SPECIAL SURVEY | IMPORT SAMPLES TO BE ANALYZED | OTHER OPERAT- IONS (HOURS) |
| | | | | | | | | | | |
| | HEADQUARTERS | | | | | | | | 40 | |
| | REGIONAL STAFF | | | | | | | | | |
| NE | NEW ENGLAND | | | | | | | | | |
| | NEW YORK | | | | | | | | | |
| | REGIONAL LAB | 302 | 152 | | 20 | 24 | 106 | | | |
| | WEAC | | | | | | | | | |
| CE | REGIONAL STAFF | | | | | | | | | |
| | BALTIMORE | | | | | | | | | |
| | CHICAGO | | | | | | | | | |
| | CINCINNATI | | | | | | | | | |
| | DETROIT | | | | | | | | | |
| | MINNEAPOLIS | | | | | | | | | |
| | NEW JERSEY | | | | | | | | | |
| SE | PHILADELPHIA | | | | | | | | | |
| | FORENSIC CHEM. CTR | | | | | | | | | |
| | REGIONAL STAFF | | | | | | | | | |
| | ATLANTA | | | | | | | | | |
| | FLORIDA | | | | | | | | | |
| SW | NEW ORLEANS | | | | | | | | | |
| | SAN JUAN | | | | | | | | | |
| | REGIONAL LAB | 269 | 137 | | 24 | 11 | 57 | | 40 | |
| | REGIONAL STAFF | | | | | | | | | |
| PA | DALLAS | | | | | | | | | |
| | DENVER | | | | | | | | | |
| | KANSAS CITY | | | | | | | | | |
| PA | SOUTHWEST IMPORT DISTRICT | | | | | | | | | |
| | REGIONAL LAB | | | | | | | | | |
| | REGIONAL STAFF | | | | | | | | | |
| | LOS ANGELES | | | | | | | | | |
| | SAN FRANCISCO | | | | | | | | | |
| PA | SEATTLE | | | | | | | | | |
| | PACIFIC REGIONAL LAB - SW | | | | | | | | | |
| | PACIFIC REGIONAL LAB - NW | 226 | 136 | | 29 | 17 | 44 | | | |
| | HOURS PER OPERATION | 7.0 | | | | | | | | |
| | TOTAL HOURS | 6889 | | | | | | | | |
| | CONVERSION FACTOR | 1180 | | | | | | | | |
| | TOTAL OPERATION FTEs | 5.84 | | | | | | | | |
| 7. REMARKS | | | | | | | | | | |

| PROGRAM ASSIGNMENT TITLE | | 2. PPS PROJECT NAME/NUMBER | | | | | | | | | | | | | | |
|--|-----------------------------|--|-------------------------|--------|-------------------------|--------|-------------------------|--------|-------------------------|--------|--------------------------|-----------------------------------|--------------------------|--------|--------------------------|--------|
| ed Contaminants - DOMESTIC | | Monitoring of Marketed Animal Drugs, Feeds and Devices - 71 | | | | | | | | | | | | | | |
| PROGRAM ASSIGNMENT CODE(S) | | 4. WORK ALLOCATION PLANNED BY | | | | | | | | | | 5. OPERATIONAL FTE POSITIONS | | | | |
| 71003 A-J | | <input checked="" type="checkbox"/> ORA <input checked="" type="checkbox"/> CENTER | | | | | | | | | | TOTAL DOMESTIC 14.2 IMPORT 2.2 | | | | |
| DISTRICT/ SPECIALIZED LABORATORY | INSPEC- TIONS (Boxes) | DOMESTIC SAMPLE COLL | DOMESTIC SAMPLE COLLECT | | DOMESTIC SAMPLE ANALYSIS | | DOMESTIC SAMPLE ANALYSIS | | DOMESTIC SAMPLE ANALYSIS | |
| | | | 71003B | 71003C | 71003E | 71003F | 71003G | 71003H | 71003I | 71003J | 71003K | 71003L | 71003M | 71003N | 71003O | 71003P |
| TOTAL FIELD | 10 | 1005 | 20 | 250 | 200 | 200 | 135 | 20 | 250 | 200 | 200 | 135 | 20 | 250 | 200 | 135 |
| HEADQUARTERS | | | | | | | | | | | | | | | | |
| REGIONAL STAFF | | | | | | | | | | | | | | | | |
| NEW ENGLAND | 1 | 16 | 3 | 3 | 3 | 3 | 3 | | | | | | | | | |
| NEW YORK | 11 | 11 | 2 | 2 | 2 | 2 | 2 | | | | | | | | | |
| REGIONAL LAB | | | | | | | | | | | | | 1 | | 5 | 11 |
| WEAC | | | | | | | | | | | | | | | | |
| REGIONAL STAFF | | | | | | | | | | | | | | | | |
| BALTIMORE | | 20 | 1 | 1 | 1 | 1 | 1 | | | | | | | | | |
| CHICAGO | | 20 | 1 | 1 | 1 | 1 | 1 | | | | | | | | | |
| CINCINNATI | 1 | 61 | 1 | 1 | 1 | 1 | 1 | | | | | | | | | |
| DETROIT | | 35 | 1 | 1 | 1 | 1 | 1 | | | | | | | | | |
| MINNEAPOLIS | 1 | 132 | 1 | 1 | 1 | 1 | 1 | | | | | | | | | |
| NEW JERSEY | | 1 | | | | | | | | | | | | | | |
| PHILADELPHIA | | 30 | 1 | 1 | 1 | 1 | 1 | | | | | | | | | |
| FORENSIC CHEM CTR | | | | | | | | | | | | | | | | |
| REGIONAL STAFF | | | | | | | | | | | | | | | | |
| ATLANTA | 1 | 81 | 2 | 2 | 2 | 2 | 2 | | | | | | | | | |
| FLORIDA | | 13 | | | | | | | | | | | | | | |
| NEW ORLEANS | 1 | 55 | 1 | 1 | 1 | 1 | 1 | | | | | | | | | |
| SAN JUAN | | 8 | | | | | | | | | | | | | | |
| REGIONAL LAB | | | | | | | | | | | | | 5 | 43 | 55 | 50 |
| REGIONAL STAFF | | | | | | | | | | | | | | | | |
| DALLAS | 1 | 122 | 3 | 3 | 3 | 3 | 3 | | | | | | | | | |
| DENVER | | 50 | 1 | 1 | 1 | 1 | 1 | | | | | | | | | |
| DENVER | | 50 | 1 | 1 | 1 | 1 | 1 | | | | | | | | | |
| DALLAS CITY | 2 | 225 | 4 | 4 | 4 | 4 | 4 | | | | | | 12 | 100 | | 113 |
| WEST NORTHWEST IMPORT DISTRICT | | | | | | | | | | | | | | | | |
| REGIONAL LAB | | | | | | | | | | | | | | | | |
| REGIONAL STAFF | | | | | | | | | | | | | | | | |
| LOS ANGELES | | 13 | | | | | | | | | | | | | | |
| SAN FRANCISCO | 1 | 38 | | | | | | | | | | | | | | |
| SEATTLE | 1 | 48 | | | | | | | | | | | | | | |
| PACIFIC REGIONAL LABORATORY-SW | | | | | | | | | | | | | | | | |
| PACIFIC REGIONAL LABORATORY-NW | | | | | | | | | | | | | | | | |
| HOURS PER OPERATION | 17.0 | 4.2 | | | | | | | | | | | 12.6 | 7.7 | 36.0 | 5.5 |
| TOTAL HOURS | 170 | 4221 | | | | | | | | | | | 240 | 1925 | 3200 | 2255 |
| CONVERSION FACTOR | 950 | 950 | | | | | | | | | | | 1180 | 1180 | 1180 | 1180 |
| TOTAL OPERATIONAL FTEs | 0.18 | 4.44 | | | | | | | | | | | 0.20 | 1.63 | 2.71 | 1.91 |

3. REMARKS

Inspections performed as FNU to violative dioxin samples

The shaded area serves as a guideline for Districts on the specific types of samples that should be collected in order to match samples expected by the laboratories for analysis.

*Domestic Sample Collections: 200 micro samples are to be collected and shipped to CVM's Office of Research for additional analysis. They will not be analyzed by JRA laboratories.

**Domestic Sample Analyses: 71003E, sample analyses are for pig ears, pet treats, and pet foods.

Workload Source: FACTS database; firms in IND 65-72 with Workload Obligation of "YES" and Firm Status of "OPERATIONAL".
 NOTE: Continued on Page 71-7


DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

LRK
↓
latest info
from CFSAN
on sample
collections.

Joe

8-25-2006

Memorandum

Date: August 11, 2006
 From: Chief, Compliance Programs Branch, HFS-636
 Subject: CFSAN Sampling Priorities
 To: FDA Field Offices Via OC Intranet

The Field Food Committee (FFC) recently requested CFSAN to provide guidance on sampling priorities to assist field offices facing budget resource shortfalls needed to cover the costs of purchasing and shipping food and cosmetic samples. The guidance below, provided to the FFC in May 2006, is to be used to help the field make consistent sampling decisions field-wide when budgets do not permit completion of full workplan obligations.

Sampling priorities should generally follow "CFSAN 2007 Field Focus Areas Within Each Priority" document, that lists the focus areas within the 5 major CFSAN priorities: Food Defense; Food Safety; Nutrition; Dietary Supplements; and Cosmetics. Please consider these priorities in effect until changed.

Sampling is stratified as "High Priority Sampling", "Medium Priority Sampling", and "Low Priority Sampling". Guidance for the stratification is as follows:

"High Priority Sampling"

- All "for cause" sampling needed to:
 - Support adverse inspectional findings;
 - Follow-up to foodborne and cosmetic outbreaks;
 - Investigate all reported adverse events related to infant formula or medical foods; and
 - Investigate bona-fide complaints of serious adverse events involving cosmetics and all other foods, including peanut allergens.
- All sampling of high priority and high-risk foods and cosmetics identified in the following CFSAN compliance programs:
 - Infant Formula – Import and Domestic Program
 - Medical Foods – Import and Domestic Program
 - Import Seafood Program;
 - Import Foods – General Program;

Workplan, and other guidance documents as low priority or non public health related, including but not limited to:

- Sampling of fresh or frozen raw shrimp and non-histamine forming finfish that is typically cooked prior to consumption. Includes analyses for decomposition, *Salmonella*, and filth. Excludes vacuum packed products;
- Imported packaged foods for filth that is not of public health significance, i.e., filth that is not indicative of the presence of known disease vectors such as certain ants, cockroaches, flies, rodents, etc.;
- Low value entries (<\$2,500/\$5,000?) of import foods that do not pose significant public health threats (Ziobro/D'Hoostelaere analysis of ~10,000 lab import filth samples from FACTS for FY 03-05 shows ~ 22% were of lots valued <\$1,000);
- Spices for pesticide residues (ginseng is not a spice);
- Repeat entries of foods from importers or foreign manufacturers previously found in violation for color or food additives (need to take broad-based enforcement action); and
- Food economic and standard of identity issues that are not of major economic impact to consumers.

Additional Recommendation: Relax sample timeframes where possible; Restrict use of overnight shipping solely to perishable and highly time-sensitive samples.

I may be contacted for questions or further information on this matter.

Thank you.

Ronald R. Roy

United States
Food & Drug Administration
Food Import Process

Energy and Commerce
March 28, 2007

Domenic Veneziano
Director
Division of Import Operations & Policy

The Import Process: Food Specific

LAWS affecting Importation of Foods

Chapter VIII of the FD&C Act, Imports and Exports

Chapter IV of the FD&C Act, foods

As amended including The BTA of 2002

The Import Process: Food Specific Tier 1 – Prior Notice

The Public Health Security and Bioterrorism
Preparedness and Response Act of 2002 (BTA),

Not all inclusive

- ✓ Prior Notice of Imports
- ✓ Food Facility Registration
- ✓ Administrative Detention
- ✓ Maintenance of Records

The Import Process: Food Specific Tier 1 – Prior Notice

Food Imports Requiring Prior Notice

- Food imported for use, storage, or distribution in the U.S.
- Food transhipped through the U.S. to another country
- Food imported for future export
- Food for use in a Foreign Trade Zone

“Food” for Prior Notice purposes does not include food contact substances or pesticides.

The Import Process: Food Specific Tier 1 – Prior Notice

Time Requirements

| For Shipments arriving: | Time Requirement: |
|--|---|
| By land via road | No less than 2 hrs. before port of arrival |
| By land via rail | No less than 4 hrs. before port of arrival |
| By air | No less than 4 hrs. before port of arrival |
| By water | No less than 8 hrs. before port of arrival |
| By international mail | Before the food is sent |
| Carried by or otherwise accompanying an individual | Within the time frame for the applicable mode of transportation |

The Import Process: Food Specific Tier 1 – Prior Notice

PN data elements required:

Not all inclusive

- Manufacturer (or Grower)
- Manufacturer Registration #
- Shipper
- U.S. Consignee
- Country of Production
- Product Identification
- FDA Product Code
- Anticipated Arrival Info.
- Anticipated Shipment Info
- Importer
- PN Transmitter
- PN Submitter
- Entry Identifier

The Import Process: Food Specific

BTA Section 305 Food Registration Requirements

All firms (Import/Domestic) who prepare, pack, or hold food intended for consumption in the U.S. must register with FDA. Registration information includes:

- ✓ Firm Name, Address, Phone, & FAX numbers
- ✓ Parent Company Information (as applicable)
- ✓ U.S. Agent Name, Address, Phone, & FAX numbers
- ✓ Trade Names Used
- ✓ Types of food products handled/manufactured
- ✓ Firm Agent in Charge – Name, Phone Number, etc.
- ✓ Optional information – Facility contact, firm type etc.
- ✓ Register on line – www.access.fda.gov

The Import Process: Food Specific Tier 2 – Admissibility

All Foods are required to provide:

- ✓ Additional Entry Data (above what is required for CBP)
- ✓ FDA Country of Origin
- ✓ Name of Manufacturer
- ✓ Name of Shipper
- ✓ FDA Product Code

Certain food products require additional information to be submitted & evaluated by FDA:

- ✓ Low-Acid Canned Foods (LACF)
(FCE) Food Canning Establishment number
Process of each commodity & can size (SID #)
- ✓ Acidified Foods (AF)
Process for adequate acidification

The Import Process: Foods Tier 2 – Admissibility

Typical evaluations performed for food products

- Filth
- Microbiological contamination
- Decomposition
- Packaging defects
- Misbranding (eg., lack of required labeling or nutritional declarations)
- Product Security & Integrity

OASIS Screening Process

- FDA maintains screening records

 - Import Alerts

 - Import Bulletins

 - Compliance Programs

 - Center Assignments

 - District Requested Criteria

 - MOUs

 - PN



Memorandum

June 6, 2007

SUBJECT: Food and Agricultural Imports From China

FROM: Geoffrey S. Becker
Specialist in Agricultural Policy
Resources, Science, and Industry Division

Overview

Food and agricultural imports have increased significantly in recent years, causing some in Congress to question whether the U.S. food safety system is sufficiently designed to keep pace. Analysts point out that domestically sourced foods also can pose safety problems, as evidenced by recent outbreaks of illness linked to consumption of raw produce and by continuing recalls of meat and poultry products due to bacterial contamination.¹ However, the recent discovery of adulterated pet food ingredients from China — some of which were fed to food animals in the United States — has heightened scrutiny of U.S. import safeguards, especially as they are applied to China. This memorandum provides an overview of U.S. food and agricultural imports globally, before examining in more detail those from China. It then briefly describes U.S. food import safeguards, examines recent data on the level and types of refused import shipments from foreign countries generally and from China in particular. Finally, the memorandum discusses efforts by Chinese and U.S. officials to improve their safeguards.

Import Trends

U.S. imports of agricultural and seafood products from all countries increased from 32.9 million metric tons (MMT) in calendar year 1996 to 46.7 MMT in 2006, or by 42%. The increase by value was 98%, from \$40.1 billion in 1996 to \$78.5 billion in 2006. Among the product categories that at least doubled in volume during the period were live animals, wine/beer, fruit/vegetable juices, wheat, coffee, snack foods, and various seafood products.²

¹ See CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*, and archived CRS Report RL33722, *Food Safety: Federal and State Response to the Spinach E. coli Outbreak*.

² U.S. Department of Agriculture (USDA), Foreign Agricultural Service (FAS), U.S. Trade Internet System, BICO (Bulk, Intermediate, and Consumer-Oriented) data.

Not all agricultural imports enter the human food supply; some products are used as ingredients in pet food and animal feed, in manufactured goods (e.g., rubber), and the nursery plant trade. Nonetheless, consumers are obtaining a growing portion of their diets from overseas. In 2005, nearly 15% of the overall volume of U.S. food consumption was imported, compared with 11-12% in 1995. The proportions for some food product categories are much higher: in 2005 as much as 84% of all U.S. fish and shellfish was imported (55% in 1995); 43% of all noncitrus fresh fruits (34% in 1995); 37% for of all processed fruits (20% in 1995), and 54% of all tree nuts (40% in 1995).³

U.S. imports of Chinese agricultural and seafood products have increased far more rapidly than the global increase, from nearly 0.411 MMT in 1996 to 1.833 MMT in 2006, a 346% rise. The increase by value was 375%, from \$880 million in 1996 to \$4.2 billion in 2006.

In 2006, China was the sixth leading foreign supplier of agricultural products to the United States (after Canada, Mexico, Italy, Australia, and Ireland, in that order) and the second leading seafood supplier (after Canada). When seafood values are combined with agricultural products, China was number three, after Canada and Mexico (see table 1, below).

Table 1. Leading Suppliers of U.S. Agricultural and Seafood Imports, CY2006
(value in billion U.S. dollars)

| Country | Agricultural | Seafood | Total |
|-------------|--------------|---------|----------|
| Canada | \$13.433 | \$2.184 | \$15.617 |
| Mexico | 9.390 | 0.454 | 9.844 |
| China | 2.262 | 1.922 | 4.184 |
| Thailand | 1.812 | 1.334 | 3.146 |
| Italy | 2.802 | .009 | 2.811 |
| Indonesia | 2.023 | 0.778 | 2.801 |
| Chile | 1.774 | .952 | 2.726 |
| Australia | 2.487 | .091 | 2.578 |
| Brazil | 2.237 | .130 | 2.367 |
| Ireland | 2.354 | .008 | 2.362 |
| World Total | 65.333 | 13.143 | 78.475 |

Source: USDA, Foreign Agricultural Service (FAS), BICO Import Commodity Aggregations.

Table 2, below, shows the major types of food and agricultural imports from China in 2006. Numerous seafood products, including shrimp, other shellfish (mollusks), and salmon were the leading food-related (i.e., agricultural and seafood) imports. Fruits, fruit juices, vegetables, tree nuts, teas, and spices also were high on the list.

³ USDA, Economic Research Service (ERS), unpublished data, obtained May 11, 2007.

| Table 2. Selected Agricultural and Seafood Imports from China, CY2006 | | |
|--|------------------------|---------------------------------------|
| Import | Value (\$1,000) | (metric tons unless specified) |
| Other fish & products (not listed below) | \$1,076,631 | 332,714 |
| Shrimp & prawns | 331,935 | 68,364 |
| Mollusks | 245,607 | 62,727 |
| Misc. horticultural products | 226,047 | 109,910 |
| Fruit, processed | 207,427 | 247,554 |
| Fruit juices (<i>kiloliters</i>) | 201,935 | 933,566 |
| Other crustaceans | 159,352 | 22,051 |
| Feed, ingredients & fodders | 147,850 | 59,988 |
| Misc. industrial use | 143,780 | 12,574 |
| Vegetables, prepared or preserved | 122,854 | 131,002 |
| Poultry, misc. (a) | 120,765 | 15,436 |
| Sugar & related products | 104,611 | 46,429 |
| Salmon | 97,792 | 26,482 |
| Vegetables, dried/dehydrated | 93,254 | 68,516 |
| Edible tree nuts | 80,853 | 10,070 |
| Fresh vegetables, excluding potatoes | 77,555 | 76,296 |
| Other oilseeds products, nonagricultural | 75,645 | 27,857 |
| Grains and feed, misc. | 75,495 | 46,422 |
| Misc. meat products (a) | 69,673 | 15,672 |
| Tea, excluding herbal | 68,174 | 24,007 |
| Misc. hair, industrial use | 59,781 | 13,513 |
| Vegetables, frozen | 54,513 | 67,893 |
| Spices | 49,929 | 43,156 |
| Cocoa & cocoa prods. | 48,278 | 11,661 |
| Misc. sugar and tropical | 46,606 | 13,433 |
| Essential oils | 40,249 | 3,896 |
| Fruit, dried | 39,766 | 7,349 |
| Rice | 36,428 | 104,894 |

Source: USDA, FAS, FAS Import Commodity Aggregations. Not all products listed.

(a): Primarily species not subject to FSIS inspection; see text, footnote 6.

The broader categories in table 2 mask some specific products that the United States imports from China. For example, The United States received \$941 million in various types of fish fillets. Mushrooms accounted for at least \$37 million of the dried vegetable category in 2006.

A recent report by Food and Water Watch, a consumer advocacy organization, notes that China became the leading exporter of seafood to the United States in 2004. Aquaculture has facilitated this growth in exports, particularly of shrimp and tilapia. Catfish, eel and crab imports also have risen significantly, according to the report.⁴

U.S. Import Safeguards

Overview. Although all food products imported into the United States must meet the same safety standards as domestically produced foods, international trade rules permit a foreign country to apply its own, differing, regulatory authorities and institutional systems in meeting such standards, under an internationally recognized concept known as “equivalence.”⁵

Two federal agencies — the U.S. Department of Agriculture’s (USDA’s) Food Safety and Inspection Service (FSIS) and the U.S. Department of Health and Human Services’ Food and Drug Administration (FDA) — are primarily responsible for the government’s food regulatory system, although a number of other federal, state and local agencies also have important roles. For imports, FSIS relies on a very different regulatory system than FDA, including a different approach to addressing equivalence, as described in the following sections.⁶

FSIS. Under section 20 of the Federal Meat Inspection Act (FMIA) as amended (21 U.S.C. 601 et seq.) and section 466 of the Poultry Products Inspection Act (PPIA) as amended (21 U.S.C. 451 et seq.), FSIS is responsible for determining the equivalence of other countries’ meat and poultry safeguards.⁷ A foreign plant cannot ship products to the United States unless FSIS has certified that its country has a program that provides a level of protection that is at least equivalent to the U.S. system.⁸ In addition, FSIS operates a reinspection program at U.S. border entry points. Generally, agency inspectors review all import records, assisted by a computerized statistical sampling program, the Automated Import Inspection System (AIIS), that enables targeting of some shipments for actual inspection, i.e., examining their physical

⁴ *Import Alert: Government Fails Consumers, Falls Short on Seafood Inspections.* Food and Water Watch, May 2007. Accessed on the Internet June 5, 2007 at: [<http://www.foodandwaterwatch.org/press/publications/reports/import-alert>].

⁵ This concept is embodied in Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), which entered into force January 1, 1995 for member nations of the World Trade Organization (WTO). For a more detailed explanation, see CRS Report RL33472, *Sanitary and Phytosanitary (SPS) Concerns in Agricultural Trade*, and the WTO SPS website at: [http://www.wto.org/english/tratop_e/sps_e/sps_e.htm].

⁶ The two systems are described in more detail in CRS Report RS22664, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*, from which this section is adapted.

⁷ FSIS coverage is of the major commercial red meat and poultry species and their products, while FDA has jurisdiction over any meat and poultry not inspected by FSIS.

⁸ A list of the 38 currently certified countries with agreements can be accessed on the FSIS website at: [www.fsis.usda.gov/regulations_%26_policies/Eligible_Foreign_Establishments/index.asp].

condition, labeling, documentation, and other aspects. China is not yet certified to ship FSIS-regulated meat and poultry products (i.e., the major commercial species) to the United States.

Meat and poultry imports from other countries, however, have increased significantly, from nearly 2.3 billion pounds presented for inspection in FY1996 to 4.3 billion pounds in FY2005. FSIS estimated that it physically examined approximately 20% of all such imports in FY1996 and 9.7% in FY2005 (after implementation of the AIIS in the early 2000s).

FDA. Under Section 801 of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), FDA can refuse entry to any food import if it “appears” based on a physical examination or otherwise, to be adulterated, misbranded, or in violation of the law.⁹ In exercising its oversight, the agency relies on a system of prior notifications by importers and document reviews at points of entry (ports). Importers must have an entry bond and file a notification for every shipment. Import information is entered into FDA’s database, the Operational and Administrative System for Import Support (OASIS). This system helps inspectors to determine a shipment’s relative risk and whether it needs closer scrutiny, i.e. actual examination, and/or testing. FDA inspectors work closely with Customs and Border Protection officials from the Department of Homeland Security on these tasks.¹⁰

The volume of FDA-regulated imports has more than tripled in the past decade. The agency received more than 10 million imported food lines (shipments) in FY2006 compared with less than 2.8 million shipments in FY1996. Just over 1% of these shipments were physically examined in FY2006, compared with 1.7% in FY1996. A food line is a single shipment, regardless of size — whether a single carton or a large carlot — making it difficult if not impossible to determine the share of the total volume of imports that is examined.

FDA’s ability to operate within other countries appears to be more limited than that of FSIS. FDA can, and does, periodically visit foreign facilities to inspect their operations, but usually in response to a concern and only with the permission of the foreign government. Furthermore, the agency asserts that it lacks the staff and funding to increase its presence overseas, regardless of whether it might have the legal authority to do so.¹¹ The FDA’s Center for Food Safety and Applied Nutrition (CFSAN) had a total budget of \$450 million and staff of 2,843 (full-time equivalent or FTE) in FY2006, of which \$285 million and 1,962 FTEs were in the field.¹²

⁹ 21 U.S.C. § 381(a); see also [www.fda.gov/ora/compliance_ref/rpm_new2/ch9auto.html].

¹⁰ The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) greatly expands the prior notification requirements for FDA-regulated imported foods. It also now requires any imported or domestic facility that manufactures, processes, packs, or holds food for U.S. consumption to register with the FDA; farms and retail establishments are among those exempted. Further, the act requires records sufficient to identify the immediate supplier as well as the subsequent recipient of the product, among other provisions.

¹¹ An FDA website notes that “Full equity in foreign inspections is far beyond the resources of FDA.” Accessed May 15, 2007 at [<http://www.cfsan.fda.gov/~comm/intl-toc.html>].

¹² Source: House Appropriations Committee Hearings, Agriculture Appropriations for FY2007. A further breakdown of field staff involved with imported foods was not immediately available, although CRS had reported it to be 595 FTEs out of a total of 1,452 field staff in FY1996 (CRS Report 98-850 STM, *The Safety of Imported Foods: The Federal Role and Issues Before Congress*, by Donna U. Vogt).

FDA theoretically has the authority to require equivalency standards for Chinese imports but the agency's situation is significantly more complex than that of FSIS (which regulates fewer types of food products), as stated by David Acheson, the FDA's Assistant Commissioner for Food Protection, at a May 9, 2007 hearing before the House Agriculture Committee. An equivalence-type approach is one possible option for the future, he added.¹³ The Government Accountability Office (GAO) in 1998 had concluded that border inspections alone were ineffective and also asserted that FDA lacks the statutory authority to mandate equivalency.¹⁴

FDA Import Refusals

Overview and Limitations of Analysis. Using the OASIS data, the FDA compiles a monthly "Import Refusal Report" for food shipments that it rejects. Such products had to be either re-exported or destroyed by the importer. The agency posts these monthly refusal reports on its website, but only for the most recent 12 months (i.e., only one year worth of refusals).¹⁵ The refusals for each month can be searched by country or by product category, but not by both at the same time. Data for only 12 months, from May 2006 through April 2007, were on the website (as of May 2007), and the months were not aggregated into annual figures.¹⁶

For each line (shipment), the system provides the name of the source company and the reason for refusal. As noted earlier, the size of each shipment in the OASIS database varies. Therefore, it is not possible to calculate the volumes of products being rejected, either as an absolute quantity or as a proportion of total imports. Also, the types or categories of imports do not necessarily correspond to the categories reported through the FAS trade databases (see tables 1 and 2, above).

Mindful of these caveats, CRS prepared a preliminary tabulation of the refusals, focusing on nearly 40 categories of FDA-regulated food and food-related products.¹⁷ For the one-year period available at the time of this CRS tabulation (May 2006-April 2007), the FDA logged a total of approximately 8,200 refusals. Of these, more than 700 separate shipments were from China. Two other countries had more shipments refused: Mexico with nearly 1,300 and India with more than 1,100 (see table 3).

It is important to note that a higher relative number does not necessarily indicate that one country's products are less safe, or its food safety system less rigorous, than another country's. The country simply might be more important source of U.S. agricultural and/or seafood imports. On the other hand, Canada, which imports much more to the United States than any other country, had far fewer refusals than either China or Mexico, the second most important U.S. importer in dollar value. India had the second highest number of refusals, even though

¹³ "Officials defend federal response to melamine contamination," *Food Chemical News*, May 14, 2007.

¹⁴ GAO Report RCED-98-103, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*. April 1998.

¹⁵ FDA website accessed May 31, 2007 at: [http://www.fda.gov/ora/oasis/ora_oasis_ref.html].

¹⁶ CRS did not examine FSIS import refusals. China currently is not certified by FSIS to export meat or poultry products to the United States. A proposed rule in the November 23, 2005, *Federal Register* to permit some types of processed poultry is pending.

¹⁷ Also listed in the OASIS refusal reports, but not examined here, are other FDA-regulated products, e.g., human and animal drugs, medical devices, and vitamins.

it is not among the top 10 exporters of food, agricultural, and seafood products to the United States.¹⁸

Table 3. Number of Import Refusals by Country, May 2006-April 2007

| | | | | | |
|------------------------|-----|---------------|-------|---------------------|-----|
| Argentina | 59 | Guatemala | 97 | Peru | 39 |
| Australia | 34 | Honduras | 113 | Philippines | 153 |
| Bangladesh | 54 | Hong Kong | 52 | Poland | 76 |
| Brazil | 123 | India (2) | 1,109 | Russia | 26 |
| Canada | 193 | Indonesia (5) | 334 | South Africa | 42 |
| Chile | 35 | Iran | 26 | Spain | 75 |
| China (3) | 720 | Italy (8) | 228 | Sri Lanka | 72 |
| Colombia | 45 | Jamaica | 36 | Syria | 70 |
| Costa Rica | 35 | Japan (7) | 295 | Taiwan | 165 |
| Dominican Republic (4) | 593 | Korea (South) | 111 | Thailand (9) | 218 |
| Ecuador | 56 | Lebanon | 26 | Turkey | 81 |
| Egypt | 47 | Malaysia | 35 | Ukraine | 25 |
| El Salvador | 25 | Mexico (1) | 1,271 | United Kingdom (10) | 206 |
| France | 178 | Netherlands | 54 | Vietnam (6) | 335 |
| Ghana | 49 | Pakistan | 140 | | |

Source: FDA Import Refusal Reports for OASIS. See text for caveats on use of data. Countries with fewer than 25 refusals are omitted here. Note: numbers in parentheses indicate top ten countries by rank of number of import refusals.

Because of technical problems with OASIS at the time this memorandum was prepared, FDA officials said they could not immediately respond in detail to CRS questions about the database which might have shed additional light on the significance, if any, of the above numbers. For example, the information published on the FDA website does not include the overall number of shipments. Thus, CRS could not calculate for this memorandum the percentage of overall shipments that had been refused for a given month, country or product. However, FDA did receive a total of nearly 15 million import shipments of all types of FDA-regulated products, including but not limited to foods, during FY2006, or an average of approximately 1.25 million shipments per month.¹⁹

Reviewing refusals by industry, vegetables/vegetable products and seafood products appear to have been the most frequently refused products (at approximately 1,700 shipments

¹⁸ Still, India's exports to the United States were valued at a significant \$1.4 billion in calendar 2006.

¹⁹ FDA e-mail communication to CRS, June 6, 2007. This CRS memorandum will be updated to reflect the receipt of any additional information on the database.

from all countries for each of these two product types). Fruits/fruit products from all countries accounted for nearly 900 refusals. Candy products accounted for nearly 600, and spices/flavors/salts for more than 500. Many fruit and vegetable product refusals originated in the Dominican Republic, Mexico, and several other Latin American and Caribbean nations; a frequently cited reason was pesticide contamination. Bacterial contamination (e.g., Salmonella) or filthy condition was cited numerous times.

Fish and shellfish were refused for a variety of reasons, often bacterial contamination, filthy condition, and/or veterinary drug residues. These products most frequently appear to have originated in Asian countries, not only China but also Vietnam, India, Bangladesh, and others. The recent report by Food and Water Watch analyzed the FDA OASIS refusals of seafood in more detail, and for all calendar years from 2002 to 2006. Among its findings were that more than 70% of all imported seafood products were processed. More than 20% of all seafood refusals were due to Salmonella, the report said, of which 40% were shrimp. It also observed that more seafood is being refused for veterinary drug residues.²⁰

Many refusals of foods of all types also appear to be due to concerns about mislabeling, failure to register, or failure to document that the product had complied with safe manufacturing practices (e.g., HACCP for low acid canned foods or seafoods).²¹

Refusals of Imports from China. Of the 720 refused shipments from China, nearly half (340) were seafood products, and approximately one-third of these products were eel. The most frequently cited reason for rejecting the eel shipments was a concern about adulteration by unsafe levels of veterinary drug residues. Catfish products also were often refused, usually because of concerns about veterinary drug residues. A wide variety of other types of finfish, from tilapia fillets to cod and salmon products, was refused for numerous apparent concerns, including veterinary drug residues, filthy appearance, and Salmonella contamination. More than three dozen separate shrimp shipments were refused because of filthy appearance, the presence of nitrofurans (a banned antibiotic), or salmonella. Other examples of refused seafoods were scallops, crawfish, and squid.

FDA also refused a total of 221 shipments of various fruits and vegetables from China, including processed products. Approximately one-fourth of these shipments were of mushrooms, often in dried form; these were most frequently rejected for filthy appearance. Other reasons for refusing fruit and vegetable product shipments ranged from concerns about the presence of violative levels of pesticides or other unacceptable ingredients including unsafe color additives, and the lack of proper documentation and/or labeling.

Seafood products and fruit and vegetable products together constituted the majority of refused shipments from China. Examples of other types of food products that were refused, although in fewer numbers, were certain candies, bean curd and bean paste, teas, and various nuts and spices.

Chinese officials strongly defend their safety record. One official asserted at a May 31, 2007 news conference that U.S. inspectors had approved "99 percent" of all Chinese food and medical shipments over the last three years and that recent reports of rejected Chinese

²⁰ *Import Alert: Government Fails Consumers, Falls Short on Seafood Inspections.*

²¹ The FDA website defines each of these terms, which are among approximately 180 possible specific reasons for refusal.

shipments had been sensationalized. He further argued that most of those that had been rejected were unauthorized shipments that had skirted Chinese controls.²² Other Chinese officials have declared that U.S. importing companies need to look beyond their emphasis on low prices and communicate more clearly what their standards are.²³

FDA officials said they could not immediately respond to a CRS request for the number of food and agricultural shipments from China during the period examined (May 2006-April 2007). They did state that in FY2006, the overall refusal rate for shipments from China (food and all other types of FDA-regulated shipments) was 0.15%. They cautioned that the 99.85% of shipments were not necessarily in compliance, because the agency only has the resources to examine 1% of all line entries (shipments) into the country (see page 5).²⁴

William Hubbard, a former FDA deputy commissioner, recently told National Public Radio (NPR) that total "individual shipments of food and ingredient exports from China to the United States have gone from 82,000 in 2002 to 199,000 in 2006. And I'm told by FDA officials that they're rapidly reaching up to 300,000 this year."²⁵ However, the same NPR report said that FDA inspectors had blocked 257 food imports from China in April 2007 alone; that number actually represented refused shipments of all FDA-regulated food, drug, and medical products, not just foods.

China's Food Safety Challenges

As noted, the FDA OASIS database does not provide answers as to whether or not Chinese imports are any less safe than those from other countries. Nonetheless, the country has come under intense criticism in the wake of several widely publicized incidents involving adulterated food, agricultural and medical exports. For example, in early 2007 pet food ingredients from China that contained the chemical melamine — apparently added to boost the ingredients' protein readings — sickened or killed an unknown number of dogs and cats in North America. The ingredients subsequently were found in some hog, chicken, and fish feed. A risk assessment indicated the problem posed virtually no risk to humans, USDA and FDA officials asserted. Another incident attracted much attention in early May 2007, when the Mississippi Commissioner of Agriculture ordered a number of stores there to stop selling catfish from China after samples tested positive for antibiotics banned in the United States.

Such concerns are not new. An FDA import inspector was quoted in 1991: "Some countries we almost never have problems with ... But others, such as India, Thailand, China, Korea, and many countries in Africa, require constant vigilance."²⁶

²² Li Yuanping, director general of the Chinese Import and Export Food Safety Bureau, as quoted in various news reports including "China Says Food Export Inspections Are Effective," *Washington Post*, June 1, 2007. Also see "China Confronts Crisis Over Food Safety," *Wall Street Journal*, May 30, 2007.

²³ "U.S., Chinese leaders try to advance trade, food safety issues," *Agri-Pulse*, May 30, 2007.

²⁴ FDA e-mail communication to CRS, June 6, 2007.

²⁵ "Q&A: Why China Tops the FDA Import Refusal List," accessed May 25, 2007 at: [www.npr.org/templates/story/story.php?storyID=10410111].

²⁶ Snider, Sharon. "From Psyllium Seeds to Stoneware: FDA Insures the Quality of Imports," *FDA Consumer Magazine*, March 1991.

A number of analysts has examined the food safety challenges China faces as it becomes a major agricultural exporter. USDA economists recently wrote:

China emerged in the 1990s as a low-cost exporter of food products such as vegetables, apples, seafood, and poultry. But in recent years, China's exports slowed when shipments of vegetables, poultry and shrimp were rejected for failing to meet stringent standards in Japan, Europe, and other countries, revealing a gap between Chinese and international food safety standards.²⁷

Some analysts contend that China's problems in complying with other — usually more developed — countries' safety requirements are typical of those faced by most developing countries. They point to a number of specific obstacles the Chinese have encountered in upgrading their safeguards, including:

- The difficulty of standardizing and monitoring production practices at the farm production level (to where many safety problems can be traced due to widespread noncompliance with existing regulations such as environmental rules), which is composed of 200 million households typically farming on plots of one to two noncontiguous acres;
- Heavy use of fertilizers and pesticides to counteract intensively cultivated soils and large pest pressures;
- Wide use of antibiotics to control diseases in intensive livestock, poultry, and aquaculture systems;
- Industrialization, lax environmental controls, and untreated human and animal waste in fields and waters, which raise concerns about toxic, metal, and microbial contaminants in food;
- A fragmented marketing system dominated by millions of small firms handling small volumes, often on a cash basis with no documentation or ability to trace products;
- A fragmented regulatory and oversight structure involving 10 national government ministries and little coordination with lower levels of government, which often have their own, differing standards for food products;
- For many commodities and industries, outdated or nonexistent standards, or standards that are inconsistent with internationally-accepted ones.²⁸

China's Efforts to Address Food Safety. To overcome such obstacles the Chinese government announced it has undertaken a number of major initiatives to bolster its food safety system. For example, officials announced their intention to update a 1995 consumer food law, and in 2006 the Chinese legislature adopted a national framework for building an agricultural product safety system. The Chinese say they now require registration of all land and

²⁷ Calvin, Linda, and others, "Food Safety Improvements Underway in China," *Amber Waves*, November 2006, USDA, ERS. The Codex Alimentarius Commission is the major international body for encouraging international trade in food while promoting the health and economic interest of consumers. Codex is a subsidiary of the Food and Agriculture Organization and the World Health Organization. One of its key functions is to develop standards, codes of practice, and guidelines for the safety of foods, in accordance with the SPS Agreement. The Codex website is at: [<http://www.codexalimentarius.net>].

²⁸ Calvin. Also, Dong, Fengxia, and Helen H. Jensen, "Challenges for China's Agricultural Exports: Compliance with Sanitary and Phytosanitary Measures," *Choices*, 1st Quarter 2007.

processing facilities used for exported products, and exporters must have facilities that can test for pesticide residues. The government also samples and tests products for export to help ensure they meet foreign buyers' standards.²⁹

China also has been encouraging investment, including foreign direct investment, in production and processing to improve technology, marketing and management skills, and transportation and infrastructure. Six types of processed foods — canned food, aquatic products, meat and meat products, frozen vegetables, fruit/vegetable juice, and some frozen convenience foods — reportedly are to be manufactured under HACCP (hazard analysis and critical control point) standards.³⁰ HACCP is a system of assessing risks, determining the points at which they might occur during production, and instituting measures to prevent them.³¹

China has announced that it will unveil, by the end of 2007, national regulations for recalling adulterated food. At a May 31, 2007 news conference, a Chinese official also pointed to the death sentence recently handed down to the former head of the government's food and drug safety agency, as an example of its determination to improve product oversight. The agency head had been convicted of taking bribes for approving potentially dangerous drugs.³²

U.S. Efforts to Improve Import Compliance. At May 15 and May 17, 2007 media briefings on adulteration of plant proteins from China, Dr. Acheson reported that he was currently reviewing all aspects of the U.S. food safety system, including imports from all countries. At the time, he and other FDA officials declined to provide specifics on ongoing efforts to secure food safety agreements of any kind with China but did point out that, after shipments of Mexican cantaloupes with Salmonella contamination several years ago, the U.S. and Mexican governments had developed an agreement to improve agricultural practices in Mexico.

FDA's Center for Food Safety and Nutrition (CFSAN) website indicates that it is "... aggressively pursuing including both informal and formal agreements with foreign government counterpart officials Memoranda of Understanding for mutual recognition of equivalence of regulatory systems." Another FDA website lists more than 90 "International Arrangements" with approximately 30 separate foreign entities, of which 36 appear to be directly food-related. Roughly a third of these address aspects of shellfish or other seafood safety.³³ FDA's agreements with China apparently do not include any for food, but are in place to lead in tableware.

During a May 22-24, 2007, economic summit with China, the U.S. Government requested a meeting soon, possibly in the fall, specifically on food safety. It asked the Chinese to respond to the following specific requests:

²⁹ Calvin.

³⁰ Dong.

³¹ FDA information on HACCP is at: [<http://www.cfsan.fda.gov/~lrd/haccp.html>].

³² *Washington Post*, June 1, 2007. Such death sentences for Chinese government officials are often commuted.

³³ Both websites accessed May 15, 2007 at [<http://www.cfsan.fda.gov/~comm/intl-toc.html>].

- To provide detailed information on Chinese food safety control measures including the procedures, methodology and technology for testing and quarantine of suspect products;
- To provide raw data from the testing the Chinese government has conducted on regulated products;
- To provide the ongoing results of all tests for melamine in ingredients destined for humans or animals;
- To impose a registration requirement for all Chinese firms intending to export food and feed products to the United States, and to prohibit exports from unregistered firms;
- To publish a regularly updated list of the registered Chinese firms;
- To issue necessary clearances including multi-year and multi-entry visas for FDA personnel to conduct health-related inspections in China and to audit systems confirming that Chinese firms are meeting U.S. requirements.³⁴

Congressional Action

Some Members of Congress, among others, have expressed sharp criticism of both China's food safety record and of U.S. efforts to insure the safety of that country's imports. The House Agriculture Committee held a hearing on May 9, 2007, to take testimony on the topic from FDA and FSIS officials. Additional hearings are anticipated in both chambers during the 110th Congress.

Concerns about China were cited by Senator Durbin and Representative DeLauro in a May 10, 2007 letter to the U.S. Trade Representative (USTR). In the letter, they requested a review of SPS measures in U.S. trade agreements and of legal options the United States has with respect to imported food products that pose a public health threat. A May 22, 2007 letter by Representative DeLauro, who chairs the House Appropriations subcommittee with responsibility for USDA and FDA, and Representative DeGette, also called on President Bush to press the food safety issue at the May 22-24 economic summit with China.

On May 2, 2007, Senator Durbin won unanimous approval of an amendment to the Senate-passed FDA Revitalization Act (S. 1082) that would require domestic and foreign facilities to notify FDA of food safety problems; FDA to establish a central registry for collecting information on adulterated foods, and for notifying the public about adulterated human or animal foods; and FDA to implement uniform national standards and labeling for pet foods. The amendment includes elements of his proposed Human and Pet Food Safety Act of 2007 (S. 1274), introduced as H.R. 2108 by Representative DeLauro. The two lawmakers also have introduced more comprehensive bills (H.R. 1148/S. 654) to combine current federal food safety oversight under a new food safety administration.

Recent developments with food imports also have spurred calls for speedier implementation of mandatory country of origin labeling (COOL) for fresh meats, produce and peanuts, now scheduled to take effect on September 30, 2008. H.R. 357 and S. 404 would mandate COOL by September 30, 2007. (For further information on COOL, see CRS Report 97-508, *Country-of-Origin Labeling for Foods*).

³⁴ "Actions Requested of the People's Republic of China by the U.S. Government to Address the Safety of Food and Feed," USDA Fact Sheet accessed on the Internet May 25, 2007 at [www.usda.gov].

FDA's Mission

- FDA regulates **One Trillion** dollars worth of food, medicines, medical devices and cosmetics.
- This is equal to one quarter of the American economy.
- Regulates 60% of the American Food Dollar
- **\$6.10 per American per year (FY2005).**
 - 1.8 billion budget/295 million Americans

606

↙ ↘



Hepatitis A in Green Onions

More than 9,100 people received antibody shots in the Pennsylvania outbreak to reduce their chances of contracting the disease after exposure.

607

USA Today 11/21/2003



- FSIS has 10,000 employee workforce
- FSIS has 7,400 inspectors working in 6,200 slaughter and processing plants

Foodborne Illness and Death in the United States

- **76 million foodborne illnesses per year**
- **325,000 hospitalizations**
- **5,000 deaths**

609

Source: Mead et.al., 1999



Viral Illnesses in the U.S. Estimated Cases

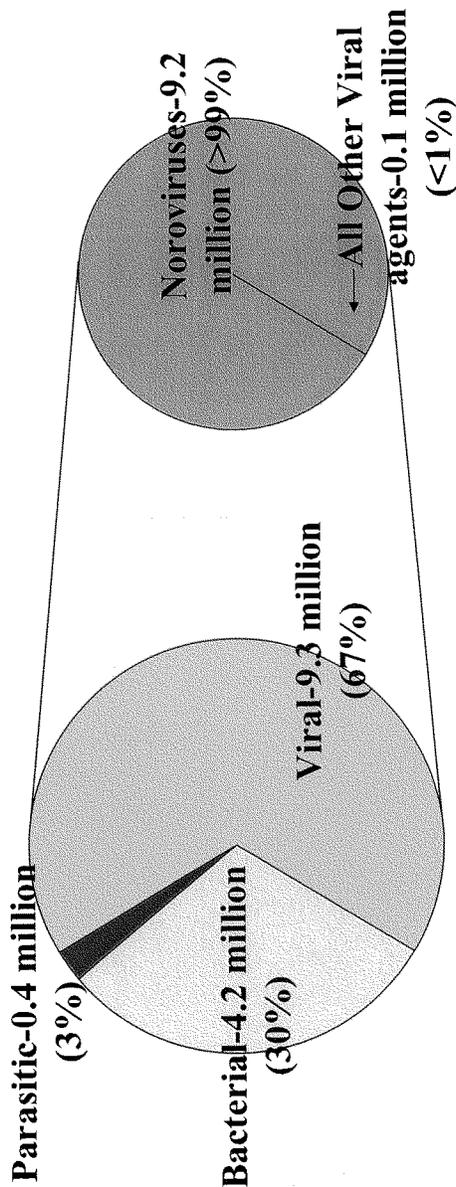
Norovirus- 23 million total cases annually
9.2 million foodborne cases
310 total deaths

Hepatitis A-83,000 total cases annually
4,100 foodborne cases
83 total deaths

Mead et al. 1999. Emerging Infectious Diseases



Estimated Annual Food-borne Illness in the US



611

Source: Mead et. al., 1999



Food Related Disease or Agent

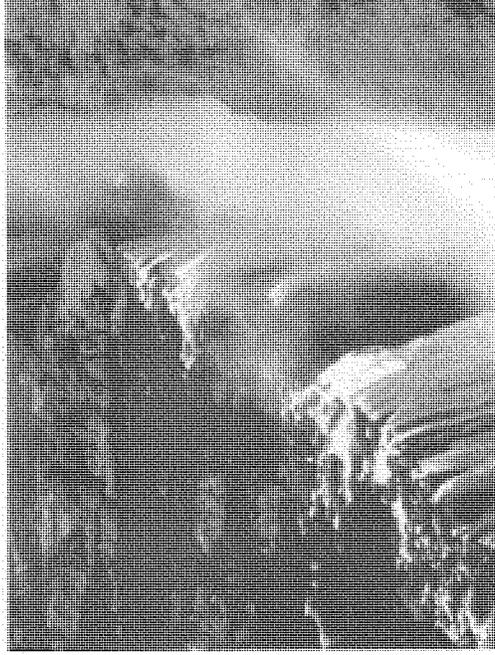
| Disease or Agent | Illnesses | Hospitalizations | Deaths |
|----------------------------|-----------|------------------|--------|
| Noroviruses | 9,000,000 | 20,000 | 124 |
| <i>Campylobacter sp.</i> | 1,963,141 | 10,539 | 99 |
| <i>Salmonella</i> | 1,342,532 | 16,102 | 556 |
| <i>Cl. perfringens</i> | 248,520 | 41 | 7 |
| Staph Enterotoxins | 185,060 | 1,753 | 2 |
| <i>E. coli</i> (all types) | 173,107 | 2,785 | 78 |

Mead et. al., 1999



The Problem

It has been estimated that in any 24 hour period, 200 million people on earth have gastroenteritis. The amount of diarrheal water passed in any given 24 hour period equals the amount of water passing over Victoria Falls in one Minute.



Do you wash your fruits and vegetables?

- Developing country farmers irrigate an estimated 20 million hectares (50 million acres) using partially diluted or undiluted wastewater, a practice that fuels the economy of thousands of small communities worldwide. In Mexico alone, some 250,000 hectares (618,000 acres) are treated with wastewater irrigation

614

AAM, 2001



FDAs No Bare Hand Contact Rule

“Toilet paper offers very little
protection against feces.”

615

Author Unknown



Loews Philadelphia Hotel

- **Illness hits Philly hotel that hosted GOP gathering**
PHILADELPHIA (AP) — Health officials are investigating an outbreak of illnesses at a Philadelphia hotel that recently played host to some of the nation's most powerful Republicans.
The Illinois Republican and about 200 other GOP leaders, including President Bush, stayed or dined at the Loews between Jan. 29 and Jan. 31 as part of an annual retreat to discuss party policy. At least 69 people went to the hospital with many more who did not seek medical attention.

616

USA Today 2/11/2004



Samples Analyzed from Loews

- 13 Samples Collected
- The 13 samples consisted of
 - 121 sub samples
 - 111 different food matrices

617



Hepatitis A in Green Onions

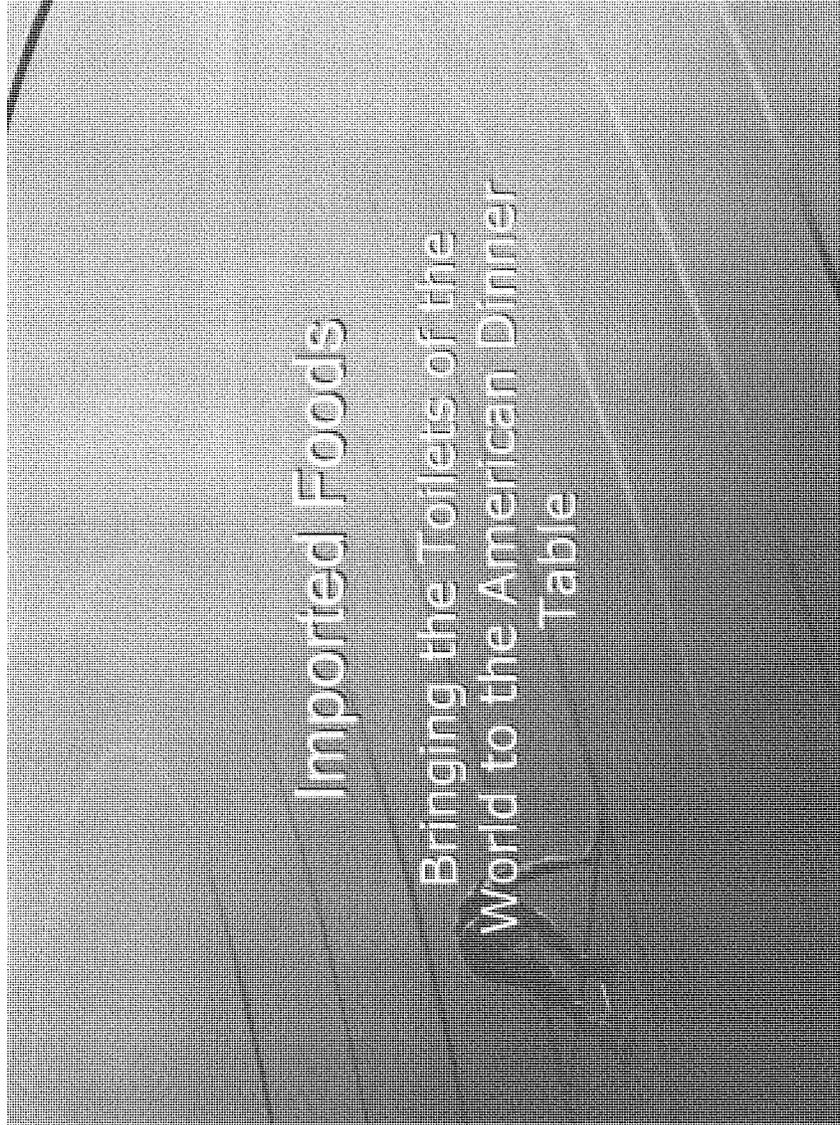
Officials link Chi-Chi's hepatitis outbreak to green onions

BEAVER, Pa. (AP) — A hepatitis A outbreak that has killed three people and sickened nearly 600 others who ate at a

Chi-Chi's Mexican restaurant was probably caused by green onions from Mexico, health officials said Friday. But how the scallions became tainted remains unclear.

USA Today 11/21/2003





The Facts

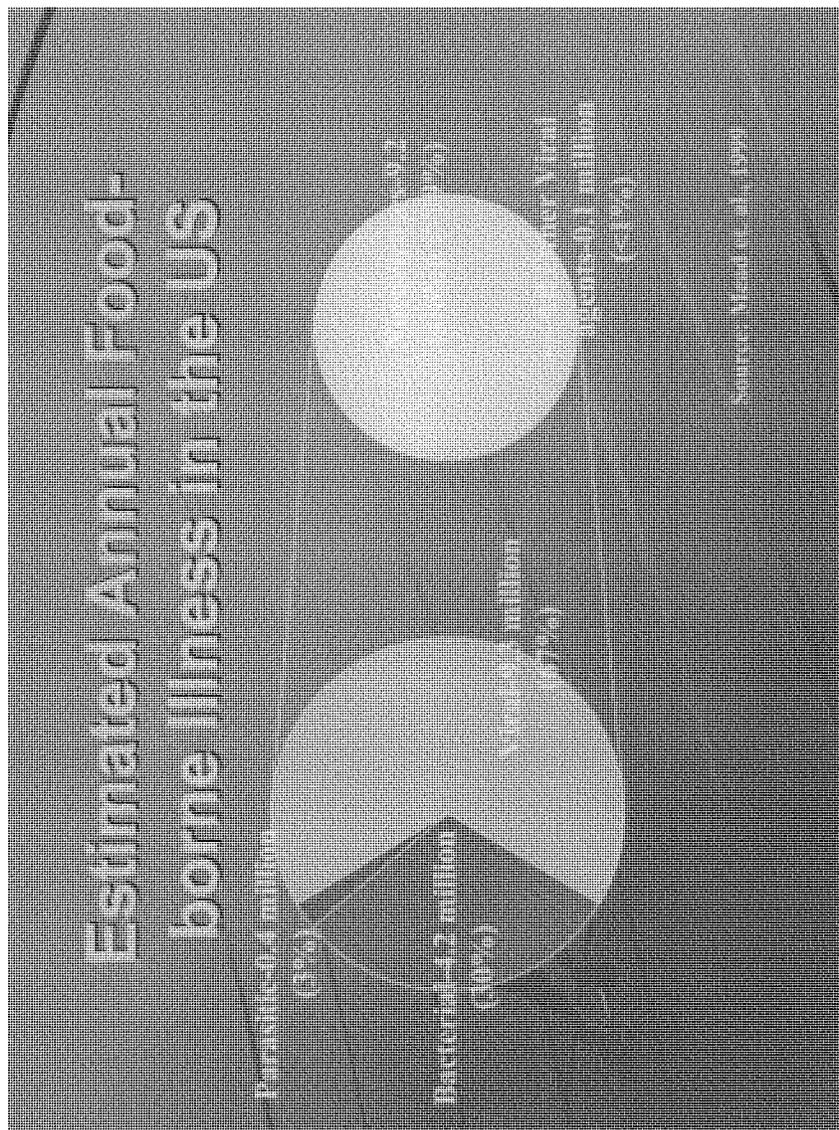
- ↗ 2.6 billion people have no place to go to the bathroom
- ↗ 1.2 billion get water from sources polluted with Human and animal feces.
- ↗ 2-6 million children die each year from adequate sanitation
- ↗ In China and India, 1.5 billion have no sanitation.

↗ Source: United Nations

Imported Foods

- Developing country farmers irrigate an estimated 20 million hectares (50 million acres) using partially diluted or undiluted wastewater.
- In Mexico alone, some 250,000 hectares (618,000 acres) are treated with wastewater irrigation.

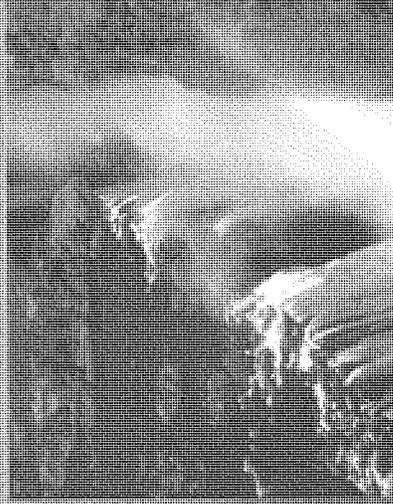
→ Source "Future Harvest"



The Problem

Globally, it is estimated that there are 6-60 billion cases of gastrointestinal illness occur annually, and largely due to fecal contamination of the environment.

Source: AAM, 2002



IA #16-B95, 5/27/99 IMPORT BULLETIN #16-B95, "TUNA PROCESSED WITH
TASTELESS SMOKE AND/OR CARBON MONOXIDE"

*****IMPORT BULLETIN*****

This bulletin responds to numerous complaints that FDA has received on the importation and distribution of frozen tuna that has been processed with "tasteless smoke" (TS) or carbon monoxide (CO). This treatment may be applied to tuna processed in Indonesia, the Philippines and Taiwan.

TS or CO is used to preserve (fix) the natural red flesh color of tuna during frozen storage. These agents may also be abused to enhance the color, making the product look of better grade or quality than it is. The complaints are from manufacturers, distributors, and federal and state agencies. Imported tuna treated with TS or CO should be: labeled as processed foods that have been treated with CO or TS, and not misrepresented as fresh frozen seafood by their label, and near normal in flesh color.

For example, at a minimum, the ingredients statement should include "tasteless smoke (preservative to promote color retention)," consistent with the labeling requirements of 21 CFR 101.22 (j). Such treated products are misbranded when labeled as "Smoked Tuna," "Lightly Smoked Tuna," and "Cold Smoked Tuna" because these are the common or usual names for traditionally processed smoked-flavored fish.

Tuna treated with either TS or CO that is not labeled to indicate it contains a preservative purports to be unprocessed, fresh or fresh frozen tuna and is, therefore, misbranded. These processed seafood products are also misbranded if their labeling fails to include other required label declarations under 21 CFR part 101, including nutrition information.

Treatment with TS or CO causes the flesh color to persist upon thawing and holding near room temperature. This color-fixing attribute provides a means of testing suspect tuna that may have been treated, but not labeled as outlined above. The length of time the color persists will vary with the agent and extent of exposure to TS or CO. In the most obvious case of misbranding, the product will appear to have an enhanced or unnatural red coloration, and its labeling will not indicate that it has been treated. In addition to being misbranded, color enhanced

Ex 1

products may be deemed to be economically adulterated under Section 402 (b)(4) of the Federal Food, Drug, and Cosmetic Act.

FDA believes that the application of these preservatives might be abused to make lower or inferior grades look better, and to mask decomposition. The flesh of treated products may display an artificial, unnaturally bright red coloration, but the degree of color enhancement may vary. Tuna that has an artificial, enhanced red color may have been exposed to TS or CO but not labeled. This product should be analyzed for decomposition and histamine, since there is no official method to test for TS or CO.

Tuna treated with TS and/or CO must bear appropriate label declarations, or the product is misbranded.

Any inquiries regarding this Import Bulletin should be referred to Frank Sikorsky at (202) 205-4606.

PREPARED BY: Stella Notzon, DIOP, 301-443-6553.

DATE LOADED INTO FIARS: May 27, 1999

IA #16-B95, CANCELLED 6/17/2003, 5/27/99 - IMPORT BULLETIN #16-B95, "TUNA PROCESSED WITH TASTELESS SMOKE AND/OR CARBON MONOXIDE"

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PRODUCT CODE: 16A--45
16D--45

EXPIRATION: 90 Days from date of issuance.

Ex 9

627

KEY WORDS: Tuna, Smoked, Carbon Monoxide, Tasteless Smoke

FOI: No purging is required.

PREPARED BY: Stella Notzon, DIOP, 301-443-6553.

DATE LOADED INTO FIARS: May 27, 1999

Violative Seafood Samples Related to Use of Carbon Monoxide
 Analyzed By NRL
 New York and New England Districts
 FY 2007

| Entry # | Sample # | Product | Results | Disposition | Refusal Date |
|---------------|----------|--------------------------------|------------|-------------|---------------------|
| D97-0381556-0 | 396812 | Frozen Tuna Steaks | Decomposed | Refused | 11/30/06 |
| 906-0782645-1 | 419483 | Frozen Tuna Steaks | Decomposed | Refused | 5/1/07 |
| AMQ-0548437-6 | 406165 | Frozen Tuna Saku | Decomposed | Refused | 3/6/07 |
| AMQ-0550359-7 | 419122 | Frozen Yellowfin Tuna | Decomposed | Refused | 5/31/07 |
| BMV-3004712-2 | 399783 | Frozen Tuna Steaks | Decomposed | Refused | 12/21/06 |
| 082-0294511-2 | 414871 | Frozen Tuna Steaks | Decomposed | Refused | 05-11-2007 |
| 530-0079073-2 | 408992 | Frozen Scarlet Snapper Fillets | Decomposed | Refused | 06-05-2007 (line 2) |
| 530-0079073-2 | 408996 | Frozen Scarlet Snapper Fillets | Decomposed | Refused | 06-05-2007 (line 3) |
| RD8-0018766-1 | 409379 | Frozen Mahi Fillet | Decomposed | Refused | 05-30-2007 |

1143

HENRY A. WAXMAN, CALIFORNIA
 EDWARD J. MARKEY, MASSACHUSETTS
 RICK BOUCHER, VIRGINIA
 EDOLPHUS TOWNS, NEW YORK
 FRANK PALLONE, JR., NEW JERSEY
 BART GORDON, TENNESSEE
 BOBBY L. RUSH, ILLINOIS
 ANNA G. ESHOO, CALIFORNIA
 BART STUPAK, MICHIGAN
 ELIOT L. ENGLISH, NEW YORK
 ALBERT R. WYNN, MARYLAND
 GENE GREEN, TEXAS
 DIANA DEGETTE, COLORADO
 KEVIN CROWLEY, MASSACHUSETTS
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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
 Washington, DC 20515-6115

JOHN D. DINGELL, MICHIGAN
 CHAIRMAN

June 5, 2007

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The Honorable Andrew C. von Eschenbach, M.D.
 Commissioner
 Food and Drug Administration
 5600 Fishers Lane
 Rockville, MD 20857

Dear Dr. von Eschenbach:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the adequacy of the efforts of the Food and Drug Administration (FDA) to protect the safety of the Nation's food supply.

The Committee is particularly concerned about the safety of food imports from China. In the last decade, the number of Chinese food imports has increased three fold. Along with this increase in imports, the amount of tainted food from China has also increased. Some recent examples of tainted food from China include mislabeled wheat flour contaminated with melamine, filthy juices and fruits, dried apples preserved with a carcinogen, and mushrooms laced with illegal pesticides. It is quite disturbing to consider that China lacks effective controls to ensure that their exported foods are safe.

The Committee is specifically concerned about the safety of fish and seafood from China. For example, it was recently discovered that catfish imported from China contained two antibiotics banned by FDA. Further, there have been numerous examples brought to the Committee's attention of imported fish and seafood containing contaminants such as salmonella, antibiotics, bacteria, and nitrofurans (a cancer-causing chemical).

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The Honorable Andrew C. von Eschenbach, M.D.
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In order to assist the Committee in its investigation of the safety of the Nation's food supply, we request that you provide us with the following information for each of the last six years (2001-2006) by no later than close of business on June 12, 2007:

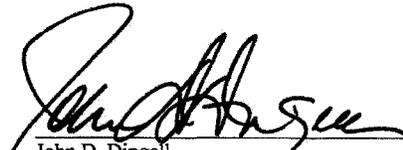
1. The number of food imports from China. Please include both the number of entries and the number of lines;
2. The declared value of all food imports from China;
3. The number of imports from China that were detained pending laboratory examination;
4. The number of Chinese food samples analyzed by private laboratories;
5. The number of Chinese food samples analyzed by FDA laboratories;
6. The number of Chinese food samples determined to be violative;
7. The number of violative Chinese food shipments that were reexported;
8. The number of violative Chinese food shipments that were destroyed;
9. The percentage of Chinese food samples found to be violative in each district and each laboratory; and
10. The number of FDA personnel (by full-time equivalent) conducting Chinese food import work for each district, each laboratory, and at headquarters.

If the Food and Drug Administration is unable to assure the safety of Chinese food imports, then the Administration should consider a complete ban of all food imports from China until such time that FDA can assure the American consumer of the safety of these imports.

The Honorable Andrew C. von Eschenbach, M.D.
Page 3

Your assistance with this request is appreciated. If you have any questions, please contact us or have your staff contact Kevin Barstow or David Nelson with the Committee on Energy and Commerce staff at (202) 226-2424.

Sincerely,



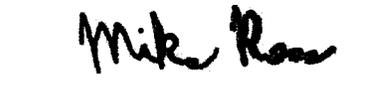
John D. Dingell
Chairman



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations



Charlie Melancon
Vice Chair
Subcommittee on Oversight and Investigations



Mike Ross
Member
Committee on Energy and Commerce



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUL 09 2007

Dear Mr. Chairman:

Thank you for the letter of June 5, 2007, co-signed by three of your colleagues, requesting information related to the adequacy of the efforts of the Food and Drug Administration (FDA) to ensure the safety of food imported from China.

We have re-stated each of your requests in bold type, followed by FDA's response. Supporting documents are enclosed as noted. The tables provide data on both human food and animal food and feed. We note that your letter requested import information going back to 2001. However, as discussed with your staff, prior to 2002, FDA's importation records are not readily accessible within FDA's automated import tracking system, the Operational and Administrative System for Import Support (OASIS). Therefore, the information we are providing goes back only to 2002.

1. **"The number of food imports from China. Please include both the number of entries and the number of lines."**

Response: A table providing information responsive to this request is enclosed at Tab A. Because the only meaningful way to report import data categorized by country of origin or by product category is at the line level, we are providing data for line entries (lines) only.

We note that import entries are not product or country of origin specific. Entries often include a combination of foods, drugs, cosmetics, devices and other FDA-regulated products, as well as products not regulated by FDA, and they can include products from a number of different countries of origin. A line entry, however, refers to each portion of an import entry that is listed as a separate item on an entry document. Line entries do contain data elements for country of origin as well as product category.

2. **"The declared value of all food imports from China."**

Response: Information responsive to this request is included in the table enclosed at Tab A.

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3. “The number of imports from China that were detained pending laboratory examination.”

Response: A table providing information responsive to this request is enclosed at Tab B. The table provides information on line entries in product categories related to human and animal food that were held under Detention Without Physical Examination (DWPE).

It is important to note that detentions are undertaken pending the refusal or release of an import line entry. We detain shipments offered for import based on an appearance of a violation under 801(a) of the Federal Food, Drug, and Cosmetic Act. Laboratory analysis is only one of many ways to overcome the appearance of a violation and may not be sufficient standing alone in many instances.

4. “The number of Chinese food samples analyzed by private laboratories.”

Response: Enclosed at Tab C is a table that details the number and types of analytical packages received by FDA from outside laboratories that include an analysis of Chinese food samples.

5. “The number of Chinese food samples analyzed by FDA laboratories.”

Response: The following two tables represent the number of Chinese food samples analyzed by FDA laboratories for fiscal years 2002 – 2006.

The table below tabulates import samples, which are samples of a commodity collected from a shipment made by a foreign firm into the U.S. before they are released into commerce.

| Number of Import Chinese Food Samples Analyzed | | | |
|--|------------------------|----------------------------------|---------------|
| FISCAL YEAR | IMPORTED HUMAN FOOD | IMPORTED ANIMAL FOOD AND FEED | GRAND TOTAL |
| FY 2002 | 1,343 | 13 | 1,356 |
| FY 2003 | 2,354 | 17 | 2,371 |
| FY 2004 | 2,295 | 35 | 2,330 |
| FY 2005 | 2,538 | 44 | 2,582 |
| FY 2006 | 2,452 | 44 | 2,496 |
| GRAND TOTAL | 10,982 | 153 | 11,135 |

Page 3 – The Honorable John D. Dingell

The following table tabulates domestic import samples, which are samples of an imported article collected after release from import status.

| Number of Domestic Import Chinese Food Samples Analyzed | | | |
|---|---------------------|-------------------------------|-------------|
| FISCAL YEAR | IMPORTED HUMAN FOOD | IMPORTED ANIMAL FOOD AND FEED | GRAND TOTAL |
| FY 2002 | 158 | | 158 |
| FY 2003 | 124 | 4 | 128 |
| FY 2004 | 110 | | 110 |
| FY 2005 | 105 | | 105 |
| FY 2006 | 91 | | 91 |
| GRAND TOTAL | 588 | 4 | 592 |

6. "The number of Chinese food samples determined to be violative."

Response: The following two tables represent the number of Chinese food samples determined to be violative for fiscal years 2002 – 2006.

| Number of Violative Import Chinese Food Samples Analyzed | | | |
|--|---------------------|-------------------------------|-------------|
| FISCAL YEAR | IMPORTED HUMAN FOOD | IMPORTED ANIMAL FOOD AND FEED | GRAND TOTAL |
| FY 2002 | 181 | 3 | 164 |
| FY 2003 | 239 | | 239 |
| FY 2004 | 204 | | 204 |
| FY 2005 | 175 | 1 | 176 |
| FY 2006 | 148 | 1 | 149 |
| GRAND TOTAL | 927 | 5 | 932 |

(Collected before release into commerce).

| Number of Violative Domestic Import Chinese Food Samples Analyzed | | | |
|---|---------------------|-------------------------------|-------------|
| FISCAL YEAR | IMPORTED HUMAN FOOD | IMPORTED ANIMAL FOOD AND FEED | GRAND TOTAL |
| FY 2002 | 66 | | 66 |
| FY 2003 | 16 | 1 | 17 |
| FY 2004 | 18 | | 18 |
| FY 2005 | 9 | | 9 |
| FY 2006 | 25 | | 25 |
| GRAND TOTAL | 134 | 1 | 135 |

(Collected after release into commerce).

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7. "The number of violative Chinese food shipments that were reexported."

8. "The number of violative Chinese food shipments that were destroyed."

Response (to both questions): Under the FD&C Act, an import shipment refused admission must be exported or destroyed within 90 days. Enforcement of this requirement is handled by U.S. Customs and Border Protection. FDA does not systematically collect or compile numerical data on the disposition of refused shipments.

9. "The percentage of Chinese food samples found to be violative in each district and each laboratory."

Response: Enclosed at Tab D are five tables that are responsive to your request. These tables represent the percentage of Chinese food samples found to be violative in fiscal years 2002 through 2006. The tables are divided into Analyzing Laboratory and Collecting District. Within each laboratory or district, the data is further divided between human food and animal food and feed. Finally, the data is divided between those samples collected in import status and those samples collected in domestic commerce after having been imported and released into commerce in the United States.

10. "The number of FDA personnel (by full-time equivalent) conducting Chinese food import work for each district, each laboratory, and at headquarters."

Response: We are unable to provide a breakdown of full-time equivalents performing Chinese food import work. FDA does not assign work or hire staff to specifically conduct work based upon the country of origin of regulated products. The duties of FDA staff are assigned by management based upon the yearly work plan, emergencies, and other needs that arise during any given year.

Thank you for your interest in this matter. If you have any further questions or concerns, please let us know. A similar response has been sent to the co-signers of your letter.

Sincerely,



Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures

FDA NEWS RELEASE

For Immediate Release: June 28, 2007

Media Inquiries: Michael Herndon, michael.herndon@fda.hhs.gov; Catherine McDermott, Catherine.mcdermott@fda.hhs.gov; 301-827-6242

Consumer Inquiries: 888-INFO-FDA

FDA Detains Imports of Farm-Raised Chinese Seafood
Products Have Repeatedly Contained Potentially Harmful Residues

The Food and Drug Administration (FDA) today announced a broader import control of all farm-raised catfish, basa, shrimp, dace (related to carp), and eel from China. FDA will start to detain these products at the border until the shipments are proven to be free of residues from drugs that are not approved in the United States for use in farm-raised aquatic animals.

This action by FDA, a part of the U.S. Department of Health and Human Services, will protect American consumers from unsafe residues that have been detected in these products. There have been no reports of illnesses to date.

“We’re taking this strong step because of current and continuing evidence that certain Chinese aquaculture products imported into the United States contain illegal substances that are not permitted in seafood sold in the United States,” said Dr. David Acheson, FDA’s assistant commissioner for food protection. “We will accept entries of these products from Chinese firms that demonstrate compliance with our requirements and safety standards.”

During targeted sampling from October 2006 through May 2007, FDA repeatedly found that farm-raised seafood imported from China were contaminated with antimicrobial agents that are not approved for this use in the United States.

The contaminants were the antimicrobials nitrofurans, malachite green, gentian violet, and fluoroquinolone. Nitrofurans, malachite green, and gentian violet have been shown to be carcinogenic with long-term exposure in lab animals. The use of fluoroquinolones in food animals may increase antibiotic resistance to this critically important class of antibiotics.

None of these substances is approved for use in farm-raised seafood in the United States, and the use of nitrofurans and malachite green in aquaculture is also prohibited by Chinese authorities. Chinese officials have acknowledged that fluoroquinolones are used in Chinese aquaculture and are permitted for use in China.

The levels of the drug residues that have been found in seafood are very low, most often at or near the minimum level of detection. FDA is not seeking recall of products already in U.S. commerce and is not advising consumers to destroy or return imported farm-raised seafood they may already have in their homes. FDA is concerned about long term exposure as well as the possible development of antibiotic resistance.

The FDA action includes conditions under which an exporter can be exempted from FDA’s detention action by providing specified information to the agency. This information must demonstrate the exporter has implemented steps to ensure its products do not contain these

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substances and that preventive controls are in place. The additional import controls placed on seafood from China will last as long as needed.

FDA may allow the entry into the United States and subsequent distribution into the marketplace of individual shipments of the Chinese farm-raised seafood products if the company provides documentation to confirm the products are free of residues of these drugs.

The Import Alert can be found at: http://www.fda.gov/ora/fiars/ora_import_ia16131.html

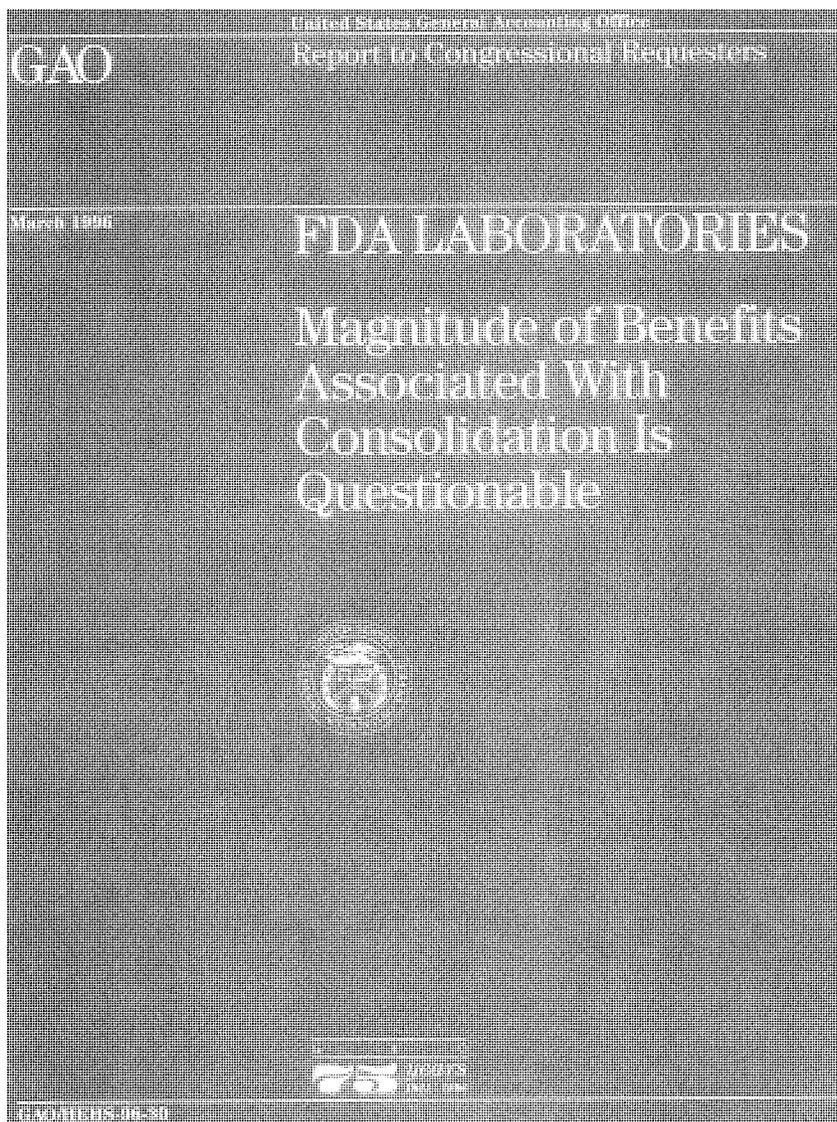
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GAO**United States
General Accounting Office
Washington, D.C. 20548****Health, Education, and
Human Services Division**

B-270022

March 19, 1996

The Honorable Paul Sarbanes
United States SenateThe Honorable John J. LaFalce
The Honorable Bill Paxon
The Honorable Jack Quinn
House of Representatives

To protect consumers from unsafe, ineffective, and mislabeled products, the Food and Drug Administration's (FDA) Office of Regulatory Affairs (ORA) tests thousands of products annually in its laboratories for possible violations of federal laws. The operating costs for ORA's 18 field laboratories in fiscal year 1995 were about \$17 million.

Because ORA officials believe that many of the office's laboratory facilities are old, need costly repairs, and do not meet the needs for conducting regulatory science in the future, ORA developed a 20-year plan to consolidate its field laboratories. As illustrated in table 1, the plan calls for closing several laboratories and building new ones, resulting in five "mega-labs" and four special-purpose labs.

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Table 1: FDA's Current and Proposed Laboratory Structure

| Current laboratory structure | Proposed laboratory structure |
|---|--|
| Multipurpose labs | Multipurpose mega-labs |
| Atlanta, Ga. | Atlanta, Ga. (expansion of current facility) |
| Baltimore, Md. | Jefferson, Ark. (new facility) |
| Buffalo, N.Y. | New York, N.Y. (new facility) |
| Chicago, Ill. | Seattle, Wash. |
| Dallas, Tex. | Special-purpose Labs |
| Denver, Colo. | Cincinnati, Ohio |
| Detroit, Mich. | Philadelphia, Pa. |
| Kansas City, Mo. | San Juan, P.R. |
| Minneapolis, Minn. | Winchester, Mass. |
| New York, N.Y. | |
| New Orleans, La. | |
| Los Angeles, Cal. | |
| San Francisco, Cal. | |
| Seattle, Wash. | |
| Multi- and special-purpose labs* | |
| Cincinnati, Ohio | |
| Philadelphia, Pa. | |
| San Juan, P.R. | |
| Winchester, Mass. | |

*These labs have a specialty focus such as forensic chemistry in addition to multipurpose functions.

On the basis of your concerns, we reviewed ORA's consolidation plan, focusing on (1) projected cost savings, (2) projected operational efficiencies, and (3) site selection criteria. To complete our work, we reviewed agency procedures and data on the consolidation plan, analyzed the assumptions in the plan, and discussed the plan with key officials at FDA headquarters and selected field locations. See appendix I for more details on our work scope and methodology.

Results in Brief

While FDA's decision to consolidate its 18 laboratories and create 5 multipurpose mega-labs and 4 special-purpose labs could yield efficiencies, we found that the documentation and estimates of the benefits resulting from consolidation are questionable.

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ORA projected that its 20-year consolidation plan would result in cost savings of about \$91 million over the life of the plan. More specifically, ORA's cost estimates projected that the consolidation plan would cost \$950 million over 20 years—about a 10-percent savings over the alternative of replacing existing labs. However, ORA made certain assumptions that may have inflated the replacement option cost. Moreover, current FDA workload data, which are the only efficiency measures presented by ORA, indicate that medium-sized labs (about 50 analysts per lab) are more efficient and effective than existing larger labs (about 100 analysts per lab).

In selecting sites for its mega-labs, ORA did little analysis of the relative efficiency of alternative sites. For example, ORA placed less emphasis on such factors as proximity to ports of entry and quantity of nearby food and other relevant businesses for its site selections. Instead, ORA's site selection decisions were based mainly on where it thought it would receive congressional funding approval.

Background

ORA, under the direction of the Associate Commissioner for Regulatory Affairs, is responsible for carrying out FDA's mission to ensure that foods, cosmetics, and medical products are safe, effective, and properly promoted and labeled.¹ ORA provides a central point to which headquarters officials can turn for field support services. It also exercises direct line authority over field operations, which are generally divided into four branches: investigations, laboratory, compliance, and administrative management. Product sampling and analyses are conducted primarily in the field by ORA's 21 district offices. Each office is headed by a district director responsible for operations.

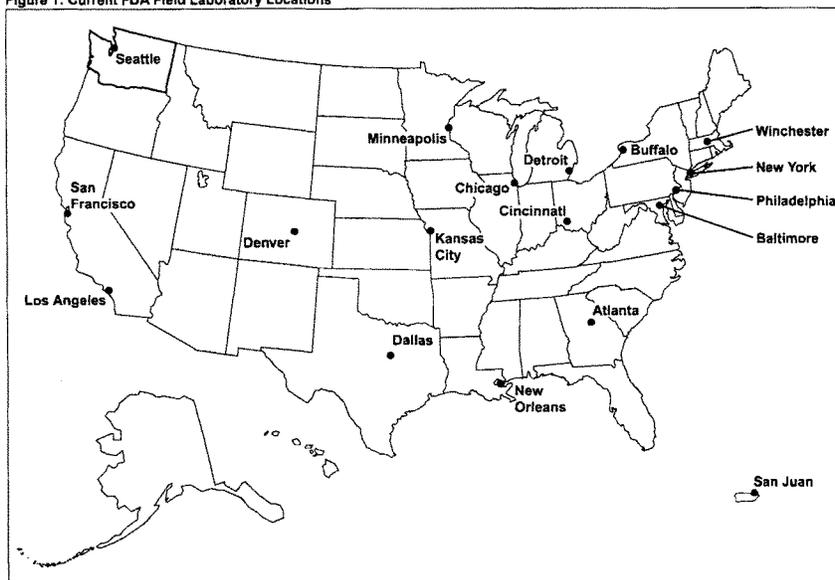
ORA's laboratories play a major role in protecting consumers from unsafe, ineffective, and mislabeled products. They provide a scientific base to support ORA enforcement and regulatory activity. The laboratories test thousands of product samples annually for possible violations of federal laws.

Current Structure Includes 18 Laboratories

ORA operates 18 field laboratories nationwide, including 1 in Puerto Rico, which FDA either owns or leases from the commercial sector or from the General Services Administration (GSA). (See fig. 1.)

¹FDA derives its authority from the Federal Food, Drug, and Cosmetic Act of 1938, as amended (21 U.S.C. 301).

Figure 1: Current FDA Field Laboratory Locations



The laboratories, which are collocated with district offices, provide two program functions: (1) surveillance and compliance and (2) research. Surveillance and compliance functions are conducted by investigators and laboratory analysts who inspect and investigate domestic establishments and imports; sample, collect, and analyze products; monitor compliance with existing regulations; initiate legal actions when health hazards are detected; and respond to crises, such as consumer tampering. Enforcement decisions are supported by research activities, such as identifying potential health hazards and developing efficient and effective laboratory testing methods.

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ORA spends about \$17 million per year, excluding salaries, to operate its laboratories. The field locations employ about 650 operating personnel—which include chemists, microbiologists, entomologists, research analysts, engineers, and physicists—and about 275 support personnel.

ORA's Restructuring Plan—ORA 21

ORA refers to the plan for the proposed laboratory structure as ORA 21. According to ORA management, the plan is designed to be a flexible blueprint for the future, allowing for changes to be made as necessary, with a 20-year implementation period extending to the year 2014.

The laboratory structure under the plan includes the following:

- five mega-labs located in New York City, New York; Atlanta, Georgia; Los Angeles, California; Seattle, Washington; and Jefferson, Arkansas, which will be expected to perform all laboratory functions; and
- four special-purpose laboratories located in Winchester, Massachusetts (radionuclide analysis and engineering center); Cincinnati, Ohio (forensic chemistry center); Philadelphia, Pennsylvania (drug analysis center); and San Juan, Puerto Rico (drug analysis center).

Table 2 shows the expected laboratory closures and their scheduled closing dates.

Table 2: Expected Laboratory Closures and Dates

| Laboratories | Closing date |
|---------------|--------------|
| Buffalo | 1997 |
| Chicago | 1997 |
| New Orleans | 1998 |
| Baltimore | 1999 |
| Dallas | 2000 |
| Detroit | 2000 |
| Minneapolis | 2000 |
| Denver | 2010 |
| Kansas City | 2014 |
| San Francisco | 2014 |

History and Rationale for Consolidation

ORA was led to consider laboratory alternatives when it decided that many of its once state-of-the-art field laboratories built in the 1960s had become

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obsolete. Over the years, FDA management has considered several options for replacing these facilities, from one-for-one replacement to consolidation.

In a 1986 consolidation plan, FDA proposed closing five laboratories to reduce the total capacity of its field laboratory system by about one-third.² In the early 1990s, ORA considered one-for-one replacement of these labs. For example, in 1991 and 1992, ORA had planned to construct new labs in New York and Baltimore, respectively. However, changes to the government's policy in 1992 precluded FDA from using GSA's federal building fund to acquire new construction projects. This caused ORA to reconsider its overall restructuring strategy. Accordingly, when ORA senior staff met in January 1993, they decided to examine how to most effectively and efficiently meet ORA's laboratory needs for the 21st century.

To accomplish this, ORA established the Working Analysts' Advisory Group (WAAG) in the summer of 1993 and the Laboratory Directors' Steering Committee in the fall of 1993. The members of these groups included laboratory analysts and directors, a field science adviser, and a representative of FDA's Division of Field Science. Also, during a strategic planning meeting in October 1993, the Associate Commissioner for Regulatory Affairs requested that the Regional Food and Drug Director for the Pacific Region develop an options paper to change ORA's field organizational alignment, including the laboratory structure, by the year 2004.

To evaluate the current field laboratory structure and to suggest modifications to it, the two committees assessed many issues, including positive and negative aspects of the current laboratories and other factors relevant to the selection of laboratory locations.

The two groups presented their recommendations to ORA senior staff. WAAG recommended that the 18 laboratories remain open and receive adequate funding support, while the Laboratory Directors' Steering Committee recommended that the 18 laboratories be reduced to 13. The committee noted, however, that it had recommended closing some laboratories because the field structure was overwhelmed with work due to overall staff attrition. According to one committee member, if FDA had adequately

²GAO was asked to review FDA's 1986 proposal. GAO issued its report, *Food and Drug Administration: Insufficient Planning for Field Laboratory Consolidation Decisions* (GAO/HRD-88-21, Dec. 4, 1987), in 1987, concluding that FDA's criteria were limited and did not adequately address whether FDA could meet its current and future laboratory needs if the five laboratories were closed or whether cost-effective alternatives to closure were available to reduce its capacity.

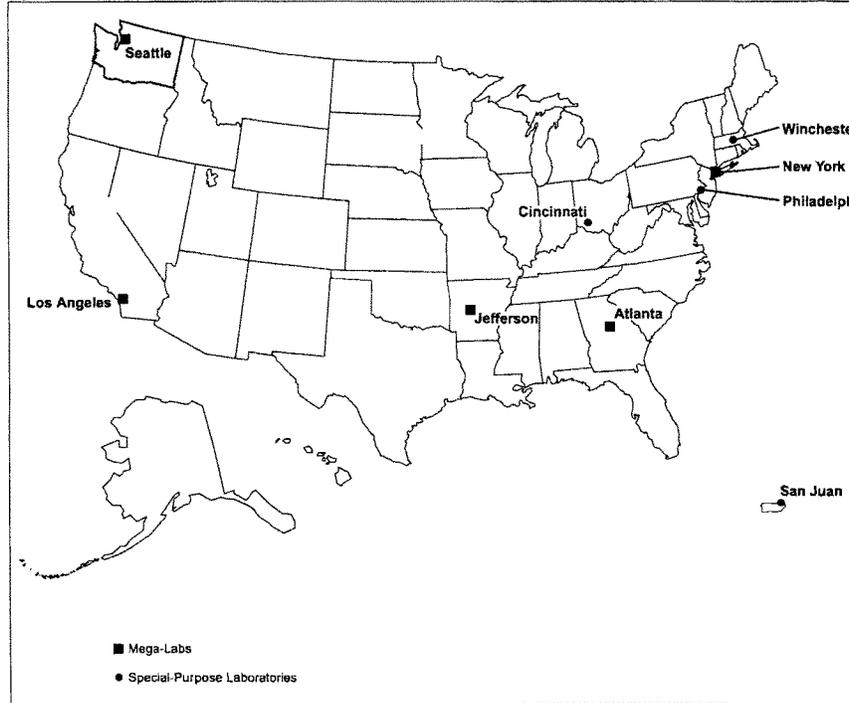
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staffed each laboratory, the committee would not have recommended certain ones for closure.

In December 1993, the Director for the Pacific Region issued the options paper, "Reorganizations of ORA for the 21st Century." The paper presented five options for restructuring the field laboratories. The options ranged from maintaining the status quo to restructuring using various consolidation options. The recommendations made by WAAG and the Steering Committee were incorporated into the paper's options and presented to ORA senior management before an ORA senior staff meeting in January 1994.

Participants in the ORA senior staff meeting discussed and reviewed each option and reached a consensus to consolidate the laboratories by creating five multipurpose mega-labs and four special-purpose labs. (See fig. 2.)

Figure 2: Proposed FDA Field Laboratory Locations



Projected Cost Savings May Be Overstated

ORA's analysis showed that its consolidation option saved money compared with continuing with the present structure by replacing labs when current leases expire. However, we found that ORA made assumptions that may have inflated the projected costs of replacing several laboratories.

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Consolidation Versus One-for-One Replacement

ORA compared the costs of two options—consolidating laboratories as proposed (ORA 21) and replacing all laboratories as their leases expire. The replacement option assumes using leased property; the consolidation plan envisions that three of the mega-lab facilities (in Los Angeles, Seattle, and Jefferson, Arkansas) would be government owned. The costs estimated for consolidating versus replacing all the laboratories were about \$950 million and \$1.041 billion, respectively. Using these figures, ORA projected that the savings from its consolidation plan would be about \$91 million over a 20-year period.

ORA's assumption that it would have to lease space to replace existing laboratories was based on the federal budgetary process. Under budget score-keeping rules, outlays are generally scored on a cash basis when they occur. Therefore, the full construction cost must be appropriated in 1 year, and FDA believed that it could not compete for such funds given HHS' budget constraints. As we have pointed out previously, the federal government has often entered into leases to satisfy long-term space needs even though GSA analyses have showed leases to be more costly in the long run than ownership.³

Space and Staffing Requirements for Replacing Labs May Be Overstated

Under its most recently revised replacement analysis (July 1995), ORA appears to have overstated the space requirement for some laboratories and the staff requirements for two proposed laboratories. Such overstatements would increase the cost estimate for replacing laboratories and, thus, increase the comparative estimated savings from consolidation.

For the new facilities, ORA estimated laboratory space per analyst at 650 square feet and office space per nonanalyst at 230 square feet. (According to a GSA official, GSA considers occupied office space of about 153 square feet to be standard, but no standard exists for laboratory space.) ORA's consolidated space estimates, however, exceed all of ORA's existing laboratories' space amounts. For example, ORA's three newest laboratories—in Kansas City, San Francisco, and Seattle—currently operate with much less laboratory space per analyst. According to regional officials and laboratory analysts, the San Francisco facility, with 369 square feet per analyst, is state-of-the-art, and the Kansas City and Seattle laboratories, with 411 and 344 square feet per analyst, respectively, were similarly characterized in a 1994 FDA Division of Field Science report.

³(Budget Issues: Budget Scorekeeping for Acquisition of Federal Buildings (GAO/T-AIMD-94-180, Sept. 20, 1994).

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Also, the Atlanta laboratory, a multipurpose lab, currently has 33,654 square feet of laboratory, light industrial, and general storage space and 92 analysts on board with a capacity for 100. ORA had originally planned to expand this laboratory by 20,000 additional square feet for 60 additional analysts or about 333 square feet per analyst. However, after we questioned this estimate, ORA revised it, increasing it to 39,000 square feet (650 square feet per 60 additional analysts). Even using ORA's revised estimate of 39,000 square feet, the Atlanta laboratory would have only about 450 square feet per analyst for its expected total capacity after expansion.

If the cost estimates for to-be-leased space were based more on the amount of space in ORA's newer laboratories, the estimated costs of replacing laboratories would be significantly less than ORA has projected. Even if the estimates were based on the projected space for the Atlanta mega-lab after expansion, they would be about \$2.2 million less per year than ORA has calculated. ORA feels justified in basing space requirements on 650 square feet per analyst and supplied us with a September 12, 1995, outside consultant's analysis performed after completion of our audit work. Although the consultant supported ORA's space requirement, this amount of space is nevertheless significantly greater than that being proposed for mega-labs in Atlanta and Seattle. Furthermore, ORA could not explain how and why existing space requirements in its newest laboratories (in San Francisco and Kansas) and in its proposed Atlanta and Seattle mega-labs are inadequate.

ORA also overestimated the staffing requirements for new laboratories in New York and Los Angeles under its replacement option. Instead of basing its estimates on the current staff size of these two laboratories—115 and 48, respectively—FDA used the mega-lab staff size of 189 analysts for New York and 75 analysts for Los Angeles. Thus, ORA came up with the same costs for the New York and Los Angeles facilities under both its replacement and consolidation options. Because the facilities' costs under the replacement option were not estimated on the basis of a smaller staff size, the resulting cost estimate for replacing the laboratories is overstated by about \$2.5 million annually.

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Operational Efficiency Gains From Consolidation Are Questionable

ORA believes that its consolidation plan would achieve certain benefits and efficiencies. Although we recognize that almost any restructuring could have some positive impact on operations, existing ORA evidence appears to contradict its claims that mega-labs will improve operations, supervisory/analyst ratios, and utilization of laboratory equipment. ORA's claims that its equipment and labs are obsolete are also questionable.

The operational efficiencies that ORA expects to gain through its consolidation plan include

- achieving a critical mass (50 or more analysts) in each lab,
- decreasing the number of mid-level managers,
- redeploying some supervisory staff to operations,
- decreasing support work required of operational staff,
- increasing efficient use of equipment, and
- being able to do shift work.

Efficiency of Medium-Sized Labs Versus Large Labs

FDA believes that efficiency involves many factors in addition to timeliness, such as overall costs per operations, staff, equipment, expertise available and utilized, accomplishments/outcomes from each sample tested, and customer service/responsiveness. However, FDA provided us evaluations of its laboratories based only on the factor of timeliness.

Current FDA timeliness statistics do not show that large laboratories are more efficient. In fact, FDA's fiscal year 1994 Sample Timeframe Report (which depicts each laboratory's timeliness in conducting analyses) showed that six out of seven medium-sized laboratories (33 to 50 analysts) were more timely than the two largest labs (New York and Atlanta). ORA officials in headquarters and in the field could not provide any explanation to contradict the data showing that its medium-sized laboratories were more timely or otherwise more efficient. In fact, WAAG and most ORA staff in the field that we spoke with stated that on the basis of their work experience an ideal laboratory size for efficiency is about 50 analysts. The Lab Directors' Steering Committee report also stated that a lab size of 50 to 75 analysts is ideal.

Supervisory/Analyst Ratio in Larger Labs Not Better Than in Most Other Labs

ORA's claim that larger labs would improve the supervisory/analyst ratio is also unsubstantiated. Data show that the supervisory/analyst ratio in ORA's two largest labs (in New York and Atlanta) with 115 and 92 analysts, respectively, is not better than in most of the other labs. For example, for

B-270022

at least the last 2 years, the labs in Atlanta and New York have generally had supervisory ratios of 1 to 7 and 1 to 8, respectively. Only the lab in Chicago (with a ratio of 1 to 6) has had a worse supervisory ratio than the labs in New York and Atlanta.

**Claims of Obsolete
Equipment and Facilities
Questionable**

In August 1994, the FDA Commissioner stated that many labs had obsolete physical plants and analytical tools. Our work, however, raises questions about FDA's assessment. For example, the older labs (about 30 years old), referred to as "Rayfield buildings," are all similarly designed, brick facilities that appear to be structurally sound. The Atlanta laboratory site, in fact, includes a 1960 Rayfield building and an addition that was built in 1985. ORA wants to expand this site into a mega-lab.

WAAG also performed an evaluation of the existing labs. It concluded that the Rayfield buildings (in Atlanta, Baltimore, Buffalo, Cincinnati, Dallas, Detroit, and Minneapolis) generally are in good shape; however, some need renovation and/or additional space. With the expenditure of some funds for these purposes, these laboratories could be expected to continue to serve for approximately another 10 years. Most of the older facilities and some of the more modern facilities have three main problems: (1) insufficient or inoperative heating, ventilation, and air conditioning systems; (2) inoperable or insufficient exhaust hood capacity; and (3) insufficient space for employees or instrumentation.

WAAG provided the following possible solutions for the three problems. It suggested that (1) insufficient or inoperative heating, ventilation, and air conditioning systems be corrected by installing booster fans and remotely controlled baffles in existing air systems; (2) inoperable or insufficient hood capacity may be solved by using smaller tabletop exhaust systems, good housekeeping practices, and modified hoods to accept moveable lab benches so that heavy or complicated equipment set-ups in the hoods may be removed when not in use; and (3) additional space for analysts and instrumentation may be found if labs implemented good housekeeping practices. In commenting on a draft of this report, HHS argued against using what it considers a stop-gap measure to continue occupation in current facilities for a few more years.

Beyond the condition of the labs, the consensus of the analysts we spoke with is that present equipment is generally state-of-the-art. Analysts at several sites we visited told us that they do not know of more current equipment that is needed in their laboratories. FDA, on the other hand,

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commented that a large percentage of field laboratory equipment is scheduled for replacement on the basis of purchase dates in accordance with the widely recognized Department of Veterans Affairs schedule of scientific equipment life expectancy. However, FDA has not demonstrated that its laboratories lack state-of-the-art equipment given its current facility capability. Furthermore, ORA provided us no support for how equipment needs would differ in the future.

One benefit of consolidation asserted by ORA was more intensive use of laboratory equipment. However, ORA did not provide evidence to refute assertions by analysts that cross-utilization of equipment is not always a viable option because instruments must be specially calibrated for particular samples.

Closures May Adversely Affect FDA's Analytical Staff

In addition to possibly overestimating the cost savings and efficiencies to be realized by consolidation, ORA may have underestimated this option's adverse impact on laboratory efficiency. For example, some analysts in the field believe that consolidation would result in a significant loss of experienced analysts.

Although ORA estimated that 75 percent of the analytical staff in labs scheduled for closure would relocate to other FDA facilities, it did not perform any analysis to support this estimate. We questioned this figure in a 1987 report⁴ when ORA previously used it in a proposed laboratory consolidation effort. ORA said that it used the relocation rate of 75 percent because it did not want to appear to understate the relocation costs. If a large percentage of analysts would not relocate, ORA's operations could be adversely affected until new analysts are trained.

Site Selections Not Based on Recognized Criteria

To guide ORA in its site selection process, WAAG—at management's request—developed and prioritized a set of criteria for consideration, recognizing that meeting each criterion might be impossible. In addition, ORA management developed its own criteria. However, ORA appears to have based site selection mainly on the availability of construction funds or congressional indications that such funds would be available for specific sites.

WAAG's criteria included quality-of-life issues, such as transportation, housing, population density, crime, and the merit of area schools; and

⁴Food and Drug Administration (GAO/HRD-88-21, Dec. 4, 1987).

B-270022

construction feasibility issues, such as costs and available land for building new or expanding existing facilities. WAAG's criteria also included projected workload distribution and the existing infrastructure to support the laboratories, such as commercial labs, workforce demographics, local universities, FDA investigation branches, and other government agencies.

ORA management considered these criteria but developed a somewhat narrower set of criteria, which included geographic dispersion (two laboratories on each coast and one centrally located), quantity of commercial establishments in the area, major shipping ports of entry, and availability of FDA-owned land.

We found, however, that the proposed mega-lab sites in New York, Los Angeles, and Jefferson do not meet many of the criteria established by WAAG and ORA. For example, the Jefferson site lacks such factors as proximity to ports of entry and quantity of nearby food and other relevant businesses. Instead, ORA appears to have placed more emphasis on the availability of funding in selecting the site locations. For the Los Angeles and Jefferson sites, the Congress has provided funds for architectural and engineering design work, with the expectation that subsequent construction funds would become available. Congressional action authorized construction funds to build a laboratory at the New York site, which committed FDA to this location. (See app. II.)

Conclusions

ORA believes laboratory consolidation is necessary to meet its pressing need to streamline and improve operations. Although consolidation may achieve efficiencies, the evidence ORA provided to us appears to have overstated the magnitude of the future benefits. For example, ORA may have overestimated its costs for replacing several labs. Also, ORA overestimated the staffing requirements for new laboratories in New York and Los Angeles under its replacement option. Such inflated replacement cost figures raise questions about ORA's estimated cost savings from ORA 21. Further, ORA's existing evidence appears to contradict its claims that the mega-labs will improve operational efficiencies.

These and other issues raised in this report suggest that FDA should revisit its plan to consolidate its regulatory laboratories.

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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
 Washington, DC 20515-6115

JOHN D. DINGELL, MICHIGAN
 CHAIRMAN

February 6, 2007

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 MICHAEL C. BURRESS, TEXAS

The Honorable Andrew C. von Eschenbach, M.D.
 Commissioner
 Food and Drug Administration
 Department of Health and Human Services
 5600 Fishers Lane
 Rockville, MD 20857

Dear Dr. von Eschenbach:

Pursuant to Rules X and XI of the Rules of United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are conducting an investigation into the adequacy of the efforts of the Food and Drug Administration (FDA) to protect the safety of the Nation's food supply. We are also concerned about the ability and willingness of the FDA to assure that the drugs and medical devices reaching American consumers are safe and effective. In the case of food safety alone, the recent outbreaks of E coli and salmonella have further increased our concern regarding FDA's domestic enforcement efforts.

Of even greater concern is the ability of the Agency to address possible terrorist assaults on our food supply. The ability of the FDA to analyze food samples quickly and accurately is critical to a viable enforcement program that can stop dangerous imports while not unnecessarily obstructing legitimate commerce in perishable goods. Likewise, the ability of FDA to guard the drug supply from counterfeits and other dangerously substandard drugs requires an efficient laboratory system with a meaningful forensic capability. Toxicology is a critical enforcement tool that should not be compromised by a lack of laboratory capacity.

Accordingly, we are dismayed to learn that the FDA is contemplating shutting down seven to nine of the 13 laboratories that the Agency operates, including the Forensic Chemistry Lab. This comes on the heels of a \$20 million proposed increase for the labs in FY2007 budget, an indication of the priority that the Administration placed on their operation just a year ago.

Further, FDA should have disclosed its planned lab closures to the Committee in your December 26, 2006, written response to questions posed by then-Committee and Subcommittee Chairmen Barton and Whitfield in an October 14, 2006, letter to the Agency. Instead, the FDA told the Committee that the Office of Regulatory Affairs (ORA) "is currently conducting a

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The Honorable Andrew C. von Eschenbach, M.D.
Page 2

strategic planning process. At this time, the plan has not been finalized; therefore, there are no changes to ORA's current laboratory structure."

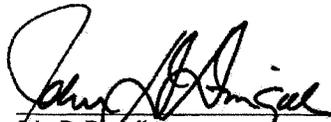
Incredibly, the Committee has learned that FDA notified the National Treasury Employees Union (NTEU) representing some of its workforce of the proposed closings in November, weeks before the Agency apparently decided to mislead the Committee. The refusal of FDA to provide Congress with accurate information in response to the request by a Committee Chairman is completely unacceptable. We ask you to inform us of the name of the individual who made this decision.

In order to evaluate the implications for the safety of food, drugs, and devices that Americans consume, we hereby request that you provide all records created on or after January 1, 2005, relating to proposed closure of FDA labs. Please note that, for the purpose of responding to the above request, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. After review of the records, we may require additional documents and/or staff interviews of FDA personnel.

We further request that you direct that all preparations to close these labs be suspended until after the Committee completes its review. We ask that you supply all requested documents no later than the close of business, Thursday, March 1, 2007.

If you have any questions relating to this request, please have your staff contact David Nelson (Majority staff (202) 225-2927) or Alan Slobodin (Minority staff at (202) 225-3641) with the Committee on Energy and Commerce.

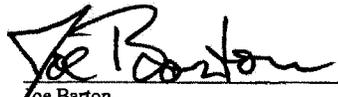
Sincerely,



John D. Dingell
Chairman
Committee on Energy and Commerce



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce



Joe Barton
Ranking Member
Committee on Energy and Commerce



Ed Whitfield
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

Attachment

Congress of the United States
House of Representatives
Washington, D.C. 20515

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 16 2007

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for your letter of February 6, 2007, co-signed by Ranking Minority Member Joe L. Barton, Chairman Bart Stupak, Subcommittee on Oversight and Investigations, and Ranking Minority Member Ed Whitfield. This is in further response to your request in that letter for all FDA documents and records created on or after January 1, 2005, relating to the proposed closure of FDA laboratories. In our partial response to you of March 2, 2005, we enclosed an initial set of documents. Additional documents are enclosed with this transmittal letter.

Certain of the enclosed documents contain deliberative information protected from disclosure to the public under the Freedom of Information Act (Title 5, United States Code, section 552) and FDA regulations. The Committee should not publish or otherwise make public any such information. We would be glad to discuss with the Committee staff the protected status of any specific information.

Thank you again for your continued interest in this matter. If we can be of further assistance please let us know. A similar letter has been sent to the co-signers of your letter, however, without enclosures.

Sincerely

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures

Ex 19



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell, Jr.
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

MAY 08 2007

Dear Mr. Chairman:

Thank you for your letter of February 6, 2007, co-signed by Ranking Minority Member Joe L. Barton, Chairman Bart Stupak, Subcommittee on Oversight and Investigations, and Ranking Minority Member Ed Whitfield. This is in response to your request in that letter for all FDA documents and records created on or after January 1, 2005, relating to the proposed closure of FDA laboratories. In our partial responses to you of March 2 and March 16, 2007, we enclosed some of the documents with each letter. The documents enclosed with this letter are our third transmission of material. Additional documents will be sent as soon as they are available.

Certain parts of the enclosed documents contain deliberative information protected from disclosure to the public under the Freedom of Information Act (Title 5, United States Code, section 552) and FDA regulations. The Committee should not publish or otherwise make public any such information. We would be glad to discuss with the Committee staff the protected status of any specific information.

Thank you again for your continued interest in this matter. If we can be of further assistance, please let us know. A similar letter without enclosures has been sent to the co-signers of your letter.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen R. Mason".

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures

EY20



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

MAY 25 2007

Dear Mr. Chairman:

Thank you for your letter of February 6, 2007, co-signed by Chairman John D. Dingell, Committee on Energy and Commerce, Ranking Minority Member Joe L. Barton, and Ranking Minority Member Ed Whitfield, Subcommittee on Oversight and Investigations. This is in response to your request in that letter for all FDA documents and records created on or after January 1, 2005, relating to the proposed closure of FDA laboratories. In our partial responses to you of March 2, March 16, and May 8, 2007, we enclosed some of the documents with each letter. The documents enclosed with this letter are our fourth transmission of material. Additional documents will be sent as soon as they are available.

Certain parts of the enclosed documents contain deliberative information protected from disclosure to the public under the Freedom of Information Act (Title 5, United States Code, section 552) and FDA regulations. The Committee should not publish or otherwise make public any such information. We would be glad to discuss with the Committee staff the protected status of any specific information.

Thank you again for your continued interest in this matter. If we can be of further assistance, please let us know. A similar letter with enclosures has been sent to the Chairman of the full Committee.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Ex 21

HENRY A. WAXMAN, CALIFORNIA
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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
 Washington, DC 20515-6115

JOHN D. DINGELL, MICHIGAN
 CHAIRMAN

June 15, 2007

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 MARSHA BLACKBURN, TENNESSEE

The Honorable Andrew C. von Eschenbach, M.D.
 Commissioner
 Food and Drug Administration
 Department of Health and Human Services
 5600 Fishers Lane
 Rockville, MD 20857

Dear Commissioner von Eschenbach:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are conducting an investigation into the adequacy of the efforts of the Food and Drug Administration (FDA) to protect the safety of the Nation's food supply.

As part of this investigation, Committee staff has reviewed documents you provided regarding the proposed closure of FDA laboratories. Although we are concerned with many aspects of the laboratory closure plan, we are particularly troubled with the plan to drastically cut the number of laboratory analysts as evidenced by the document entitled, "New Organization Staffing," dated December 11, 2006 (see attachments). This drastic cut comes at a time when the volume of food imports doubles every five years and at a time when the American public appears to be exposed to an increasing amount of unsafe, contaminated food. Thus, we are shocked to learn that FDA has plans to cut 196 microbiologists, chemists, and engineers from the Agency. This number represents 37 percent of the total number of laboratory analysts currently working in Office of Regulatory Affairs laboratories. This slashing of analysts comes after an already 24 percent reduction in lab analysts between 2003 and 2007. To say the very least, these numbers are deeply disturbing.

In order to assist the Committee in its investigation into the adequacy of the efforts of the FDA to protect the safety of the Nation's food supply, we request that you provide the Committee with the following information:

E y 22

The Honorable Andrew C. von Eschenbach, M.D.
Page 2

1. The number and types of samples that FDA currently analyzes but will not be able to analyze due to the reduction in the number of laboratory analysts;
2. The type of domestic or import inspections that FDA currently performs that involve taking samples that will not be able to rely on FDA laboratory analyses in the future due to the reduction in the number of laboratory analysts; and
3. All records reflecting the plans, budget analyses, and contracts intended to replicate the work currently performed by the 196 analysts that you plan to eliminate from the Agency.

Please provide your response and supply all calculations and other records relating to the requested information no later than the close of business two weeks from the date of this letter. Please note that, for the purpose of responding to the above request, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter.

If you have any questions relating to this request, please contact us or have your staff contact David Nelson or Kevin Barstow with the Committee on Energy and Commerce staff at (202) 226-2424.

Sincerely,



John D. Dingell
Chairman



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

TEL DRAFT CONFIDENTIAL

12/17/2006

| 15 Districts with 10 Compliance Branches | | ORA TOTAL | | |
|---|----------|---------------------|----------|----------------------------|
| | New Org. | Transition Staffing | On-Board | Short-Term Placement Needs |
| ACRA OFFICE | 3,144 | 3,125 | 3,182 | 57 |
| DACRA OFFICE | 26 | 20 | 14 | (6) |
| Office of Criminal Investigations (OCI) | 18 | 18 | 16 | (2) |
| Office of Resource Management (ORM) | 226 | 226 | 218 | (6) |
| Office of Enforcement (OE) | 119 | 108 | 94 | (14) |
| Office of Policy (OP) | 53 | 52 | 33 | (19) |
| Office of Field Operations (OFO) | 33 | 20 | 8 | (14) |
| Inspection/Compliance Directorate (ICD) Districts | 115 | 111 | 97 | (14) |
| Science Directorate (SD) | 10 | 13 | 30 | 17 |
| Office of Import Operations (OIO) | 1,768 | 1,766 | 1,724 | (42) |
| | 556 | 582 | 782 | 200 |
| | 223 | 209 | 168 | (41) |

New Org. is what ORA should look like at the end of the transition.
 Transition Staffing is what ORA needs to stand-up ORA on October 1, 2007.
 On-board is ORA's current staffing as of the end of November of 2006.

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 EDWARD J. MARKEY, MASSACHUSETTS
 RICK BOUCHER, VIRGINIA
 ESOL PILES TOWNE, NEW YORK
 FRANK PALLONE, JR., NEW JERSEY
 BART GORDON, TENNESSEE
 BOBBY L. RUSH, ILLINOIS
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DEVINIS B. FITZGERIBONS, CHIEF OF STAFF
 GREGG A. ROTHCHILD, CHIEF COUNSEL

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
 Washington, DC 20515-6115

JOHN D. DINGELL, MICHIGAN
 CHAIRMAN

June 20, 2007

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 CHARLES W. "CHIP" PICKERING, MISSISSIPPI
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 STEVE BUYER, INDIANA
 GEORGE RAGAN, WYOMING, CALIFORNIA
 JOSEPH R. PITTS, PENNSYLVANIA
 BARRY BOND, CALIFORNIA
 GREG WALDEN, OREGON
 LEE TERRY, NEBRASKA
 MIKE FERGUSON, NEW JERSEY
 MIKE ROGERS, MICHIGAN
 BUE MYRICK, NORTH CAROLINA
 JOHN SULLIVAN, OKLAHOMA
 TIM MULPHY, PENNSYLVANIA
 MICHAEL C. BURGESS, TEXAS
 MARSHA BLACKBURN, TENNESSEE

The Honorable Andrew C. von Eschenbach, M.D.
 Commissioner
 Food and Drug Administration
 Department of Health and Human Services
 5600 Fishers Lane
 Rockville, MD 20857

Dear Dr. von Eschenbach:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the adequacy of the efforts of the Food and Drug Administration (FDA) to protect the safety of the Nation's food supply.

On February 6, 2007, the Committee sent you a written request asking you to provide all records created on or after January 1, 2005, relating to the proposed closure of FDA laboratories. As the investigation into the adequacy of the efforts of FDA to protect the safety of the Nation's food supply is ongoing, we are expanding this record request to include all records relating to the proposed reorganization. Please provide all records created on or after January 1, 2005, relating to the proposed reorganization, which have not already been provided to the Committee. This request includes, but is not limited to, all records created between February 6, 2007, and the current date, and all documents that will be created between the current date and August 1, 2007, relating to the proposed closure of FDA laboratories.

To further assist us in our investigation, please also furnish all records relating to contaminated spinach, lettuce, peanut butter, imported vegetable proteins, and imported seafood created since the requests on January 29, 2007; February 15, 2007; March 30, 2007; and May 25, 2007. Certain of these requests were made by Committee staff under the authority of these Chairman's letters. For example, the peanut butter investigation involves the product produced at the ConAgra plant in Sylvester, GA; hence, this updated request applies only to records related to actions involving that plant or its production—not all peanut butter produced in the United States.

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The Honorable Andrew C. von Eschenbach, M.D.
Page 2

Please note that, for the purpose of responding to the above request, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. After review of the records, we may require additional documents and/or staff interviews of or briefings by FDA personnel. Committee staff will make such subsequent requests, if necessary. Please treat requests within the scope of this letter as requests from us.

Please supply all requested documents no later than the close of business two weeks from the date of this letter. If you have any questions relating to this request, please contact us or have your staff contact David Nelson or Kevin Barstow with the Committee on Energy and Commerce staff at (202) 226-2424.

Sincerely,



John D. Dingell
Chairman



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

HENRY A. WAGMAN, CALIFORNIA
 EDWARD J. MARKEY, MASSACHUSETTS
 RICK SCUDIERE, VIRGINIA
 EDOLPHUS TOWNS, NEW YORK
 FRANK PALLONE, JR., NEW JERSEY
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 BARON P. HILL, INDIANA
 DENNIS B. FITZGERALDS, CHIEF OF STAFF
 GREGG A. ROTHSCHILD, CHIEF COUNSEL

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
 Washington, DC 20515-6115

JOHN D. DINGELL, MICHIGAN
 CHAIRMAN

June 26, 2007

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 RANKING MEMBER
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The Honorable Andrew C. von Eschenbach, M.D.
 Commissioner
 Food and Drug Administration
 Department of Health and Human Services
 5600 Fishers Lane
 Rockville, MD 20857

Dear Dr. von Eschenbach:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the adequacy of the efforts of the Food and Drug Administration (FDA) to protect the safety of the Nation's food supply.

As part of this investigation, we are reviewing FDA's proposed plan to close seven of its Office of Regulatory Affairs laboratories. To date, Committee staff have reviewed documents that you have provided regarding this proposed closure of laboratories and have met with FDA personnel in Atlanta, Denver, Detroit, Kansas City, New York, San Francisco, and Winchester, MA. As we previously stated in a letter to you, we are very concerned with many aspects of the laboratory closure plan. One particular area of concern is the plan to close the Winchester Engineering and Analytical Center (WEAC).

Among its many capabilities, WEAC is the only FDA laboratory that performs radionuclide analyses of food. This means that WEAC is the only FDA facility capable of detecting radiological contaminants in food products. Further, as part of the Food Emergency Response Network, WEAC is the sole FDA laboratory for radionuclide analysis in event of a nuclear disaster and/or counterterrorist event. WEAC also has a Memorandum of Understanding with USDA/FSIS, whereby WEAC would analyze USDA regulated products for radiological contamination in the event of an actual or threatened act of deliberate contamination of the food supply. To put it mildly, the thought of losing WEAC's capabilities is frightening.

Ex 24

The Honorable Andrew C. von Eschenbach, M.D.
Page 2

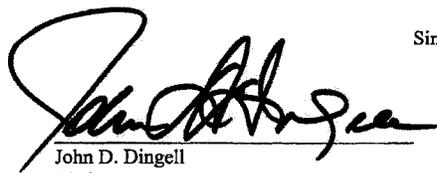
In order to assist the Committee in its investigation into the adequacy of the efforts of FDA to protect the safety of the Nation's food supply, we request that you provide the Committee with the following information:

1. If WEAC is closed, will FDA move WEAC's capabilities to another laboratory?
2. If WEAC capabilities are moved, what will be the time interval between closure and movement when the Nation will be unprotected from nuclear threats to the food supply?
2. If FDA would move WEAC's capabilities to another laboratory, what laboratory would it move them to?
3. How will FDA replace the expertise and experience of those analysts currently working at WEAC who choose not to remain with the Agency?
4. Does FDA have a plan to contract out the work currently performed by WEAC? If so, to whom?

Please provide your response and all records relating to the requested information no later than the close of business two weeks from the date of this letter. Please note that, for the purpose of responding to the above request, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. After review of your response and the requested records, we may require additional documents and/or staff interviews of FDA personnel.

If you have any questions relating to this request, please contact David Nelson or Kevin Barstow with the Committee on Energy and Commerce staff at (202) 226-2424.

Sincerely,



John D. Dingell
Chairman



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

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2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

From: Glavin, Margaret
Sent: Thursday, June 28, 2007 6:45 PM
To: ORA All Employees
Subject: Congressional Requests for Documents

Attachments: 2007-855 incoming.pdf; EC Cmte_Addtl Doc Req_Safety of Nations Food Supply.pdf

Dear Colleagues:

As some of you are already aware, ORA has received written requests from Congress for all records relating to the proposed closure of FDA labs and ORA's proposed reorganization. The requests, which were sent to FDA by the Chairman of the Committee on Energy and Commerce in the U.S. House of Representatives, are attached. We are sending this email to all of you because we want to make sure that we collect all responsive documents. We recognize that some recipients of this email may not have responsive documents.

Action Item: Request for documents relating to the proposed closure of FDA labs AND the proposed ORA Reorganization

Due Date: Documents MUST be Received In ORA HQ by COB, Tuesday, 7/3/07

What Documents Should I Search For?

You should search for and produce the following:

All documents created on or after January 1, 2005, through August 1, 2007, relating to the proposed closure of FDA labs and ORA's proposed reorganization. As the attached requests explain, the terms "records" and "relating" should be construed broadly.

Responsive documents include the following:

- All internal reviews, reports, memos, presentations, and briefings related to the laboratory consolidation and/or ORA's proposed reorganization;
- All studies or assessments related to laboratory consolidation and/or ORA's proposed reorganization, including the results of ZBB analyses relating to lab closures;
- All meeting minutes, notes of meetings, and telecon records relating to the laboratory consolidation and/or ORA's proposed reorganization, including all handwritten records;
- All correspondence, e-mails, or telecon records from headquarters to the field (and vice-versa) relating to laboratory consolidation and/or ORA's proposed reorganization;
- All records related to the FDA website on the ORA transformation, including all documents submitted to the website, posted on the website, or related to the creation of the website;
- All documents and minutes related to the TLT meetings in which the laboratory consolidation and/or proposed reorganization were considered or discussed, including any handwritten notes from such meetings;
- All documents relating to any all-hands meetings regarding the laboratory consolidation and/or ORA's proposed reorganization, including all hand-written notes from such meetings;
- All documents relating to any consultation or discussion with the states regarding the laboratory consolidation and/or ORA's proposed reorganization; and
- All documents relating to any consultation or discussion with any state or private lab regarding the laboratory consolidation and/or ORA's proposed reorganization.

You should send 4 COPIES of all responsive documents to the address set forth below. If you think any of the documents contain confidential commercial information, trade secrets, or privileged information, please flag that information for consideration by FDA's Office of Legislation.

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Please Note: The congressional letter dated June 20, 2007 (attached), also requests documents related to contaminated spinach, lettuce, peanut butter, imported vegetable proteins, and imported seafood. You do not need to respond to that part of the letter at this time. This e-mail relates solely to the laboratory consolidation and proposed reorganization. ORA is collecting documents responsive to the request on food contamination and seafood through another process.

What Documents Are Excluded From The Search?

You do not need to search for, or collect, the following categories of documents:

- Publicly-available documents from FDA's website.

Where Should I Look For These Records?

To represent to Congress that FDA has conducted a thorough search, you must review all files in your possession, custody, or control, including those stored electronically, for any documents that refer or relate to the requested items.

How Should I Direct My Staff?

If you are in charge of an organizational unit that may have responsive documents, you must direct your staff to review all files in the possession, custody or control of the unit for any documents that refer or relate to the requested item.

Where Should I Send The Records I Find?

Please send **four (4) COPIES** (not the originals) of all documents (and any attachments to the documents), with a cover page indicating: (1) the sender; and (2) whether the sender is an individual or organizational unit.

Please make copies single sided on 8½ x 11 paper; please do not staple documents.

Please send all documents to:

FDA/Office of Regulatory Affairs
Executive Operations Staff
5600 Fishers Lane, Room 13-91
Rockville, MD 20857

What if I have already produced responsive records to ORA's Executive Operations Staff?

I know that some of you have already produced records responsive to the congressional request on lab closures based on prior e-mails from Jamie Hughes (dated 2.13.07) and Jeanne Roman (dated 2.14.07 & 2.15.07). If, in response to those e-mails, you have already produced to ORA's Executive Operations Staff some or all of the responsive records in your possession, custody, or control, you need not re-produce those particular records. Rather, at this time, we ask you to copy and produce only those responsive records that you have not already provided to ORA's Executive Operations Staff.

Who Should I Call If I Have Questions?

If you have any questions, please call Jamie Hughes at 301-827-0948

2/6/07 & 6/20/07 Letters from the Committee on Energy & Commerce



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Thank you.

Margaret O'K. Glavin
Associate Commissioner for Regulatory Affairs



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 10 2007

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for your letter of June 20, 2007, co-signed by Bart T. Stupak, Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce regarding, among other things, the Food and Drug Administration's (FDA) Office of Regulatory Affairs (ORA) proposed transformation.

Your letter requests all records related to the proposed ORA transformation from January 1, 2005, to the current date and all records that will be created between the current date and August 1, 2007. A portion of the requested records is provided as enclosures with this letter and additional documents will be provided to you as soon as they are available.

Certain enclosed documents contain deliberative information protected from disclosure to the public under the Freedom of Information Act (Title 5, United States Code [U.S.C.], section 552) and FDA regulations. The Committee should not publish or otherwise make public any such information. We would be glad to discuss with the Committee staff the protected status of any specific information.

Thank you again for contacting us concerning this matter. A similar letter, without enclosures, has been sent to Chairman Stupak. If you have further questions, please let us know.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen R. Mason", written over a circular stamp or seal.

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures

Ex 26



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUL 11 2007

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Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures

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Kansas City District Laboratory

The Kansas City District (KAN-DO) Lab is fully equipped to perform the chemical analyses of food and drugs regulated by the agency. The Lab has program capabilities in food chemistry including pesticides and industrial chemical residues, toxic and nutritional elements (metals), mycotoxins, dioxins, and micro-analytical analyses (entomology, food sanitation, and food standards) and other counter terrorism capabilities. In 2006 the KAN-DO Lab was accredited to international standards (ISO 17025).

The KAN-DO Lab is the national servicing center for FDA's Total Diet Study, an ongoing food surveillance program that originated in 1961. Sophisticated detection methods are utilized in the analyses of volatile organic chemicals, herbicides, fungicides, more than 350 pesticides, toxic elements (for example lead, mercury, and arsenic), and nutritional elements (for example iodine, calcium and magnesium). The Lab sets an example for other countries to establish their own total diet studies. KAN-DO Lab scientists have trained scientists from other countries, such as Mexico, China, and Kuwait. The Lab has received international recognition for the Total Diet Study program, including recognition from World Health Organization (WHO). KAN-DO employees hosted the first international Total Diet Workshop.

The Total Diet Research Center at KAN-DO supports the work of the Total Diet Program and Pesticide Programs by improving methods or developing new methods for determining chemical contaminants in the foods of the Total Diet Study. Numerous methods have been developed, published, validated and eventually incorporated into the Total Diet Program and other states and national pesticide programs.

KAN-DO's Lab also analyzes human and animal foods for mycotoxins. Mycotoxins are toxins produced by molds that grow on corn, wheat, apples, nuts and other foods. The samples come from all over the nation. Many are imports and come from other countries. This is the only field lab to analyze samples for fumonisins, a mycotoxin found in corn products.

KAN-DO's Lab has a pesticide group which has a broad capacity to analyze for 300 pesticide residues, solvents and other chemical contaminants. It also analyzes samples for dioxins.

The KAN-DO Lab elemental analysis group can perform trace level analysis for toxic and nutritional elements (metals). Products include domestic and imported foods (for example Mexican candies, juices, raisins) and ceramic ware. This is the only lab in the FDA known to be able to analyze foods for iodine.

The Drug Lab at KAN-DO provides analyses of a variety of pharmaceutical products and also tests analytical methods for new pharmaceutical products. KAN-DO's Lab furnishes chemists to assist in regional and international pharmaceutical inspections.

The KAN-DO Lab ranks fifth among all FDA field labs for the number of chemists/scientists working on the bench.

In 2002 major investments in new laboratory equipment (\$5 million) were made to enhance the Lab's ability to respond to counter terrorism threats.

Facility

The Kansas City District Office is centrally located in Lenexa, KS, a safe and economical suburb of the Kansas City Metro area. The Kansas City International Airport is opening a large distribution center with further expansion planned. Kansas City has one international railroad center with two more planned. The largest Fed Ex trucking center is located in Kansas City.

The Kansas City District Office including the Lab was opened in June of 1992 and was remodeled in 2001. The complex consists of two buildings totaling 60,000 square feet, divided almost equally between lab and investigation, compliance, and administrative functions. The larger building, with 32,000 square feet of lab space, features a computer-controlled air handling system. This controlled atmosphere is necessary to minimize contamination of the highly sensitive analyses performed in the Total Diet Study and regulatory operations. The system provides a HEPA-filtered air supply for the 30 lab rooms. A large portion of the non-lab space was built with the infrastructure (plumbing, electrical, etc.) to convert it into additional lab areas if needed. The building complex is leased until 2012.

San Juan District Laboratory

The San Juan District laboratory is a specialized laboratory dedicated to the analysis of pharmaceutical products. It is co-located with the District office in

San Juan, Puerto Rico. The analysts are extremely knowledgeable in the area of drug analysis and drug inspection techniques.

The island of Puerto Rico has a large concentration of pharmaceutical manufacturers accounting for approximately 30% of the world's production of pharmaceuticals and 60% of the drugs consumed in the USA. Of the top 20 world wide Pharmaceutical companies, 14 have facilities in Puerto Rico.

The laboratory is located on about 8 acres of park-like grounds by the San Juan Bay. From the grounds, you can see ships in the Bay.

The district's main building was constructed through renovation of a 50 year-old Public Health Service clinic in 1985. This one-story building has about 14,800 square feet of combined laboratory and office space. The laboratory currently occupies an area of approximately 5,156 square feet.

The laboratory underwent a major renovation in FY'99, resulting in a new laboratory dedicated to Pharmaceutical Analysis. The analyst's office space is conveniently located nearby the laboratory.

The San Juan Laboratory is unique in that it is the only ORA field laboratory outside of the continental United States.

It is one of only two field facilities owned by FDA.

Scientific Personnel

The branch has a total staff of 23 with 13 chemists (including two GS-13 specialists), two Laboratory Support Technician, and two Science Advisors. The management staff consists of two Supervisors, one Quality Assurance Manager, and the Science Branch Director.

The analysts in San Juan have strong backgrounds in pharmaceutical science. The majority of the analysts worked with drug manufacturers prior to joining FDA. The pharmaceutical industry in Puerto Rico is large and very diverse. As a result, SJN-DO analysts are experienced in the analysis of a wide variety of sample types requiring the use of sophisticated laboratory instrumentation and a strong knowledge of analytical chemistry.

SJN-DO analysts have acquired considerable knowledge and experience conducting inspections of this complex industry. They are familiar with the most complex and novel manufacturing drug processes. Analysts participate very actively in domestic and foreign drug inspections. Five analysts are active participants on the FDA Foreign Inspection Cadre. SJN-DO analysts also conduct independent inspections of Drug Contract Laboratories in Puerto Rico and in foreign countries. The Chemists in SJN-DO always bring a high level of technical expertise to the work they do.

The expertise and knowledge of SJN-DO analysts is well recognized among the pharmaceutical industry, local government, and the Academia. As a consequence, analysts are frequently requested to participate as speakers in training courses and conferences on regulatory and analytical issues. All analysts are bi-lingual in Spanish and English. They have given presentations in both languages. They have participated in GMP training provided to regulators from Central and South America using their native Spanish language. Analysts have participated as speakers in a variety of conferences with industry, speaking on topics such as Laboratory inspections and regulatory requirements. The majority of chemists have been licensed by the Chemists' Examination Board of the Department of State of Puerto Rico. The Laws of the Commonwealth of Puerto Rico require the approval of a board examination in the areas of general, analytical, organic and physical-chemistry in order to exercise the profession on the island. One chemist is a Certified Quality Auditor.

Instrumentation

San Juan District has a full range of analytical instrumentation typical of other ORA laboratories, as well as specialized equipment necessary to conduct a full range of drug analytical techniques. This includes the following:

San Juan District Laboratory Equipment (Quantity)

- Automated Dissolution Baths, Apparatus 1 and 2 (6)
- UV/VIS Spectrophotometer (2)
- Gas Chromatographs with Headspace and FID and NPD Detectors (2)
- GC/MS (2)
- HPLC (11) with UV, Diode Array, and Fluorescence Detectors
- Capillary Electrophoresis (1)
- Melting point Apparatus (1)
- FTIR (1)
- Water Titrator (1)
- KF Coulometer (1)
- Potentiometer Titrator (1)
- Polarimeter (1)
- Ion Chromatograph (1)

Program Capabilities

The San Juan District Laboratory is a drug specialty laboratory performing a full range of analyses on human drugs. The laboratory has experience in the analysis of a wide variety of drug samples such as tablets, capsules, creams, suspensions, sterile solutions, metered dose inhalers, nasal sprays, drug patches, and active pharmaceutical ingredients. The laboratory analyzes a variety of compliance and consumer complaint samples, as well as samples

collected by the Office of Criminal Investigations (OCI). The Laboratory is the servicing lab for the San Juan District drug programs and also receives samples from Headquarters offices, the Center for Drug Evaluation & Research, as well as OCI. Work plan obligations include the following:

- **Active Pharmaceutical Ingredient (API) “Fingerprinting” Program**
Evaluation of impurity profiles of APIs from different manufacturers to verify if the drugs are authentic or counterfeit. These projects are conducted in conjunction with the Forensic Chemistry Center.
- **Method Validation Program - (New Drug Applications (NDA)/Abbreviated New Drug Applications (ANDA) Assessment of analytical methods to determine if they are suitable for regulatory purposes. (These two programs, even though we have 1 FTE for it, has been put on hold probably pending lab. closure)**
- **Domestic and Foreign Drug Inspections**
Audits analytical raw data to assure data integrity, to evaluate method validation procedures, and to assess the firm’s laboratory operations.
- **Department of Defense (DOD) Shelf-life Extension Program**
Evaluation of the quality of drug products after their established expiration date. (This program has increased to 3 FTE)
- **Headquarters Initiated Drug Surveillance Program**
Analysis of post-market samples.

Technology Transfer

The San Juan District Laboratory frequently provides training and technical assistance to local agencies including the Puerto Rico Department of Agriculture. San Juan District Laboratory analysts have trained representatives from Puerto Rico and various other Central and South American countries including Mexico, Costa Rica, Ecuador, Argentina, and Guatemala in drug analysis. Chemists in San Juan are frequently requested by drug manufacturers to give training and presentations on FDA Guidelines and current policies.

Analysts also participate in FDA expert panels, along with Consumer Safety Officers and Compliance Officers, providing updated regulatory information to the drug industry. All of the SJN-DO chemists are fully bilingual in Spanish and English. They have provided GMP training to Regulators from Central and South America using their native Spanish language. SJN-DO analysts participate in National training Cadres, National FDA committees, and professional associations.

The laboratory was actively involved in the development of several Partnership initiatives between FDA and the Commonwealth of Puerto Rico, Department of Health and the Department of Consumer Affairs, involving the analysis of honey, vanilla, rice, and juice samples. The Southeast Regional Laboratory analyzed samples of vanilla, rice, and juice. San Juan Lab performed label reviews and coordinated the analysis of honey samples to determine adulteration.

Research

San Juan District Laboratory has a research project for the Development of an HPLC Method for Commercially Available Melatonin Preparations. This method will use liquid chromatography with fluorescence detection to quantify melatonin in over the counter natural products.

Science Advisors

Joseph Bloom, Ph.D. was appointed as the Science Advisor for San Juan District in 2002. Dr. Bloom is an Associate Professor in the Pharmaceutical Science Department, School of Pharmacy, Medical Sciences Campus, University of Puerto Rico. He is also a Research Associate at the Center for Environment and Toxicological Research (CETR), Medical Sciences Campus, University of Puerto Rico. Dr. Bloom currently serves as a member of the Advisory Committee in Pharmaceutical Sciences of the FDA.

Areas of Expertise:

- Mass Spectrometry
- Capillary Electrophoresis
- HPLC & GC
- Solid Phase Extraction

Dr. Bloom has taught courses on Mass Spectrometry and Practical Laboratory Experiences for the Public Ministry in Guatemala; on Instrumental Analysis for the Doctoral Program at the Public Health School, Medical Sciences Campus; and on Advanced Biochemistry for the Masters Program of Clinical Laboratory at the College of Health Allied professions, Medical Sciences Campus. As researcher he had the opportunity to perform as research fellow in the Department of Pharmacology of the Medical University of South Carolina, and as research scientist in FDA's National Center for Toxicological Research. He is currently as research associate at the CETR.

Osvaldo Rosarion, PH D:

Dr. Osvaldo Rosario is serving as science advisor to FDA in San Juan, especially to the laboratory branch. He has twenty nine years of teaching and research experience in the area of analytical chemistry, twenty seven of which as Research Professor at the University of Puerto Rico. He has twentyfive peer-reviewed publications, over seventy presentations at the national and international level, and has mentored thirty nine graduate theses (31 PhD and 8 MSc). His area of expertise is in method development for the analysis of low concentrations of organic compounds in complex matrices using chromatographic separations with spectroscopic and mass spectrometric detection. This vast experience has been very valuable in training, analytical troubleshooting, and the overall operation of the FDA Laboratory Facilities. He

also brings a strong networking not just between FDA and the University of Puerto Rico, but also to the overall science community on the island.

Innovations/Highlights/Accomplishments/Contributions

SJN Chemists participated in domestic drug inspections resulting in two important Consent Decrees. One of these resulted in a 500 million dollar settlement which was the largest monetary settlement in FDA history. The analysts' expertise was pivotal to the findings in the cases. Analysts have participated in several other inspections that resulted in important enforcement actions for the District.

In the foreign arena, the work performed by SJN Chemists has prevented the importation of drug products and APIs that do not meet the minimum cGMP requirements. One of SJN's Drug Specialists participated in a foreign inspection to observe and evaluate the foreign government's auditing techniques under the FDA the Mutual Recognition Agreement (MRA). A SJN analyst participated in a national workgroup to develop a Laboratory Control Section which was incorporated into FDA's uniform inspection format for Pharmaceutical Inspections under the MRA.

SJN chemists participate in National Laboratory training courses as members of Course Advisory Groups and as trainers. SJN hosted a national training course on Inspections of Pharmaceutical Laboratories where several members of the lab were trainers. SJN Chemists also participate in numerous conferences sponsored by drug manufacturers. Their role is to convey the Agency's current thinking regarding regulatory policies.

The San Juan lab has evaluated and reported several errors in the USP which have been subsequently corrected and published. Analysts have been participated in collaborative studies and review of Journal articles. San Juan Laboratory personnel were actively involved in updating the Drug Training Chapter in the ORA Lab Manual.

San Juan Laboratory has a QA Manager and is actively working toward keeping the accreditation granted on April 2006.

San Francisco District Laboratory

The San-Francisco District Lab not only participated in the analysis for E. coli in the recent foodborne outbreak which implicated spinach from the Salinas Valley, but actually analyzed approximately 800 samples from this outbreak which included raw spinach, pig feces, irrigation water and soil samples. Due to its location, it was able to send investigators to the farms and then begin analysis either on the same day or on the following day, thus providing a rapid analytical

response. The San Francisco lab also analyzes, on a regular basis, foods and drugs produced both locally and imported, for other pathogens such as Salmonella, Listeria, and Hepatitis, to name but a few.

After its participation in this widely-reported foodborne out break, which sickened over 300, hospitalized over 100 and actually resulted in the deaths of 3 people, Commissioner von Eschenbach gave the San Francisco lab the highest praise for its rapid and excellent analytical work.

Not only does this lab analyze for bacterial pathogens, but our lab also examines food, drugs, cosmetics and candy (especially imported Mexican candy) for toxic elements such as lead, cadmium and arsenic-to name just a few poisonous contaminants we find in these products-many of which are used or consumed by children.

In addition to the above, this lab also is a FERN Lab-this is a "Food Emergency Response Network" Lab, which means it is prepared to respond to potential terrorist attacks against food and drugs that come into the country by water (seaports), across borders (Canada, Mexico) or by air. Again, due to its proximity to the Oakland, San Francisco and Stockton ports, it has a significant role in the economy of these port cities.

Winchester (MA) Engineering and Analytical Center

WEAC is an **FDA owned** and accredited National Servicing Laboratory which is uniquely capable of testing foods for radioactive contamination and medical devices for safety and efficacy.

It is the only FDA laboratory capable of analyzing food for radioactive contamination.

It handles the radiation equipment, calibration, and safety training for FDA field personnel.

It employs the Lead Project Coordinators for the radiological component of the national Food Emergency Response Network (FERN).

It is collaborating with entities like Boston College, Dartmouth College, UNH, and the EPA on such important food contamination concerns as Anthrax and the Plague virus.

It is the FDA's Center for Devices and Radiological Health only field laboratory capable of performing comprehensive analyses of various medical devices, diagnostic X-ray systems, and radiation-emitting products.

It analyzes numerous devices for the Office of Criminal Investigations, including suspected fraudulent devices and those linked to homicide investigations.

As a 2006 FDA Office of Management document put it: "...*The Winchester Engineering and Analytical Center (WEAC) located in Winchester, MA, serves as a national resource for evaluation of radiological and other medical devices. WEAC is the only FDA facility that provides specialized engineering and analytical services and radionuclide analysis.*"

Denver FDA Lab

The FDA lab in Denver is part of the FDA's Southwest Region, an 11-state area including Arkansas, Colorado, Iowa, Kansas, Nebraska, Missouri, New Mexico, Oklahoma, Texas, Utah and Wyoming.

The Denver laboratory -- home to the Animal Drugs Research Center (ADRC) -- is the only FDA lab in the country to test the safety of all veterinary drugs.

The labs test all food (both domestic and imported) pathogens and additives.

National experts in salmonella detection are based at the Denver laboratory. They specialize in salmonella speciation and antibiotic resistance testing.

The Denver lab also houses the FDA's facilities testing for Bovine Spongiform Encephalopathy, known as Mad Cow Disease.

Detroit District Laboratory

The Detroit District Laboratory is located in the former Stroh Brewery Research Laboratory. This modern facility was leased in 2002 to replace the former leased laboratory that was constructed in 1958. The laboratory is designed to meet all current laboratory requirements and is particularly suited for the wide array of modern instruments required for FDA work. It provides exceptionally good stable electric power required for modern instruments and even has a back-up generator for key instrumentation. It also has excellent safety features incorporated into the labs and meets all requirements for air handling. The building management provides an excellent security system as well as its own on site security staff.

The primary workload is the analysis of "Shelf Life" samples for DOD and CDC to extend the expiration date for drugs stored for national defense and homeland security. The analysis of import food samples for mold, insect, or rodent contamination is a high priority program. Import foods are also screened for illegal colors or chemical additives.

Compliance drug samples are analyzed to support investigator observations and compliance actions. Prior to the decrease in staff the lab routinely conducted evaluations and validations for both NDA's and Generic Drugs prior to market approval.

All of the laboratory scientists routinely accompany investigators on in plant inspections to assist in evaluating the adequacy of their testing and quality control procedures. This teamwork provides for a more comprehensive evaluation of the firm's compliance with FDA regulations.

The laboratory is well equipped with instrumentation required for FDA work. Instruments include a range of High Performance Liquid Chromatographs (HPLC's), Gas Chromatographs (GC's), GC/MassSpec, FTIR and various spectrophotometers. The laboratory was one of the original labs designated for bioequivalency testing of drugs and has two units for this work.

The analysts have significant expertise in separation science and the advantage of having Wayne State Univ. Professor Colin Poole as a Science Advisor. Dr. Poole is internationally recognized for his knowledge in separation science (Chromatography). The lab was one of the first to have a FTIR spectrophotometer and is recognized for its use in FDA applications. The lab has had student intern agreements with Wayne State University and University of Detroit. The lab has access to the Central Instrument Facility at Wayne State. This lab has a number of high resolution NMR's and Mass Spectrometers.

The continued reduction in staff has significantly reduced the analytical support that could be provided to the district office.

Detroit is one of only three FDA labs nationwide to routinely test medicine stockpiles from the Defense Department that are nearing expiration. Stockpiles are tested for continued viability.

Lab is a testing site for food and drug samples imported from Canada. More than 25 percent of all merchandise traded between the United States and Canada crosses the Ambassador Bridge.

DOD SHELF LIFE PROGRAM

The "Shelf Life" program for DOD was started prior to the first Gulf War. DOD contacted FDA to determine if they could extend the expiration date of drugs they maintained in large quantities for national emergencies. An agreement was made that FDA would undertake a program to determine if this was feasible and DOD would reimburse FDA for the work.

The original assignment was to the Detroit and New York laboratories. Detroit working with the Center for Drug Evaluation and Research (CDER) piloted a procedure where by the drugs were placed in environmentally controlled chambers to purposely cause degradation and breakdown. The drugs were then assayed for potency and breakdown products. From the data obtained the CDER pharmacologist and pharmacist developed a model to predict drug stability.

DOD identified the drugs to be tested for the program and testing was implemented. In addition to testing for extending the expiration date the program included follow up testing at predetermined intervals to insure that the model predictions were correct.

New York laboratory dropped out of the program and the Philadelphia laboratory was added (Philadelphia is now also scheduled to be closed).

Prior to this program when the drugs reached their expiration date they were destroyed and replaced with new drugs. The program has saved DOD hundreds of millions of dollars. Now CDC is included in the program because of drugs they maintain in large quantities for homeland security emergencies.

The Detroit laboratory has developed a significant expertise in drug stability and breakdown products. All of the methods and procedures for analysis had to be developed and validated along with quality assurance procedures. This expertise was valuable when the Detroit laboratory was conducting validation of the analytical procedures submitted in New Drug Applications and Generic Drug applications.

A significant operation occurred at the beginning of the first Gulf War when a company submitted to DOD that they had a topical lotion that would protect exposed skin against Mustard Gas. DOD had tested it and found that it did provide protection. They entered into a contract for large-scale production. They requested the Detroit laboratory to test some of the initial production. Detroit found that the product did not contain the active ingredient. In follow up investigation we established that the firm had not properly characterized the original active ingredient and were not able to scale up to large production runs. Not only that, but a chemist had falsified analytical results to indicate the product met requirements. Based on a Detroit chemist's testimony both the firm and individual were successfully prosecuted in federal court and we prevented an ineffective product from being used on our military.

Philadelphia Lab

Philadelphia lab tests for counterfeit drugs from overseas

This lab lies in the heart of the most concentrated pharmaceutical company region in the United States.

The only FDA lab to test asthma inhalers for children and adults, as well as the testing of transdermal patches (fentanyl patches used for extreme pain in cancer patients as well as for high blood pressure and heart patients.)

The bulk of all Department of Defense drug testing is handled by the Philadelphia laboratory, including antibiotics, nerve agents and antivirals.

SAN FRANCISCO DISTRICT LABORATORY

Microbiology Section

Personnel

The San Francisco District of the FDA employs 13 dedicated and highly skilled Microbiologists, one Food Pathogen Specialist, and 2 Microbiology Supervisors. The Microbiologists are all Certified Level 1 FDA-Office of Regulatory Affairs Analysts, having successfully completed the required training and proficiency testing. The Microbiology lab adheres to a strict ISO 17025 Quality Management System to ensure the integrity of its work and is accredited by A2LA.

Facilities

In addition to the Microbiology lab bench spaces, SAN-Micro has the following dedicated facilities:

- BSL2+ suite with pass-through Autoclave
- Clean Room for sterility analyses
- Virology Room
- PFGE Room
- Clostridium botulinum* toxin analysis room
- PCR analysis room
- Media kitchen

The ability to dedicate specific areas for designated functions minimizes the risk of cross contamination, and ensures the analysts' safety.

Instrumentation

| | |
|-------------------------------|---------------------|
| Smartcyclers | Micro Plate Readers |
| Vidas | Micro Plate Washers |
| Vitek | Pathatrix |
| Thermocyclers | Steritest System |
| Gel Electrophoresis equipment | Gel Doc System |
| PFGE equipment | |

Lab Capabilities

Analyses

- Pathogen Detection
- Microbial Toxin Detection
- Canned Foods/Can Seam Integrity
- Cosmetic Analyses
- Alkaline Phosphatase Analysis of Dairy Products
- Sterility/Endotoxin/Microbial Limits Analysis of Drugs/Medical Devices
- BSL 2+ *Yersinia pestis*, *Bacillus anthracis*
- Rapid Methods

Capacity

During the 2006 spinach outbreak of *E. coli* O157:H7, the laboratory was able to handle over 450 samples with a staff of 14 microbiologists (53% of the total samples received by San Francisco District Laboratory, California Department of Health Services Food and Drug Laboratory Branch, and USDA ARS Laboratory).

Programs

| 2007 workplan | |
|------------------------------|-------------------------------|
| Import Acidified and LACF | Domestic Seafood |
| Domestic Acidified and LACF | Domestic & Imported Cosmetics |
| Food Safety Micro Samples | Drug Surveillance |
| Animal Feeds | EHEC Emergency |
| Imported Foods | Counter Terrorism |
| Domestic and Imported Cheese | Import Produce Assignment |
| | Method Validation |

Special Capabilities:

FERN- Network of state and federal laboratories that are committed to analyzing food samples in the event of a biological, chemical, or radiological terrorist attack in this country.

LRN- Network of state/ government public health laboratories developed to provide surge capacity for samples resulting from a public health emergency caused by a select agent.

Cal-FERT- Works co-operatively with California State Food and Drug Branch personnel to respond to foodborne outbreaks, including field investigations and laboratory analyses.

Virology- Researching, developing and validating new methods for the detection of Norwalk viruses, and Hepatitis A virus in foods.

PFGE- Pulsed Field Gel Electrophoresis subtyping bacterial isolates for epidemiological investigations.

Current SAN-Micro Research Projects:

- Isolation of *Shigella sp.* Using Immunomagnetic Separation (Pathatrix) and detection with real time PCR.
- Recovery of *Shigella sp.* Using Chromogenic media.
- Real Time – Reverse Transcription PCR for detection of Hepatitis A virus
- Multiplex Real Time – Reverse Transcription PCR for simultaneous detection of Hepatitis A virus and Norwalk like viruses
- Subtyping of *E. coli* O157:H7 by Multi-locus Variable Number Tandem Repeat Analysis
- Optimization of Shiga toxin producing *E. coli* O26 Detection.

SAN-Micro Collaborations:**Lawrence Livermore National Laboratory**

- Formal collaborative agreement to develop detection methods for enteric viruses using TaqMan assays and Low Density Micro Arrays such as Luminex Bead Technology

USDA- Agricultural Research Service, Western Regional Research Center

- Formal collaborative agreement to work on concentration, extraction, and detection of Noroviruses in fresh produce and oysters.

USDA- Food Safety and Inspection Service

- Surge capacity coverage for food microbiology testing
- Media preparation

California Department of Health Services Food & Drug Laboratory Branch

- Partnership to work on the development of E. coli O157:H7 methods using immunomagnetic isolation and Real Time PCR
- Partnership to work on the development of Salmonella sp. method using immunomagnetic isolation and real time PCR
- Surge capacity coverage for food microbiology testing

California Animal Health and Food Safety Laboratory

- Development of multipathogen and multiviral detection methods using the Luminex Bead Technologies
- Collaborative work in the development of a C. botulinum toxin detection method using Luminex Bead Technology

Hawaii Public Health Laboratory

- Collaborative work in the development of a Salmonella method using immunomagnetic isolation and real time PCR.

Laboratory Information Bulletins:

- Detection of *Escherichia coli* O157:H7 in Produce Rinse by Pathatrix Immunomagnetic Extraction and Conventional Methods. *Laboratory Information Bulletin* 2006 No. 4371.
- A RT-PCR Protocol for the Simultaneous Detection of Norovirus and Enteroviruses. *Laboratory Information Bulletin* 2006 No. 4369.
- A Rapid One-Step RT-PCR for the Detection and Screening of Hepatitis A Virus. *Laboratory Information Bulletin* 2005. No. 4360.

- Detection of Shigella from Produce using FTA DNA Isolation. *Laboratory Information Bulletin* 2002. No. 4285.
- Environmental Sampling for Microbiological Analysis. *Laboratory Information Bulletin* 2001. No. 4266.
- Rapid determination of chromium in stainless steel via X-Ray Fluorescence spectrometry. Submitted for publication 4-24-07.
- On the Suitability of Portable X-Ray Fluorescence analyzers for Rapid Screening of Toxic Elements. *Laboratory Information Bulletin* 2006. No.4376.
- Determination of Lead in Mexican Candy and Flavored Salt Products. *Laboratory Information Bulletin* 2005. No. 4346.

Recent Poster Sessions:

International Association for Food Protection 2006 Annual Meeting: Rapid and Effective Method to Improve Detection and Isolation of E. coli O157:H7 from Fresh Produce. Sunee Himathongkham, Jenny Yee, Henry Lau, Andrew Lin, and David K. Lau.

International Union of Microbiological Societies 2005 Conference: Detection of *Shigella* using Real Time PCR. David Lau

Pacific Southwest AOAC 2005 Conference: Evaluation of a Rapid DNA Isolation for PCR Detection. David Lau

Sigma XI Poster Session: 2002 FDA Forum on Regulatory Sciences, Rapid Detection of *Salmonella* in Produce using Real Time PCR. David Lau.

Sigma XI Poster Session: 2000 FDA Forum on Regulatory Sciences, Extraction of Viable *Cryptosporidium parvum* Oocysts from Foods. David Lau and R.L. Bernstein

Participation in Cadre Advisory Groups:

FDA National Food Emergency Response Network (FERN) Training Cadre.
 FDA National Basic Microbiology Training Cadre.
 FDA Mobile Laboratory Training Cadre, Microbiology section.
 FDA Mobile Laboratory Implementation Cadre, Microbiology section.
 FDA BAM Revision Cadre
 FDA Sterility Analytical Manual Revision Cadre
 FDA National Check Sample Cadre
 FDA Analyst Certification Board
 FDA Web Based Module Development Cadre
 FDA Viral Method Development Cadre

Practicalities:

| | |
|--|----------|
| Port of Oakland | 8 miles |
| Salinas Valley | 94miles |
| USDA-FSIS | 6 miles |
| USDA- ARS | 16 miles |
| California State Food and Drug Branch Laboratory | 20 miles |
| Lawrence Livermore National Laboratory | 34 miles |

Awards:

2004-FDA Group Service Award for Rapid Analysis of High Priority Microbiology Samples under Operation Liberty Shield.

2000-FDA Group Recognition Award for exceptional performance which contributed to the successful accomplishment of the Imported Produce Sampling Assignment in San Francisco District.

Chemistry Section**Personnel**

- 14 analyst and 1 physical science technician working in the 3 sections of chemistry
- Expertise include 1 toxic elements expert, 2 sensory-organoleptic experts, 1 color expert.

Lab capabilities**Analyses:**

- Toxic elements in Foods by ICP-MS
- Toxic elements screen by X-Ray Fluorescence (XRF)
- Lead (Pb) and Cadmium (Cd) in Foodware by FAAS, and GFAAS
- Pb and Cd in Food by GFAAS
- Total Mercury (Hg) in Seafood by CVAAS
- Seafood Sensory Evaluation
- Seafood Decomposition: Histamine, Indole
- Sulfites
- Nitrites
- Non-nutritive Sweeteners
- Color Additives in Cosmetics
- Color Additives in Foods
- Vanillin, Ethyl Vanillin and Coumarin
- % Salt (chloride) and Moisture

Capacity:

- Analysis of 264 Hurricane Katrina seafood sample for toxic elements in fiscal year 2006
- Analysis of all toxic elements samples for Pacific region (SEA-DO, SAN-DO, LOS-DO)
- Analysis of all colors and food additive samples for Pacific region

Projects:

- XRF Field Pilot for screening of products for toxic elements in the field
 - XRF field program to be implemented FY2008
- Mercury Speciation Method Verification completed
 - SAN-LAB to analyze all FDA samples requiring Hg speciation starting FY2008

Presentations:

- 8-14-06 - the 55th Annual Denver X-Ray Conference (“Evaluation of Analytical Figures of Merit for Rapid Screening of Toxic Elements in Food via EDXRF” & “Application of PEDXRF to Rapid Screening for Toxic Elements in Foods and Asian Patent Medicines”).
- 4-26-06 - “Lead in Candy” at the Northern California Regional Meeting of the Childhood Lead Poisoning Prevention Program (CLPP)
- 1-24-06 update on SAN-DO’s activities related to toxic elements to the California Animal Health and Food Safety Lab, UC Davis, School of Veterinary Medicine
-

Award:

- 2007 Lead in Chocolate Group Award SAN-DO and SEA-DO
- 2006 Commissioner’s Special Citations

Publications:

Rapid determination of chromium in stainless steel via X-Ray Fluorescence spectrometry; submitted for publication 4-24-07

On the Suitability of Portable X-Ray Fluorescence analyzers for Rapid Screening Of Toxic ELEMENTS; LIB 4376, July, 2006.

Determination in Lead in Mexican Candy and Flavored Salt Products; LIB #4346, April 2005.

U.S. Food and Drug
Administration
San Francisco District Laboratory

1431 Harbor Bay Parkway
Alameda, CA

698

2x 32

U.S. Food and Drug
Administration
San Francisco District Laboratory
1431 Harbor Bay Parkway
Alameda, CA

FDA's Mission Statement

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.



SAN-Micro Personnel

- 14 FDA Office of Regulatory Affairs Certified Level 1 Microbiology Analysts
 - Including 1 Food Pathogen Specialist
- 2 Microbiology Supervisors

SAN-MICRO 2007 Workplan

- Import Acidified and Low Acid Canned Foods
- Domestic Acidified and Low Acid Canned Foods
- Food Safety Micro Samples
- Imported Foods
- Domestic & Imported Cheese
- Imported Seafood
- Domestic Seafood
- Domestic & Imported Cosmetics
- Drug Surveillance
- Animal Feeds
- EHEC Emergency
- Counter Terrorism
- Import Produce Assignment
- Method Validation

SAN-Micro Special Projects

- FDA Food Emergency Response Network participant
 - Network of state and federal laboratories trained and committed to analyzing food samples in the event of a biological, chemical, or radiological terrorist attack in this country.
- CDC Laboratory Response Network participant
 - Network of state/ government public health laboratories developed to provide surge capacity for samples resulting from a public health emergency caused by a select agent.
- California Food Emergency Response Team participant
 - CAL-FERT members work co-operatively with California State Food and Drug Branch personnel to respond to foodborne outbreaks- including field investigations and laboratory analyses.
- Detection of Enteric Viruses
- PFGE subtyping for epidemiological investigations



Current SAN-Micro Research Projects

- Isolation of *Shigella* sp. Using Immunomagnetic Separation (Pathovix) and detection with real time PCR.
- Recovery of *Shigella* sp. Using Chromogenic media.
- Real Time – Reverse Transcription PCR for detection of Hepatitis A virus
- Multiplex Real Time – Reverse Transcription PCR for simultaneous detection of Hepatitis A virus and Norwalk like viruses
- Subtyping of *E. coli* O157:H7 by Multi-locus Variable Number Tandem Repeat Analysis
- Optimization of Shiga toxin producing *E. coli* O26 Detection

SAN-Micro Collaborations

- Lawrence Livermore National Laboratory
 - Collaborative agreement to develop detection methods for enteric viruses
- USDA- Agricultural Research Service
 - Collaborative agreement to improve concentration, extraction and detection of Noroviruses
- USDA- Food Safety and Inspection Service
 - Surge capacity coverage for food microbiology testing
- California Department of Health Services, Food and Drug Laboratory Branch
 - Development of E. coli O157:H7 detection methods
 - Development of Salmonella detection methods
 - Surge capacity coverage for food microbiology testing
- California Animal Health and Food Safety Laboratory
 - Development of multipathogen and multiviral detection methods
- Hawaii Public Health Laboratory
 - Development of Salmonella detection methods

Recent SAN-Micro Laboratory Information Bulletins

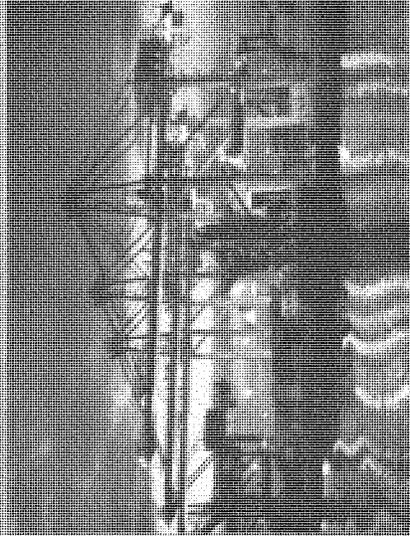
- Detection of *Escherichia coli* O157:H7 in Produce Rinse by Pathatrix Immunomagnetic Extraction and Conventional Methods. *Laboratory Information Bulletin* 2005, No. 4371.
- A RT-PCR Protocol for the Simultaneous Detection of Norovirus and Enteroviruses. *Laboratory Information Bulletin* 2006, No. 4369.
- A Rapid One-Step RT-PCR for the Detection and Screening of Hepatitis A Virus. *Laboratory Information Bulletin* 2005, No. 4360.
- Detection of Shigella from Produce using FTA DNA Isolation. *Laboratory Information Bulletin* 2002, No. 4285.
- Environmental Sampling for Microbiological Analysis. *Laboratory Information Bulletin* 2001, No. 4266.

Recent SAN-Micro Abstracts/Poster Presentations

- 2006-International Association for Food Protection 2006 Annual Meeting: Rapid and Effective Methods to Improve Detection and Isolation of E. coli O157:H7 from Fresh Produce.
- 2005-International Union of Microbiological Societies 2005 Conference: Detection of Shigella Using Real Time PCR.
- 2005-Pacific Southwest AOAC 2005 Conference: Evaluation of a Rapid DNA Isolation for PCR Detection.
- 2002-Sigma XI Poster Session: 2002 FDA Forum on Regulatory Sciences, Rapid Detection of Salmonella in Produce Using Real Time PCR.
- 2000-Sigma XI Poster Session: 2000 FDA Forum on Regulatory Sciences, Extraction of Viable Cryptosporidium parvum Oocysts from Foods.

SAN-Micro Awards

- ↳ 2004-FDA Group Service Award for Rapid Analysis of High Priority Microbiology Samples under Operation Liberty Shield.
- ↳ 2000-FDA Group Recognition Award for exceptional performance which contributed to the successful accomplishment of the Imported Produce Sampling Assignment in San Francisco District.



Port of Oakland

- ↳ 4th busiest port in the U.S.
- ↳ 2.4 million TEU's moved in 2006 (record year)
- ↳ Projected increase in imported goods
 - Expansion of port
 - Increase in trade with Pacific
- ↳ Currently <1% of imported goods are inspected



The Analytical Capabilities of FDA's Winchester Engineering and Analytical Center – NTEU Chapter 288

Analytical Services

The Winchester Engineering and Analytical Center (WEAC) laboratory is the only FDA facility capable of providing both specialized analytical services in medical device and radionuclide analyses.

In July of 2006, WEAC was accredited by the American Association for Laboratory Accreditation (A2LA) to ISO/IEC 17025:2005 for the following test methods:

Biological tests:

- Radionuclides in Foods
- Filth in Seafood, Listeria and Salmonella
- Sterility of Medical Devices
- Disinfectants
- Sensory Analysis
- Chromium in Medical Devices

Mechanical tests:

- Performance of medical X-ray Machines
- Blood Pressure Measurement Devices
- Electronic/ Mercury-in-Glass Thermometers.
- Defects in Gloves
- Defects in Condoms
- Tensile Strength of Condoms
- Impact Resistance of Optical Lenses
- Radiation Emissions of Microwave Ovens

Device analysis work at the WEAC facility involves chemical, microbiological, and engineering evaluations of medical devices and engineering analyses of radiation emitting products. This work supports programs under FDA's CDRH (Center for Devices and Radiological Health). WEAC is the primary field laboratory upon which CDRH relies for its analytical services.

WEAC also supports programs under FDA CFSAN (Center for Food and Applied Nutrition) and FDA CDER (Center for Drug Safety and Evaluation). Analytical capabilities include chemical, microbiological, biological and radionuclide analyses.

Program Capabilities and Specialized Expertise

WEAC is the national servicing laboratory for medical device and radionuclide analyses.

WEAC's unique expertise in its Analytical Branch includes:

- testing foods for radioactive contamination,
- analyzing in vitro diagnostic test kits,
- microbiological (including sterility) analyses in medical devices.

WEAC's expertise also includes:

- organoleptic examination of seafood,
- trace metal analyses,
- microanalytical (filth) analyses,
- microbiological analysis of foods.

The expertise in WEAC's Engineering Branch, the only such group in ORA, includes:

- mechanical and electrical testing of medical devices such as:
 - medical gloves,
 - syringes,
 - clinical thermometers,
 - infusion pumps,
 - hearing aids,
 - ventilators,
 - defibrillators.
 - diagnostic X-ray systems including:
 - mammographic,
 - dental,
 - portable units,
 - computed tomographic X-ray systems.
- FDA performance standard testing for radiation-emitting devices such as:
 - microwave ovens,
 - CRT-based computer monitors and receivers,
 - mercury vapor lamps,
 - sun lamps,
 - diagnostic ultrasound devices.

The Analytical Capabilities of FDA's Winchester Engineering and Analytical Center – NTEU Chapter 288***WEAC provides health physics services to the FDA field force including:***

- the dissemination of radiation monitors,
- radiation pagers to FDA investigators,
- calibration of radiation survey equipment,
- training and guidance for the completion of radioactive materials license applications,
- radiation safety training.

WEAC analyzes a number of devices from OCI (Office of Criminal Investigations) including suspected fraudulent devices and devices linked to homicide investigations. WEAC also analyzes devices for various federal, state and local law enforcement and regulatory agencies including state and county medical examiners' offices. Many of these devices require the development of test methods and the fabrication of test fixtures. Recent examples include:

❖ **Alaris® Infusion Pump**

WEAC's analytical tests confirmed the presence of "key bounce" design defect in a model of Alaris infusion pumps, and provided critical evidentiary support for a very recent seizure of \$1.8 million worth of these devices.

❖ **Cardiac and Blood Pressure Monitoring Devices – Healthcare Fraud**

WEAC in collaboration with CDRH and OCI, performed analyses of several cardiac and blood pressure monitoring devices to determine equipment capabilities in connection with a case involving the alleged defrauding of federal insurance programs of more than \$500,000. WEAC testing found that these devices could not perform certain functions purportedly billed by the defendants. Two defendants pleaded guilty to federal health care fraud charges as a result of this multi-agency effort which, in addition to FDA included the US Attorney's Office, OPM, DOD, DHHS, FBI and IRS.

❖ **Muscle stimulator sample analyses**

WEAC's analysis of Dr-Ho muscle stimulators supported two subsequent seizure actions of these devices with a total value of \$3.7 million. WEAC's analysis determined that these devices did not conform to an electrical safety performance standard and had serious labeling deficiencies.

❖ **Bausch & Lomb Renu with MoistureLoc – *Fusarium keratitis***

WEAC assisted in the analytical investigation of a multi-state cluster of contact lens-associated *Fusarium keratitis*, a fungal infection of the eye. Patients with confirmed cases of *Fusarium keratitis* had reported using various contact lens cleaning solutions including various types of ReNu products. The Agency was involved in testing the efficacy of ReNu MoistureLoc against *Fusarium keratitis*. The WEAC lab performed the ISO Stand Alone test on ten lots of product. All tests showed that the product was able to meet the labeled claims under laboratory test conditions. This effort assisted CDRH in their evaluation of the products biocidal claims as part of their comprehensive approach to determine the cause of the infections.

The Analytical Capabilities of FDA's Winchester Engineering and Analytical Center – NTEU Chapter 288❖ **Counterfeit condoms**

WEAC's Analytical and Engineering Branches recently conducted water leakage and air inflation testing of literally thousands of seized counterfeit condoms labeled as the "Trojan" brand to ascertain the potential risk to the general population.

❖ **Self Monitoring Blood Glucose Devices**

WEAC assisted the OCI in an investigation/study of "shrink wrapped" Self Monitoring Blood Glucose Devices (Test Strips). The retail units of glucose test strips were being subjected to a process which involved heating cellophane like material "shrink wrapping" in order to combine various numbers of retail units into one package. The OCI investigators wanted to determine if the process was adversely affecting the performance of the glucose test strips. WEAC analysts in concert with a CDRH statistician evaluated the performance of "shrink wrapped" product compared to product that was not "shrink wrapped" and found that the process did not adversely affect the product.

❖ **TRUST Antigen Syphilis screening kit**

Recently WEAC participated in the post market evaluation of an in-vitro diagnostic medical device that had recently obtained a 510k clearance for marketing. The device was designed as a screening diagnostic test for Syphilis. In cooperation with the Centers for Disease Control and Prevention, WEAC obtained the necessary supplies to evaluate the performance of this test kit used for the serological detection of syphilis. The results of the testing indicated that the performance of the product did not meet the CDC product specifications as claimed. The investigation is ongoing and a recent contact with OCI indicated that further testing may be done in the near future.

Collaborative Activities

Collaborative studies investigating new methods, directed surveillance assignments evaluating products not traditionally found in the workplan, and effective execution of the workplan is accomplished through successful communications with the CDRH laboratories.

- ❖ WEAC maintains a close liaison with the University of New Hampshire and Boston College providing ongoing research opportunities for the analysts resulting in publications.
- ❖ WEAC provides scientific guidance on device analysis and sampling procedures to field laboratories and device investigators.
- ❖ WEAC employees serve as FDA liaisons to various ASTM and ISO committees. Responsibilities include drafting new standards, reviewing proposed standards, participating in round robin studies to evaluate new methods, and representing the agency at the meetings.
- ❖ A WEAC analyst has been selected as one of two ORA representatives on the nation-wide CAFDAS committee (Committee for the Advancement of FDA Science).
- ❖ WEAC engineers, chemists, physicists, and microbiologists form an integral part of teams performing complex medical device and radiopharmaceuticals investigations.

*The Analytical Capabilities of FDA's Winchester Engineering and Analytical Center – NTEU Chapter 288***Recent Activities and Accomplishments**❖ **Food Emergency Response Network (FERN) activities**

WEAC's radionuclide section serves as lead Project Coordinators for the radiological component of the FERN. The FERN is a network of state and federal laboratories that are committed to analyzing food samples in the event of a biological, chemical, or radiological terrorist attack in this country. Surveillance and proficiency sampling programs for all areas have been developed.

For the FERN, WEAC has:

- distributed and evaluated three radiological proficiency studies to twenty-six FERN laboratories,
- developed and validated radiological analysis methods for regulatory sample analysis and counter-terrorism arena method validation studies,
- developed surveillance studies,
- hosted FERN Radiological Training Courses,
- prepared the Food Safety and Security Project – Radiological Health Announcement / Cooperative agreement.

WEAC is charged with FERN:

- method validation studies,
- proficiency studies,
- recommendations for equipment,
- audits,
- WEAC serves on several International Consortium Laboratory Network Committees.

❖ **National Radiological Activities**

- WEAC has a memorandum of Agreement with US Department of Agriculture/FSIS for radionuclide analysis in food samples collected as part of an emergency related to an actual or threatened act of deliberate contamination of the food supply.
- WEAC collaborates with the EPA Regional Laboratory in Chelmsford, MA, and the National Marine Fishery Service (NIMFS) laboratory in Gloucester, MA.
- WEAC's Radiation Safety Officer is a member of the New England Radiological Health Committee. WEAC will assist the New England states in the radionuclide analysis in food samples collected as part of an emergency.

❖ **Microbiological Activities**

WEAC is conducting counterterrorism food research at the University of New Hampshire's biocontainment level three laboratory. *Yersinia pestis*, the Plague bacterium, has emerged as a concern to the FERN due to the possibility of a deliberate contamination of the US food supply via terrorist activity. Working with CFSAN and other FDA and State labs, WEAC is evaluating the Pathatrix Immunomagnetic Capture System in the hopes of increasing the number of laboratories capable of isolating and identifying *Yersinia pestis*.

The Analytical Capabilities of FDA's Winchester Engineering and Analytical Center – NTEU Chapter 288

❖ **Fabrication of Testing Devices**

WEAC, in collaboration with FDA's Forensic Chemistry Center, is currently fabricating handheld testing devices to be used by FDA field staff.

❖ **Sporicidal Activity Test Method (EPA Interlaboratory Collaborative Study)**

WEAC participated in an EPA interlaboratory collaborative study to improve the AOAC (Association of Analytical Communities) Sporicidal Activity Test Method. This study led to modifications to the method. A second study has been initiated with its purpose being to evaluate a quantitative sporicidal activity Three Step Method. These studies will help improve the methodology used to determine the performance of liquid disinfectants.

❖ **Medical Glove Residual-Powder Collaborative Study**

WEAC participated in the Enersol interlaboratory trial for removable powder on medical gloves. This study was performed on behalf of the ISO technical committee responsible for test methods in medical gloves. The technical committee has been working on a standard for the determination of residual powder on medical gloves. The trial involved methods for both powdered and powder-free gloves that are currently in the ASTM *Standard Test Method for Residual Powder on Medical Gloves*. Data generated from the study was presented at the ISO TC45 annual meeting.

❖ **Toxoplasma gondii IgM ("Cat Scratch Fever") Pilot Study**

WEAC participated in a *Toxoplasma gondii* IgM pilot study which evaluated six commercial *T. gondii* IgM detection kits. *T. gondii* IgM, commonly known as Cat Scratch Fever, is a parasite carried by cats which can be transferred to pregnant women. This was a joint venture among WEAC, CDRH, CDC and the Palo Alto Medical Foundation, Palo Alto, CA. The study resulted in a public health advisory on the limitations of *Toxoplasma* IgM Commercial Test Kits.

❖ **ASTM D11.40 ELISA Working Group Collaboration (Latex Protein Measurement)**

WEAC participated in three round robin studies to evaluate revisions to the ASTM (American Society for Testing and Materials) *Inhibition Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and its Products*. The goal is to improve the quantitative measurement of antigenic natural rubber latex proteins found in latex medical gloves. Additional studies in this area are anticipated.

❖ **ASTM Synthetic Condom Round Robin**

WEAC participated in a comprehensive evaluation of various test methods for synthetic condoms. The study evaluated the following methods: thickness measurements, tensile testing using dumbbell and ring specimens, whole condom tensile testing, air burst testing, and modified air burst testing. The whole condom tensile test and the modified air burst test required the development of special fixtures for the test equipment. Results will be used to determine appropriate methods for the ASTM standard and to provide precision and bias statement for the various methods

The Analytical Capabilities of FDA's Winchester Engineering and Analytical Center – NTEU Chapter 288❖ **ASTM Lubricant Compatibility Round Robin**

WEAC participated in another ASTM round robin evaluating a new test method to evaluate the effect of various user added lubricants on latex gloves and condoms through tensile testing. WEAC was also involved in the development of the test protocol. Results of this round robin will be used to validate the proposed new method.

❖ **ASTM Testing of Sized Condoms Round Robin**

WEAC has been actively participating in the development of a protocol to evaluate modifications to the condom water leak test and air burst test for sized condoms. The effectiveness of the proposed water volumes were evaluated at WEAC by measuring the static pressure generated in the condoms and comparing the pressures to that of a standard sized condom. Results of this round robin will be used to support changes to the ISO and ASTM condom standards.

❖ **Tensile Testing of Vinyl Gloves**

WEAC conducted a center initiated short-term evaluation of the tensile properties of vinyl gloves. WEAC measured the tensile properties of twenty-one samples of vinyl gloves to provide CDRH and ASTM with a snapshot of the current state of the industry. This data was used to support a proposed increase to the ASTM standard for vinyl gloves.

Method Development

WEAC is actively involved in the development and validation of regulatory test methods.

Past FDA/ORA Method Validation Studies Projects:

- Completed a method validation study, "Investigation of density effect of foods on radionuclides analysis using gamma spectroscopy." This novel method, using High Purity Germanium Detectors, is applicable for analyzing gamma activity for all food matrices.
- Developed the current medical glove product water leak test method,
- Developed regulatory protocols for the female condom and synthetic condoms,
- Developed a regulatory protocol for the evaluation of self-monitoring blood glucose devices,
- Developed improved procedures for the detection of antibodies in human sera to Herpes Simplex Virus (HSV)-1 and HSV-2 by the Western blot technique,
- Assessment of the Durability of Medical Exam Gloves.

Current FDA/ORA Method Validation Studies Projects:

- Determination of Plutonium (Pu) and Americium (Am) Radioactivity in Food Samples by Inductively Coupled Plasma Mass Spectrometry (ICP-MS) and Alpha Spectrometry
- Development of Liquid Scintillation Counting Method for Determination of Gross Alpha and Beta Radioactivity in Food and Its Packaging
- Development of Radiochemical Procedures for Determination of 89Strontium (Sr) and

The Analytical Capabilities of FDA's Winchester Engineering and Analytical Center – NTEU Chapter 288

- 90Sr in Food Using Sr-Specific Extraction Chromatography
- Development of real time PCR method for the rapid detection of Yersinia enterocolitica in green leafy vegetables
- Development of methods for identification of Yersinia pestis (Plague bacterium) in produce and bottled water
- Assessment of the Durability of Surgical Gloves
- Enhancement of WEAC Capabilities in Air Inflation Testing of Condoms
- Development of a Rapid Version of the Tampon Test Method Based on 21CFR801.430
- Revision of the Test Methodology (Method Development) for Insulin Pumps

Staff and Facility**WEAC Staff (12/06)**

| Organization | # | Series | Title |
|---------------------------------|-----------|-------------------|---|
| <i>Center Director's Office</i> | 1 | 0318 | Secretary (OA) |
| | 1 | 1320 | Chemist |
| | 1 | 0690 | Ind. Hygienist/Radiation Safety Officer |
| | 1 | 0342 | Support Services Supervisor |
| | 2 | 6901 | Sample Custodian |
| <i>Analytical Branch</i> | 1 | 1301 | Physical Scientist |
| | 2 | 0401 | Biologist |
| | 8 | 0403 | Microbiologist |
| | 1 | 0403 | Consultant (CON) |
| | 1 | 0856 | Electronics Technician |
| | 2 | 1311 | Physical Science Technician |
| | 10 | 1320 | Chemist |
| 1 | 3511 | Laboratory Worker | |
| <i>Engineering Branch</i> | 3 | 0801 | General Engineer |
| | 5 | 0830 | Mechanical Engineer |
| | 6 | 0855 | Electronics Engineer |
| | 1 | 0856 | Electronics technician |
| | 1 | 0858 | Biomedical Engineer |
| | 1 | 1301 | Physical Scientist |
| | 2 | 1310 | Physicist |
| | 1 | 1310 | Consultant (CON) |
| Total Staff | 52 | | |

The Winchester Engineering and Analytical Center is located at 109 Holton Street, Winchester, Massachusetts in a one-story structure owned by FDA. Auxiliary buildings include mobile trailers which abut the main building and are accessible from within the main building, a pilot building, two warehouses and solvent/hazardous waste storage buildings. WEAC also maintains a class 100 clean room for sterility testing of radiopharmaceuticals and medical devices.

NOTE: Laboratory environmental conditions easily met all the stipulations of accreditation requirements under ISO 17025: 2005. This facility has been and would continue to be more than serviceable for all of WEAC's needs well into the future.

Hughes, Jamie

From: Chappell, Michael
Sent: Monday, November 13, 2006 12:35 PM
To: Singleton, Emma R
Cc: Anderson, Erika; Ralston, Deborah D; Riggio, Lynnette I; Strachan, James M
Subject: Laboratory Workgroup

Emma, I trust you will/did/are having a pleasant trip to Rockville without being removed from the aircraft for failing to pay for your ticket.

Last week the OOGSC met and we discussed several issues. I don't recall if I shared this with you or not. If I did not, I apologize. The issue was "laboratory capacity". Is the laboratory work group going to look at different levels of capacity? For instance, there is current capacity vs. workplan. I am sure that your group will be looking at consolidation and how that will affect capacity. In theory, if leveraging permits us to reduce our surveillance sampling, predominately in the food area, our need for capacity will diminish over time. That may not happen overnight, but I believe it is a goal. I believe we hear the figure now that 80% of our laboratory activity is directly related to surveillance samples. As risk management kicks in and rapid field tests become available, in theory, we will be better targeting samples for full laboratory analysis that are more likely to be violative. The result may be more total resources per sample but fewer samples because they are violative. Regardless, "capacity" needs to be defined and understood.

Will this issue be part of your recommendation on laboratory consolidation?

Michael A. Chappell, Director
Dallas District
Food & Drug Administration
(214) 253-5201

Hughes, Jamie

From: Anderson, Erika
Sent: Monday, January 22, 2007 4:03 PM
To: Strachan, James M; Holman, Brenda J
Subject: Lab Closing Bullets

Attachments: Lab Closings.doc

Jim & Brenda,

Here is the first draft of the lab closing bullets. I need help strengthening the San Francisco one. I don't have compelling information as to why that one should be closed other than 5 scored higher than it.



Lab Closings.doc
(33 KB)

Thanks.

Erika Anderson
US Food and Drug Administration
Office of Regulatory Affairs
Office of Resource Management
Phone: 301-827-1037
erika.anderson@fda.hhs.gov

ORA Laboratory Facilities

| | Lease/Own | Lease Expires | Square Feet (lab space only) | Lab Space Occupied | Condition | Major Repairs Needed | Est. Cost of Repairs | Staff |
|--------------------------------|-----------|---------------|------------------------------|--------------------|-----------------------|----------------------------------|--|-------|
| Arkansas Regional Lab | Own | N/A | 146,000 | 100% (3) | Excellent; built 2003 | none | N/A | 70 |
| Denver District Lab | Own | N/A | 23,000 | 100% | Good | Renovations planned for 2010 (9) | Will be amortized and rolled into rent | 54 |
| Detroit District Lab | Lease | 2017 | 5,800 | 100% | Excellent | none | N/A | 10 |
| Forensic Chemistry Center | Lease | 2018 | 30,000 | 100% | Very good (2) | none | N/A | 55 |
| Kansas City District Lab | Lease | 2012 | 32,000 | 100% | Good | Uninterruptible power supply | \$100,000 | 64 |
| Northeast Regional Lab | Lease | 2019 | 113,000 | 92% (4) | Good | none | N/A | 143 |
| Seattle District Lab (Bothell) | Own | | 16,791 | 100% | Good | Electrical and security upgrades | \$140,000; \$100,000 already committed | 69 |
| Pacific Regional Lab, (Irvine) | Own | | 80,000 | 100% (5) | Excellent; built 2003 | De-ionized water system | \$25,000 | 94 |
| Philadelphia District Lab | Own | | 18,100 | 100% | Fair to Good | none | | 30 |
| San Francisco District Lab | Lease | 2014 | 22,420 | 100% | Good | none | N/A | 49 |

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| | | | | | | | | |
|---|-------|-------------------|--------|----------|--------------|-----------------------------------|----------------------------|-----|
| San Juan District Lab | Own | | 8,000 | 100% | Fair | none (10) | N/A | 24 |
| Southwest Regional Lab | Lease | 2005; 2017 (1) | 76,000 | 100% (6) | Fair to poor | Annex2: air balance (7) | \$1 million | 140 |
| Winchester Engineering Analytical Center | Own | | 15,696 | 100% | Poor | Old facility; high maintenance | \$75 - \$80 million (8) | 61 |

1 3 buildings on 2 separate leases. Lease for Crawford office bldg and Annex 1 lab expire 11/2005; lease for Annex 2 lab expires 2017. Lease for Crawford and Annex 1 under negotiation.

2 Renovations recently completed. BSL-3 certified 4/2005.

3 9,400 s.f.. occupied by NCTR. Could compress ORA lab space to make room for additional personnel.

4 8,500 s.f.. of lab space unused. Approximately 70,000 s.f.. of total leased space unused.

5 Could compress 20%-30% to accommodate additional staff.

6 3,000 s.f.. of Crawford office space unused.

7 Major repairs needed for Crawford and Annex 1: steam generator, HVAC, hot water generator, steam hoods.

8 Both equipment and facility are worn out. This figure encompasses total renovation.

9 GSA renovating entire Federal complex, including new roofs, HVAC systems, etc. DEN-DO lab now designing its space.

10 Location is hard on the facility. Salt air corrodes HVAC and ductwork. Mold is persistent. Equipment in fair condition. No investment planned

| ORA LABORATORY FACILITY EVALUATION TOOL | | | | | | | |
|---|-------------------|--------|----------|-----------------------|-----------------|----------|----|
| Lab | Site | Region | Facility | Capacity/Capabilities | Geographic Area | Rankings | |
| | | | | | Total | | |
| NRL | Jamaica, NY | NER | 2.6 | 3 | 3 | 8.6 | 2 |
| WEAC | Winchester, MA | NER | 1.4 | 2.5 | 2.5 | 6.4 | 7 |
| SRL | Atlanta, GA | SER | 1.6 | 2.8 | 3 | 7.4 | 5 |
| San Juan | San Juan, PR | SER | 1.6 | 2 | 2 | 5.6 | 10 |
| Detroit | Detroit, MI | CER | 1.8 | 1.5 | 1.5 | 4.8 | 12 |
| Philadelphia | Philadelphia, PA | CER | 1.4 | 2 | 2 | 5.4 | 11 |
| Denver | Denver, CO | SW | 1.6 | 2.8 | 1.5 | 5.9 | 8 |
| Kansas City | Kansas City, KS | SW | 2 | 2.3 | 1.5 | 5.8 | 9 |
| ARL | Jefferson, AR | SW | 3 | 2.7 | 2 | 7.7 | 3 |
| PRL-SW | Irvine, CA | PAR | 3 | 2.8 | 3 | 8.8 | 1 |
| San Francisco | San Francisco, CA | PAR | 1.8 | 2.5 | 2.5 | 6.8 | 6 |
| PRL-NW | Bothell, WA | PAR | 1.8 | 2.8 | 3 | 7.6 | 4 |

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TLT laboratory Working Group
ORA Laboratory Facility Evaluation Tool

Phase 1: Facility

- Fit-for-use (Modern state-of-the-art laboratory)
- Building condition/age
- Ability for expansion: FTEs, program work
- Operational costs
 1. lease expiration/term
 2. rental cost
 3. gov't/FDA owned
 4. maintenance including costs associated with necessary service upgrades, building specs
- Unique/specialty units i.e. BSL-3
- Location
 1. cost of living
 2. safety
 3. recruiting issues

Phase 2: Capacity and Capabilities

- diversity of laboratory capabilities
- surge capacity (FERN, natural disasters, outbreaks) while maintaining base operational workload
- analyst experience (expertise, institutional knowledge, national/international recognition)
- degree of risk losing expertise
- inspectional assistance, district/satellite offices dependant on lab assistance to carry out program work, recalls, training, outbreak investigations, etc.

Phase 3: Geographic area

- leveraging with non-ORA counterparts (federal, state, local, academia, industry)
- strategically located across the US (imports, major cities, trade flow/shipping routes/ports of entry, food safety/food defense)
- inspectional activity
- import operations – impact, meeting stakeholders needs, rule in/rule out, clearance of import commodities (district + lab)

ORA FTE Information

| | Lab FTE | Analyst FTE |
|-------|---------|-------------|
| FY 01 | 753 | 547 |
| FY 02 | 767 | 563 |
| FY 03 | 941 | 698 |
| FY 04 | 838 | 633 |
| FY 05 | 798 | 606 |
| FY 06 | 763 | 569 |
| FY 07 | 722 | 531 |

What ORA Will Look Like in October 2008

| E | TLT Mafia Outcome Statements |
|--|---|
| <p>6 9 12 18 23 24 25 26 27 28 29 30 31 32 33 34</p> | <p>A. Our organization is designed to support the delivery of our core functions (sample collection, analyses, inspections, investigations, entry reviews) which support our mission.</p> <ul style="list-style-type: none"> a. We are at a place where we are extremely efficient and cost-effective. We are structured (organizationally, geographically, etc) to achieve this, e.g., appropriate support/operational ratios, supervisory ratios, analysis/inspection ratios, investigator/compliance ratios. We have IT systems, org structure, and facilities and infrastructure that enable us to be as efficient and effective as possible. b. Our resources (e.g., KSAs, analytical capability, locations) are aligned with program needs and stakeholder expectations. c. We have a plan in place to maintain over time the alignment of resources with program needs and stakeholder expectations. d. Employees believe in our mission, are committed to our organization, understand and support our priorities, and are empowered to do their jobs right. <ul style="list-style-type: none"> i. Employees have the skills they need and understand the purpose and import of their assignments. ii. Employees have the skill needed to make a timely determination of "substantial compliance" as appropriate and are supported in these decisions. iii. Employees have the skill and experience to appropriately decide to extend an inspection beyond the scheduled time. |

What ORA Will Look Like in October 2008

Attachment # 1 - Cross Reference Document # 1 - 36, page 11 & 12

| | |
|--|---|
| <p>Maggie's 7/24/06 Document Cross reference</p> | <p>TLT Mafia Outcome Statements</p> |
| <p>6 9 12 18 23 24 25 26 27 28 29 30 31 32 33 34</p> | <p>A. Our organization is designed to support the delivery of our core functions (sample collection, analyses, inspections, investigations, entry reviews) which support our mission.</p> <ul style="list-style-type: none"> a. We are at a place where we are extremely efficient and cost-effective. We are structured (organizationally, geographically, etc) to achieve this, e.g., appropriate support/operational ratios, supervisory ratios, analysis/inspection ratios, investigator/compliance ratios. We have IT systems, org structure, and facilities and infrastructure that enable us to be as efficient and effective as possible. b. Our resources (e.g., KSAs, analytical capability, locations) are aligned with program needs and stakeholder expectations. c. We have a plan in place to maintain over time the alignment of resources with program needs and stakeholder expectations. d. Employees believe in our mission, are committed to our organization, understand and support our priorities, and are empowered to do their jobs right. <ul style="list-style-type: none"> i. Employees have the skills they need and understand the purpose and import of their assignments. ii. Employees have the skill needed to make a timely determination of "substantial compliance" as appropriate and are supported in these decisions. iii. Employees have the skill and experience to appropriately decide to extend an inspection beyond the scheduled time. |

TL DRAFT CONFIDENTIAL

25% of Analytical Staff Moving Laboratory Costs & Closing Costs

| Lab | Rent Savings | Above Standard Savings | Renovation Savings | Repair savings | Total Savings | TI Payoff/Rent Buyout | DECOMMISS-IONING COSTS | Equipment Move Costs | PSC Costs moving 25% of analytical staff | Total Costs for Closing |
|--------------|--------------------|------------------------|---------------------|----------------|---------------------|-----------------------|------------------------|----------------------|--|-------------------------|
| DEN | \$370,780 | \$26,578 | | | \$397,358 | \$0 | (\$460,000) | | (\$600,000) | (\$1,060,000) |
| DET | \$777,268 | \$0 | | | \$777,268 | (\$87,000) | (\$250,000) | | (\$100,000) | (\$417,000) |
| KAN | \$738,200 | \$1,218,881 | | | \$1,956,181 | (\$1,478,400) | (\$450,000) | | (\$655,000) | (\$2,578,400) |
| PHI | \$408,278 | \$16,600 | | | \$425,778 | \$0 | (\$460,000) | | (\$1,050,000) | (\$1,500,000) |
| SAN | \$445,120 | \$455,519 | | | \$900,639 | \$0 | (\$460,000) | | (\$400,000) | (\$860,000) |
| SJN | \$0 | \$861,870 | \$650,000 | | \$1,511,870 | \$0 | (\$385,000) | | (\$200,000) | (\$585,000) |
| MEAC | \$0 | \$355,440 | \$10,000,000 | | \$10,355,440 | \$0 | (\$2,000,000) | | (\$650,000) | (\$2,650,000) |
| TOTAL | \$2,741,628 | \$3,086,898 | \$10,950,000 | | \$16,778,526 | (\$1,648,400) | (\$4,435,000) | | (\$3,860,000) | (\$9,830,400) |

Averaging costs over three years of biologic

| Year | Avg Rent Savings | Avg Above Standard Savings | Renovation Savings ² | Avg. Repair Savings | TOTAL Savings ⁴ | TI Payoff/Rent Buyout | Avg Decommiss-ioning Costs ⁵ | Avg Equipment Move Costs | Avg PSC cost ⁶ | Total |
|----------------|------------------|----------------------------|---------------------------------|---------------------|----------------------------|-----------------------|---|--------------------------|---------------------------|---------------|
| Year 1 (FY 08) | \$913,875 | \$267,645 | \$5,000,000 | \$530,513 | \$1,078,038 | (\$87,000) | (\$738,187) | | (\$687,500) | (\$1,628,807) |
| Year 2 (FY 09) | \$1,827,750 | \$1,433,848 | \$5,000,000 | \$530,513 | \$3,822,111 | (\$1,478,400) | (\$1,478,333) | | (\$1,775,000) | (\$4,088,803) |
| Year 4 (FY 11) | \$2,741,628 | \$4,532,413 | \$5,000,000 | \$690,840 | \$8,964,881 | (\$1,478,400) | (\$1,478,333) | | (\$887,500) | \$6,088,128 |
| Year 5 (FY 12) | \$2,741,628 | \$4,985,855 | | \$690,842 | \$8,418,325 | \$0 | (\$738,187) | | \$0 | \$7,680,138 |
| TOTAL | | | | \$820,531 | \$8,347,811 | | | | | \$0 |

- NOTES:
- 1.) Assuming 10% increase in above standard costs each year based on the average increase over the last three years. Above standard = overtime utilities, guard services, maintenance contracts, etc.
 - 2.) Assuming MEAC's renovations would cost \$10M and that would be spent in FY 08 & FY 10.
 - 3.) Assuming that above standard costs are cut by 50% in the first year and during the second year. Rent cost and after two years of decommissioning and decommissioning lasted two years.
 - 4.) Assuming decommissioning costs are even for each lab over the two year period. 1/6 of total would be paid in year one and year four with 1/3 being paid each year in years two and three.
 - 5.) Assuming analysis are moved over three years - 1/4 first year, 1/2 second year, and 1/4 third year.

| Sample Numbers | Product | Code | Date Collected | Date Rec'd | Status |
|----------------|--|------------|----------------|------------|--------------------------|
| 366076 | Peter Pan crunchy 11/16/06 | | 2/14/2007 | 2/16/2007 | negative |
| 366079 | Peter Pan creamy 11/19/06 | | 2/14/2007 | 2/16/2007 | negative |
| 366080 | Great Value Crunchy 12/7/06 | | 2/14/2007 | 2/16/2007 | negative |
| 366077 | 25 swabs | | 2/15/2007 | 2/16/2007 | negative |
| 366078 | 25 swabs | | 2/15/2007 | 2/16/2007 | negative |
| 389113 | 24 swabs | | 2/15/2007 | 2/16/2007 | negative |
| 389114 | 25 swabs | | 2/15/2007 | 2/16/2007 | negative |
| 389115 | Peter Pan stabilizer, 3 subs | | 2/16/2007 | 2/17/2007 | negative |
| 409450 | Smart Choice stabilizer, 1 sub | | 2/16/2007 | 2/17/2007 | negative |
| 409451 | Peanut oil, 2 subs | | 2/16/2007 | 2/17/2007 | negative |
| 409452 | 10 swabs, jars | | 2/16/2007 | 2/17/2007 | negative |
| 409453 | 10 swabs, jar lids | | 2/16/2007 | 2/17/2007 | negative |
| 409454 | corn starch, 7 subs | | 2/16/2007 | 2/17/2007 | negative |
| 366081 | 23 swabs | | 2/16/2007 | 2/17/2007 | 5 (Salmonella Tennessee) |
| 366082 | Peter Pan Vit/Mineral bien, 12 subs | | 2/16/2007 | 2/17/2007 | negative |
| 366083 | Soy Protein, 6 subs | | 2/16/2007 | 2/17/2007 | negative |
| 366084 | Smart Choice Vit/Mineral bien, 10 subs | | 2/16/2007 | 2/17/2007 | negative |
| 366085 | Corn Syrup solids, 10 subs | | 2/16/2007 | 2/17/2007 | negative |
| 409606 | bulk salt, 8 subs | | 2/17/2007 | 2/18/2007 | negative |
| 409607 | 10 swabs | | 2/17/2007 | 2/18/2007 | negative |
| 409455 | bulk honey, 5 subs | | 2/17/2007 | 2/18/2007 | negative |
| 409456 | bulk molasses, 2 subs | | 2/17/2007 | 2/18/2007 | negative |
| 409457 | granulated sugar, 4 subs | | 2/17/2007 | 2/18/2007 | negative |
| 409458 | sucralose, 3 subs | | 2/17/2007 | 2/18/2007 | negative |
| 409459 | powdered sugar, 5 subs | | 2/17/2007 | 2/18/2007 | negative |
| 409786 | Peter Pan honey roasted creamy | | 2/21/2007 | 2/23/2007 | negative |
| 409787 | Peter Pan No sugar added creamy | | 2/21/2007 | 2/23/2007 | negative |
| 409788 | Great Value Reduced Fat | | 2/21/2007 | 2/23/2007 | negative |
| 409789 | Great Value Creamy | | 2/21/2007 | 2/23/2007 | negative |
| 409790 | Great Value Crunchy | | 2/21/2007 | 2/23/2007 | negative |
| 409791 | Great Value Creamy | | 2/21/2007 | 2/23/2007 | negative |
| 409792 | Great Value Reduced Fat | 2111702900 | 2/21/2007 | 2/23/2007 | Salmonella Tennessee |
| 409793 | Peter Pan honey roasted creamy | | 2/21/2007 | 2/23/2007 | negative |
| 409794 | Peter Pan Plus Creamy | | 2/21/2007 | 2/23/2007 | negative |
| 409795 | Peter Pan Creamy | | 2/21/2007 | 2/23/2007 | negative |
| 409796 | Peter Pan Crunchy | | 2/21/2007 | 2/23/2007 | negative |

EX41

| | | | |
|---|-------------------|-----------|--------------------------------|
| 409797 Peter Pan Crunchy | | 2/21/2007 | 2/23/2007 negative |
| 381058 consumer compliant (4 subs) | | 2/21/2007 | 2/23/2007 negative |
| 410591 consumer compliant (1 sub) | | 2/23/2007 | 2/24/2007 negative |
| 409798 raw peanuts | | 2/26/2007 | 2/27/2007 negative |
| 410961 Peter Pan Crunchy (FLA) | | 2/26/2007 | 3/1/2007 negative |
| 403882 Peter Pan Natural Honey Crunchy (SAN) | 2111633200 | 2/26/2007 | 3/1/2007 negative |
| 403883 Peter Pan Natural Honey Crunchy (SAN) | 2111630600 | 2/26/2007 | 3/1/2007 negative |
| 403885 Peter Pan Natural Honey Crunchy (SAN) | 2111627700 | 2/26/2007 | 3/1/2007 negative |
| 403886 Peter Pan Natural Honey Crunchy (SAN) | 2111618100 | 2/26/2007 | 3/1/2007 negative |
| 410572 Peter Pan Whipped Creamy (LOS) | 2111631500 | 2/23/2007 | 3/1/2007 negative |
| 410573 Peter Pan Whipped Creamy (LOS) | 2111626500 | 2/23/2007 | 3/1/2007 Salmoneilla Tennessee |
| 410574 Peter Pan Reduced (LOS) | 2111619900 | 2/23/2007 | 3/1/2007 negative |
| 410575 Peter Pan Reduced Fat(LOS) | 2111634700 | 2/23/2007 | 3/1/2007 negative |
| 410576 Peter Pan Reduced Fat (LOS) | 2111634600 | 2/23/2007 | 3/1/2007 negative |
| 410577 Peter Pan Reduced Fat Crunchy (LOS) | 2111622200 | 2/23/2007 | 3/1/2007 negative |
| 410578 Peter Pan Reduced Fat Crunchy (LOS) | 2111625100 | 2/23/2007 | 3/1/2007 Salmoneilla Tennessee |
| 410579 Peter Pan Reduced Fat (LOS) | 2111618800 | 2/23/2007 | 3/1/2007 negative |
| 410587 Peter Pan Crunchy (LOS) | 2111628300 | 2/23/2007 | 3/1/2007 negative |
| 404028 Creamy Smart Choice | 2111630600 | 2/26/2007 | 3/2/2007 negative |
| 404029 Creamy (SAN) | 2111633600 | 2/26/2007 | 3/2/2007 negative |
| 404030 Creamy Smart Choice (SAN) | 2111621900 | 2/26/2007 | 3/2/2007 negative |
| 404031 Creamy Smart Choice (SAN) | 2111633700 | 2/26/2007 | 3/2/2007 negative |
| 404032 Creamy(SAN) | 2111624300 | 2/26/2007 | 3/2/2007 negative |
| 404033 Creamy Smart Choice (SAN) | 2111633300 | 2/26/2007 | 3/2/2007 negative |
| 404034 Creamy, NSA (SAN) | 2111629200 | 2/26/2007 | 3/2/2007 negative |
| 404035 Creamy, Plus (SAN) | 2111619500 | 2/26/2007 | 3/2/2007 negative |
| 404036 Creamy (SAN) | 2111621600 | 2/26/2007 | 3/2/2007 Salmoneilla Tennessee |
| 404037 Creamy (SAN) | 2111633500 | 2/26/2007 | 3/2/2007 negative |
| 343927 Crunchy (SAN) | 2111622000 | 2/26/2007 | 3/2/2007 negative |
| 343928 Crunchy (SAN) | 2111627100 | 2/26/2007 | 3/2/2007 negative |
| 343929 Crunchy (SAN) | 2111634000 | 2/26/2007 | 3/2/2007 negative |
| 403884 Creamy (SAN) | 2111634700 | 2/26/2007 | 3/2/2007 negative |
| 403887 Crunchy, Honey (SAN) | 2111633800 | 2/26/2007 | 3/2/2007 negative |
| 403888 Creamy (SAN) | 2111634600 | 2/26/2007 | 3/2/2007 negative |
| 403889 Creamy (SAN) | 2111628900 | 2/26/2007 | 3/2/2007 negative |
| 401884 Crunchy (SAN) | 2111629000 | 2/26/2007 | 3/2/2007 negative |
| 401885 Crunchy (SAN) | 2111630300 | 2/26/2007 | 3/2/2007 negative |

| | | | |
|-----------------------------------|------------|-----------|-------------------------------|
| 401886 Crunchy (SAN) | 2111627600 | 2/26/2007 | 3/2/2007 negative |
| 401887 crunchy (SAN) | 2111629000 | 2/26/2007 | 3/2/2007 negative |
| 401888 Crunchy Smart Choice (SAN) | 2111629100 | 2/26/2007 | 3/2/2007 negative |
| 401889 Crunchy (SAN) | 2111634900 | 2/26/2007 | 3/2/2007 negative |
| 362645 Creamy,Plus (SAN) | 2111633400 | 2/26/2007 | 3/2/2007 negative |
| 410958 Crunchy (FLA) | 2111625100 | 2/26/2007 | 3/2/2007 Salmonella Tennessee |
| 410960 Crunchy (FLA) | 2111628900 | 2/26/2007 | 3/2/2007 negative |
| 410962 Crunchy (FLA) | 2111626200 | 2/26/2007 | 3/2/2007 negative |
| 410963 Crunchy (FLA) | 2111633600 | 2/26/2007 | 3/2/2007 negative |
| 410964 Crunchy (FLA) | 2111626300 | 2/26/2007 | 3/2/2007 negative |
| 410965 Creamy (FLA) | 2111633700 | 2/26/2007 | 3/2/2007 negative |
| 410966 Creamy (FLA) | 2111633600 | 2/26/2007 | 3/2/2007 negative |
| 410967 Creamy (FLA) | 2111624300 | 2/26/2007 | 3/2/2007 Salmonella Tennessee |
| 403190 Creamy (DAL) | 2111628300 | 2/26/2007 | 3/3/2007 negative |
| 403191 Creamy (DAL) | 2111627800 | 2/26/2007 | 3/3/2007 negative |
| 403192 Creamy (DAL) | 2111634900 | 2/26/2007 | 3/3/2007 negative |
| 403193 Crunchy (DAL) | 2111633600 | 2/26/2007 | 3/3/2007 negative |
| 403194 Creamy, Reduce (DAL) | 2111703700 | 2/26/2007 | 3/3/2007 negative |
| 410580 Crunchy, Reduce (LOS) | 2111618700 | 2/26/2007 | 3/3/2007 negative |
| 410581 Creamy, Honey (LOS) | 2111618100 | 2/26/2007 | 3/3/2007 negative |
| 410582 Creamy, Honey (LOS) | 2111618000 | 2/23/2007 | 3/5/2007 negative |
| 410583 Creamy, Honey (LOS) | 2111627700 | 2/23/2007 | 3/5/2007 negative |
| 410584 Creamy (LOS) | 2111631500 | 2/23/2007 | 3/5/2007 negative |
| 410585 Creamy (LOS) | 2111620300 | 2/23/2007 | 3/6/2007 negative |
| 410586 Creamy (LOS) | 2111629000 | 2/23/2007 | 3/5/2007 negative |
| 410588 Crunchy (LOS) | 2111634900 | 2/23/2007 | 3/5/2007 negative |
| 403195 Crunchy (DAL) | 2111631900 | 2/26/2007 | 3/6/2007 negative |
| 403196 Creamy (DAL) | 2111631900 | 2/26/2007 | 3/6/2007 Salmonella Tennessee |
| 403197 Creamy (DAL) | 2111628600 | 2/26/2007 | 3/6/2007 negative |
| 403198 Creamy (DAL) | 2111633600 | 2/26/2007 | 3/6/2007 negative |
| 403199 Creamy (DAL) | 2111630300 | 2/26/2007 | 3/7/2007 negative |
| 403200 Crunchy (DAL) | 2111630400 | 2/26/2007 | 3/7/2007 negative |
| 403201 Crunchy (DAL) | 2111630000 | 2/26/2007 | 3/7/2007 negative |
| 403202 Creamy (DAL) | 2111633100 | 2/26/2007 | 3/6/2007 negative |
| 403203 Crunchy (DAL) | 2111632100 | 2/26/2007 | 3/7/2007 negative |
| 403204 Crunchy (DAL) | 2111633300 | 2/26/2007 | 3/6/2007 negative |
| 403205 Creamy (DAL) | 2111630800 | 2/26/2007 | 3/7/2007 negative |

| | | | |
|----------------------------|-------------------|-----------|-------------------------------|
| 411254 Creamy, Honey (NOL) | 2111630300 | 2/27/2007 | 3/6/2007 negative |
| 411255 Crunchy(NOL) | 2111630400 | 2/27/2007 | 3/6/2007 negative |
| 411256 Crunchy(NOL) | 2111630000 | 2/27/2007 | 3/6/2007 negative |
| 411257 Creamy, Honey (NOL) | 2111634700 | 2/27/2007 | 3/7/2007 negative |
| 411258 Creamy, Honey (NOL) | 2111627700 | 2/27/2007 | 3/6/2007 negative |
| 411259 Creamy, Honey (NOL) | 2111625700 | 2/27/2007 | 3/6/2007 Salmonella Tennessee |
| 411260 Creamy, Honey (NOL) | 2111625800 | 2/27/2007 | 3/6/2007 Salmonella Tennessee |
| 411261 Creamy, Honey (NOL) | 2111624300 | 2/27/2007 | 3/6/2007 negative |
| 411262 Creamy, Honey (NOL) | 2111627200 | 2/27/2007 | 3/6/2007 negative |
| 411263 Crunchy(NOL) | 2111631800 | 2/27/2007 | 3/6/2007 negative |
| 411264 Crunchy(NOL) | 2111633600 | 2/27/2007 | 3/6/2007 negative |
| 411265 Crunchy(NOL) | 2111629000 | 2/27/2007 | 3/6/2007 negative |
| 411266 Creamy, Honey (NOL) | 2111631900 | 2/27/2007 | 3/6/2007 negative |
| 411267 Crunchy(NOL) | 2111634900 | 2/27/2007 | 3/6/2007 negative |
| 411268 Crunchy(NOL) | 2111620600 | 3/1/2007 | 3/7/2007 negative |
| 325728 Crunchy (PHI) | 2111627800 | 3/1/2007 | 3/7/2007 negative |
| 325729 Creamy (PHI) | 2111625600 | 3/1/2007 | 3/7/2007 negative |
| 325730 Creamy (PHI) | 2111625700 | 3/1/2007 | 3/7/2007 negative |
| 325731 Creamy (PHI) | 2111625100 | 3/1/2007 | 3/7/2007 Salmonella Tennessee |
| 325732 Creamy (PHI) | 2111622000 | 3/1/2007 | 3/8/2007 negative |
| 411501 Crunchy (PHI) | 2111628200 | 3/1/2007 | 3/7/2007 negative |
| 411502 Creamy (PHI) | 2111624900 | 3/1/2007 | 3/7/2007 negative |
| 411503 Creamy (PHI) | 2111621900 | 3/1/2007 | 3/7/2007 Salmonella Tennessee |
| 411504 Creamy (PHI) | 2116289000 | 3/1/2007 | 3/7/2007 negative |
| 411505 Crunchy (PHI) | 2111631800 | 3/1/2007 | 3/7/2007 negative |
| 411506 Crunchy (PHI) | 2111633300 | 3/1/2007 | 3/7/2007 negative |
| 411507 Crunchy (PHI) | 2111632100 | 3/1/2007 | 3/7/2007 negative |
| 411508 Creamy (PHI) | 2111634900 | 3/1/2007 | 3/7/2007 negative |
| 411509 Crunchy (PHI) | 2111633100 | 3/1/2007 | 3/7/2007 negative |
| 411510 Creamy (PHI) | 2111633100 | 3/1/2007 | 3/7/2007 negative |
| 411511 Crunchy (PHI) | 2111620100 | 3/1/2007 | 3/7/2007 negative |
| 411512 Creamy (PHI) | 2111631800 | 3/1/2007 | 3/7/2007 negative |
| 411513 Creamy (PHI) | 2111634700 | 3/1/2007 | 3/7/2007 negative |
| 411514 Crunchy (PHI) | 2111631900 | 3/1/2007 | 3/7/2007 negative |
| 411515 Crunchy (PHI) | 2111632000 | 3/1/2007 | 3/7/2007 negative |
| 411516 Creamy (PHI) | 2111631900 | 3/1/2007 | 3/7/2007 negative |
| 411517 Crunchy (PHI) | 2111633300 | 3/1/2007 | 3/7/2007 negative |

392664 Consumer Complaint (PHI)
363161 Consumer Complaint(DET)

2111609500

3/7/2007
3/15/2007

3/9/2007 negative
3/16/2007 in-progress



May 11, 2007

VIA HAND DELIVERY

The Honorable Bart Stupak
 Chairman
 Subcommittee on Oversight and Investigations
 House Committee on Energy and Commerce
 2125 Rayburn House Office Building
 Washington, DC 20515

The Honorable Ed Whitfield
 Ranking Member
 Subcommittee on Oversight and Investigations
 House Committee on Energy and Commerce
 2125 Rayburn House Office Building
 Washington, DC 20515

Re: April 24, 2007 Hearing

Dear Chairman Stupak and Ranking Member Whitfield:

ConAgra Foods, Inc. ("ConAgra") appreciated the opportunity to testify before the Subcommittee on Oversight and Investigations ("Subcommittee") on April 24, 2007 regarding the company's recent recall of its peanut butter products. During the hearing and in subsequent discussions with Subcommittee staff, we were asked to provide the following additional information for the hearing record:

1. Copies of any inspection reports for ConAgra's Sylvester, GA facility for 2000 to present.
2. Details on any prior situations where ConAgra did not provide the Food and Drug Administration (FDA) with records it requested, whether verbally or in writing.
3. Details for the past five years of any positive pathogen findings for finished products from any routine testing conducted by ConAgra for its current food businesses at its manufacturing facilities.

ConAgra is still reviewing its internal records in order to fully respond to the Subcommittee's request with respect to positive pathogen findings; however, we anticipate being able to provide this information by the end of the thirty (30) day period in which the hearing record is open (i.e., by May 24, 2007). In the interim, what follows is our response to the first two requests outlined above.

In response to the first request, in Attachment A to this letter, we provide copies of the reports associated with inspections of our Sylvester, GA facility by FDA and the Georgia Department of Agriculture for 2000 through 2003. We previously provided the Subcommittee with copies of such inspection reports for 2004 forward.

Providing a response to the second request outlined above is particularly challenging given the size of ConAgra and its numerous facilities (almost 100 in the U.S.) that are subject to regulatory inspection. However, we are able to provide the Subcommittee with the following information:

EY 4L

May 11, 2007
Page 2

- Upon checking with the appropriate company personnel, to the best of our knowledge, we are not aware of any situation in the past in which ConAgra refused to provide FDA with certain records in response to a written request from the Agency.
- With regard to verbal requests for records from FDA, there likely have been instances in the past where FDA made a verbal request for records in connection with a plant inspection, was asked by ConAgra's plant personnel (consistent with company policy at the time) to make the request in writing, but did not follow up with a written request -- so that the records were not provided. To the extent any such requests were not in writing, it is not possible to track and keep a record of them. Indeed, this along with the ability to provide any responsive records in a manner that protects them from inappropriate disclosure under the Freedom of Information Act are the primary reasons why ConAgra has historically asked that FDA put requests for the company's information in writing. In that regard, consistent with our historical policy, we would not have refused to provide FDA with the information verbally requested; rather, we would have simply responded by asking that the request be made in writing.
- We believe our historical policy is consistent with long-standing practice in the food industry. Even where there is no statutory authority granting FDA access to records, it has been industry's experience that FDA inspectors will make verbal requests for them.¹ In response, it has been a long-standing industry practice to ask that these types of requests be made in writing.²
- We also believe our historical policy is consistent with the relevant law in this area. Specifically, Section 703 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 373) provides that it is unlawful to deny FDA access to records concerning interstate shipment of FDA-regulated articles *when such request is accompanied by a statement in writing*. The regulation implementing Section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) also makes clear that requests for records pursuant to the Act will be made by *written notice*.³ We further note that FDA regulations provide for agency access to company records for low-acid canned foods and acidified foods, yet the regulations granting this authority make clear that all such requests are to be made *in writing* on a designated FDA form.⁴ ConAgra believes, therefore, that it should not be considered unreasonable for companies to ask for written requests from FDA for company records, particularly in those situations where the agency has no explicit statutory or regulatory authority granting access to such records.

¹ See e.g., James T. O'Reilly, FOOD AND DRUG ADMINISTRATION, 2ed. (2006) 20-56; James W. Swanson, *How To Handle and FDA Inspection--The Investigator's View*, 33 FOOD DRUG COSM. L.J. 109 (1978); Laurie Burg, *A Trade Association View of the FDA Food Inspection Programs*, 35 FOOD DRUG COSM. L.J. 170 (1980). A copy of these articles is included in Attachment B to this letter.

² See e.g., Arthur W. Hansen, *An FDA Inspection: Preparing for the Inevitable*, 36 FOOD DRUG COSM. L.J. 641 (1981); see also, Stephen H. McNamara, *The FDA Inspection: What You Need to Know to Protect Your Company*, 36 FOOD DRUG COSM. L.J. 245 (1981). A copy of both articles is included in Attachment B to this letter.

³ 21 C.F.R. § 1.361; this written notice is further evidenced in a records access guidance document found at <http://www.cfsan.fda.gov/~dms/secgui13.html>. The designated FDA form (Form FDA 482c) for providing this written notice also indicates that the records being requested are to be described on the form.

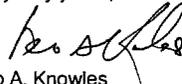
⁴ 21 C.F.R. §§ 108.25(g) and 108.35(h).

May 11, 2007
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- Notwithstanding industry practice, ConAgra provided the Subcommittee on April 23, 2007 with a letter confirming that the company's current policy for providing FDA with access to company information would be formalized to reflect the approach the company followed in connection with its recent peanut butter recall. Specifically, we will suspend any written request requirement in a recall-related situation, provide on-site review of records for routine inspections, and provide copies of routine, non-sensitive information (i.e., non-confidential and non-proprietary information) upon a verbal request from FDA. Understandably, we will continue to ask for a written request for copies of any sensitive proprietary company information.

Should you have any questions regarding this additional information, please let us know.

Very truly yours,



Leo A. Knowles
Senior Vice President

Attachments A and B

HENRY A. WAXMAN, CALIFORNIA
 EDWARD J. MARKEY, MASSACHUSETTS
 RICK BOEHLER, VIRGINIA
 EDOLPHUS TOWNS, NEW YORK
 FRANK PALONE, JR., NEW JERSEY
 BART GORDON, TENNESSEE
 BOBBY L. RUSH, ILLINOIS
 ANNA G. ESHOO, CALIFORNIA
 BART STUPAK, MICHIGAN
 SLOTT L. ENGEL, NEW YORK
 ALBERT R. MYNN, MARYLAND
 GENE GREEN, TEXAS
 DIANA DEGETTE, COLORADO
 YEE GARRIBAS
 LOIS CAPPS, CALIFORNIA
 MIKE DOYLE, PENNSYLVANIA
 JANE HARRMAN, CALIFORNIA
 TOM ALLEN, MAINE
 JAN SCHATZKINDY, ILLINOIS
 HILDA L. SOLIS, CALIFORNIA
 CHARLES A. GONZALEZ, TEXAS
 JAY INSLEE, WASHINGTON
 TAMMY BALDWIN, WISCONSIN
 MIKE ROSE, ARKANSAS
 DARLENE HODLEY, OREGON
 ANTHONY D. WEINER, NEW YORK
 JIM MATHESON, UTAH
 G.K. BUTTERFIELD, NORTH CAROLINA
 CHARLIE MELANCON, LOUISIANA
 JOHN BARRROW, GEORGIA
 BARON P. HILL, INDIANA
 DENNIS R. FITZGIBBONS, CHIEF OF STAFF
 GREGG A. ROTHSCHILD, CHIEF COUNSEL

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
 Washington, DC 20515-6115

JOHN D. DINGELL, MICHIGAN
 CHAIRMAN

April 12, 2007

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 TIM MURPHY, PENNSYLVANIA
 MICHAEL C. BURGESS, TEXAS
 MARSHA BLACKBURN, TENNESSEE

The Honorable Andrew von Eschenbach, M.D.
 Commissioner
 Food and Drug Administration
 5600 Fishers Lane
 Rockville, MD 20857

VIA FAX

Dear Dr. von Eschenbach:

Pursuant to Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations have opened an inquiry into compensation practices at the Food and Drug Administration (FDA).

In particular, we are interested in FDA's use of Title 42 consultant compensation and other mechanisms to boost compensation above base salary including retention bonuses, locality bonuses, performance, or any other salary enhancements or awards. Please provide the following information within two weeks of receipt of this letter:

1. A list of all current FDA employees and their positions enjoying higher total compensation (includes salary, bonuses, cash awards or other cash enhancements) than the highest Senior Executive Service (SES) salary grade or the salary of an Admiral in the Public Health Service (currently \$168,120 per annum) if in a senior management position, or the highest General Schedule (GS) salary grade (currently \$154,600) if paid under the GS scales. For each such individual for each year from calendar year 2002 forward, please provide the annual compensation and the mechanism of compensation (Title 42, Commissioned Corps, SES, physician comparability allowance, etc.). For all such employees compensated under Title 42, please also list the date of their appointment.

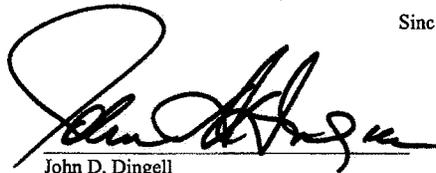
EY 43

The Honorable Andrew von Eschenbach, M.D.
Page 2

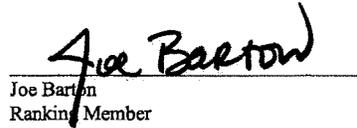
2. A list of all FDA employees, regardless of total compensation, and their positions who have received retention, locality, performance bonuses or awards, or other extraordinary payments in excess of \$5,000 in any given year and the amounts of such bonuses, awards, or other extraordinary payments since January 1, 2002.

Please also provide the records justifying the bonuses, awards, or other extraordinary payments. For the purpose of responding to this request for information and documents, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. If you have any questions, please contact David Nelson of the Majority Committee staff at (202) 226-2424 or Alan Slobodin of the Minority Committee staff at (202) 225-3641.

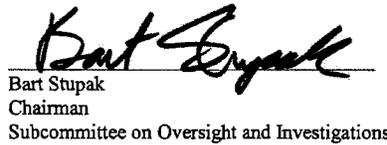
Sincerely,



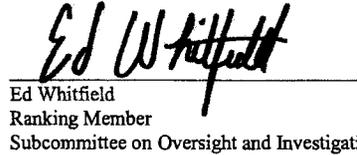
John D. Dingell
Chairman



Joe Barton
Ranking Member



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations



Ed Whitfield
Ranking Member
Subcommittee on Oversight and Investigations

Attachment

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUN 11 2007

Dear Mr. Chairman:

Thank you for the letter of April 12, 2007, co-signed by Ranking Member Joe L. Barton, Chairman Bart Stupak, Subcommittee on Oversight and Investigations, and Ranking Member Ed Whitfield. Your letter requests data on compensation practices at the Food and Drug Administration (FDA or the Agency).

We have restated your questions in bold followed by our response.

1. **A list of all current FDA employees and their positions enjoying higher total compensation (includes salary, bonuses, cash awards or other cash enhancements) than the highest Senior Executive Service (SES) salary grade or the salary of an Admiral in the Public Health Service (currently \$168,120 per annum) if in a senior management position, or the highest General Schedule (GS) salary grade (currently \$154,600) if paid under the GS scales. For each individual for each year from calendar year 2002 forward, please provide the annual compensation and the mechanism of compensation (Title 42, Commissioned Corps, SES, physician comparability allowance, etc.). For all such employees compensated under Title 42, please also list the date of their appointment.**

Enclosed, at Tabs A, B & C, is the Agency's response to the first item of your request. Please note that at Enclosure A we have included a list that explains the compensation thresholds we used. These thresholds coincide with the pay plans issued by the Office of Personnel Management (OPM) for all federal workers. This enclosure also contains a key to other abbreviations used in the tables. In the table under Enclosure B, there are five cases where the date of appointment for Title 42 employees is missing for AD (administratively determined) employees. This information will be supplied as soon as it becomes available. The tables in Enclosure C list the employees whose compensation exceeds specific total compensation thresholds from calendar years 2002 through 2006.

EX 44

Page 2 – The Honorable John D. Dingell

2. A list of all FDA employees, regardless of total compensation, and their positions who have received retention, locality, performance bonuses or awards, or other extraordinary payments in excess of \$5,000 in any given year and the amounts of such bonuses, awards, or other extraordinary payments since January 1, 2002. Please also provide the records justifying the bonuses, awards, or other extraordinary payments.

This information is still being compiled. It will be forwarded as soon as it is available.

Thank you again for your interest in FDA matters. A similar copy of this response is being sent to the three co-signers of your letter, however, the enclosures are being sent only to you and to the Ranking Member of the Committee.

Sincerely,

A handwritten signature in black ink, appearing to read 'Stephen R. Mason', with a long horizontal flourish extending to the right.

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures

ENCLOSURE A

**Explanation of Compensation Data Collected for
April 12, 2007 Congressional Request**

The information contained in the enclosures responds to Item #1 of the letter from Chairman John D. Dingell and three other members of the House Committee on Energy and Commerce dated April 12, 2007. Item #1 from this letter is stated in bold below followed by an explanation of FDA's responses:

"In particular, we are interested in FDA's use of Title 42 consultant compensation and other mechanisms to boost compensation above base salary including retention bonuses, locality bonuses, performance, or any other salary enhancements or awards. Please provide the following information within two weeks of receipt of this letter:

- 1. A list of all current FDA employees and their positions enjoying higher total compensation (includes salary, bonuses, cash awards or other cash enhancements) than the highest Senior Executive Service (SES) salary grade or the salary of an Admiral in the Public Health Service (currently \$168,120 per annum) if in a senior management position, or the highest General Schedule (GS) salary grade (currently \$154,600) if paid under the GS scales. For each such individual for each year from calendar year 2002 forward, please provide the annual compensation and the mechanism of compensation (Title 42, Commissioned Corps, SES, physician comparability allowance, etc.) For all such employees compensated under title 42, please also list the date of their appointment."**

Response:

Current employees whose salaries exceed certain thresholds are grouped in the enclosures by pay plans. Please note that in some instances an employee will be listed under more than one pay plan when they served under different pay plans during the calendar year. This will also explain why some employees are listed even though their salary under one pay plan does not exceed the threshold - their combined salary under all pay plans exceeds the stated threshold. In addition, please note that the chart with AD employees (those in Title 42) provides the date the employee entered Title 42.

We used the following thresholds based on Office of Personnel Management (OPM) salary tables from 2006:

GS (General Schedule) employees exceeding \$143,000 because that was the maximum base and locality pay for the GS in 2006. (Total compensation cap for GS employees was \$183,500, Executive Level I).

SL (Senior Level) employees exceeding \$143,000 because that equates to Executive Level IV in 2006. SL employee base salary cannot exceed Executive Level IV and total compensation cannot exceed Executive Level III (\$152,000 in 2006).

SES (Senior Executive Service) employees exceeding \$165,200 because that equates to Executive Level II – the maximum base salary an SES employee may receive under a certified SES Performance Management System. Total SES compensation was limited to \$212,100 for agencies with a certified Performance Management System. HHS (including FDA) was a certified agency.

RS (senior biomedical research service) employees exceeding \$143,000 because RS employees are subject to the same total compensation cap as GS employees - \$183,500 in 2006. Therefore to simplify data collection we used the same base salary threshold. Please note that RS employees only receive base pay (no locality) and total pay could have been as high as \$183,500 in 2006.

AD (administratively determined) employees exceeding \$143,000. Title 42 is often used as an appointment mechanism for employees whose responsibilities and pay are higher than that of a GS-15. Therefore we used the \$143,000 threshold because it equates to the GS threshold used above.

The AD employees whose entrance into Title 42 date is left blank is because we are still awaiting that information. The human resources (HR) database only goes back to 2002 and these people may have been hired after that. We will supply this information when we have received it.

Special Notes:

GP (physicians under GS pay plan) employees were formerly covered under the GS pay plan. They are medical officers receiving physician or dentist special pay under Title 38. FDA medical officers were converted from GS to GP in October 2006; therefore most of their information will be reported under the GS pay plan.

Locality pay is not discretionary. It is part of the General Schedule compensation tables issued by OPM.

Other Abbreviations for Types of Pay Plans Used on the Chart

EG – Consultant

EI – Consultant Member of an Advisory Committee

ES – SES or Senior Executive Service

GM – General Schedule Manager – no longer used for new hires. We still have a few employees in this pay plan. GS thresholds are used for this category.

Abbreviations Used in Column Headings That Identify Types of Compensation

PCA – Physician Comperability Allowance – for medical officers who are not eligible to go into Title 38.

MKT PAY – Market Pay for medical officers in Title 38. Intended to equate what their expertise could command in the marketplace.

PSP – Physician Special Pay – for medical officers in Title 38. Used up until October 2006 when FDA converted to Market Pay.

RETENT, RELOC, RECRUIT – Incentives expressed as a percentage of salary intended to entice a new employee to join the agency (recruitment), mover from another geographical location (relocation), or retain valuable expertise so the employee won't leave the Agency (retention).

CASH AWARD – Includes cash awards and SES bonuses.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUN 21 2007

Dear Mr. Chairman:

Thank you for the letter of April 12, 2007, co-signed by Ranking Member, Joe L. Barton and Oversight and Investigations Subcommittee Chairman Bart Stupak and Ranking Member, Ed Whitfield. Your letter requests data on compensation practices at the Food and Drug Administration (FDA or the Agency). We provided a partial response to your letter on June 11, 2007. The following is in further response to your request.

We have restated your questions in bold followed by our response.

1. **A list of all current FDA employees and their positions enjoying higher total compensation (includes salary, bonuses, cash awards or other cash enhancements) than the highest Senior Executive Service (SES) salary grade or the salary of an Admiral in the Public Health Service (currently \$168,120 per annum) if in a senior management position, or the highest General Schedule (GS) salary grade (currently \$154,600) if paid under the GS scales. For each individual for each year from calendar year 2002 forward, please provide the annual compensation and the mechanism of compensation (Title 42, Commissioned Corps, SES, physician comparability allowance, etc.). For all such employees compensated under Title 42, please also list the date of their appointment.**

On June 11, 2007, we produced a list of FDA employees whose salary exceeded the threshold for their particular salary plan. Salary data for United States Public Health Service Commissioned Corps (Commissioned Corps) officers was not included in our first response. Information on Commissioned Corps offices is provided at Tabs A and B. Enclosed at Tab A is a list of current Commissioned Corps officers, assigned to FDA in senior management positions. Salaries for Commissioned Corps officers follows the basic pay tables established by the Department of Defense and are not determined by the FDA. Tab B provides the historical salary data (2002 forward) for those officers listed in Tab A. Enclosed at Tab C is the current pay table for Commissioned Corps officers.

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Page 2 – The Honorable John D. Dingell

Additionally, salary data for Title 38 staff was not included in that response. We will provide that information to the Committee when it becomes available.

2. A list of all FDA employees, regardless of total compensation, and their positions who have received retention, locality, performance bonuses or awards, or other extraordinary payments in excess of \$5,000 in any given year and the amounts of such bonuses, awards, or other extraordinary payments since January 1, 2002. Please also provide the records justifying the bonuses, awards, or other extraordinary payments.

Enclosed at Tab D are spreadsheets that contain the requested information separated by the Office of the Commissioner, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), Center for Devices and Radiological Health (CDRH), National Center for Toxicological Research (NCTR), and the Office of Regulatory Affairs (ORA).

This information was obtained from the Program Support Center (PSC) payroll database of the Department of Health and Human Services (HHS) and therefore shows all extraordinary payments (as defined in the question above) made between January 1, 2002, and April 14, 2007, (the ending of the relevant pay period) for the individuals listed. There are separate columns for cash awards (including SES performance bonuses), incentives (retention, recruitment, and relocation), PCA (physician comparability allowances), Market Pay, and PSP (Physician Special Pay). Also, student loan repayments are included under the recruitment incentive column.

We provided the supporting payment justification documentation that was able to be located. Please note that in some cases, one document will be the basis for more than one entry on the chart. In addition, the dollar amounts on the chart may not match exactly the amount approved on the documentation. For example, a retention incentive that was approved in August 2004 for \$15,000 (for the next 12 month period) may not be listed as a line item for the employee in the year 2004 on the spreadsheet. The reason for this is that 4 months worth will be listed in 2004 earnings, and the balance will be listed in the first 8 months of 2005.

Many of the employees receive compensation under a categorical retention, in which case, a general business case was made for a category of employees and a blanket justification was developed for those employees that fell within those categories. For example, Medical Officers in CDER all receive a categorical retention. Lists of employees falling under any of these categorical retentions have been included for your reference.

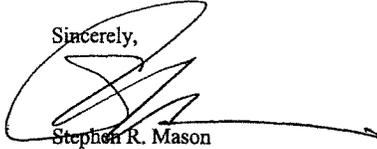
On January 25, 2004, HHS consolidated its human resources functions. As a result, FDA's Office of Personnel and its functions officially were transferred to the HHS Rockville Human Resources Center (HR Center) where FDA employees' Official Personnel Folders (OPF) are now maintained. The official custodian of many of the records is now the HR Center. We are continuing to try to locate any missing copies of records justifying extraordinary payments through the employees' program areas and the employees' Official Personnel Folder (OPF) located in the HHS Rockville HR Center. We will provide additional justification documentation as it becomes available.

Page 3 -- The Honorable John D. Dingell

The time frame in which we will be able to locate and deliver any missing documentation will be dependent on several factors including the sources and workload of the Rockville HR Center locations and the need to possibly request records of former employees from the National Personnel Records Center in St. Louis, Missouri.

Thank you again for your interest in FDA matters. A similar copy of this response is being sent to the three co-signers of your letter.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen R. Mason", with a long horizontal flourish extending to the right.

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUN 27 2007

Dear Mr. Chairman:

Thank you for the letter of April 12, 2007, co-signed by Ranking Member, Joe L. Barton and Oversight and Investigations Subcommittee Chairman Bart Stupak and Ranking Member, Ed Whitfield. Your letter requests data on compensation practices at the Food and Drug Administration (FDA).

In our June 21 response, we provided the Committee with justification documentation for FDA staff that received a cash award in excess of \$5,000. The production of documents was divided by Centers and Offices within FDA, and a chart listing the staff and their respective cash awards was attached. At the time of our response, we had not located all records related to this request. We are resubmitting an updated chart that reflects which justifications were, or were not available at the time of submission. Accordingly, we will update the chart as we locate, receive, and produce additional documents to the Committee.

Thank you again for your interest in FDA matters. A similar copy of this response is being sent to the three co-signers of your letter without enclosures.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures

Ex 46

Follow-up Responses to Congressional Questions on Title 42

1) Is it still HHS policy that use of Title 42 section 209(f) authority is limited to scientists and science administrators? If not, when did the policy change and why? If yes, what positions does FDA consider to be scientific administrative positions?

Answer: Yes, it is HHS policy that Title 42 209 (f) authority is used for employees who will be performing work that requires scientific expertise – a minimum of a bachelor's degree in a scientific discipline directly related to the position, as well as, related professional experience commensurate with the position being filled. Scientific positions would include those who are performing scientific investigations, developing scientific policy and guidances, research, or analysis, or those managers who are directing and/or supervising the conduct of the scientific investigations, scientific policy and guidances, research, or analysis and who are recognized as experts in their field.

2) When did HHS specifically authorize the use of Title 42 pay for FDA employees?

Answer: FDA does not have an exact date, but Title 42 encompasses 209(f) and 209(g) and both of these authorities have been in existence and authorized for use by HHS for several decades. Over the years, HHS has expanded the use of and the definitions of these authorities.

3) What base salary level and/or total compensation level requires HHS approval in addition to FDA approval? What policy is that based on?

Answer: The current policies governing compensation for Title 42 209 (f) employees are contained in HHS Personnel Instruction 42-1, Appointment of 42 U.S.C. Section 209(f) Scientists, dated August 2004 and the memorandum dated March 15, 2007 from the Department of Health and Human Services, Assistant Secretary for Administration Management (ASAM). HHS Operating Divisions (OPDIVs), including FDA, are granted authority to set base salary and grant pay increases for Title 42 employees up to \$350,000 in a calendar year and total compensation not to exceed \$375,000 in a calendar year.

Beginning March 15, 2007, the following limitations applied:

1. Recommendations for base salary or pay increases above the amount specified in the aforementioned memorandum, must be submitted to the ASAM, for approval by the Secretary. Such requests must be fully justified.

2. For officials who directly report to the OPDIV Head (Commissioner), all appointments under Title 42, Section 209(f) must be submitted to the ASAM, for approval by the Secretary.
3. Approval of annual salaries in excess of \$250,000 and total compensation in excess of \$275,000 must be approved by the OPDIV Head (Commissioner). This authority cannot be redelegated.

4) What are the current limitations on FDA's authority to approve salaries and/or total compensation?

Answer: FDA is in compliance with the limitations on appointments and pay setting described in the response to Question 3. In addition, all recommended appointments are reviewed by a peer review committee and a final recommendation made to the Commissioner. The criteria and guidelines for annual performance based pay adjustments for Title 42 209 (f) employees are announced by the Commissioner each year. Within those guidelines, the Commissioner grants specific authorities to the Deputy Commissioners, Associate Commissioners and Center Directors to approve pay adjustments. For example, this past year, those officials could approve individual pay increases up to an organization-wide average of 4%; however any increase above 6% had to have the Commissioner's approval.

5) Based on ASAM's response, HHS or FDA would have records of the peer review and approval for each of the Title 42 appointments and conversions. Is that correct?

Answer: Depending on the timeframe, FDA would have records of peer reviews and/or approvals for each of the Title 42 appointments and conversions. Starting in August 2005, Peer Review meetings, which include the Deputy Commissioner/Chief Medical Officer and the Associate Commissioner for Science, are conducted for approval of the Title 42 appointments and conversions. Prior to the August 2005 date, the Director, Office of Human Resources Management Services reviewed the Title 42 cases and made recommendations to the Commissioner regarding approval of those appointments and conversions.

Casey Hemard
Counselor on Oversight
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Legislation
Casey.Hemard@hhs.gov
(202) 690-7627

Terrell L. Vermillion
 Director, Office of Criminal Investigations

| Year | Cash Awards | Retention Bonuses | Total Bonuses | Total Compensation | ORA Total Bonuses | % of ORA Bonuses |
|--------|-------------|-------------------|---------------|--------------------|-------------------|------------------|
| 2003 | \$9,086 | \$0 | \$9,086 | \$150,778 | \$228,804 | 4.0% |
| 2004* | \$13,380 | \$13,440 | \$26,820 | \$171,703 | \$294,232 | 9.1% |
| 2005 | \$14,560 | \$24,036 | \$38,596 | \$198,868 | \$425,112 | 9.1% |
| 2006 | \$10,875 | \$23,003 | \$33,878 | \$198,389 | \$401,368 | 8.4% |
| 2007** | \$11,310 | \$9,229 | \$20,539 | -- | \$191,878 | 10.7% |

Data for this table provided to the Committee by HHS.

* Mr. Vermillion's retention bonus justification forms were provided to the Committee only for 2004. Bonus amounts and total compensation amounts differ between justification forms and HHS pay data sheets due to the time period covered by justification forms (justifications allow payment across two calendar years). Data from HHS pay sheets were used for this table.

** partial year

***Bonus justification based on qualifications for Mr. Vermillion. No comparable salary in private sector provided in justification.

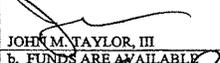
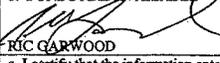
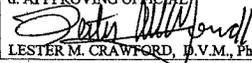
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Food and Drug Administration
DEPARTMENT OF HEALTH AND HUMAN SERVICES

REQUEST FOR RECRUITMENT BONUSES, RELOCATION BONUSES,
RETENTION ALLOWANCES, and RETENTION ALLOWANCE RENEWALS

| EMPLOYEE INFORMATION | | |
|---|-------------------------------|--|
| NAME (Print or Type) | SERIES/GRADE/STEP | SOCIAL SECURITY NUMBER |
| VERMILLION, TERRELL L. | ES-1811-00 | [REDACTED] |
| TITLE | ORGANIZATION | ANNUAL BASE SALARY |
| Director, Office of Criminal Investigations | HHS/ FDA/ ORA/ OCI | \$142,500 p.a. |
| OFFICIAL DUTY STATION | TYPE OF APPOINTMENT | OFFICIAL TOUR OF DUTY |
| Rockville, Maryland | X Permanent Term () Years | X Full Time Part Time (If Part Time, Regularly Scheduled Hours per Pay Period:) |

| AMOUNT OF BONUS/ALLOWANCE TO BE PAID | |
|--|---|
| BONUS/ALLOWANCE | COMPENSATION |
| Recruitment: % = \$ _____ | Base: \$ 142,500 |
| Relocation: % = \$ _____ | Locality: \$ _____ |
| Retention: 15 % = \$ 21,375 | Other Continuing Pay: \$ _____ |
| Renewal: % = \$ _____ | Bonus/Allowance: \$ 21,375 |
| <input type="checkbox"/> Renewal: The conditions giving rise to the original determination to pay the retention allowance still exist. | Total Compensation: \$ 163,875 |
| | (Total Pay cannot exceed EX-1 in a calendar year) |

| REVIEWS AND APPROVALS | | |
|---|---|------------|
| a. RECOMMENDING OFFICIAL | TITLE | DATE |
|  | ARRA | 5/8/04 |
| JOHN M. TAYLOR, III | Associate Director for Regulatory Affairs | |
| b. FUNDS ARE AVAILABLE | TITLE | DATE |
|  | | 3/9/04 |
| RIC GARWOOD | Acting Director, DMO | |
| c. I certify that the information entered on this form is accurate and that the proposed bonus/allowance is in compliance with statutory and regulatory requirements. | TITLE | DATE |
|  | | 03.02.2004 |
| MICHELE HIMELRIGHT | Supervisory Human Resources Specialist | |
| d. APPROVING OFFICIAL | TITLE | DATE |
|  | | 3/31/04 |
| LESTER M. CRAWFORD, D.V.M., Ph.D. | Deputy Commissioner | |

EFFECTIVE DATE (To be completed after approval)

Effective date: ~~5/14/04~~ ^{5/2/04} Retention allowance expiration date: 4/2/05
Service agreement expiration date: _____



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration**Memorandum**

Date February 25, 2004

From John M. Taylor, III, Associate Commissioner for Regulatory Affairs

Subject Retention Allowance for Terry Vermillion

To Dr. Lester Crawford, Deputy Commissioner

I am recommending the approval of a retention allowance for Terry Vermillion. I believe that he is likely to leave the Federal Government for private industry if the retention bonus is not approved. I would be happy to discuss. Thank you for your consideration.
John.



FOOD AND DRUG ADMINISTRATION

Headquarters

DIRECTOR

Office of Criminal Investigations
7500 Standish Place, Suite 250N
Rockville, Maryland 20855

MEMORANDUM

Date: February 23, 2004
From: Terry Vermillion
Subject: Retention Allowance
To: John M. Taylor
Associate Commissioner
Office of Regulatory Affairs

Reference our past conversations and after due consideration, I am likely to leave the Federal government for a higher paying private sector position if the retention allowance is not approved.

Respectfully,

Terry Vermillion

**RECOMMENDATION FOR RETENTION ALLOWANCE
TERRELL L. VERMILLION**

ACTION REQUESTED

Approval is requested to grant a retention allowance of 15% of base pay to Terrell L. Vermillion as authorized under the Federal Employees' Pay Comparability Act of 1990. This request is based on Mr. Vermillion's unique and superior qualifications, his outstanding contributions to the vital enforcement mission of the Agency, and that he is in an essential management position that is difficult to recruit for.

Mr. Vermillion is serving in an ES-1811-00 as the Director, Office of Criminal Investigations, Office of Regulatory Affairs. Mr. Vermillion's base salary is \$142,500. I am requesting that he be granted a retention allowance of 15 percent (\$21,375) of his base pay. This will make Mr. Vermillion's total compensation in this position, \$163,875.

QUALIFICATIONS AND ACCOMPLISHMENTS

Terry Vermillion began his federal career in 1969 as a Special Agent of the U. S. Secret Service in the Department of Treasury. In March 1992 he was selected to be the founding Director of the newly established Office of Criminal Investigations (OCI). This office was established in response to concern from congressional oversight committees that FDA lacked an adequately trained and effective criminal investigations capacity with which to respond to increasing instances of criminal violations of the Federal Food, Drug and Cosmetic and related Acts. Mr. Vermillion was instrumental in creating OCI which included the establishment, recruitment, staffing, equipping and training of a nationwide cadre of federal law enforcement criminal investigations and technical support staffs. OCI which began with a staff of 30 in 1992 has now grown to over 225 personnel. OCI cases have brought about hundreds of convictions, and conducting over 4000 national and international criminal investigations, which have been instrumental in protecting the public health and preventing criminal and fraudulent enterprises from negatively impacting both the citizenry and legitimate regulated industry. Today Mr. Vermillion continues to provide the leadership that FDA needs to maintain a highly trained, motivated and effective criminal investigations organization.

Mr. Vermillion is widely recognized and respected by his law enforcement peers, and has forged strong working bonds with other federal, State and international law enforcement entities. His leadership and executive direction over agency criminal investigative efforts on emerging regulatory issues facing FDA at this time, such as counterfeit drugs, internet drug sales, product tampering, and terrorism threats to FDA regulated products has been outstanding. He is constantly sought out for advice and guidance on a wide variety of industry security and regulatory issues from the FDA perspective. His criminal investigation and counter-terrorism expertise is valuable to the agencies mission and the public.

CONTRIBUTIONS TO THE AGENCY

Beyond his broad knowledge of federal criminal laws, procedures, counter-terrorism and investigative operations acquired in 34 years as a federal criminal investigator and manager, Mr. Vermillion has far-reaching expertise in relating these attributes to the critical mission of the FDA. Additionally, Mr. Vermillion has a wide range of professional contacts, both domestic and international which provide this agency with immediate credibility and organizational respect to enhance OCI as an organization as well as FDA's role in criminal investigations and counter-terrorism efforts. He negotiated important MOU's with the Federal Bureau of Investigation (FBI), U.S. Customs Service (now BICE), Department of Justice (DOJ), U.S. Secret Service (USSS), U.S. Marshals Service (USMS) and the Department of Defense (DOD). These MOU's have provided for critical needs, services and timely effective sharing of information.

Through Mr. Vermillion's leadership, the FDA OCI has developed from a concept in 1992 to a highly respected and very effective criminal law enforcement organization. Additionally the original role of OCI has expanded by the demands of the Agency as well as the current needs related to counter-terrorism. These are highlighted by OCI responding to the internal need for conducting professional investigations relating to misconduct. To respond to this need, Mr. Vermillion, at the request of the Commissioner, developed and implemented the creation of the Office of Internal Affairs in 1994. In response to the war on terror, Mr. Vermillion expanded the scope of interactions with the intelligence community by establishing an OCI Counter-Terrorism Section in OCI headquarters which conducts critical interactions with federal law enforcement and intelligence agencies as well as coordination of OCI field office counter-terrorism activities.

Mr. Vermillion produces policies, procedures, and guidelines, based on existing law and regulations, either in response to novel circumstances, emerging situations or as an extension or revision of existing policies or guidelines. His work products significantly affect the entire scope of FDA's import program.

SCARCITY OF QUALIFIED CANDIDATES

As the founder and creator of OCI, Mr. Vermillion's historical knowledge cannot be replaced. He has 34 years of Federal law enforcement experience that is invaluable to the effectiveness of his position. Additionally, his specialized training allows him to recruit the highly qualified professional law enforcement officers that have the training and caliber needed to fill the crucial positions in OCI to meet the mission of FDA

Based on our experience, it is impossible to recruit someone of Mr. Vermillion's stature. It is unlikely that other candidates could step in and fill the range of responsibilities and necessary to lead the Office of Criminal Investigations.

INDUSTRY DEMAND FOR SIMILARLY QUALIFIED PERSONNEL

In the past several years there has been an increasing demand by private industry or other agencies for individuals with Mr. Vermillion's knowledge, skills, and background in criminal investigations, security and counter terrorism. Due to his recognized expertise in the areas mentioned previously, Mr. Vermillion would be in great demand by the private sector. Trade associations and industry, as well as other private security organizations would welcome an opportunity to employ Mr. Vermillion.

IMPACT OF THE POSSIBLE LOSS OF MR. VERMILLION

Mr. Vermillion's separation from the FDA will be very detrimental for the Agency. Currently there is no one else in the FDA with the same broad and profound knowledge of criminal investigations and counter terrorism investigations relating to the mission of the FDA. Since the September 11th attacks, the private sector demand for individuals with Mr. Vermillion's skills and experience has increased dramatically. Mr. Vermillion has indicated a desire to explore private sector opportunities. It would be difficult if not impossible to replace Mr. Vermillion in these areas. His loss to FDA at this critical juncture, with increasing criminal activity and terrorism threats would be devastating to agency effectiveness.

SUMMARY

Mr. Vermillion's base salary is \$142,500. With the approval of Mr. Vermillion's retention allowance (\$21,375), his total compensation would be \$163,875 per annum. I believe that Mr. Vermillion qualifies for the 15% retention allowance authorized under law and urge swift approval of the FECPA flexibility to demonstrate our commitment to rewarding and recognizing his expertise and bringing these talents into management of the import operations division. Because of his exceptional qualifications for the position and his demonstrated ability to do the job in an outstanding manner, it is in the Agency's best interest that he be retained.

Margaret O'K. Glavin
 Director of Counter-terrorism Policy, 2003 - 2005
 Associate Commissioner for Regulatory Affairs, 2005 - present

| Year | Cash Awards | Retention Bonuses* | Total Bonuses | Total Compensation | ORA Total Bonuses | % of ORA Bonuses |
|-------|-------------|--------------------|---------------|--------------------|-------------------|------------------|
| 2003 | \$0 | \$29,400 | \$29,400 | \$171,900 | \$228,804 | 12.8% |
| 2004 | \$0 | \$31,942 | \$31,942 | \$175,700 | \$294,232 | 10.9% |
| 2005 | \$14,350 | \$34,473 | \$48,823 | \$193,050 | \$425,112 | 11.5% |
| 2006 | \$10,811 | \$33,803 | \$44,614 | \$210,611 | \$401,368 | 11.1% |
| 2007* | \$12,004 | \$11,339 | \$23,343 | -- | \$191,878 | 12.2% |

Data for this table provided to the Committee by HHS.

* partial year

**Ms. Glavin's retention bonus justification forms were provided to the Committee only for years 2003-2005. Bonus amounts and total compensation amounts differ between justification forms and HHS pay data sheets due to the time period covered by justification forms (justifications allow payment across two calendar years). Data from HHS pay sheets were used for this table.

***Bonus justification based on Salary.com figures for "Top Government Affairs Executive (Federal Level)," median \$179,744 in 2003 and 2004, \$195,531 in 2005. It is important to note that a "Government Affairs Executive" is different than a Government Executive.

^Total bonuses for all employees who received more than \$5,000 in bonuses, awards or other extraordinary payments for that year.

Food and Drug Administration
DEPARTMENT OF HEALTH AND HUMAN SERVICES

REQUEST FOR RECRUITMENT BONUSES, RELOCATION BONUSES,
RETENTION ALLOWANCES, and RETENTION ALLOWANCE RENEWALS

| EMPLOYEE INFORMATION | | |
|--|--|---|
| NAME (Print or Type) Margaret O'K. Glavin | SERIES/GRADE/STEP ES-301-06 | SOCIAL SECURITY NUMBER [REDACTED] |
| TITLE Director of Counter-terrorism Policy | ORGANIZATION Office of Policy Office of Policy & Planning | ANNUAL BASE SALARY \$134,000 |
| OFFICIAL DUTY STATION Rockville, MD | TYPE OF APPOINTMENT <input checked="" type="checkbox"/> Permanent Term () Years | OFFICIAL TOUR OF DUTY <input checked="" type="checkbox"/> Full Time <input type="checkbox"/> Part Time (If Part Time, Regularly Scheduled Hours per Pay Period:) |

| AMOUNT OF BONUS/ALLOWANCE TO BE PAID | |
|--|---|
| BONUS/ALLOWANCE | COMPENSATION |
| Recruitment: _____ % = \$ _____ | Base: \$ 134,000 |
| Relocation: _____ % = \$ _____ | Locality: \$ 8,500 |
| Retention: 21.94 % = \$ 29,400 | Other Continuing Pay: \$ _____ |
| Renewal: _____ % = \$ _____ | Bonus/Allowance: \$ 29,400 |
| <input type="checkbox"/> Renewal: The conditions giving rise to the original determination to pay the retention allowance still exist. | Total Compensation: \$ 171,900 |
| | (Total Pay cannot exceed EX-1 in a calendar year) |

| REVIEWS AND APPROVALS | | |
|---|---|---------|
| a. RECOMMENDING OFFICIAL | TITLE | DATE |
| <i>[Signature]</i> | Associate Commissioner for Policy & Planning | 8/3/03 |
| b. FUNDS ARE AVAILABLE | TITLE | DATE |
| <i>[Signature]</i> | Supv. Management Officer | 8/3/03 |
| c. I certify that the information entered on this form is accurate and that the proposed bonus/allowance is in compliance with statutory and regulatory requirements. | | |
| PERSONNEL OFFICIAL | TITLE | DATE |
| <i>[Signature]</i> | Supv. Personnel Management Specialist OHRMS | |
| d. APPROVING OFFICIAL | TITLE | DATE |
| <i>[Signature]</i> | Commissioner of Food & Drugs | 8/20/03 |

EFFECTIVE DATE (To be completed after approval)

Effective date: 9/21/03 Retention allowance expiration date: 9/18/04
Service agreement expiration date: _____

Recommendation for Retention Allowance
Margaret O’K. Glavin

I am requesting approval of a retention allowance for Margaret O’K. Glavin as authorized under the Federal Employees Pay Comparability Act (FEPCA) of 1990. This request is based on Ms. Glavin’s exceptional and superb qualifications, her outstanding contributions to the Agency’s mission, and the critical need for her services in the position of Director of Counter-terrorism Policy, Office of Policy and Planning.

Ms. Glavin’s qualifications include a BA degree in English from Trinity College and MA degree in Government from Georgetown University. Ms. Glavin has received numerous awards and honors including two Presidential Rank Awards. She received the Meritorious Rank in 1991 for her work in developing and implementing Federal labeling requirements for food products, and the Distinguished Rank in 1999 for strengthening the Food Safety and Inspection Service’s effectiveness through a revitalized organizational structure and innovative applications of science in inspection methodology.

This position will serve as the primary advisor to the Commissioner and other key FDA officials on the issues that have an impact on the counter-terrorism policies that cut across the agency. This position will also be critical to FDA’s efforts to meet the Secretary’s “One-HHS” goal of preparing for and effectively responding to bioterrorism and other public health emergencies. Furthermore, this position will be responsible for articulating FDA’s CT policy and for representing the Commissioner at high level meetings within and outside the Department concerned with resolution of interagency, intergovernmental (Federal, state, and local), and international issues related to incidents of terrorism.

Discussions on agency preparedness often center around two major topics – drugs and foods. In past recruitment efforts, the agency has been unable to identify or attract one individual with a strong background in both areas. Therefore, the search committee concluded that a strong manager, respected in their field of expertise (either foods or drugs) could represent the agency’s interests, relying on other experts within the centers, as necessary. The Commissioner in many of his speaking engagements has noted that the terrorist activities of 2001 highlighted new potential risks of deliberate food contamination. The agency has initiated a scientific assessment of the vulnerability of various categories of food to intentional contamination – including the economic impact of a potential bioterrorist attack on our food supply. FDA is also taking part in two multi-agency efforts to give our bioterrorism counter-measures greater scientific depth and geographic distribution, joining with the Food Safety and Inspection Service (FSIS).

Ms. Glavin is superbly qualified to serve as the Director of Counter-terrorism Policy. She is a nationally recognized food safety policy leader. For over thirty years, she has held increasingly more responsible positions with the U.S. Department of Agriculture (USDA), the last twenty of which have been with the Food Safety and Inspection Service (FSIS). FSIS is USDA’s food safety agency overseeing a workforce of over 9,000 federal inspectors who carry out federal inspection laws for meat, poultry, and egg

products in over 6,200 plants across the country. Ms. Glavin's leadership in these critical program areas has tangibly strengthened FSIS effectiveness and is easily transferable to the programs administered by FDA.

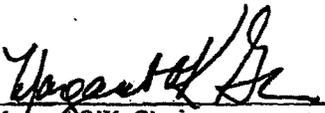
The following are just a few examples of Ms. Glavin's outstanding performance and contributions to the food safety programs which are related to this agency's mission:

- Led the implementation of the FSIS final rule on the Pathogen Reduction/Hazard Analysis Critical Control Point (PR/HACCP) that fundamentally changed how meat and poultry foods are produced in USDA-inspected establishments.
- Oversaw the development of a new model for conducting audits of foreign inspection systems in order to assure that foreign meat and poultry exported to the US is produced under the same HACCP controls applied domestically.
- Developed a comprehensive program to review and revise all meat and poultry inspection regulations – rewrite some more clearly, cut red tape, permitting rapid adoption of new technologies and interventions to further reduce meat and poultry pathogen risks.
- Assembled an internal FSIS group the Food Biosecurity Action Team (F-BAT) and created, with FDA, the Food Threat Preparedness Network (PrepNet), a collaboration of all food safety agencies of the Federal Government designed to protect the food supply, respond to emergencies, and enhance the sharing of Federal resources to protect the food supply from terrorist threats.

Based on the HR Edition of Salary.Com, the website recommended by OHRMS for salary determinations, current salary comparisons for a Top Government Affairs Executive (Federal Level) falls between \$147,558 and \$217,146, with a median pay of \$179,744. This is considerably more than FDA is able to offer Ms. Glavin in base and locality pay, which is capped at \$142,500. Therefore, I am requesting that Ms. Glavin be granted a retention allowance of 21.94 percent of base pay (or \$29,400) to bring her total pay to \$171,900.

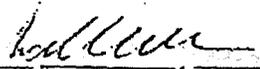
If Ms. Glavin were to resign from this position, the result would seriously undermine the Agency's ability to provide continuity in a program of critical importance. Over the past three years, FDA has filled this position by rotating various managers through in an acting capacity and briefly on a permanent basis. The responsibilities of the position demand a seasoned manager, who has the technical expertise in either food safety or drugs, who is respected in the field, and has strong interpersonal and coalition building skills. Margaret Glavin meets all those requirements. If we are unable to provide a retention allowance to place her salary in-line with that potentially offered in the private sector, it is doubtful that we will be able to retain her.

If I am unable to receive a retention allowance, I am likely to leave the Federal Government for a higher paying position in the private sector.



Margaret O'K. Glavin

I believe that Margaret O'K. Glavin is likely to leave the Federal Government service for a higher paying position in the private sector if she does not receive a retention allowance.



William K. Hubbard
Associate Commissioner for Policy and Planning

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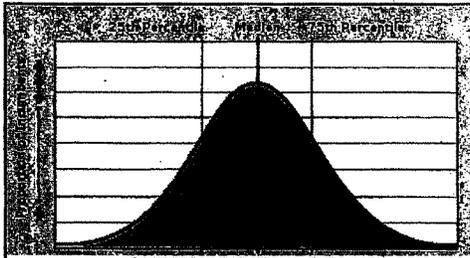
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A typical **Top Government Affairs Executive (Federal Level)** working in **Washington, DC** earns a median base salary of **\$179,744**, according to our analysis of data reported by corporate HR departments. Half of the people in this job earn between **\$147,558** and **\$217,146**.

Base Salary Bonuses Benefits Data as of July 2003

Base pay only 1 2 3



| Top Government Affairs Executive (Federal Level) | 25th Percentile | Median | 75th Percentile |
|--|-----------------|-----------|-----------------|
| Washington, DC | \$147,558 | \$179,744 | \$217,146 |

Top Government Affairs Executive (Federal Level) (Executive and Management)
Plans and directs all aspects of an organization's policies and objectives involving matters of federal government and regulations. Requires a bachelor's degree with at least 15 years of experience in the field. Familiar with a variety of the field's concepts, practices, and procedures. Relies on extensive experience and judgment to plan and accomplish goals. Performs a variety of tasks. Leads and directs the work of others. A wide degree of creativity and latitude is expected. Typically reports to top management.

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REQUEST FOR RENEWAL OF RETENTION ALLOWANCE
(To be approved by the Authorized Management Official)
(To be used in conjunction with PHS Instruction 575-1 AND in lieu of PHS-6340)

10/11/04
Kim Holden
this is fine.

1. EMPLOYEE INFORMATION

| | | |
|--|---|--|
| NAME (Print or Type) Margaret O. Glavin | | SOCIAL SECURITY NUMBER [REDACTED] |
| POSITION TITLE Assist. Comm. for Counterterrorism | SERIES / GRADE / STEP ES-301-06 | POSITION NO. |
| ORGANIZATION (AGENCY / BUREAU / CENTER) Policy | LOCATION Rockville, MD | |
| FDA/OC/OCTP | EMPLOYEE HAS SERVED IN HHS SINCE DATE 8/2003 | OFFICIAL TOUR OF DUTY <input checked="" type="checkbox"/> Full Time <input type="checkbox"/> Part Time if Part-time, regularly scheduled hours per pay period: |

2. ORIGINAL RETENTION ALLOWANCE INFORMATION AND JUSTIFICATION (as of the effective date of the original allowance)

| | | |
|---|----------------------------|---|
| EFFECTIVE DATE OF ORIGINAL ALLOWANCE 9/21/03 | EXPIRATION DATE 9/18/04 | RETENTION ALLOWANCE AUTHORIZED 22.44 % = \$ 32,202 |
| ANNUAL BASE SALARY \$ 143,498 | OTHER CONTINUING PAY \$ | TOTAL COMPENSATION \$ 175,700 |

CONDITIONS FOR APPROVAL OF RETENTION ALLOWANCE:
a. There is an essential need for the employee's services;
b. The employee is likely to leave Federal service if the retention allowance is not paid;
c. The employee's departure would hamper a crucial function or mission; and
d. The employee occupies a position for which there is significant recruitment or retention problem as demonstrated by special salary rate or direct hire authority or specific recruitment/retention data.

THESE CONDITIONS WERE EVIDENCED IN THE ORIGINAL RETENTION ALLOWANCE DOCUMENTATION AS FOLLOWS:
The conditions giving rise to the original determination to pay the retention allowance still exist. See attached.

3. CERTIFICATION AND APPROVAL OF RETENTION ALLOWANCE RENEWAL

(NOTE: Any changes to the conditions under which the original retention allowance determination was made, or a proposed increase to the percentage of allowance approved, will necessitate submission of a new retention allowance request.)

| | | |
|--|---|------------|
| I certify that the conditions giving rise to the original determination to pay the retention allowance as stated in item 2., above, still exist and that a continued retention allowance of 22.44% is warranted. (Current evidences of continued need, e.g., employment offers, labor market surveys, etc., should be attached if available.) | Current Annual Base Salary..... | \$ 143,498 |
| | Retention Allowance Renewal Amount .. | \$ 32,202 |
| | Other Continuing Pay | \$ |
| | Total Compensation* | \$ 175,700 |
| | * Base + Other Continuing Pay + Allowances (Total cannot exceed EX-1) | |

a. RECOMMENDING OFFICIAL (Signature) (Title) (Date)
[Signature] Director, OEO 9/18/04

b. APPROVING OFFICIAL (Signature) (Title) (Date)
[Signature] Acting Commissioner SEP 30 2004

4. EFFECTIVE DATE (All contracts must begin on the first day of a pay period and end on the last day of a pay period.)
This agreement is effective on 9/19/04 and expires on 9/18/05.

5. FUNDS AVAILABILITY AND PERSONNEL REVIEW

| |
|--|
| a. Funds are available (Signature) (Title) (Date) <i>[Signature]</i> for Management Advisor |
| b. I certify that the information entered on this form is accurate and that the proposed allowance is in compliance with statutory and regulatory requirements. PERSONNEL OFFICIAL (Signature) (Title) (Date) |

1. Original (white)-OPF

2005

Recommendation for Retention Allowance
Margaret O'K. Glavin

I am requesting approval of a renewal of a retention allowance for Margaret O'K. Glavin as authorized under the Federal Employees Pay Comparability Act (FEPCA) of 1990. This request is based on Ms. Glavin's exceptional and superb qualifications, her outstanding contributions to the Agency's mission, and the critical need for her services in the position of Assistant Commissioner for Counterterrorism Policy in the Office of the Commissioner.

Ms. Glavin's qualifications include a BA degree in English from Trinity College and an MA degree in Government from Georgetown University. Ms. Glavin has received numerous awards and honors, including two Presidential Rank Awards. She received the Meritorious Rank in 1991 for her work in developing and implementing Federal labeling requirements for food products, and the Distinguished Rank in 1999 for strengthening the Food Safety and Inspection Service's effectiveness through a revitalized organizational structure and innovative applications of science in inspection methodology.

This position will serve as the primary advisor to the Commissioner and other key FDA officials on the issues that have an impact on the counterterrorism policies that cut across the agency. This position will also be critical to FDA's efforts to meet the Secretary's "One-HHS" goal of preparing for and effectively responding to bioterrorism and other public health emergencies. Furthermore, this position will be responsible for articulating FDA's counterterrorism policy and for representing the Commissioner at high-level meetings within and outside the Department concerned with resolution of interagency, intergovernmental (Federal, State, and local), and international issues related to incidents of terrorism.

Discussions on agency preparedness often center around two major topics—drugs and foods. In past recruitment efforts, the agency has been unable to identify or attract one individual with a strong background in both areas. Therefore, the search committee concluded that a strong manager, respected in their field of expertise (either foods or drugs) could represent the Agency's interests, relying on other experts within the centers, as necessary. The Commissioner, in many of his speaking engagements, has noted that the terrorist activities of 2001 highlighted new potential risks of deliberate food contamination. The agency has initiated a scientific assessment of the vulnerability of various categories of food to intentional contamination—including the economic impact of a potential bioterrorist attack on our food supply. FDA is also taking part in two multi-agency efforts to give our bioterrorism counter-measures greater scientific depth and geographic distribution, joining with the Food Safety and Inspection Service (FSIS).

Ms. Glavin is superbly qualified to serve as the Assistant Commissioner for Counterterrorism Policy. She is a nationally recognized food safety policy leader. For over thirty years, she has held increasingly more responsible positions with the U.S. Department of Agriculture (USDA), the last twenty of which have been with the FSIS. FSIS is USDA's food safety agency overseeing a workforce of over 9,000 federal inspectors who carry out federal inspection laws for meat, poultry, and egg products in over 6,200 plants across the country. Ms. Glavin's leadership in these critical program areas has tangibly strengthened FSIS effectiveness and is easily transferable to the programs administered by FDA.

The following are just a few examples of Ms. Glavin's outstanding performance and contributions to the food safety programs which are related to this agency's mission:

- Led the implementation of the FSIS final rule on the Pathogen Reduction/Hazard Analysis Critical Control Point (PR/HACCP) that fundamentally changed how meat and poultry foods are produced in USDA-inspected establishments.
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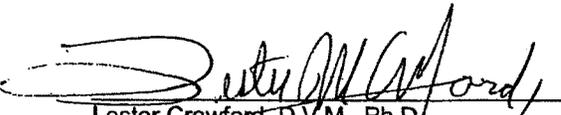
If Ms. Glavin were to resign from this position, the result would seriously undermine the Agency's ability to provide continuity in a program of critical

importance. Over the past three years, FDA has filled this position by rotating various managers through in an acting capacity and briefly on a permanent basis. The responsibilities of the position demand a seasoned manager, who has the technical expertise in either food safety or drugs, who is respected in the field, and has strong interpersonal and coalition building skills. Ms. Glavin meets all those requirements. If we are unable to continue to provide a retention allowance to place her salary in line with that potentially offered in the private sector, it is doubtful that we will be able to retain her.

If I am unable to receive a retention allowance, I am likely to leave the Federal Government for a higher paying position in the private sector.


Margaret O.K. Glavin

I believe that Margaret O.K. Glavin is likely to leave the Federal Government service for a higher paying position in the private sector if she does not continue to receive a retention allowance.


Lester Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs

Food and Drug Administration
DEPARTMENT OF HEALTH AND HUMAN SERVICES

REQUEST FOR RECRUITMENT BONUSES, RELOCATION BONUSES,
RETENTION ALLOWANCES, and RETENTION ALLOWANCE RENEWALS

| EMPLOYEE INFORMATION | | |
|--|---|---|
| NAME (Print or Type) Margaret O' K. Glavin | SERIES/GRADE/STEP 0301/ES | SOCIAL SECURITY NUMBER [REDACTED] |
| TITLE Assoc. Comm. for Regulatory Affairs | ORGANIZATION DHHS/FDA/ORA | ANNUAL BASE SALARY \$154,440 |
| OFFICIAL DUTY STATION Rockville, Maryland | TYPE OF APPOINTMENT <input checked="" type="checkbox"/> Permanent <input type="checkbox"/> Term () Years | OFFICIAL TOUR OF DUTY <input checked="" type="checkbox"/> Full Time <input type="checkbox"/> Part Time (If Part Time, Regularly Scheduled Hours per Pay Period:) |
| AMOUNT OF BONUS/ALLOWANCE TO BE PAID | | |
| BONUS/ALLOWANCE | | COMPENSATION |
| Recruitment: _____ % = \$ _____ | | Base: \$ 154,440 _____ |
| Relocation: _____ % = \$ _____ | | Locality: \$ _____ |
| Retention: 25 % = \$ 38,610 _____ | | Other Continuing Pay: \$ _____ |
| Renewal: _____ % = \$ _____ | | Bonus/Allowance: \$ 38,610 _____ |
| <input type="checkbox"/> Renewal: The conditions giving rise to the original determination to pay the retention allowance still exist. | | Total Compensation: \$ 193,050 _____ |
| | | (Total Pay cannot exceed EX-1 in a calendar year) |

| REVIEWS AND APPROVALS | | |
|--|--|-------------|
| a. RECOMMENDING OFFICIAL | TITLE | DATE |
| <i>James Strachan</i> James Strachan | Executive Officer, ORA | 6/23/05 |
| b. FUNDS ARE AVAILABLE | TITLE | DATE |
| <i>James Strachan</i> James Strachan | Executive Officer, ORA | 6/23/05 |
| I certify that the information entered on this form is accurate and that the proposed bonus/allowance is in compliance with statutory and regulatory requirements. | | |
| PERSONNEL OFFICIAL | TITLE | DATE |
| <i>Michele Himelright</i> Michele Himelright | Supv. HR Specialist, Rockville HR Center | 6/23/05 |
| d. APPROVING OFFICIAL | TITLE | DATE |
| <i>Lester M. Crawford</i> Lester M. Crawford, D.V.M., Ph.D. | Acting Commissioner of Food and Drugs | JUN 24 2005 |

EFFECTIVE DATE (To be completed after approval)

Effective date: 6/26/05 Retention allowance expiration date: 04-29-2006
Service agreement expiration date: _____

Recommendation for Retention Allowance
Margaret O'K. Glavin

Action Requested

I am requesting approval of a retention allowance for Margaret O'K. Glavin as authorized under the Federal Employees Pay Comparability Act (FEPCA) of 1990. This request is based on Ms. Glavin's unique and superb qualifications, her outstanding contributions to the Agency's mission, and the critical need for her services in the position of Associate Commissioner for Regulatory Affairs.

Qualifications and Accomplishments

Ms. Glavin's qualifications include a BA degree in English from Trinity College and an MA degree in Government from Georgetown University. Ms. Glavin has received numerous awards and honors, including two Presidential Rank Awards. She received the Meritorious Rank in 1991 for her work in developing and implementing Federal labeling requirements for food products, and the Distinguished Rank in 1999 for strengthening the Food Safety and Inspection Services effectiveness through a revitalized organizational structure and innovative applications of science in inspection methodology.

Ms. Glavin serves with distinction as the Associate Commissioner for Regulatory Affairs. She has outstanding qualifications. She has an outstanding record of providing leadership and management of regulatory functions. She has brought to this position extensive experience in the planning, development, implementation, and administration of the Food and Drug Administration's nationwide compliance, enforcement, and regulatory activities. Ms. Glavin has held executive positions at the Food Safety and Inspection Service and the Food and Nutrition Service at the U.S. Department of Agriculture. She was Associate Administrator and Acting Administrator of the Food Safety and Inspection Service, a 10,000-person regulatory public health agency responsible for the safety of the U.S. meat and poultry supply. She is a nationally recognized food safety policy leader. Ms. Glavin's leadership in these critical program areas has tangibly strengthened FSIS effectiveness and is easily transferable to the inspection functions of ORA and to the programs administered by FDA. The Associate Commissioner for Regulatory Affairs is responsible for overseeing the field force, including inspectional, import and laboratory activities as well as public education and out reach initiatives, which is a direct link to her experience and responsibilities at FSIS.

Role in Agency

The critical nature of this position stems from the fact that the Associate Commissioner for Regulatory Affairs manages five Regional Offices and District Offices across the country and four Offices and in headquarters. Ms. Glavin is accountable for the operations and safety of 3,600 employees. This position serves as principle advisor to the Commissioner. She is responsible for preserving, promoting, protecting, and advancing

the public health. This position is responsible for directing the field in risk-priority inspections, inspections of high-risk human drug manufacturers, and high-risk domestic food establishments. In addition, she directs and oversees the consistent implementation of the procedures that govern the means by which the Agency prioritizes its work at international mail facilities and courier hubs. This position is also responsible for leading the organization to meet or exceed its performance goals in the Commissioner's Performance Plan. This position is responsible for collaborating with Centers regarding regulatory policies, methodology issues, and field assignments; coordinating delivery of equipment and methodology to appropriate field laboratories, provide guidance to laboratories as analytical or program-related issues arise; provide appropriate information to FDA upper management, White House staff and congressional staff regarding the regulatory analyses of food products for a number of Category A Threat Agents.

Industry's Demand for Similarly Qualified Employees

An individual with Ms. Glavin's background is extremely attractive to private industry and can command much higher compensation.

Based on the HR Edition of Salary.com, the website recommended for salary determinations, current salary comparisons for a Top Government Affairs Executive (Federal Level) falls between \$160,730 and \$239,113, with a median pay of 195,531. This is considerable more than the FDA is able to offer Ms. Glavin in base pay. Therefore, I am requesting that Ms. Glavin be granted a retention allowance of 25 percent of base pay to bring her pay to \$154,440 (base) plus \$38,610 (retention) for a total pay of (base and retention) \$193,050.

Impact of Possible Loss

If Ms. Glavin were to resign from this position to leave the agency to accept a higher-paid position in the private sector, the FDA and ORA will suffer an immediate loss in several critical areas. First, the departure would seriously disrupt ORA's mission as it relates to public health. Most importantly it would negatively impact the agency's ability to coordinate and resolve policy, enforcement, compliance, and regulatory issues. In addition, if Ms. Glavin left the agency it would hurt the agency's efforts in protecting the American vaccine and blood supply, ensuring that dangerous and illegal medical products are not sold over the Internet, that contaminated feed will not reach American cattle, and that foods, drugs, devices, and biological products are processed and manufactured in accordance with the agency's quality assurance regulations. Most of our regulated industries strive to comply with FDA's laws and regulations but in order to protect the American public it is important to be able to respond quickly in those instances where firms produce products that are not in compliance with the law. For all the reasons stated above the loss of Ms. Glavin would compromise FDA's ability to coordinate its regulatory efforts so that unsafe and ineffective products do not reach the American public.

The last SES incumbent was hired from within the FDA, and filled the position between October 2002 and April 2005. His predecessor was hired in 1999, after an exhaustive nationwide merit search conducted by the agency. If Ms. Glavin were to leave FDA, we would be faced with conducting a SES nationwide search to fill the position which would leave the agency with a void. A vacancy in this position would result in seriously undermining the Agency's ability to provide continuity of critical importance. The responsibilities of this position demand a seasoned manager, who has the technical expertise, who is respected in the field, and has strong interpersonal and coalition building skills. Ms. Glavin meets all those requirements.

Summary

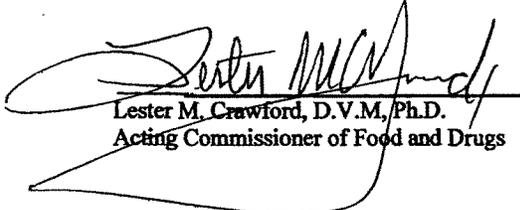
We believe that Ms. Glavin qualifies for the 25 percent retention allowance requested. The retention allowance will enable us to come one step closer to the non-Federal salary that she can obtain on the outside. Because of her exceptional qualifications, it is not only in the Agency's best interest, it is essential that she be retained.

If we are unable to continue to provide a retention allowance to place her salary in line with that potentially offered in the private sector, it is doubtful that we will be able to retain her. This Agency, the Department, and most importantly, the American consumer, cannot afford to lose individuals with Ms. Glavin's exceptional capabilities because of salary considerations, especially when use of an already existing legal provision would at least allow us to come closer to meeting her salary requirements.

If I am unable to receive a retention allowance, I am likely to leave the Federal Government for a higher paying position in the private sector.


Margaret O'K. Glavin

I believe that Margaret O'K. Glavin is likely to leave the Federal Government service for a higher paying position in the private sector if she does not receive a retention allowance.


Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs

See Also...

- ▶ [Salary Wizard](#)
- ▶ [Executive Compensation Wizard](#)
- ▶ [Cost-of-Living Wizard](#)
- ▶ [Job Assessor](#)
- ▶ [College Tuition Planner](#)
- ▶ [Millionaire Maker](#)
- ▶ [Salary Timer](#)
- ▶ [Job Search](#)
- ▶ [Canadian Salary Wizard](#)

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Despite IRS rules aimed at reinining excessive executive pay, many companies are still giving managers hefty bonuses -- even when they the performance goals that are supposed to trigger the payouts.

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In a palatable alternative to separating the chairman and chief executive jobs, many companies are naming lead directors to provide some independent oversight of the boards.

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Still uncertain about the fragile economic recovery, companies are hiring "contingent" staff members. These individuals work full-time for months, collecting hourly wages -- but no benefits -- from an outside staffing agency.

San Juan District Office
Toothpaste / Toothbrush Kit
Revisions on FDA Import Alert

The attached FDA import alert (IA6674, http://www.fda.gov/ora/fiars/ora_import_ia6674.html) was revised June 8, 2007 to reflect a new product code for combination toothbrush / toothpaste kits. Prior to this revised import alert, only stand-alone toothpaste could be detained for diethylene glycol (DEG). Based on work in the San Juan district office, investigators discovered several types of combination kits that contain a toothbrush with tubes of toothpaste. The toothpaste in these kits also contained DEG, but codes for these kits were not included in the original import alert. Inspectors could not detain such kits without their codes being included in the import alert. The San Juan district office staff alerted the FDA to this omission and the import alert was revised to include the new code for "dental hygiene kits," allowing detention of DEG-containing toothpaste that would otherwise have escaped detention.

EX 60

IMPORT ALERT IA6674

Page 1 of 8

IA #66-74, 6/8/07, IMPORT ALERT #66-74, "DETENTION WITHOUT PHYSICAL EXAMINATION OF DENTIFRICE PRODUCTS CONTAINING DIETHYLENE GLYCOL (DEG)", Attachment 6/20/07

The revision of this Import Alert dated June 8, 2007 includes a new product code for dentifrice products contained in kits. The revision also adds the appropriate Charge Codes that should be used for detention. Changes are denoted by asterisks (***)

TYPE OF ALERT: Detention Without Physical Examination (DWPE)

NOTE: This import alert contains the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or product(s) at issue. It does not create or confer any rights for or on any person and it does not operate to bind FDA or the public.

PRODUCT: All dentifrice products, including aerosols, liquids, toothpastes, and tooth powders with or without fluoride containing DEG

See attachment for specific product and manufacturers

PRODUCT CODE: 53I[] []01 Toothpaste without Fluoride
63R[] []06 Toothpaste with Fluoride
*** 76N[] []XZ Kit, Dental Hygiene ***

PROBLEM: Unapproved and adulterated drugs; adulterated and/or misbranded cosmetics; contains DEG

PAP: AAP *** (for toothpaste with fluoride and dental kits containing toothpaste with fluoride) ***

PAD *** (for toothpaste without fluoride and dental kits containing toothpaste without fluoride) ***

COUNTRIES: See attachment

MANUFACTURER/

SHIPPER: See attachment

CHARGES: For fluoride containing dentifrice drug products:

"The article is subject to refusal of admission pursuant to

Section 801(a)(3) in that it appears to be a new drug within the meaning of Section 201(p) without an effective new drug application (NDA) [Unapproved New Drug, Section 505(a)]."

*** Charge code: UNAPPROVED ***

and

"The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess [Adulterated Drugs, Section 501(a)(2)(B)]."

*** Charge Code: DRUG GMPS ***

For non-fluoride containing dentifrice cosmetic products:

"The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be adulterated in that it contains a poisonous or deleterious substance, namely diethylene glycol, which may render it injurious to users under such conditions of use as are customary or usual [Adulterated Cosmetic, Section 601(a)]."

*** Charge Code: POISONOUS ***

RECOMMENDING

OFFICE: CDER, OC, Division of New Drugs and Labeling Compliance
(HFD-310) and CFSAN, Office of Cosmetic and Colors, HFS-608

REASON FOR

ALERT: Diethylene glycol (DEG) is a glycol compound possessing toxicity similar to ethylene glycol. It is a Central Nervous System depressant and potent kidney and liver toxin when ingested. It is commonly used in industry as a solvent, a thickening agent, a humectant, and as a component in antifreeze and gas conditioning formulations.

DEG has been improperly used as a low-cost substitute for glycerin and propylene glycol in pharmaceutical preparations resulting in various lethal poisoning incidents in humans worldwide. Among these incidents are, elixir sulfanilamide

in the U.S., sedative mixtures in South Africa, paracetamol elixirs in Bangladesh and Nigeria, acetaminophen syrup in Haiti, and a cough expectorant product in India. Most recently, a cough syrup resulted in serious man injury and over 40 deaths in Panama in September 2006. These recent DEG poisoning incidents involved a "glycerin" product manufactured in China that was a mixture of sorbitol and DEG and less than one percent glycerin.

In May 2007, FDA received accounts that toothpaste from China shipped to Panama, Australia, and the Dominican Republic was found to contain DEG. A significant amount of toothpaste from China is imported into the United States. FDA is presently sampling dentifrice products manufactured in China to determine potential contamination with DEG.

To date, FDA has found DEG in three products manufactured by Goldcredit International Trading, China. The products are Cooldent Fluoride, Cooldent Spearmint, and Cooldent ICE. Analysis of these products has revealed that they contain between 3 and 4 percent diethylene glycol. FDA has also found DEG in one product manufactured by Suzhou City Jinmao Daily Chemicals Co., China. Analysis of that product, Shir Fresh Mint Fluoride Paste, found that it contained approximately 1% DEG. These products have been included in the DPWE list attachment of this alert. As the agency identifies other toothpaste products containing DEG, these products and their manufacturers will also be added to the Import Alert.

The products were labeled as containing diglycol. Diglycol is one of many synonyms of diethylene glycol. According to REPROTEXT System, diethylene glycol may be also known as:

1. Brecolane ndg
2. Carbitol
3. Deactivator E
4. Deactivator H
5. DEG
6. Degrees
7. Dicol
8. Diethylene ether
9. Diethylene glycol
10. Diethylenglykol (Czech)
11. Digenos

12. Diglycol
13. Digol
14. Dihydroxydiethyl ether
15. 2,2'-Dihydroxydiethyl ether
16. beta,beta'-Dihydroxydiethyl ether
17. Dihydroxyethylether
18. 2,2'-Dihydroxyethyl ether
19. Dissolvant APV
20. Ethanol, 2,2'-oxybis-
21. Ethanol, 2,2'-oxydi-
22. Ethylene diglycol
23. Glycol ether
24. Glycol ethyl ether
25. 2-Hydroxyethyl ether
26. bis(2-Hydroxyethyl)ether
27. 3-Oxapentane-1,5-diol
28. 3-Oxa-1,5-pentanediol
29. 2,2'-Oxybisethanol
30. 2,2'-Oxybis-ethanol
31. 2,2'-Oxydiethanol
32. 2,2'-Oxyethanol
33. TL4N

FDA has also identified a number of other dentifrice products manufactured by Goldcredit that are labeled as containing DEG (or a synonym thereof). These products have also been included in the DWPE list on this alert.

Dentifrice products may be marketed in the United States as drugs or cosmetics. Dentifrice products intended to prevent or mitigate dental cavities/decay (anticaries toothpaste) are regulated as over the counter (OTC) drugs. OTC anticaries toothpaste containing diethylene glycol cannot be marketed in the U.S. without an approved new drug application (NDA). DEG can be toxic and even fatal in humans and FDA is not aware of DEG having been used for a material extent and time in formulating OTC anticaries drug products. Thus, FDA regards any OTC anticaries drug product containing DEG to be a "new drug" as defined by section 201(p) of the Federal Food, Drug, and Cosmetic Act (the Act). "New drugs" must be the subject of an approved NDA under section 505 of the Act to be legally marketed in the United States. Presently, there are no OTC anticaries drug products containing DEG approved for marketing in the U.S.

The use of DEG in OTC anticaries drug products causes them to be adulterated under section 501(a)(2)(B) of the Act because of the toxicity of DEG when ingested, and therefore, the methods or controls used to manufacture the anticaries drug containing the DEG do not conform to current Good Manufacturing Practices to assure the drug meets the requirements of the Act regarding safety.

Non-fluoride dentifrices products that are not drugs are ordinarily marketed as cosmetics, as their intended use is for oral hygienic cleansing.

At this time, the only DEG-containing dentifrice products identified by FDA as being offered for import into the U.S. are from China. However, no DEG-containing dentifrice products manufactured in China or any other country may be imported into the U.S. Therefore, this alert covers dentifrice products containing DEG from any source.

GUIDANCE: Districts may detain without physical examination all shipments of dentifrice products listed in the attachment.

Districts may detain without physical examination any shipment of dentifrice products labeled as containing diethyleneglycol or any of its synonyms.

*** Districts may detain without physical examination all shipments of dental hygiene kits which contain dentifrice products listed in the attachment or which contain dentifrice products labeled as containing diethylene glycol or any of its synonyms. ***

For questions regarding dentifrice product marketed as drugs please contact CDER Import-Export Team at 301-827-8967.

For questions regarding dentifrice product marketed as cosmetics please contact, Richard Jewell, CFSAN, Labeling Compliance Team, at 301-436-2596 or Richard.jewell@fda.hhs.gov

PRIORITIZATION

GUIDANCE: I

FOI: No purging required

IMPORT ALERT IA6674

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KEYWORDS: Toothpaste, mouthwash, dentifrice, DEG

PREPARED BY: Ada Irizarry /CDER/OC/DNLC, 301-827-8967
 Richard Jewell, CFSAN, HFS-608, 301-436-2596
 Doug Randes, DIOP, 301-443-6553

DATE LOADED
 INTO FIARS: June 8, 2007 ATTACHMENT TO IMPORT ALERT #66-74 6/20/07

"LIST OF DENTIFRICES PRODUCTS MANUFACTURED THAT CONTAINS DIETHYLENE GLYCOL
 (DEG) AND/OR ARE LABELED AS CONTAINING DIETHYLENE GLYCOL"

CHINA (CN)

| Manufacturer | Products |
|---|--|
| 1. Goldcredit International Enterprises LTD 666 Shuguang BeiRd Hangitown Yangzhou, China FEI# 3005396179 | CooldentFluoride Cooldent Spearmint Cooldent ICE Dr Cool Toothpaste Everfresh Toohpaste Superdent Toothpaste 5/31/07 |
| Other addresses: Goldcredit International Enterprises, LTD 9 F Wuxi National Ind. Design District Liyuan Economic Dev Zone Wuxi Chin , China FEI# 3005043484 3005446962 | |
| Goldcredit International Enterprises, LTD #151 Lakebank Elegant Gardenwest Jincheng Road Wuxi, Jiangsu, China 214123 FEI# 3005775027 3005854733 | |
| 2. Gold Credit International Trading Co LTD 17th fl Changquing Bldg. 6 Jie Fang North Rd Wuxi 214005 Jiangsu, China | Clean Rite Toothpaste Clean Rite Toothpaste Kit Oralmax Extreme Action Kit |

IMPORT ALERT IA6674

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| | |
|-----------------|-------------------------|
| FEI# 3005535612 | Oralmx Extreme Action 3 |
| 3005566861 | Pack Kit |
| 3005970990 | Oral Bright Fresh |
| 3003883350 | Spearmint Flavor |
| | Bright Max Peppermint |
| | Flavor |
| | 5/31/07 |

Other addresses:

Gold Credit International Trading Co LTD
 20 Floor Unit G Wah KwongBldg. 333
 Zhongnan Rd , Wuxi 214001
 Jiangsu , China
 FEI# 3003754241

| | |
|--|-----------------|
| 3. Suzhou City Jinmao Daily Chemicals Co. Ltd. | Shir Fresh Mint |
| Jingeng Village Huangqiao Town | Fluoride Paste |
| Xiangcheng Dist. Suzhou Jiangsu China | 5/31/07 |
| Suzhou City, China | |
| FEI# 3005225258 | |

| | |
|-----------------------------------|-----------------------|
| 4. Shanghai Light Industrial | Freshh Spearmint Type |
| Products Imp & Exp Corp. Ltd. | Toothpaste |
| 16th-18th Floor Hong Yun Building | 6/13/07 |
| 501 Wu Ning Road | |
| Shanghai, China 200063 | |
| FEI# 3001110041 | |

| | |
|------------------------------------|----------------|
| 5. Suzhou Qing Xin Daily | All Toothpaste |
| Chemical Co., Ltd. | 6/20/07 |
| (AKA)Yen Chu Heng Uun Daily | |
| Chemical Products | |
| 158 Jingjiang Rd., New Development | |
| Suzhou, China | |
| FEI# 3006296210 | |

| | |
|--|--------------------|
| 6. Guangdong Well-known Ceramics Co., Ltd. | Tian Qi Toothpaste |
| Ceramics Building | 6/20/07 |
| No. 268 Huanshi Rd. Central | |
| Guangzhan, China | |
| FEI# 3004058513 | |

Other Address:

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Guangdong Well-known Ceramics Co., Ltd.
Rm.917-920, No.316 Huanshi Road Central,
Guangzhou, China
FEI# 3005451313

Muriella's Corner

Whatever life throws at us, we blog about it

- [Home](#)
- [Muriella's Corner - Whatever life throws us, we blog about it](#)

Toothpaste recall in USA culprit diethylene glycol

June 28th, 2007

Toothpaste made in China

CNN News this morning - June 28 2007 - has announced the recall of millions of tubes of toothpaste with ingredient diethylene glycol (a sort of anti-freeze).

Muriella's Corner has been on the trail of [diethylene glycol](#) and the toothpaste fiasco for a while now.

At the root of all this is the fact that consumers must be cognizant of what goes into their mouths and the mouths of their children for cleaning and brushing teeth.

Given the flurry and widespread concern at one time regarding [fluoride in toothpaste](#), and now diethylene glycol, [brushing with soap](#) seems a healthy alternative.

↻ 4 Comments | Ⓗ Alliance for a Healthier Generation, [brush with soap](#), [muriella's corner](#), [rocket fuel contaminant](#), [perchlorate](#), [toxic tap water](#), [environment pollution](#), [chemicals in cosmetics](#), [toothpaste recall](#), [antifreeze](#), [toothpaste from china](#), [bone cancer and fluoride](#), [mercury in mascara](#), [bottled water vs tap water](#), [toxic chemicals](#), [chemicals](#), [toxic](#), [health issues](#), [china](#), [Health](#), [toxins](#), [Blog Roll](#), [toothpaste](#), [fluoride](#), [toxicity](#), [pesticides](#), [colgate](#), [Environment](#) | Ⓗ [Permalink](#)
 & Posted by muriella

Diethylene glycol | A Detective Story

June 18th, 2007

On the trail of diethylene glycol

It's happening. Again...

The masked killer/terrorist – **diethylene glycol** - masquerading as glycerin.

The “Federal Detective Agency” (**the FDA**) is on the trail of the mystery of diethylene glycol, a product

<http://muriella.wordpress.com/tag/china/>

2x61
7/15/2007

great for anti-freeze but not for human consumption.

1997 - Haiti

The trail was hot about 10 years ago, in 1997 when it was discovered that tainted glycerin from China used in medicinal children's products and taking the lives of 88 Haitian children.

The mission of the detective work was to learning how diethylene glycol, a syrupy poison used in some antifreeze, ended up in Haitian fever medicine, because an official thought that this information might "prevent this tragedy from happening again".

So far - no traces of records, closed factories, dead end, with no one fessing up nor accepting responsibility.

Diethylene glycol is almost always fatal when consumed by humans, typically leading to acute renal failure. The CDC's National Centre for Environmental Health reported that any formulations intended for oral consumption which may contain or are suspected of containing diethylene glycol should be immediately withdrawn from any possibility of human consumption and reserved for future analysis. According to laboratory analysis performed by the U.S. Centers for Disease Control, diethylene glycol, an ingredient of automobile, i.e. anti-freeze, was found in two samples of liquid acetaminophen called "Afébril" and "Valodon" manufactured locally in Haiti. There is no known antidote.

One of the main reasons for FDA's alarm bells to chime at that time was not necessarily because of the deaths of children Haiti, but, given the proximity of Haiti to the US, the FDA feared that such an event could occur in the US.

Fast forward to 2006 – Panama

About 100 people died in Panama as a result of antifreeze diethylene glycol in consumable products.

China itself suffered about 10 deaths when consumers used diethylene glycol tainted products.

At least five other mass poisonings were documented involving the killer/terrorist chemical in the past two decades — in **Bangladesh, Nigeria, Argentina** and twice in **India**.

In 2007, toothpaste manufactured in China and containing diethylene glycol was found in the United States and seven other countries, prompting tens of thousands of tubes to be recalled.

The chemical was also found in a batch of Chinese-made toothpaste exports in **Nicaragua** about two weeks ago, after which the FDA warned consumers to avoid toothpaste exported from China. Recent information sustained this fear as toothpaste made in China was put on the FDA's list of products recalled. And wait, there's more...

Brands are being hijacked. For example, **Colgate-labelled** toothpaste made in South Africa is sold in five-ounce (100ml) tubes in discount stores in the US.

Officials from Colgate clarified that they do not make or sell toothpaste in that size tube nor do they import toothpaste into the US from **South Africa**.

While the government, companies and other agencies are doing their detective work, what can we do?

Consumers can first of all educate themselves about chemicals in consumer products and seek alternatives - for an alternative to toothpaste [click here](#)

Questionable products have been dumped, are being dumped, and will continue to be dumped overseas in record numbers and volume. Consumers abroad are at increased risk of consuming tainted, outdated products. Local watchdog groups need to be developed to alert the public to this phenomenon, which might be central to any debate on poverty.

Read up on labels, ingredients, be very aware of products manufactured **anywhere**. There seems to be no safe haven for the consumer as regards product integrity.

🔍 2 Comments | 🗨️ Alliance for a Healthier Generation, glycerin, diethylene glycol, antifreeze, muriella's corner, colgate, south africa, panama, haiti, Blog Roll, china | 🔗 Permalink
 📄 Posted by muriella

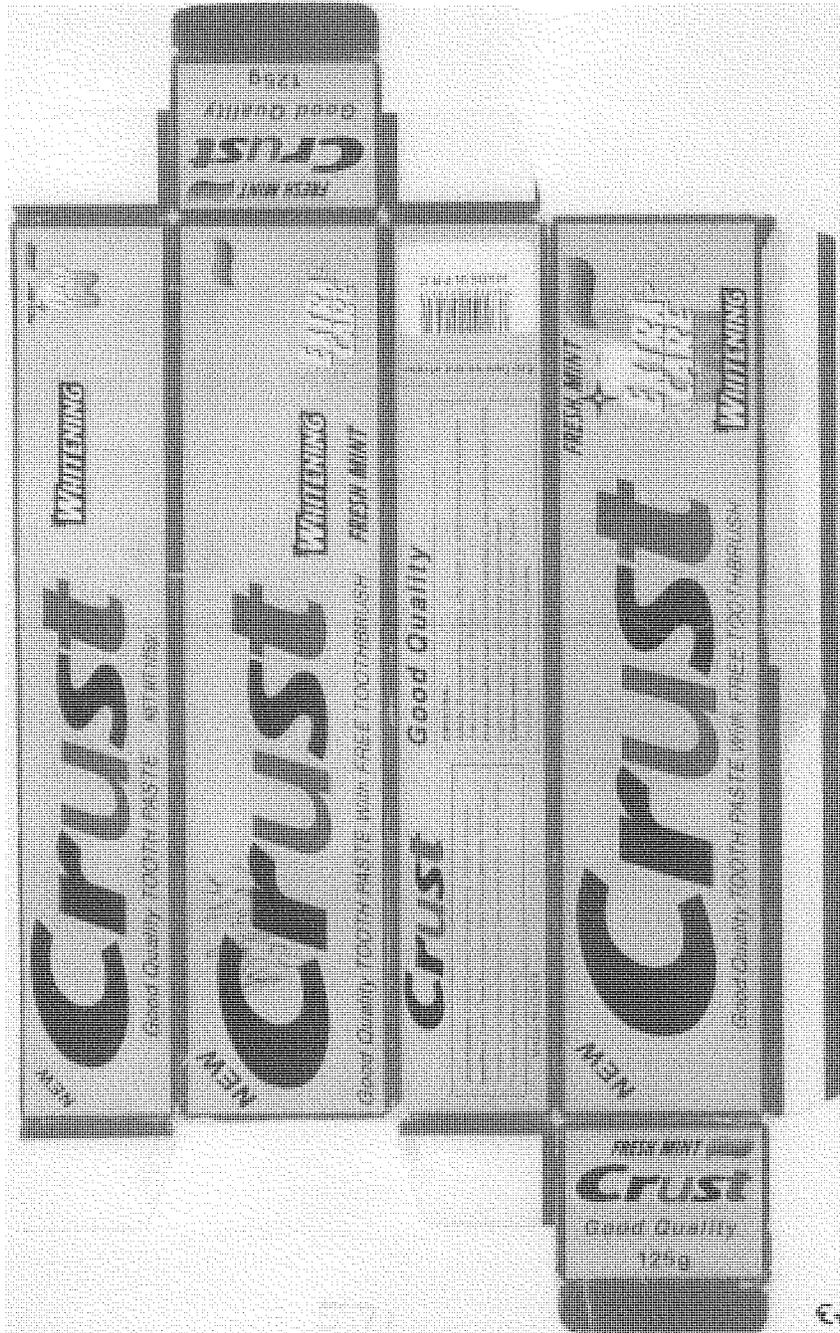
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- [October 2006](#)
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- [March 2006](#)
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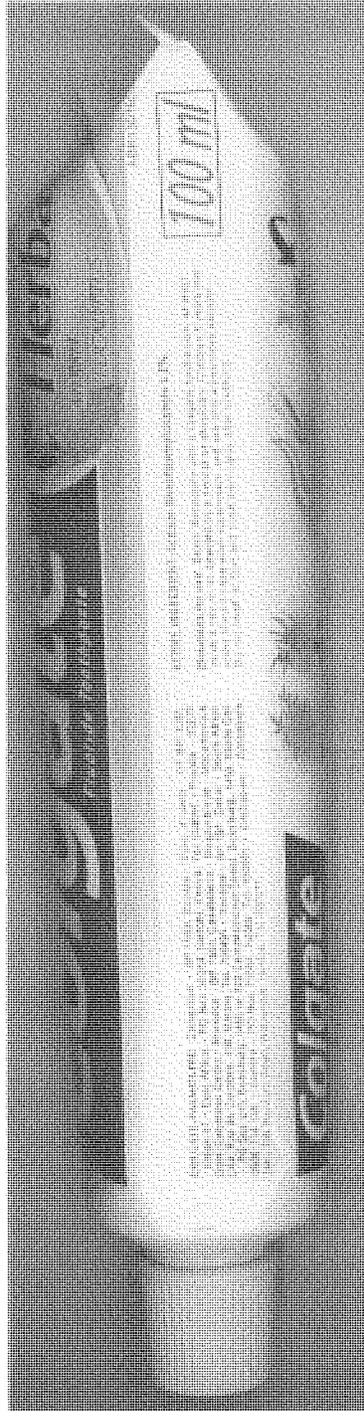
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- [Alliance for a Healthier Generation](#) (4)
- [alternative treatment](#) (4)
- [American Beverage Association](#) (2)
- [antifreeze](#) (2)
- [AP-AOL-Pew Poll](#) (1)
- [apple](#) (1)
- [apple store product red](#) (1)
- [arsenic](#) (1)
- [artesian water](#) (3)
- [artesian well water](#) (3)
- [aryurvedic](#) (1)
- [Asian-Americans](#) (1)
- [asparagus](#) (1)















Michael D. Maves, MD, MBA, Executive Vice President, CEO

September 22, 2006

Ms. Aleta Sindelar
Veterinary Medicine Advisory Committee
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Place
Rockville, MD 20855

Dear Ms. Sindelar:

The American Medical Association (AMA) respectfully submits the following comments for consideration by the Food and Drug Administration's Center for Veterinary Medicine's Veterinary Medicine Advisory Committee (VMAC) regarding the proposed approval of the use of a 4th generation cephalosporin in food animals (cattle) in the United States.

The AMA notes that currently no 4th generation cephalosporins are approved for use in food animals in this country. The AMA is concerned by data that have accumulated on the use of a 3rd generation cephalosporin in food animals. The only 3rd generation cephalosporin approved for use in these animals in the United States is ceftiofur, which is widely used in cattle, chickens, and turkeys, in part because there is no withdrawal time. With the unrestricted use of ceftiofur, data from the National Antimicrobial Resistance Monitoring System (NARMS) indicate that ceftriaxone-resistant *Salmonella* and *E. coli* have emerged and spread in the United States. Ceftriaxone is commonly used for the treatment of severe infections, and the spread of resistance to this agent is therefore of clinical concern. Given the current outbreak of *E. coli* O157:H7 in this country, this increase in resistance is particularly troubling.

The scientific association between the use of ceftiofur in food animals and increased clinical resistance to ceftriaxone is compelling. In the United States, almost all ceftiofur and ceftriaxone resistance is due to a novel AmpC *cmv-2* gene. For many years, ceftiofur has not been used in many countries in Europe, such as Denmark and Sweden, and, indeed, the AmpC *cmv-2* mechanism for resistance to ceftriaxone is rare. However, cefquinome, a 4th generation cephalosporin, is approved for use in food animals in Europe and its use in some

American Medical Association 515 North State Street Chicago Illinois 60610
phone: 312 464 5000 fax: 312 464 4184 www.ama-assn.org

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Ms. Aleta Sindelar
September 22, 2006
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food animals has been associated with dissemination of extended-spectrum beta-lactamase resistance, including cefepime-resistance in humans, due to the production of the novel beta-lactamase, CTM-X, by the resistant bacteria.

While the AMA recognizes that the proposal in question is for use of the 4th generation cephalosporin by injection only and only for "treatment," significant concerns remain. Current technology enables injection of tens of thousands of chickens at one time through injection of the antibiotic into eggs one day prior to hatching, thereby increasing the unnecessary use of the drug. Indeed, this is the current mechanism by which 3rd generation cephalosporins are used in chickens in this country. "Treatment" does not mean the antibiotic is only employed when animals are sick; a veterinarian can choose to use a antibiotic for "treatment" when there is only a threat of infection (that is, as a preventive measure). Thus, while the 4th generation cephalosporin is not intended for use in animal feed at subtherapeutic levels, in the absence of appropriate regulation, it will be administered to a large number of animals, thereby increasing the risk of resistance that will eventually adversely affect public health.

For these reasons, the AMA opposes the use of 4th generation cephalosporins in food animals. Furthermore, if 4th generation cephalosporins are approved for such use, the AMA strongly recommends that public health safeguards be put in place. Minimally, these must include:

1. Enhanced national surveillance to include data on the quantity of 4th generation cephalosporins used in food animals. (Currently, no drug use reporting is available.)
2. Enhanced national surveillance to include monitoring for emergence of the CTM-X mechanisms.
3. Enactment of an extra-label prohibition to ensure that 4th generation cephalosporins are used only according to the label.

Thank you for considering the AMA's concerns.

Sincerely,



Michael D. Maves, MD, MBA



Michael D. Maves, MD, MBA, Executive Vice President, CEO

March 19, 2007

Andrew C. von Eschenbach, MD
Commissioner
Food and Drug Administration
5600 Fishers Lane
Parklawn Building, Room 1471
Rockville, MD 20857

Dear Commissioner von Eschenbach:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express the AMA's concern about the potential approval by the Food and Drug Administration (FDA) of the use of a 4th generation cephalosporin to treat specific bacterial infections in cattle in the United States. Approval of the use of this drug in animals potentially could increase resistance to 4th generation cephalosporins currently used in humans. The AMA previously submitted comments in September of 2006 on this issue to the FDA's Veterinary Medicine Advisory Committee (VMAC). The VMAC voted to reject InterVet Inc.'s request to market cefquinome for use in cattle in the United States. We strongly urge you to follow VMAC's recommendation.

Currently, no 4th generation cephalosporins are approved for use in food animals in this country. The AMA is concerned by data that have accumulated on the use of a 3rd generation cephalosporin in food animals. The only 3rd generation cephalosporin approved for use in these animals in the United States is ceftiofur, which is widely used in cattle, chickens, and turkeys. With the unrestricted use of ceftiofur, data from the National Antimicrobial Resistance Monitoring System (NARMS) indicate that ceftriaxone-resistant *Salmonella* and *E. coli* have emerged and spread in the United States. Ceftriaxone is commonly used for the treatment of severe infections in humans, and the spread of resistance in bacteria to this agent is therefore of clinical and public health concern. Given the recent outbreaks of *E. coli* O157:H7 and *Salmonella* in this country, this increase in resistance is particularly troubling.

The scientific association between the use of ceftiofur in food animals and increased clinical resistance to ceftriaxone is compelling. In the United States, almost all ceftiofur and ceftriaxone resistance is due to a novel AmpC *cmv-2* gene. For many years, ceftiofur has not been used in many countries in Europe, such as Denmark and Sweden, and, indeed, the AmpC *cmv-2* mechanism for resistance to ceftriaxone is rare. However, cefquinome, a 4th generation cephalosporin, is approved for use in food animals in Europe and its use in some food animals has been associated with dissemination of extended-spectrum beta-lactamase resistance, including cefepime-resistance in humans, due to the production of the novel beta-lactamase, CTM-X, by the resistant bacteria.

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Ex 67

Andrew C. von Eschenbach, MD
March 19, 2007
Page 2

While the AMA recognizes that the proposal in question is for use of the 4th generation cephalosporin by injection only and only for "treatment," we continue to have significant concerns. Current technology enables injection of tens of thousands of chickens at one time through injection of the antibiotic into eggs one day prior to hatching, thereby increasing the unnecessary use of the drug. Indeed, this is the current mechanism by which 3rd generation cephalosporins are used in chickens in this country. "Treatment" does not mean the antibiotic is only employed when animals are sick; a veterinarian can choose to use an antibiotic for "treatment" when there is only a threat of infection (that is, as a preventive measure). Thus, while the 4th generation cephalosporin is not intended for use in animal feed at subtherapeutic levels, in the absence of appropriate regulation, it will be administered to a large number of animals, thereby increasing the risk of resistance that will eventually adversely affect public health.

In reviewing an antimicrobial new animal drug application, CVM must determine that the drug is safe and effective for its intended use in the animal. In addition, an antimicrobial new animal drug intended for use in food-producing animals must be shown to be safe with regard to human health (21 CFR 514.1(b)(8)). FDA considers an antimicrobial new animal drug to be "safe" if it concludes that there is reasonable certainty of no harm to human health from the proposed use of the drug in food-producing animals. Based on the data showing the increase in resistance to ceftiofur and ceftriaxone in the United States and the evidence of cefepime resistance in humans associated with the use of cefquinome in food animals in Europe, it is clear that the "reasonable certainty of no harm to human health" standard is not met in this case.

For these reasons, the AMA opposes the use of 4th generation cephalosporins in food animals, and urges the FDA to reject the application for the use of cefquinome in cattle. If 4th generation cephalosporins are approved for such use, however, the AMA strongly recommends that public health safeguards be put in place. Minimally, these must include:

1. Enhanced national surveillance to include data on the quantity of 4th generation cephalosporins used in food animals. (Currently, no drug use reporting is available.)
2. Enhanced national surveillance to include monitoring for emergence of the CTM-X mechanisms.
3. Enactment of an extra-label prohibition to ensure that 4th generation cephalosporins are used only according to the label.

Thank you for considering the AMA's concerns.

Sincerely,



Michael D. Maves, MD, MBA

cc: Stephen F. Sundlof, DVM, PhD

INFORMATION PAPER

April 23, 2007

SUBJECT: FY2006 Financial Summary for the DoD/FDA Shelf-Life Extension Program

1. Background.

a. In January of 1986, an interagency agreement was signed that formed the DoD/FDA Shelf-Life Extension Program (SLEP). The Defense Medical Standardization Board (DMSB) was tasked to provide executive oversight of the program. The program's original focus was to defer drug replacement costs of date-sensitive Pre-positioned War Reserve Stock items by testing and extending their useful product shelf-life.

b. The DMSB Staff Office consolidates all requirements from the SLEP participants and identifies those expiring items that are viable candidates for extension testing by the FDA. If the test results warrant, the FDA grants approval to remark those products with an extended expiration date. The size of the program expanded significantly with the addition the Strategic National Stockpile (SNS) in 2003 and the Department of Veterans Affairs (VA) in 2005.

2. Cost Avoidance for FY-2006.

The table below shows the financial outcome and benefit of the DoD/FDA Shelf Life Extension Program for FY 2006. Note: The cost avoidance figures do not include labor costs from the DMSB or the SLEP participants.

| For FY-2006 | Participants | | | Total |
|----------------------|--------------|-------------|-----------|-------------|
| | Combined DoD | SNS | VA | |
| Cost of Testing (\$) | 518,482 | 898,254 | 100,264 | 1,517,000 |
| Cost Avoidance (\$) | 34,934,242 | 556,814,239 | 5,156,096 | 596,904,577 |

3. Point of Contact.

For additional information from the DMSB Staff Office you can contact: COL Kent Maneval, at (301) 619-4413 or kent.maneval@us.army.mil; or Maj Kevin Wright, at (301)619-4143 or kevin.wright8@us.army.mil.

Major Wright/(301)619-4143
Approved by: COL Maneval

Ex 61

NEWS from CPSC

U.S. Consumer Product Safety Commission

Office of Information and Public Affairs

Washington, DC 20207

FOR IMMEDIATE RELEASE
June 13, 2007
Release #07-212

Firm's Recall Hotline: (866) 725-4407
CPSC Recall Hotline: (800) 638-2772
CPSC Media Contact: (301) 504-7908

RC2 Corp. Recalls Various Thomas & Friends™ Wooden Railway Toys Due to Lead Poisoning Hazard

WASHINGTON, D.C. - The U.S. Consumer Product Safety Commission, in cooperation with the firm named below, today announced a voluntary recall of the following consumer product. Consumers should stop using recalled products immediately unless otherwise instructed.

Name of Products: Various Thomas & Friends™ Wooden Railway Toys

Units: About 1.5 million

Importer/Distributor: RC2 Corp., of Oak Brook, Ill.

Hazard: Surface paints on the recalled products contain lead. Lead is toxic if ingested by young children and can cause adverse health effects.

Incidents/Injuries: None.

Description: The recall involves wooden vehicles, buildings and other train set components for young children listed in the chart below. The front of the packaging has the logo "Thomas & Friends Wooden Railway" on the upper left-hand corner. A manufacturing code may be located on the bottom of the product or inside the battery cover. Toys marked with codes containing "WJ" or "AZ" are not included in this recall.

| Recalled Product Name |
|--|
| Red James Engine & Red James' # 5 Coal Tender |
| Red Lights & Sounds James Engine & Red James' #5 Lights & Sounds Coal Tender |
| James with Team Colors Engine & James with Team Colors #5 Coal Tender |
| Red Skarloey Engine |
| Brown & Yellow Old Slow Coach |
| Red Hook & Ladder Truck & Red Water Tanker Truck |
| Red Musical Caboose |
| Red Sodor Line Caboose |
| Red Coal Car labeled "2006 Day Out With Thomas" on the Side |
| Red Baggage Car |
| Red Holiday Caboose |

<http://www.cpsc.gov/cpscpub/prereq/html/prhtml07/07212.html>

06/13/07

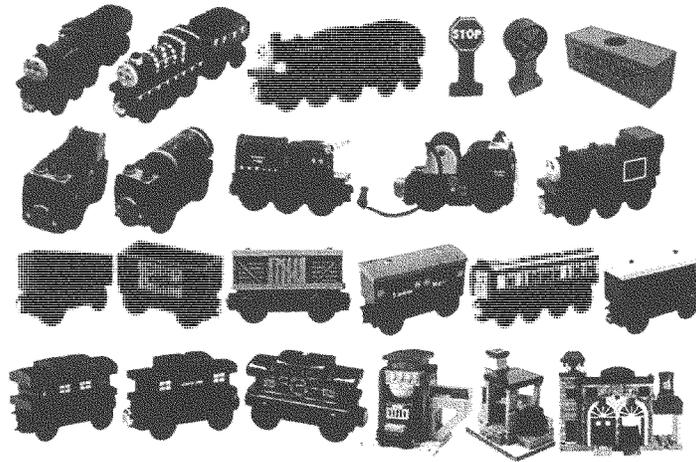
| |
|--|
| Red "Sodor Mail" Car |
| Red Fire Brigade Truck |
| Red Fire Brigade Train |
| Deluxe Sodor Fire Station |
| Red Coal Car |
| Yellow Box Car |
| Red Stop Sign |
| Yellow Railroad Crossing Sign |
| Yellow "Sodor Cargo Company" Cargo Piece |
| Smelting Yard |
| Ice Cream Factory |

Sold at: Toy stores and various retailers nationwide from January 2005 through June 2007 for between \$10 and \$70.

Manufactured in: China

Remedy: Consumers should take the recalled toys away from young children immediately and contact RC2 Corp. for a replacement toy.

Consumer Contact: For additional information, contact RC2 Corp. toll-free at (866) 725-4407 between 8 a.m. and 5 p.m. CT Monday through Thursday and between 8 a.m. and 11 a.m. CT Friday, or visit the firm's Web site at recalls.rc2.com



RC2 Corp. Recalls Various Thomas & Friends™ Wooden Railway Toys Due to Lead Poisoning ... Page 3 of 3

Send the link for this page to a friend! The U.S. Consumer Product Safety Commission is charged with protecting the public from unreasonable risks of serious injury or death from more than 15,000 types of consumer products under the agency's jurisdiction. Deaths, injuries and property damage from consumer product incidents cost the nation more than \$700 billion annually. The CPSC is committed to protecting consumers and families from products that pose a fire, electrical, chemical, or mechanical hazard or can injure children. The CPSC's work to ensure the safety of consumer products - such as toys, cribs, power tools, cigarette lighters, and household chemicals - contributed significantly to the 30 percent decline in the rate of deaths and injuries associated with consumer products over the past 30 years.

To report a dangerous product or a product-related injury, call CPSC's hotline at (800) 638-2772 or CPSC's teletypewriter at (800) 638-8270, or visit CPSC's web site at www.cpsc.gov/talk.html. To join a CPSC email subscription list, please go to www.cpsc.gov/cpscist.asp. Consumers can obtain this release and recall information at CPSC's Web site at www.cpsc.gov.

Congress of the United States
Washington, DC 20515

July 11, 2007

The Honorable Bart Stupak
 Chairman
 House Energy and Commerce Committee
 Subcommittee on Oversight and Investigation
 2125 Rayburn House Office Building
 Washington, DC 20515

The Honorable Ed Whitfield
 Ranking Member
 House Energy and Commerce Committee
 Subcommittee on Oversight and Investigation
 2322A Rayburn House Office Building
 Washington, DC 20515

Dear Chairman Stupak and Ranking Member Whitfield:

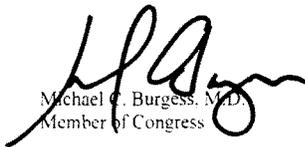
Thank you for your continued oversight regarding a multitude of issues of national concern. In recent months, this Committee has conducted an aggressive investigation regarding a variety of recalled products that could cause serious harm to consumers. Thank you again for your leadership regarding this important safety issue.

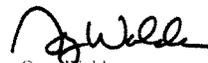
I am sure that you are aware of the most recent consumer product recall, this time involving a children's toy—Thomas the Train. As you probably know, the U.S. Consumer Product Safety Commission (CPSC) issued a recall on June 13, 2007, for the popular Thomas & Friends Wooden Railway toys. According to CPSC's press release, the 1.5 million toys that were recalled had lead contaminated paint, which can cause serious health effects if ingested. Children are prone to place items in their mouths, so it is very likely that many children consumed small doses of lead during the two and half years the products were on the market. For your information, attached is a copy of the CPSC press release.

While the consumption of any amount of lead in children is disturbing, what is equally disturbing is the country of origin of the product. Sadly, Thomas the Train is only the latest in the line of Chinese product recalls: the list also includes melamine laced wheat gluten found in pet food and diethylene glycol laced toothpaste. It's hard to imagine that these "additives" were added by mistake. We strongly urge the leadership of this Committee to conduct an intense investigation regarding the recall of Thomas the Train and other recalled products made in the Republic of China.

Thank you again for your time and consideration regarding this imperative issue. We look forward to further discussing this matter with each of you. As always, if we can be of any assistance, please do not hesitate to contact us.

Sincerely,


 Michael C. Burgess, M.D.
 Member of Congress


 Greg Walden
 Member of Congress



FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA

FDA News

FOR IMMEDIATE RELEASE
July 13, 2007

Media Inquiries:
Michael Herndon, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

Update on Tainted Veggie Booty Snack Food *FDA Testing Confirms Presence of Salmonella Contamination*

The Food and Drug Administration (FDA) today confirmed that a strain of Salmonella Wandsworth bacteria found in Veggie Booty snack food is responsible for the disease outbreak that occurred between March and June 2007.

Epidemiological testing conducted by the Minnesota Agricultural Lab previously implicated Veggie Booty snack food as the source of the outbreak. The results of FDA's own testing added confirmation.

Veggie Booty is marketed by Robert's American Gourmet, of Sea Cliff, N.Y.

FDA continues to advise consumers not to eat any Veggie Booty and to throw away product they have. FDA also advises consumers not to eat Super Veggie Tings Crunchy Corn Sticks, and to throw out any supplies they have, because this product also may be contaminated.

No illnesses have been associated with any other Robert's American Gourmet products.

Salmonella typically causes diarrhea (may be bloody), often accompanied by abdominal cramps and fever. Symptoms typically begin within one to four days after exposure to the bacteria. In infants and persons with poor underlying health and those with weakened immune systems, Salmonella can invade the bloodstream and cause life-threatening infections.

Individuals who have recently eaten Veggie Booty or Super Veggie Tings Crunchy Corn Sticks and who have experienced any of the symptoms described below should contact a doctor or other health care provider immediately. Both products may appeal to children, so parents should be especially vigilant and seek medical care if they observe signs of illness.

The Centers for Disease Control and Prevention (CDC) has identified 60 children from 19 states who have become ill. Six children were hospitalized. There are no reported deaths. States reporting illnesses include: California (seven cases), Colorado (five), Connecticut (two), Georgia (one), Illinois (one), Indiana (one), Massachusetts (four), Minnesota (two), New Hampshire (two), New Jersey (two), New York (15), Oregon (one), Pennsylvania (four), Tennessee (one), Texas (two), Virginia (one), Vermont (three), Washington (four), and Wisconsin (two).

FDA, the States, and CDC are continuing the investigation. Preliminary testing suggests that the seasoning mix used in Veggie Booty may be the source of the contamination. FDA will continue to trace back the ingredients and processing methods used for the seasoning mix, seeing to determine whether the seasoning actually is the source of the problem.

Veggie Booty is sold in a flexible plastic foil bag in four ounce, one ounce and one-half ounce packages. Some gift baskets available for purchase on the internet include Veggie Booty or Super Veggie Tings Crunchy Corn Sticks.

Robert's American Gourmet ceased distributing Veggie Booty and began recalling the product on June 28. The company has also voluntarily recalled all lots and sizes of Super Veggie Tings Crunchy Corn Sticks snack food because the same potentially contaminated seasoning may have been used in making that product, too. In addition, the manufacturer of Veggie Booty and other products for Robert's has ceased production until this investigation is complete. Robert's American Gourmet and its contract manufacturer are fully cooperating with FDA's investigation into the cause of the contamination.

FDA will provide additional updates as the investigation progresses and more information becomes available.

[Wellbaskets.com](http://www.fda.gov/ohrt/tonics/NEWS/2007/NEW01666.html) is Alerting Customers of the Veggie Booty Voluntary Recall Issued on June 28, 2007 by

<http://www.fda.gov/ohrt/tonics/NEWS/2007/NEW01666.html>

Ex 71
7/16/2007



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUN 07 2007

Dear Mr. Chairman:

Thank you for the letters of January 29, February 15, and February 21, 2007. In your letters, you indicated that the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are conducting an investigation into the adequacy of the efforts of the Food and Drug Administration (FDA) to protect the safety of the food supply.

Your letters asked FDA to provide a briefing about recent outbreaks of foodborne illness and other recent incidents involving food contamination. You indicated you may need FDA to provide records subsequent to the briefing to assist with your investigation. As you know, FDA provided a briefing for Committee and Subcommittee staff on February 23, 2007, to discuss the issues raised in your letters. FDA also provided a briefing for Committee and Subcommittee staff on March 28, 2007, per your request, regarding food imports.

At the briefings, your staff requested additional information and documents. With this letter, we are providing the requested information. We have already provided some of this information to your staff. However, for your convenience, we are providing all of the requested information with this response. We have repeated your question or request below in bold type followed by our response.

Follow-up from February 23, 2007 Briefing

The number of food recalls per year for the past ten years

FY1997 - 255;
FY1998 - 219;
FY1999 - 273;
FY2000 - 314;
FY2001 - 319;
FY2002 - 400;
FY2003 - 296;
FY2004 - 293;
FY2005 - 278;
FY2006 - 214;

Ex-72

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Is irradiation approved for leafy greens?

FDA regulations allow fresh produce, including leafy greens, to be irradiated at a dose of up to 1 kGy for the purpose of killing insects (Title 21, *Code of Federal Regulations* [CFR], section 179.26(b)(2)) or for maturation inhibition (21 CFR 179.26(b)(3)) (e.g., slowing sprouting or spoilage). Although doses of this level may be helpful in reducing pathogen load to some extent, higher doses may be required for effective pathogen control in fresh produce. FDA has issued regulations permitting higher doses of irradiation for microbial control in certain foods including raw meat (21 CFR 179.26(b)(8)) and poultry (21 CFR 179.26(b)(6)), shell eggs (21 CFR 179.26(b)(9)), seeds for sprouting (21 CFR 179.26(b)(10)) and molluscan shellfish (21 CFR 179.26(b)(11)). However, leafy greens are sensitive to higher doses of irradiation, which may result in undesirable changes including organoleptic effects (changes in texture, smell, flavor). FDA is currently reviewing a petition (FAP 9M4697) filed on January 5, 2000, (Federal Register/Vol. 65, No. 3/Wednesday, January 5, 2000), to approve irradiation for pathogen control in a wide variety of foods including fresh produce. FDA is currently addressing significant questions raised during review of the petition.

Guidance document on good agricultural practices:

Below are links to the good agricultural practices document as well as links to commodity-specific guidance:

FINAL GUIDANCE FOR INDUSTRY: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (October 6, 1998)
<http://www.foodsafety.gov/~dms/prodguid.html>

DRAFT FINAL GUIDANCE FOR INDUSTRY: Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables (March 12, 2007)
<http://www.cfsan.fda.gov/~dms/prodgui3.html>

GUIDANCE FOR INDUSTRY - Sampling and Microbial Testing Of Spent Irrigation Water During Sprout Production (October 27, 1999)
<http://www.cfsan.fda.gov/~dms/sproug2.html>

GUIDANCE FOR INDUSTRY - Reducing Microbial Food Safety Hazards for Sprouted Seeds (October 27, 1999)
<http://www.cfsan.fda.gov/~dms/sproug1.html>

Commodity Specific Food Safety Guidelines for the Melon Supply Chain 1st Edition (November 7, 2005)
<http://www.cfsan.fda.gov/~dms/melonsup.html>

Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain 1st Edition (May 2006)
<http://www.cfsan.fda.gov/~dms/tomatsup.html>

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Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain 1st Edition (April 25, 2006)

<http://www.cfsan.fda.gov/~dms/lettsup.html>

The categories of food processing facilities FDA inspects fall under the following programs:

- Import acidified and low acid canned foods
- Domestic and imported cheese and cheese products
- Domestic food safety
- Domestic Acidified and Low-Acid Canned Foods
- Import foods-general
- Domestic fish and fishery products
- Import seafood products
- Juice HACCP Inspection Program
- Interstate Travel Program - Conveyances and Support Facilities
- Medical foods – domestic and import
- Infant Formula Program
- Dietary supplements
- Milk Safety
- Molluscan shellfish evaluation

For *E. coli* O157:H7 outbreaks in 2006, what % were related to spinach vs. other foods?

FDA data indicates that there were a total of three *E. coli* O157:H7 outbreaks in 2006. One of these outbreaks involved spinach and the other two involved lettuce.

Inspections that were classified as Voluntary Action Indicated (VAI) or worse each year for the past ten years.

In attachments Tab A and Tab B, please find a compilation of all food firms that were issued Notices of Inspectional Observations (FDA-483s) from October 1999 through April 26, 2007, and whose inspection classifications were indicated as VAI or worse (Official Action Indication or OAI). This information is presented for both FDA (Tab A) and state (Tab B) inspections and was obtained from the Field Accomplishments and Compliance Tracking System (FACTS), which went into effect in FY 2000. The compilation also includes those firms whose inspection classifications were listed as “Referred to State” (RTS). An RTS classification is used when the findings of the inspection were such that any action towards correction should be taken by a state or local authority or another federal authority. Normally, only violative Establishment Inspection Reports (EIRs) are referred to states.

This compilation does not include data going back to February 1997, as requested, because the FACTS database from which this information was obtained does not go back 10 years. While the inspection classifications that are provided are for matters identified as closed, it is possible that a few do not accurately reflect the actual final inspection classification.

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Please note that the attached documents may contain information the disclosure of which is subject to the Federal Food, Drug, and Cosmetic Act, Section 415, Registration of Food Facilities. This provision was added by section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. We would be glad to discuss the protected status of any particular information with the Committee staff.

Are all the warning letters for the past ten years on the web?

FDA strives to post on the FDA website all warning letters sent by its district offices. Some warning letters are issued by FDA’s program centers. Not all of these warning letters are posted; in some cases, only those warning letters that were most frequently requested were posted to the FDA website.

Follow up from March 28, 2007 Briefing

Provide data over the past 5 years on outbreaks linked to imported vs. domestic food.

In Tab C, we have provided the requested data.

The number of samples collected and tested in FDA labs, broken down by lab.

In Tab D, we have provided the requested data.

The number of shipments (or lines) looked at by a reviewer.

| | FY’05 | FY’06 |
|------------------|-----------|-----------|
| Human Food | 6,650,000 | 6,930,000 |
| Animal Food/Feed | 195,500 | 187,000 |

The number of shipments (or lines) physically examined.

FDA defines an import Field Exam as a visual and sensory examination of a product to determine whether it is in compliance with FDA requirements or can be reconciled with existing shipment data. It involves the actual examination of a product for admissibility and regulatory factors such as storage or in-transit damage; accurate product description; inadequate refrigeration; rodent or insect activity; lead in dinnerware; odor; manufacturer verification and labeling compliance. However, an import Field Exam does not ascertain microbiological or chemical contamination and therefore, might be supplemented with other activities, e.g., a laboratory analysis. Import Field Exams and laboratory analyses represent different types of physical examinations. To calculate total physical examinations, FDA adds the number of import Field Exams it conducts to the number of import samples it analyzes since these are considered separate activities.

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Entry Lines Physically Examined

| | FY'05 | FY'06 |
|------------------|---------|---------|
| Human Food | 110,500 | 115,207 |
| Animal Food/Feed | 4,815 | 3,975 |

Provide data for the last 2 years on the number of foreign food inspections and the reasons for the inspections.

In 2005, we did 125 inspections. In 2006, we did 129. (These figures do not include feed.)

Foreign inspections are conducted for a variety of reasons. Some of these are:

- firm was involved with foodborne illness outbreak;
- firm has previous violative inspectional history or other problems;
- firm submitted a process for low-acid canned food products that FDA's Center for Food Safety and Applied Nutrition (CFSAN) believes should be evaluated on site;
- surveillance inspections of firms identified using factors such as risk, volume of products, complexity of processes, etc.

Thank you again for your letters and for your interest in food safety issues. We look forward to continuing to work with you and your staff on these important public health matters. A similar letter has been sent to the co-signers of your letters. A copy of the enclosures has been provided to the Ranking Member of the full Committee.

Sincerely,



Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures