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AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2010

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

ROSA L. DELAURO, Connecticut, *Chairwoman*

SAM FARR, California
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NOTE: Under Committee Rules, Mr. Obey, as Chairman of the Full Committee, and Mr. Lewis, as Ranking Minority Member of the Full Committee, are authorized to sit as Members of all Subcommittees.

MARTHA FOLEY, LESLIE BARRACK, CLIFF ISENBERG, and MATT SMITH, *Staff Assistants*

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Printed for the use of the Committee on Appropriations

PART 4—AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2010

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AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2010

THURSDAY, MARCH 26, 2009.

FOOD SAFETY OVERSIGHT: U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL

WITNESSES

DANIEL R. LEVINSON, INSPECTOR GENERAL
JODI NUDELMAN, REGIONAL INSPECTOR GENERAL, OFFICE OF EVALUATION AND INSPECTIONS, NEW YORK, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
THOMAS E. STENZEL, PRESIDENT AND CEO, UNITED FRESH PRODUCE ASSOCIATION
CRAIG HENRY, SENIOR VICE PRESIDENT FOR SCIENCE AND REGULATORY AFFAIRS, GROCERY MANUFACTURERS ASSOCIATION

OPENING STATEMENT, CHAIRWOMAN DELAURO

Ms. DELAURO. The committee is called to order.

Good morning. And let me thank all of you and welcome you here this morning. And a special welcome to our witnesses:

Daniel Levinson, the Inspector General for the Department of Health and Human Services;

We have Tom Stenzel, President of United Fresh Produce Association, someone who is very familiar with many of us on the subcommittee—we thank you, Tom, it is good to see you back here; I am glad you got through the traffic; and

Craig Henry, Senior Vice President for Science and Regulatory Affairs for the Grocery Manufacturers Association.

Now, Jodi, you tell me your title here because you are at the table here.

Ms. NUDELMAN. I am Regional Inspector General in New York.

The CHAIRMAN. Okay. Lovely. Thank you so much for being here.

I guess we are not sure yet as to when and where and how, but to the Inspector General, thank you, we don't know when the last time was that you appeared before the committee, but we are delighted to have you here.

Mr. LEVINSON. I think this is my first time.

The CHAIRMAN. All right; let's hear it for that. Thank you very, very much.

I want to say thank you again to everyone for taking the time to share your insight and experience. And again, a special thanks

to Tom and Craig, it was short notice, but we are delighted you are here.

My colleagues and I all believe that we have a responsibility on this subcommittee to confront issues of public health and public safety. And when families can no longer trust that the food they eat is safe, government has to respond. We need to be there.

For many years we have fought to reform—and I will make this my own view—a dysfunctional Federal agency, an FDA that is unable to meet its most basic regulatory responsibilities. And our work continues as we strive to provide the resources and the tools in order to effect change.

Today's hearing focuses on a very important tool for combating food-borne illness outbreaks. That is traceability, traceability in the food supply chain, the ability to follow a food product's path back from the store where it was purchased to the place at which the contamination occurred. It is critical to identifying both the source of a potentially dangerous outbreak and the location where contaminated products have been sold and may even be still available.

We were reminded just how important traceability is during last year's salmonella outbreak, originally linked to tomatoes. As we all know, the FDA later turned its attention away from tomatoes, ultimately determining that peppers from Mexico may have been the source of the outbreak, but not before the market for tomatoes shrank dramatically and tomato growers suffered.

And so this outbreak raised some important questions. What if an effective traceability system had been in place? Would the FDA have been able to find peppers as the original source sooner in its investigation, minimize the impact on the tomato industry, prevent needless additional illnesses?

We are going to attempt these questions, review the report on traceability released today by the Office of the Inspector General at the Department of Health and Human Services. The report assesses the traceability of selected food products.

In its examination, the Inspector General's Office was able to trace only 5 of the 40 products through each stage of the food supply chain. What is more, the Inspector General found 59 percent of food facilities failed to meet FDA's requirement to maintain records on their sources, recipients or transporters. The tools were put in place by the 2002 bioterrorism law, yet neither the law nor the implementing regulations gave FDA authority to put a system in place ensuring companies comply with the requirements under the law.

There are other gaps as well. The law exempted farms and restaurants from the recordkeeping requirement. And in moving from the draft rule to the final rule, the Office of Management and Budget exempted foreign facilities completely and significantly limited the kinds of companies required to maintain lot-specific information.

Traceability today simply is not good enough; it is inconsistent, it is unreliable. I think these findings confirm what many in the Congress already believe, that we can do better, that we have a responsibility in the event of a food-borne illness outbreak to effectively find the source of contamination as quickly as possible and prevent further illness, and even death.

To be sure, the Inspector General study involved only 220 facilities. And I want to just say, I am pleased to have this report. I think it is a good beginning; I think it points us in the direction of what we have to try to do, but it involved only 220 facilities.

OMB has estimated that more than 700,000 facilities are subject to the traceability requirements we are discussing today. And yet, while this study is not a valid statistical sample of the entire industry, it provides us with a glimpse into how these requirements are actually being carried out.

In its report, the Inspector General recommends that the FDA seek additional authority, and in fact, the FDA has formally requested some authority related to traceability in its food protection plan. At the same time, traceability has considerable support in the Congress and will likely be included in food safety legislation that moves forward this year.

But also, as we study the Inspector General's findings, I think we also have an obligation to ask whether the FDA could have done a better job with the authority it had. When tomatoes were first suspected as the potential source of last year's salmonella outbreak, I know some growers were frustrated by the Agency's inability to act on what it knew.

I think it is fair to say that the United Fresh Produce Association has been out front on the issue of traceability, and I hope Mr. Stenzel will speak to the issue.

We also look forward to hearing Mr. Henry discuss the Grocery Manufacturers Association's use on traceability.

Mr. Stenzel, Mr. Henry, we value your perspective and your experience as the Congress works to craft legislation, that it does not interfere with the traceability technologies that are already working in the marketplace. I think your testimony will help the subcommittee determine where FDA can best leverage its resources to strengthen traceability systems.

From farm to fork, our food system is vast, it is complicated, and we need to build an effective traceability system. And it is not easy to do. But with the public health at stake, I believe that it is essential, and I believe this subcommittee believes it is essential for us to do.

So I thank all of our witnesses this morning for their participation. I look forward to the testimony. And let me ask our ranking member, Mr. Kingston, if he would like to make an opening statement.

OPENING STATEMENT OF RANKING MEMBER KINGSTON

Mr. KINGSTON. Thank you, Madam Chair. I look forward to the hearing, and I look forward to hearing from these panelists. And particularly, it is good to see Mr. Levinson again; I hadn't seen him in a while. I didn't know he has already been here 4 years, so time does fly.

But two things that I really want to focus on in terms of the traceability debate are, number one, what is the critical safety point in the processing of the food? For example, it might not matter so much where a chicken was raised as much as it is important where it was cooked. We may need to trace back to the very begin-

ning, but maybe we don't. And we should focus on where can you put the most effort and get the most benefit from.

And then the second part of that is, what is the risk benefit? For example, there is going to be some food where it is easy to trace because we are already kind of doing it, but maybe there is no real benefit in it. Or there may be another question as to where is the risk and which foods are riskiest.

I think we should actually cherry-pick certain food groups to say, these are the ones that are the most critical, they seem to have a relationship with food-borne illnesses more than this group. And those are the ones that, from a starting point, we should focus on, rather than try to embrace the whole world of consumption as an initial step.

So those would be my comments. And I will yield back. Thank you.

Ms. DELAURO. Thank you, Mr. Kingston. Let's move to our testimony.

And I will just let our witnesses know that your full statement will be in the record, so feel free to just outline and summarize your comments for the committee, and then we will move to questions and answers.

Mr. Levinson. Thank you.

OPENING STATEMENT, DANIEL LEVINSON

Mr. LEVINSON. Thank you, Madam Chair. I would like to just read a brief summary of my lengthier written testimony, which I would request be made a part of the record.

Good morning, Madam Chair, and members of the subcommittee. I am Daniel Levinson, Inspector General for the U.S. Department of Health and Human Services. I am here today with Jodi Nudelman, our Regional Inspector General for the Office of Evaluation and Inspections in New York.

Recent outbreaks of food-borne illness involving peanut butter, peppers and spinach have raised serious questions about FDA's ability to protect the Nation's food supply. The Office of Inspector General has identified FDA oversight of food, drugs, and medical devices as a top management challenge and has conducted several reviews of FDA's oversight of food safety over the past decade. I appreciate the opportunity to appear before you today to discuss our most recent work on the traceability of the food supply.

In short, we conducted a food traceability exercise and found that only 5 of the 40 products we purchased could be traced through each stage of the food supply chain back to the farm or border.

Several factors limited our ability to trace the remaining products. These factors would also limit FDA's ability to respond quickly and effectively to a food emergency. In addition, many food facilities did not comply with FDA's records requirements, and existing records requirements are not sufficient to ensure traceability. These findings demonstrate that more needs to be done to protect public health and to ensure that FDA has the necessary resources and tools to respond to a food emergency.

Each year, more than 300,000 Americans are hospitalized and 5,000 die after consuming contaminated foods and beverages. In a food emergency, FDA is typically responsible for finding the source

of the contamination and removing unsafe food products from retail shelves. FDA's ability to fulfill its duties largely depends upon whether it can follow a food product's movement through each stage of the food supply chain, a process referred to as traceability.

The food supply chain typically starts on farms and can involve manufacturers, processors, packers, distributors, transporters and retail stores before reaching the consumer. Beginning in 2005, FDA required these facilities, with several exceptions, most notably farms, to maintain records with contact information for all sources, recipients, and transporters.

Additionally, some of these facilities, specifically processors, packers and manufacturers, must also record what is known as lot-specific information to the extent that it exists. Lot-specific information distinguishes one production batch from another, and can be a number or other identifier that is printed on the product. These records help FDA to trace a product through each stage of the food supply chain during a food emergency.

Our review had two objectives. First, we assessed the traceability of 40 selected food products that we purchased from retail stores around the country. Second, we determined the extent to which food facilities maintained the required information about their sources, recipients and transporters. We found that only 5 of the 40 products we purchased could be traced through each stage of the food supply chain. In these five cases, every facility that handled the product was able to link it to lot-specific information in their records.

For 31 of the 40 products, we were only able to identify facilities that likely handled the products. Many of the facilities that handled these products could only estimate a range of deliveries that likely included the product. These estimates may have included more facilities than actually handled the product, or may not have included all of the facilities that handled the product.

For the remaining four products, we could not even identify the facilities that likely handled them. In these cases, at least one facility in the food supply chain failed to provide any information about the potential source of the product. In a food emergency, there could be a serious health consequence if FDA cannot, at a minimum, identify the facilities that potentially handled a contaminated food product.

We identified three factors that limited the traceability of food products. First, food facilities did not always maintain lot-specific information. A few processors did not maintain this information even though they were required to do so. In addition, many other types of facilities did not maintain lot-specific information.

Second, several products did not have lot-specific information on the product or packaging, which is not currently required by the FDA.

Third, a number of facilities mixed raw food products from a large number of farms, a process known as commingling. For example, a single bag of flour we purchased contained wheat from more than 100 farms.

The second objective of our review was to assess facilities' compliance with FDA's requirements to maintain contact information about their sources, recipients and transporters. We found that 59

percent of the food facilities did not maintain this required contact information. In addition, a quarter of the food facilities reported that they were not aware of FDA's requirements to maintain this contact information. Noncompliance with these requirements affects FDA's ability to trace food products through the food supply chain.

Based on these findings, we made six recommendations to the FDA:

One, FDA should strengthen the existing records requirements regarding lot-specific information. Specifically, FDA should seek statutory authority, if necessary, to require processors, packers, and manufacturers to create lot-specific information and maintain it if it does not exist. FDA also should extend the requirements to include facilities that are currently not required to maintain this information.

Two, FDA should consider seeking additional statutory authority to require food facilities to further strengthen food traceability. This could include a variety of approaches, such as requiring facilities to use information technologies to help facilitate recordkeeping.

Three, FDA should work with the food industry to develop guidelines on traceability.

Four, FDA should address issues related to mixing raw food products from a large number of farms.

Five, FDA should seek statutory authority to request facilities' records at any time.

And finally, FDA should conduct education and outreach activities to inform the food industry about its record requirements.

In conclusion, in the event of an outbreak of a food-borne illness, FDA needs to be able to quickly identify the source of a contamination and remove unsafe products from retail shelves. Our review demonstrates that more needs to be done to protect public health and to ensure that FDA has the necessary resources and tools to respond to a food emergency.

We share your commitment to this issue, and we currently have work under way related to FDA's inspections of food facilities and whether facilities register with the FDA. And we have ongoing work as well on FDA's procedures for recalls.

This concludes my oral testimony. I will welcome your questions.

Ms. DELAURO. Thank you very much, Mr. Levinson.

[The information follows:]

Testimony of:
Daniel R. Levinson
Inspector General
Office of Inspector General, U.S. Department of Health and Human Services

Good morning, Madam Chairwoman and Members of the Subcommittee. I am Daniel Levinson, Inspector General for the U.S. Department of Health and Human Services.

Recent outbreaks of foodborne illness involving peanut butter, peppers, and spinach have raised serious questions about the Food and Drug Administration's (FDA) ability to protect the Nation's food supply. The Office of Inspector General (OIG) has identified FDA oversight of food, drugs, and medical devices as a top management challenge, and has conducted several reviews on FDA's oversight of food safety over the past decade. I recognize your leadership on this and other important issues related to FDA and appreciate the opportunity to appear before you today to discuss OIG's most recent work on the traceability of the food supply.

In short, our most recent work, being released today and now available on our Web site at http://oig.hhs.gov, found that only 5 of the 40 products we purchased could be traced through each stage of the food supply chain back to the farm or border. The ability to trace the remaining food products through each stage of the food supply chain was limited because: (1) food facilities often did not maintain lot-specific information, (2) some products were not labeled with lot-specific information, and (3) a number of food facilities mixed raw food products from a large number of farms. In addition, more than half of the facilities that handled these food products failed to meet FDA requirements to maintain records about their sources, recipients, and transporters of food. A quarter of food facilities reported that they were not even aware of these requirements. These factors affect FDA's ability to identify the source of a contamination and remove unsafe food products from the food supply chain.

ROLE AND RESPONSIBILITIES OF OIG

Our office was created in 1976 as the first statutory OIG in the Federal Government. Two years later, the Inspector General Act of 1978 established OIGs at other Cabinet-level departments of the Federal Government, as well as at some independent Government agencies. Congress created OIGs to be independent and objective units within Federal departments and agencies for the purposes of: (1) conducting audits and investigations of programs and operations; (2) coordinating and recommending policies to promote economy, efficiency, and effectiveness in the administration of programs; (3) preventing and detecting fraud and abuse; and (4) keeping the department Secretary or agency administrator and Congress informed about the necessity for corrective action.

To achieve these important objectives, our office reviews programs to identify systemic vulnerabilities; makes recommendations to improve programs' economy, efficiency and effectiveness; investigates instances of potential fraud or abuse and takes appropriate enforcement actions; audits specific payments, providers, and programs to identify and recommend recovery of overpayments; and promotes voluntary compliance by issuing guidance to industry.

1 House Committee on Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies: Hearing March 26, 2009.

BACKGROUND

Each year, more than 300,000 Americans are hospitalized and 5,000 die after consuming contaminated foods and beverages.[1] FDA is responsible for ensuring the safety of about 80 percent of the Nation's food supply, including $417 billion in domestic food and $49 billion in imported food.[2] In a food emergency, FDA's responsibilities include finding the source of the contamination and helping to remove unsafe food products from retail shelves. FDA's ability to fulfill its duties largely depends upon whether it can follow a food product's movement through each stage of the food supply chain, a process referred to as traceability. The food supply chain typically starts on farms and involves many different types of facilities—including processors, packers, distributors, transporters, and retail stores—before finally reaching the consumer.

Beginning in 2005, FDA required facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records.[3] The purpose of these records is to help FDA trace a food product through each stage of the food supply chain if FDA has a reasonable belief that a food product presents a serious health threat. Pursuant to the regulations, these records must include contact information for all sources, recipients, and transporters.[4] Some of these facilities—specifically processors, packers, and manufacturers—must also record what is known as "lot-specific information" to the extent that this information exists.[5] Other facilities—including distributors, storage facilities, and retailers—are not required to record any lot-specific information. Lot-specific information distinguishes one production batch from another; it can be a number printed on the packaging or some other identifier, such as a "best if used by" date. Lot-specific information can help FDA trace a specific batch of food products through each stage of the food supply chain.

PURPOSE OF OUR REVIEW

Our review had two objectives: (1) to assess the traceability of selected domestic food products; and (2) to determine the extent to which selected food facilities maintain information about their sources, recipients, and transporters, as required by FDA. This review provides important information about FDA's ability to ensure the safety of our Nation's food supply. Our findings and recommendations are based on a traceability exercise of 40 selected food products, a review of the records maintained by the food facilities that handled these products, and structured interviews with managers at these facilities. For this exercise, we purchased 40 food products from retail stores around the country.[6] We then requested that each of the facilities that handled these food products provide information

[1] Centers for Disease Control and Prevention, "National Center for Infectious Diseases." Available online at http://www.cdc.gov/ncidod/diseases/food/. Accessed April 16, 2008.

[2] FDA is responsible for ensuring the safety of almost all food products sold in the United States, with the exception of meat, poultry, and some egg products, which are regulated by the U.S. Department of Agriculture.

[3] The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 made a number of significant amendments to the Federal Food, Drug, and Cosmetic Act. One of these amendments, the Maintenance and Inspection of Records provision, stipulates that FDA promulgate regulations to require persons who "manufacture, process, pack, transport, distribute, receive, hold, or import food" to establish and maintain records.

[4] The regulations refer to sources as "nontransporter immediate previous sources," to recipients as "nontransporter immediate subsequent recipients," and to transporters as "transporter immediate previous sources" and "transporter immediate subsequent recipients."

[5] 21 CFR § 1.337(a)(4) and § 1.345(a)(4).

[6] We purchased 10 food products in each of the following four Metropolitan Statistical Areas: New York City, Chicago, San Francisco, and Washington, DC. The products—selected in consultation with FDA officials—included bottled water, ice, milk, eggs, yogurt, flour, oatmeal, tomatoes, leafy vegetables, and juice.

about the products' sources, recipients, and transporters. We used this information to try to trace each product through the food chain back to the farm or border.[7]

Based upon the information we received from the facilities, we categorized the 40 food products into three groups: (1) products that could be traced through each stage of the food supply chain, meaning that every facility that handled the product could provide information that was specific to the product we purchased; (2) products that could not be traced but the facilities that likely handled the products could be identified; and (3) products that could not be traced and the facilities that handled the products could not be identified. Additionally, we determined the extent to which facilities maintained information required by FDA and were aware of these requirements.

TRACEABILITY OF FOOD PRODUCTS

Only 5 of the 40 products we purchased could be traced through each stage of the food supply chain. In these cases, every facility that handled these products was able to link the product we purchased to lot-specific information in their records. In a food emergency, if FDA is able to trace the product through each stage of the food supply chain, then it can more easily pinpoint the source of a contamination and target the products that need to be removed from retail shelves.

For 31 of the 40 products, we were unable to trace these products through each stage of the food supply chain; instead, we were only able to identify facilities that likely handled the products. Many of the facilities that handled these products did not maintain lot-specific information and, as a result, could only estimate a range of deliveries (from one or more facilities) that likely included the product we purchased. These estimates may have included more facilities than those that actually handled the product or may not have included all of the facilities that handled the product. For example, for one product—a bag of flour—the storage facility did not know the exact farms that contributed to the product and, therefore, had to give us information about every farm that provided wheat during the previous harvest season. If FDA is only able to identify those facilities that likely handled a food product, it may not be able to quickly or accurately pinpoint the source of a contamination or target which products need to be removed from the food supply.

For the remaining four products, we could not even identify the facilities that likely handled them. In these cases, at least one facility in the food supply chain failed to provide any information about the potential sources of the products. In a food emergency, there could be serious health consequences if FDA cannot—at a minimum—identify the facilities that potentially handled a contaminated food product.

FACTORS THAT AFFECT TRACEABILITY

We identified three factors that limited the traceability of food products. If FDA encounters any one of these three factors during a food emergency, it would also likely affect how quickly FDA could trace food products through the food supply chain.

First, food facilities did not always maintain lot-specific information. Although processors, packers, and manufacturers are required to maintain lot-specific information, 2 of the 38 in our review did not

[7] Our review only assessed traceability within the U.S. food supply. For eight of the products, the beginning of the food supply chain was a public or private water source. For the purposes of our review, these sources are referred to as farms.

do so. In addition, most distributors, wholesalers, and storage facilities in our review did not maintain lot-specific information. Note that these facilities are not required to do so by FDA; however, the lack of lot-specific information limits the ability to trace food products through each stage of the food supply chain back to the farm or border.

Second, some food products were not labeled with lot-specific information, which is not required by FDA. Six of the products we purchased had no lot-specific information on the product label or packaging. Three of the six products were unpackaged whole tomatoes. Another three of these products—a package of tomatoes, a bag of lettuce, and a bag of ice—were packaged products. None of the facilities that handled these products could link them to lot-specific information in their records.

Third, a number of facilities received and mixed raw food products from a large number of farms—a process known as commingling. For example, a single production batch of flour we purchased contained wheat from more than 100 farms. If this bag of flour were implicated in a foodborne illness, FDA would need to contact more than 100 farms to identify the source of the contamination.

RECORDS REQUIREMENTS

In addition to conducting the traceability exercise, we also assessed compliance with FDA's requirements to maintain contact information about sources, recipients, and transporters.[8] Of the facilities that were required to maintain these records, 59 percent did not maintain the contact information required by FDA about its sources, recipients, and transporters. Facilities reported that they could not provide all of the required contact information for several reasons. In some cases, managers had to look through large numbers of records—many of them paper, as opposed to electronic—for the required information. Additionally, some facilities did not have integrated recordkeeping systems that linked sources and recipients to specific shipments of products, and managers had to search multiple recordkeeping systems for the required information. In addition, a quarter of the food facilities reported that they were not aware of FDA's records requirements. A lack of compliance with these records requirements affects FDA's ability to trace food products through the food supply chain.

RECOMMENDATIONS

Based on these findings, we made six recommendations to FDA to improve traceability of the food supply. We recommended that FDA:

- Seek statutory authority, if necessary, to strengthen the existing records requirements regarding lot-specific information. Specifically, FDA should require processors, packers, and manufacturers to create lot-specific information—and maintain it—if it does not exist. FDA also should extend the requirements to include facilities that are currently not required to maintain this information.

- Consider seeking additional statutory authority to require food facilities to further strengthen the traceability of food products. This could include a variety of approaches such as requiring facilities that handle food products to maintain records about every facility or farm

[8] These requirements apply to facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food.

that handled the product, or requiring facilities to use certain information technologies to help facilitate recordkeeping.

- Work with the food industry to develop guidance on traceability.
- Address issues related to mixing raw food products from a large number of farms.
- Seek statutory authority to request facilities' records at any time, as opposed to its current authority to request records only when FDA has a reasonable belief that an article of food presents a serious health threat. With this added authority, FDA could verify that facilities are complying with its records requirements during its food facility inspections.
- Conduct education and outreach activities to inform all segments of the food industry about its records requirements.

CONCLUSION

In conclusion, the traceability of food products and the ability of food facilities to provide information about their sources, recipients, and transporters are essential to ensuring the safety of our Nation's food supply. In the event of an outbreak of a foodborne illness, FDA needs to be able to quickly identify the source of a contamination and remove unsafe products from retail shelves. Our review found that several factors limit traceability and that a significant proportion of food facilities are not in compliance with FDA's records requirements. We also found that these requirements are not sufficient to ensure traceability. Taken together, these findings demonstrate that more needs to be done to protect public health and to ensure that FDA has the necessary resources and tools to respond to a food emergency.

OIG recognizes the importance of ensuring the safety of the food supply and will continue our work in this area. We are currently conducting a review that assesses the extent to which food facilities have registered with FDA, as required. We are also reviewing FDA's inspections of food facilities and the extent to which FDA follows up on violations. Finally, we are conducting several audits evaluating FDA's authority and procedures for recalls.

This concludes my testimony. I welcome your questions.

5 House Committee on Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies: Hearing March 26, 2009.

Ms. DELAURO. Tom Stenzel.

OPENING STATEMENT, TOM STENZEL

Mr. STENZEL. Thank you very much, Madam Chairwoman. Thank you for holding this hearing today on the important issue of traceability for the entire food industry.

I think all of you on the committee know of our industry's call for mandatory Federal oversight of produce safety standards, and I assure you today that we feel the same way about traceability. It is an important cornerstone of our food safety efforts.

Let me mention three specific areas this morning: first, the general state of traceability today in the produce industry; secondly, major initiatives that we now have under way to build more streamlined whole-chain traceability; and finally, share some brief recommendations for the Congress and FDA moving forward.

Traceability of fresh produce is a very complex and expensive undertaking, linking multiple partners in a sometimes long supply chain. Each company is responsible for maintaining the information required to comply with the Bioterrorism Act, mandating one step up and one step back. But just to give you a sense of the enormity of that effort, we estimate that six billion cases of fresh produce a year are shipped in the United States.

I think it is best to look at produce traceability in three groups: individually packaged produce that often carries a UPC code, bulk produce in its original carton, and then bulk produce that may have been repacked or commingled with other lots for product quality.

With prepackaged produce, such as fresh salads, a bag of fruit or cut vegetables in a package, UPC codes serve as the product identifier, linking back to specific codes identifying the product source. We are unaware of any instances in which public health investigators having a package in hand have been unable to quickly and efficiently reach the company that packaged the product.

Bulk produce poses a different challenge in that the produce is often removed from the original carton for final display and consumer sale. For those products, recordkeeping by the retail establishment or the food service company that has dropped that product at a specific restaurant is required to begin linking an individual produce commodity back down the chain.

Finally, bulk produce is sometimes repacked between the farm and final consumer destination. Because produce commodities are likely to be of different sizes, colors, shapes, and stages of ripeness, repackers play an important role in our industry in sorting the highest quality produce very close to its final consumer destination.

Most frequently today, individual lot integrity is maintained during this sorting process, but there are times when different lots of produce must be mixed for product quality, and outgoing cases are still expected to carry information that is traceable to the incoming different produce lots that have gone into that single case.

The industry is fully committed to one up, one down requirements of the Bioterrorism Act, and we have repeatedly urged FDA to enforce this law. I am particularly pleased and interested in reading the Inspector General's report today, as this is precisely the type of analysis that we need conducted before an outbreak,

that can help us focus on the areas where individual operators need to improve in their own traceability systems.

In a similar initiative last summer, investigators from the Energy and Commerce Committee, Oversight and Investigation Subcommittee, conducted several real-world trace-backs, tracing tomatoes from a restaurant that was picked randomly out of a phone book. They were amazed at the results. They were able to get back to the original farm source within a matter of hours.

Next, let me talk about some of the exciting new initiatives that are under way in the produce industry to take traceability another step forward. More than a year ago, our association joined with industry partners to develop a common, industry-wide framework to standardize case coding for all produce sold in the United States.

While today most companies have the ability to track one up, one down in their own systems, the adoption of a standardized coding system across our industry will connect each stage more quickly and efficiently. Every case of produce will be labeled with a global trade item number, called a GTIN, which identifies the originator of the case and the type of product inside. It will also carry a lot number specifically identifying the produce, including its packing or harvest date. Labels will carry a bar code with this information which each member of the supply chain will be able to scan so that the information can be stored and readily available.

Adoption of these standards is now in motion; it is not just an idea. With commitments from retailers, wholesalers, and produce growers across the chain, we are promoting this initiative through a new Web site, *producetraceability.org,* numerous industry meetings; and, in fact, we are building a 10,000-square-foot produce traceability demonstration center at our association's upcoming annual convention to help the industry begin to adopt these practices.

One last item I would mention in the emerging technology area is what is called the GS–1 data bar, an electronically readable code small enough to even fit on a fruit or vegetable sticker. I brought several examples of those and include one in my testimony.

You will begin to see in your store now on this little sticker that has the price look-up number——

Ms. DELAURO. Man, after my own heart with a green pepper. If you cook that with sausage, it is very good.

Mr. STENZEL. Madam Chair, I will leave this for you after the hearing.

These codes are going to be very helpful to us in the emerging technology area.

Ms. DELAURO. All the information is on that little sticker? Can you pass that up?

Mr. STENZEL. Sure.

The information that is contained on these codes today includes the company or the packer who originates it. The codes are not actually big enough to include the lot number, so that is an important point for us in new technology development, but it is going to be a step forward in the ability to track exactly where that piece of produce came from.

We are also early in the stage of adoption at the retail level. Most retailers cannot actually scan that data yet. They need a new generation of scanning technology at the checkout line. But I think

that does lead me to my final point and recommendations for the committee and Congress.

One is to look at the ability of technology to help us in this effort. First, please look at the unique aspects of tracking bulk fresh produce. We are certainly going to be different from other sections in the food industry. We are likely to find that overly prescriptive mandates from the top down are not as likely to be as effective as efficiencies from the bottom up in the industry, the new technologies that we are talking about here. We believe that we are on the right course with the produce traceability initiative I have discussed, and we ask that Congress set the goal that we need to achieve, not mandate the process.

Secondly, I would ask the committee to consider ways of assisting in meeting the cost of traceability requirements. While larger companies may adopt these technologies on their own, it is essential that cost burdens do not prevent all companies from adopting these protocols.

Third, let me suggest that the FDA engage in more practical, hands-on traceability exercises just as the IG has done here. Our industry stands ready to cooperate with the committee, the FDA, the IG, and any others, in doing mock trace-back exercises on an ongoing basis.

Fourth, I recommend that we urge FDA to enforce the current law before we completely call it a failure. If, in an outbreak situation, FDA finds companies not in compliance, then take action, take highly visible action. That is what signals the importance of proper behavior to those in any industry who might be inclined to cut corners.

Finally, Madam Chair, I need to share a little frustration with you, as I am sure you anticipate. But the enhancements we are talking about today would not have prevented the anxiety of last summer's salmonella outbreak. This past summer, we saw what could only be called a "wild goose chase" or, rather, a "wild tomato chase." For weeks and weeks, officials blamed the slow search on the lack of traceability.

We now know the problem was we were searching for the wrong product. In reality, FDA was able to trace tomatoes back to the farm, the only problem was those trace-backs kept pointing to different farms. FDA called that inconclusive, but we now know better. Trace-back was conclusive, and it showed that there was no common point where all of those tomatoes could have been contaminated. Trace-back worked, it just didn't confirm the original hypothesis.

Once jalapenos were identified as the real culprit, Minnesota health officials quickly traced the peppers back, from a small restaurant in Minneapolis to a food service distributor, to a tiny wholesaler in Texas, and a farm 500 miles south of the Mexican border. The Minnesota investigators were quoted as saying, "It took a few phone calls, and you can work it fairly quickly back to the grower."

Now, I know our industry is far from perfect in our ability to track product, and we want to understand the gaps; but that description more closely resembles the industry I know today. We are capable of tracking most produce one step up and one step back,

but just as importantly, we are committed to streamlining and expediting that process just as fast as we can. Thank you.

Ms. DELAURO. Thank you very much, Mr. Stenzel.

[The information follows:]

Prepared Statement

Thomas E. Stenzel
President and CEO
United Fresh Produce Association
Washington, DC

Before the
U.S. House of Representatives
Committee on Appropriations

Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies

March 26, 2009

Good morning Chairwoman DeLauro, Ranking Member Kingston, and Members of the Subcommittee. My name is Tom Stenzel and I am President and CEO of the United Fresh Produce Association. Our organization represents more than 1,500 growers, packers, shippers, fresh-cut processors, distributors and marketers of fresh fruits and vegetables accounting for the majority of produce sold in the United States. We bring together companies across the produce supply chain from farm to retail, including all produce commodities, both raw agricultural products and fresh ready-to-eat fruits and vegetables, and from all regions of production.

Thank you for holding this hearing to bring attention to the challenges and progress needed in the area of food traceability as one of the cornerstones of our nation's overall food safety system. As I've testified before your committee in the past, the fresh produce industry is committed to providing consumers with safe and wholesome foods, and we are committed to being part of the solution to the food safety and traceability challenges we all face together. Madam Chairwoman, you know personally of our call more than two years ago for a strong system of mandatory federal oversight of food safety standards for fresh produce. We have worked hard toward that end with this committee, other committees in the House and Senate, and with leaders of the Department of Health and Human Services and the Department of Agriculture.

As today's hearing is focused broadly on food traceability, let me discuss three issues with specific regard to the fresh produce industry.

1. The general state of traceability in the produce industry today, and compliance under the Bioterrorism Act;
2. Major initiatives now well underway within our industry to build streamlined, whole-chain traceability for produce; and finally,
3. Some brief thoughts on what may be most appropriate for Congress and FDA moving forward.

Let me begin with this – just as our industry is committed to providing consumers the safest possible foods, we are also committed to ensuring our ability to track fresh produce from the retail store or restaurant back to the farm.

Traceability of fresh produce is a complex and expensive undertaking, linking multiple partners in a sometimes long supply chain. Each company is responsible for maintaining information required to comply with the Bioterrorism Act, mandating 'one-step-up' and 'one-step-back' tracking of all foods. Their efforts collectively serve to link the produce supply chain from one point to another. Just to give you a sense of the enormity of this effort, we estimate that 6 billion cartons of fresh produce a year are shipped in the United States.

I think it's best to look at produce traceability in three groups – individually packaged produce most often carrying UPC codes; bulk produce in its original carton; and bulk produce that is repacked and may be commingled with other lots for product quality.

With prepackaged produce such as bagged salads, a bag of apples, or mixed vegetables, UPC codes serve as the product identifier, linking back to specific lot codes identifying the product's source. We are unaware of any instances in which public health investigators, having a package in hand, have been unable to quickly and efficiently reach the company that packaged the product and obtain information about the product's component ingredients.

Bulk produce poses a different challenge, in that produce is often removed from the original carton for final display and consumer sale. For these products, record-keeping by the retail establishment, or foodservice company that has dropped product at specific restaurants, is required to begin linking an individual produce commodity back down the chain.

Finally, bulk produce is sometimes repacked between the farm and final consumer destination to maintain quality standards. Because some produce commodities are likely to be of different sizes, colors, shapes and stages of ripeness, repackers play an important role in sorting the highest quality produce by size, color, shape, etc. close to the final consumer destination. Most frequently today, individual lot integrity is maintained during this sorting process. But even when different lots of produce are mixed, repackers are still expected to label the outgoing cases with lot code information that is internally traceable to the different produce lots used in that case. For example, in the tomato industry's *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain*, recommendations specify that "if incoming lots are mixed/commingled, then documentation shall be maintained to identify all included sources."

The industry is fully committed to the one-up, one-down requirements of the Bioterrorism Act, and has repeatedly urged FDA to rigorously enforce this law if they find companies out of compliance. However, we know of no instances where FDA has taken any regulatory action to cite a produce company or its customers for failure to provide adequate records as required by the Act.

I am particularly interested in reading the Inspector General's report today, in hope that this work does identify any needed areas of improvement. Just last summer, investigators from the Energy and Commerce Oversight and Investigation Subcommittee conducted several real-world tracebacks selecting tomatoes from a restaurant at random. They actually picked the restaurant out of the phone book so as not to be "set up" by industry in doing this test. They were amazed at the results – they were able to get back to the original farm source within a matter of hours.

But, honestly, we do know that there is diversity in traceability sophistication among produce facilities, just like in other sectors across the food industry. The IG's research provides precisely the type of analysis we need – conducted before an outbreak investigation – that can help us focus on the areas where individual operators can improve in their own traceability systems.

Next, let me talk about initiatives under way in the produce industry to take traceability another huge step forward.

More than a year ago, our association joined with industry partners at the Produce Marketing Association and Canadian Produce Marketing Association to launch an initiative to build a common framework and standardized coding for carton labeling of all produce sold in the United States. Our mandate was to develop an industrywide system and action plan to drive streamlined connectivity across the supply chain. While today most companies have the ability to track one-up, one-down in their own systems, the adoption of standardized coding across our industry will connect each stage more quickly and efficiently, not only for food safety tracking but for business process management.

Whole-chain connectivity is based on two pieces of information that will be labeled on every case of produce: (1) a Global Trade Item Number (GTIN), which will identify who the originator of the case is and the type of product that is inside, and (2) a lot number specifically identifying the produce, including its packing or harvest date. This information will be labeled on each case so that the numbers may be read and understood universally throughout the supply chain. Labels will also carry a barcode, which each member of the supply chain will be able to scan so that the information can be stored.

Adoption of these standards is now in motion, and complete details on this initiative can be found on our website www.producetraceability.org. As an example of our efforts to drive widespread industry adoption, our association will feature a 10,000 sq.ft. Produce Traceability Demonstration Center at our upcoming annual convention next month, complete with more than a dozen vendors offering technology solutions and teams of experts to help companies learn how to adopt these standards in their own operations.

One last item I would mention in the new technology area is the increasing use of what's called the GS1 databar, an electronically readable code reduced for size to even fit on a fruit or vegetable sticker. If you've ever wondered why all those stickers are on produce, they carry a four-digit code number that cash register clerks type in to ensure that the register rings up the correct price. While most retail check-out systems cannot yet scan these new databar symbols, the adoption of this new technology is growing, and will thus lead to even greater item-level traceability. For much of our individually stickered produce, we will be able to scan this little code and tell you the farm and specific lot this produce came from.

Actual Size

That leads me to my final point – what should Congress and the FDA be doing to help advance traceability?

First, as you weigh various traceability provisions of all the food safety bills under consideration by Congress, I ask you to look at the unique aspects of tracking bulk fresh produce. We are likely to find that overly prescriptive mandates from the top down are not as likely to be as effective as bottom up efficiencies and systems designed for unique challenges. That's what we believe we have achieved in the Produce Traceability Initiative.

I would ask the Committee to support our efforts in this regard, rather than create a different model. Allow industry innovation similar to what I've shared here to flourish. We suggest that Congress should set the goal, not mandate the process.

Second, I ask the committee to consider some way of supporting the cost of traceability requirements in a similar vein to the cost of food safety requirements. It is essential that cost burdens do not prevent companies from adopting either food safety or traceability protocols. Perhaps funds to support implementation of traceability systems will be just as important in meeting our goals as the mandates of legislation.

Third, let me suggest that the FDA engage in more practical, hands-on traceability exercises with industry, just as the Inspector General has done. We don't want to learn of any weaknesses in an outbreak; we need to learn now, and correct any weaknesses ahead of a crisis. Our industry stands ready to cooperate with this Committee, the FDA, the IG and any others in mock traceback exercises at anytime.

Fourth, I recommend that we urge FDA to enforce the current law before we all call it a failure. If in an outbreak situation FDA finds companies not in compliance, then take action. Take highly visible action. That's what signals the importance of proper behavior to those in any industry who might be inclined to cut corners. And, if FDA needs additional authority to ensure that companies are in compliance before an outbreak, that should be part of the solution.

Finally, I need to close with some comments about traceback investigations in general. Madam Chair, I apologize in advance that I am now sharing my frustrations with you. None of the enhancements to traceability that we've talked about today would have prevented the weeks and weeks of anxiety consumers and industry alike experienced last summer during the Salmonella outbreak.

This past summer saw what can only be called a wild goose chase – or perhaps a "wild tomato chase" – go on for weeks and weeks, while officials blamed their slow search on a lack of traceability. We all know now they were simply searching for the wrong product.

In reality, traceback of tomatoes was working effectively last summer, as FDA in fact was able to trace tomatoes eaten by sick consumers back to the farm. The only problem was those tracebacks kept pointing to different farms. The evidence of multiple tracebacks showed there was no common point where all of these tomatoes could have been contaminated, whether at the farm or in repacking at the wholesale level. Traceback worked; it just didn't confirm the original false hypothesis.

One of the more interesting developments in this outbreak investigation was the report from Minnesota health officials that once they identified jalapenos as the real culprit, not tomatoes, they were quickly able to trace the peppers back from a small restaurant in Minneapolis, to the distributor, a tiny wholesaler in Texas, and a farm 500 miles south of the Mexican border. The Minnesota investigator is quoted as saying, it takes "a few phone calls and you can work it fairly quickly back to the grower."

I assure you we are far from perfect in our ability to track product, but that description more closely resembles the industry I know today. We *are* capable of tracking most produce one-step up and one-step back today.

And we are committed to streamlining and expediting that process just as fast as we can.

Ms. DELAURO. Mr. Henry.

OPENING STATEMENT, CRAIG HENRY

Mr. HENRY. Thank you, Madam Chairwoman, and the members of the subcommittee, for allowing me to testify today.

My name is Craig Henry. I am the Senior Vice President and Chief Operating Officer for the Science and Regulatory Affairs Division of the Grocery Manufacturers Association. I have over 30 years of experience in manufacturing operations and related food safety programs, which includes traceability.

As stated earlier, Americans enjoy one of the safest food supplies in the world, but food and beverage companies recognize that steps must be taken to make our food supply even safer. Ensuring the safety of our products and maintaining the confidence of consumers is the single most important goal of the food and beverage industry today and going forward.

Product safety is the foundation of consumer trust, and our industry devotes enormous resources to ensure that our products are safe. Our industry strongly supports efforts to continually improve the safety of America's food supplies and urges the subcommittee to continue to make the prevention of contamination the foundation of our Nation's food safety strategies.

Recommendations that we have are as follows:

One, increase FDA food-related spending. GMA, and the members that it represents, strongly supports proposals to increase FDA food-related spending to rebuild FDA scientific and regulatory capacity.

We applaud the subcommittee for providing FDA with the critical resources in the 2009 fiscal year Omnibus Appropriations bill, and urge you to provide a comparable increase for food-related activities in the subsequent fiscal year of 2010.

Regarding food safety plans, certainly GMA strongly supports proposals in House and Senate legislation requiring every food company manufacturing food for the U.S. market to conduct an evaluation of food safety risks that identifies potential sources of contamination, identifies appropriate food safety controls, and documents those controls in their food safety plan.

We should require foreign supplier safety programs and build foreign capacity. GMA strongly supports proposals in both the House and Senate legislation to build the capacity of foreign governments to regulate food safety and to require every food importer to police their foreign suppliers. In particular, we support proposals to require that food importers document the food safety measures and controls being implemented by their foreign suppliers, and to require foreign importers to make a foreign supplier food safety plan available to FDA.

On fruits and vegetables, again, we support proposals to give FDA the power to establish Federal safety standards for certain fruits and vegetables when science and risk demonstrate that standards are needed. FDA should be permitted to work with States and to tailor standards to meet local growing conditions and to ensure that those standards are met.

On risk-based inspection, GMA strongly supports House and Senate legislation to focus domestic and foreign inspections on fa-

cilities that pose the greatest risk of contamination that could result in food-borne illness or injury. To focus scarce resources, FDA should permit expedited entry for imports that pose no meaningful risk.

On traceability, government and industry should work collaboratively to identify and address gaps in our current traceability system, including measures that will ensure that responsibility for traceability is shared throughout the supply chain, measures that will improve the interoperability of current and future traceability systems, and that are built upon and encourage industry innovation. In particular, GMA strongly supports the House and Senate proposals to develop and test promising new traceability systems through pilot programs in the produce sector.

Lastly, on authorization of mandatory recalls, GMA strongly supports proposals in the House and Senate legislation to give FDA the authority to order a mandatory recall when a company producing FDA-regulated products has refused to conduct a voluntary recall and there is a significant risk to public health. Specifically, where the responsible party refuses to voluntarily recall a product for which there is a reasonable probability that the food will cause serious adverse health consequences or death, the Secretary of Health and Human Services should be permitted to order an FDA-regulated company to recall immediately.

GMA applauds your efforts to seek swift and lasting improvements to our food and safety system. We look forward to working with you to continually improve the safety of America's food supplies.

I would be pleased to entertain any questions.

Ms. DELAURO. Thank you very much.

[The information follows:]

Testimony of Dr. Craig Henry
Senior Vice President for Science and Regulatory Affairs
Grocery Manufacturers Association

Before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies

Of the House Committee on Appropriations

On "Food Safety Oversight"

March 26, 2009

Thank you for the opportunity to testify. My name is Craig Henry and I am the Senior Vice President for Science and Regulatory Affairs for the Grocery Manufacturers Association (GMA). I have over 30 years experience in manufacturing operations and related food safety programs such as traceability.

Americans enjoy one of the safest food supplies in the world, but food and beverage companies recognize that steps must be taken to make our food supply even safer. Ensuring the safety of our products – and maintaining the confidence of consumers – is the single most important goal of the food and beverage industry. Product safety is the foundation of consumer trust, and our industry devotes enormous resources to ensure that our products are safe.

Our industry strongly supports efforts to continually improve the safety of America's food supplies and urges the Subcommittee to continue to make the prevention of contamination the foundation of our nation's food safety strategies.

Recommendations:

- **Increase FDA food-related spending.** GMA strongly supports proposals to increase FDA food-related spending to rebuild FDA's scientific and regulatory capacity. We applaud the Subcommittee for providing FDA with critical new resources in the FY

2009 omnibus appropriations bill and urge you to provide a comparable increase for food-related activities in FY 2010.

- **Require Food Safety Plans.** GMA strongly supports proposals in House and Senate legislation to require every food company manufacturing food for the US market to conduct an evaluation of food safety risks that identifies potential sources of contamination, identifies appropriate food safety controls, and documents those controls in a food safety plan.

- **Require Foreign Supplier Safety Plans and Build Foreign Capacity.** GMA strongly supports proposals in House and Senate legislation to build the capacity of foreign governments to regulate food safety and to require every food importer to police their foreign suppliers. In particular, we support proposals to require that food importers document the food safety measures and controls being implemented by their foreign suppliers, and to require food importers to make a foreign supplier food safety plan available to FDA.

- **Regulate Fruits and Vegetables.** GMA strongly supports proposals to give FDA the power to establish federal safety standards for certain fruits and vegetables – when risk and science demonstrate that standards are needed. FDA should be permitted to work with states to tailor standards to meet local growing conditions and to ensure that standards are being met.

- **Adopt a Risk-Based Approach to Inspections.** GMA strongly supports proposals in House and Senate legislation to focus domestic and foreign inspections on facilities that pose the greatest risk of contamination that could result in foodborne illness or injury. To focus scarce resources, FDA should permit expedited entry for imports that pose no meaningful risk.

- **Improve Traceability Systems.** Government and industry should work collaboratively to identify and address gaps in our current traceability system,

including measures that will ensure that responsibility for traceability is shared throughout the supply chain, measures that will improve the interoperability of current and future traceability systems, and that which build upon and encourage industry innovation. In particular, GMA strongly supports House and Senate proposals to develop and test promising new traceability systems through pilot programs in the produce sector.

- **Authorize Mandatory Recalls.** GMA strongly supports proposals in House and Senate legislation to give FDA the authority to order a mandatory recall when a company producing FDA-regulated products has refused to conduct a voluntary recall and there is a significant risk to public health. Specifically, where the responsible party refuses to voluntarily recall a product for which there is a reasonable probability that the food will cause serious adverse health consequences or death, the Secretary of Health and Human Services should be permitted to order an FDA-regulated company to conduct a recall.

GMA applauds your efforts to seek swift and lasting improvements to our food safety system and look forward to working with you to continually improve the safety of America's food supplies.

Ms. DELAURO. Thank you all for your testimony. And let me just ask a couple of questions if I can.

I am going to start, if I can, Mr. Levinson, with the recommendations. I will ask our other two panelists to comment as well, because I am going to try and make my way in a number of rounds to deal with the recommendations and see where we go.

Excuse my voice, I have laryngitis. It is been about a week now. So, in any case, it is a little squeaky.

The first recommendation that is made is that FDA should seek statutory authority, if necessary, to strengthen existing requirements related to lot-specific information, specifically, to require processors, packers, manufacturers to create and maintain lot-specific information and extend it to all entities not required to maintain this information.

Now, to be clear, you are recommending that lot codes be mandated for all products and that all persons be required to maintain those codes for all products under FDA's jurisdiction. Is that correct?

LOT SPECIFIC INFORMATION

Mr. LEVINSON. We are talking about lot-specific information with a recognition that lot-specific information may, in terms of the technology, involve a variety of approaches. And I would ask my colleague, Jodi, to talk more about that.

Ms. NUDELMAN. The other thing, from the study, we are not making any comments about farms. So in our study, we are saying, to extend the requirement to keep lot-specific information to distributors, wholesalers, storage facilities, and the retailers. But from the extent of our study, we could not make any comments on farms.

Ms. DELAURO. Or foreign entities?

Ms. NUDELMAN. Correct. That was the limitation to our study. We traced these 40 products back to the border or to the source, and it did not include any foreign entities.

Ms. DELAURO. Restaurants were exempted as well; is that right?

Ms. NUDELMAN. Correct.

Ms. DELAURO. So it is restaurants, farms, and the foreign facilities?

Ms. NUDELMAN. Correct. We cannot speak from them.

STATUTORY AUTHORITY

Ms. DELAURO. Let me ask you this question. Why do you suggest that statutory authority might be needed for this? Did FDA suggest that to you? And for what parts of the proposal do you think legislative authority would be needed?

I ask this because you are talking about statutory authority, again versus regulatory authority. And we did deal with a rule—I have comments on the rule and where we weakened the rule before, but there was a rule-making authority that the Agency had.

But here you are suggesting that there be, again, as I say, a statutory authority. Can you explain why?

Mr. LEVINSON. Well, I think we have included that without necessarily, as an office, opining on whether that authority already exists or not. And not serving as the chief legal officer of the Depart-

ment and having gotten the sense that there is, at least historically, some uncertainty about how far the original 2002 law goes in the kinds of authorities we are talking about, our purpose really was to take this very important, we thought, snapshot of the historic record when it came to what has transpired since the passage of the law and the regulation.

And noting how nearly 60 percent of those we contacted were not in compliance, and with one out of four not even knowing about compliance, we certainly felt strongly that Congress needed to revisit this. And if, indeed, there need to be some statutory changes, it would be certainly timely.

BIOTERRORISM ACT

Ms. DELAURO. Well, I will make the point here about the earlier rule, which were the limitations of the Bioterrorism Act; because at the outset, it was more fulsome, if you will, than what it turned out to be, and farms totally excluded, all foods under the exclusive jurisdiction of USDA totally excluded, restaurants totally excluded.

Access to records, FDA must have reason to believe that food is adulterated and that it presents a threat of serious adverse health consequences or death to humans or animals.

And the final rule was weaker than what the draft rule was. I mean, this was in the act, if you will. But then, you know, the final rule was weaker than the draft rule.

All foreign persons except those transporting food in the U.S., were excluded. And at the time, OMB estimated that it exempted about 225,000 foreign entities, even though it said that the large number of excluded foreign entities increased the likelihood of hampering trace-back investigations.

The requirement to keep a record of lot-specific information, which applies to all entities, was limited to manufacturers, processors, and packers in the final rule. And yet, again, OMB said that the reduction in benefits from doing so was high, estimated that the length of trace-back times would be sharply higher under the final rule than under the draft rule.

And there was a change in that the requirement to make records available to the FDA in a food emergency was changed from 4 to 8 hours, to not to exceed 24 hours. And then all retail outlets with fewer than 10 full-time-equivalent employees were excluded.

I am just going to ask, I understand the issue of the high cost on other firms, if they—you know, a number of these folks were included, but it is estimated that trace-back times for many of the products would be 1 to 14 days, with all parties keeping code records, compared to 6 to 8 weeks without all companies keeping them. And that was really known at the time, and so forth.

I want to ask our two other panelists—I know my time has expired, but very briefly—not to comment on statutory versus rulemaking, but just on strengthening the existing requirements with regard to lot-specific information, if you could briefly comment.

Craig.

Mr. HENRY. Thank you, Madam Chairwoman.

I think the best person or best entity to address the value of it is certainly FDA, and I think that Mr. Levinson qualified that in his statement.

As I stated before, in order to address traceability and strengthening it through the supply chain, responsibility needs to be levied at all levels. As the testimony, I think, across the board today shows, there are two primary directions that we must be focused on. One is certainly the upstream, which gets back to the source of the contamination, and that needs to happen with rapidity. The downstream is going to be the turnabout, once you know where it is coming from.

Now we have to get to the consumer's pantry to build their confidence as quickly as possible. If there is a breakdown in not being able to identify a particular product by lot code, either for the consumer or for the person vending that product, there is now a gap. And I think that is very evident in the survey that the IG has quoted.

And then I would default, I think, to Tom, because his process does speak to the entire trackability or traceability all the way down the system.

But I would also like to qualify and bring the subcommittee's attention to the idea of interoperability. It is not as easy as it sounds. And GMA fully supports the need to focus in on the pilot program, the pilot study, so that we can define from the bottom up what is practical, what is feasible, what is cost effective; and make sure we are getting the response we need, an end result which is better consumer confidence and safer food products.

Ms. DELAURO. Tom.

Mr. STENZEL. In my layman's opinion, I would suggest a rulemaking issue, even though you have asked us not to comment on that.

Ms. DELAURO. Well, I am happy to have you comment because we apparently have the ability to do that.

Mr. STENZEL. I believe so.

The two key aspects, I think, for the produce industry—the farm exemption I don't think is a problem; I think it is still appropriate. In our case, the product is sent to a first handler, the person who packs the box, and it is that person's responsibility to maintain the lot information, where it came from. So having a set of records at the farm level would probably just be a duplication of what it goes through at the packer level. So we think that is acceptable.

On the question of FDA access, other than when they suspect that there is a contamination problem, we do think that is important. FDA should be able to go out and look at records now when there is not problem and help find those problems.

Ms. DELAURO. Mr. Kingston.

Mr. KINGSTON. Thank you. I am going to yield to Ms. Emerson for right now and then come back, because she was here first.

Ms. DELAURO. Yes, she was. Ms. Emerson.

Mrs. EMERSON. Thanks, that is great. I appreciate it.

Thank you all so much for being here, Madam Chairman or chairwoman or chair—I don't know what to call it.

Ms. DELAURO. It makes no difference.

TRACEABILITY REGULATIONS

Mrs. EMERSON. Mr. Levinson, I want to ask you about the traceability regulations you tested in this study and which were required by the Public Health Security and Bioterrorism Preparedness and Response Act.

The authorizing language gives the Secretary authority to access records when there is a belief the food has been adulterated and threatens public health. Your testimony states a concern for the thousands of Americans who have become ill after eating contaminated food and beverages.

In your opinion, is the fact that the authorizing language refers to adulterated food and was included in the Bioterrorism Act relevant to the purpose of the regulations? And, essentially, is the authority granted under the Bioterrorism Act to respond to adulterated food broad enough to cover all discovered food-borne illness, or should it be limited to terrorist incidents?

And then my last question about this subject is, should we be trying to patch together a traceability system from a Bioterrorism Act, or should we start with a whole new public law, as Rosa kind of referred to?

Mr. LEVINSON. Mrs. Emerson, we, as an office, like virtually every OIG office in government, doesn't try to serve as a policymaker to advance a particular policy proposal. This study came about, in large measure, because in talking with FDA, FDA itself told us it was unsure as to whether there was enough compliance with being able to know, when it comes to food traceability, whether it would be possible to trace foods subsequent to the 2002 law.

And we actually moved from one project to this one, sharing their concern that this looked to be a pretty important matter.

I would leave the science, really, to others as far as contaminated versus adulterated, but I think we move forward on the study on the assumption that the law, as passed by Congress, envisioned the ability in a food emergency to be able to trace food in a way that, given these results, indicate that we don't have the compliance that was envisioned by Congress.

Mrs. EMERSON. Well, it certainly seems that—and obviously this is not your fault, and we are happy that you found it. But when you consider that only 5 of 40 products were traceable, to me, that is a pretty disappointing record of compliance. And with only 2 of the 38 facilities having lot-specific information, it does suggest that we have a significant issue with enforcement.

Am I mistaken in that?

ENFORCEMENT

Mr. LEVINSON. Well, with respect to enforcement, I think one of the hurdles that exists in the structure now is that the FDA can take action on the criminal side if it believes that there has been a failure to adhere to the requirements of the Food, Drug and Cosmetic Act.

That is almost too severe a regulatory regime, if you will. And it would actually be helpful, as per our recommendations, to think about a compliance regime that wouldn't put FDA to the test of having to, in effect, build a criminal case. And I think our own ex-

perience indicates that there is a lot of noncompliance that has nothing to do with some kind of criminal motive to evade the law.

Mrs. EMERSON. So fines, or something like that, might be better?

Mr. LEVINSON. This is a good time for Congress to revisit this provision. There are many areas of human endeavor where 7 years doesn't make a whole lot of difference, but when you consider where we were as a nation, and in this area of information technology in 2002 and where we are today, and I think the conversation about the GS–1 data bar is a good example of how things continue to evolve in IT at a very rapid rate.

We have talked about health IT for these last few years, we obviously now are in the world of food IT. And things are moving rapidly enough that these are the kinds of issues that perhaps can be grappled with in a much more cost-efficient way than perhaps could have been done historically, making the revisiting of this issue especially timely today.

Mrs. EMERSON. Okay. It looks like I am out of time. Thank you, Madam Chair.

Ms. DELAURO. Thank you for the questioning. And I just might say that technology has moved ahead, yet we haven't moved ahead with public policy.

But, also, there needs to be a monitoring system that exists. You can have the information, but not be able to do anything with it, which is where we are at the moment in whatever the information is. As limited as it is, there isn't any way to track or to monitor anything that is happening.

Mr. Bishop.

Mr. BISHOP. Thank you very much. This testimony is very fascinating and I think it is very timely. And I want to thank you for the information you are bringing to us.

FUNDING LEVELS

Dr. Levinson, from your perspective as the IG, I am interested in whether or not, based on your study and your knowledge, you feel that FDA has sufficient resources and tools at this point in time to accomplish—let's assume that we are able to tighten up the traceability and give what is necessary for that, do you have the necessary personnel, do you have the necessary laboratories, the equipment?

Is your organizational structure such and are you staffed such that adequate time and effort can be placed on the food safety issues that we are concerned about, as opposed to your other responsibilities with drugs?

And are you in a position to say that Congress needs to look at perhaps some reorganization in terms of how those responsibilities are handled and how the resources are allocated? Because, as I understand it, USDA, with meat, fish and the poultry, has many more inspections, many more personnel available per facility, than FDA does on a ratio basis.

So tell me about that, about the resources, the organization, the structure, do you have what you need, or do we need to look at trying to provide some additional resources?

Mr. LEVINSON. Mr. Bishop, this particular study was not undertaken to look at FDA in any global way and, indeed, it is one

among at least a dozen reviews of FDA work that the OIG has done over the last few years in specific areas. We really don't serve—we wish we could, perhaps, in a more ideal world, but given our own resources, if you set aside Medicare and Medicaid, as an office we have about $40 million to oversee over $100 billion of HHS programs. And therefore, we do our own cost-benefit analysis of what we are going to look at.

We have looked at this particular area, and we really can't speak to the overall picture of FDA. We certainly, in the course of the reviews we have undertaken of FDA work, we have revealed, surfaced a number of recommendations for change that we would strongly——

Mr. BISHOP. I am not sure that I understand from your rhetoric the answer to my question. What I want to know is, do you have enough resources? Do you have enough funding? Do you have enough staff, anything else that you need to satisfy the American public, to satisfy the Congress that you can do what is necessary to keep our food safe?

And if you don't, tell us, so we can try to make provisions so you can have what you need. But if you don't tell us what you need, we can't provide it.

Mr. LEVINSON. I understand and I appreciate the question.

Mr. BISHOP. Having done all of these studies that you are talking about, and as the IG, you have to look at the whole Agency. And looking at the whole Agency, you have to know whether you have to make, as you say, cost-benefit analysis decisions on how you use the $40 million of resources that you have.

So if that is not enough, tell us. If you need more people, tell us. If you need more authority, tell us.

Mr. LEVINSON. Well, we are very grateful for the funding that the OIG does get at HHS, and we would need—

Mr. BISHOP. Is it enough?

Mr. LEVINSON. We are certainly stretched with the responsibilities that we have. But I think what you are getting at, really, are the resources of the FDA, not so much the resources of the OIG. And with respect to the resources of the FDA——

Mr. BISHOP. That is what I am asking.

Mr. LEVINSON. Yes. In the first instance, it is important to have that question posed to the FDA.

Mr. BISHOP. I am sorry, I didn't mean to be ambiguous. I thought that you were the OIG for the FDA; is that correct?

Mr. LEVINSON. Well, the FDA is one of 300 programs and agencies of HHS——

Mr. BISHOP. The HHS, okay.

Mr. LEVINSON [continuing]. That the OIG, as an independent body, looks at. So we do consider the FDA part of our oversight responsibility, and we feel an important responsibility to report to Congress on what we find when we do reviews like this of FDA operations.

But we think it is very important that you have an opportunity to pose exactly that question to the FDA when the opportunity presents itself.

Mr. BISHOP. We will.

Ms. DELAURO. I can't let the moment pass. It is one of the reasons why we should have a food safety agency that is independent, because then it would have its own IG. And I am not saying that you haven't done your job, you have done a great job, but it would be a different set of circumstances.

Mr. Kingston.

Mr. KINGSTON. Thank you, Madam Chair. I want to just walk through some numbers to make sure everybody keeps something in perspective here. We certainly want to do everything we can on food-borne illnesses, to attack this, but frequently in politics we concentrate on the factor of fear, to use our own positions to get reelected and prove our own importance.

These are facts. This is a number—and of course if anybody can dispute it, that is what we are here for, but as I recall, 76 million people a year get food-borne illnesses. According to our testimony, Mr. Levinson, 300,000 get hospitalized, 5,000 die.

Big number, 74 million, but if you look at eating three meals a day, supposing we never have snacks, 300 million people in the population of the United States, 365 days a year, if you divide that 76 million by that number, you are talking about a .002 percent in terms of food illnesses—the point being, we have a remarkably safe food supply.

And we need to keep that in mind, that there are a lot of things out there working—no thanks to the Federal Government; it is there because the private sector works. They have an incentive to have their customers keep buying from them because dead customers don't return.

And so we need to keep that in mind. Sometimes we just continuously beat ourselves up and spend a lot of money.

I want to pick on my friend's testimony—not my friend, Mr. Henry, but I want to pick on GMA a second.

FDA FUNDING LEVELS

In terms of FDA funding, do you know how much of an increase they got last year?

Mr. HENRY. Mr. Kingston, I believe that they got—I am going to say close to $100 million. I know we were originally proposing, in the coalition, a $200 million increase over a 5-year period. And I did not bring that number with me, but I want to say that—for sure, I know they got $40 million, but I don't know exactly what that number is.

Mr. KINGSTON. Actually, it was about $200 million in the supplemental and then in the omnibus——

Ms. DELAURO. Three hundred million total.

Mr. KINGSTON. Three hundred million.

Now, that being the case, your first recommendation was to give a comparable increase. If you thought it was 100, and you are shooting to double that to get to 200, and now that we have told you it is over 300 million, should we drop this recommendation from your testimony?

Mr. HENRY. No, absolutely not.

Mr. KINGSTON. The sky is the limit when it comes to tax-funded—there is no deficit problem here.

Mr. HENRY. Right.

Mr. KINGSTON. Okay. I just want to say the FDA got a ton of money in the last cycle.

COMPETENT HANDLING OF FDA

Do you feel that they competently handled spinach, tomatoes or peanut butter?

Mr. HENRY. I believe that they handled those issues as effectively as they could with the resources that they were able to apply at the time, yes.

Mr. KINGSTON. You know, there was a lot of collateral damage, millions of dollars lost by innocent, law-abiding farmers and producers because of, you know, tomatoes, peanuts, and there is no compensation for those folks.

Mr. HENRY. No.

Mr. KINGSTON. I think one of the things we have to focus on is not just giving FDA more money, but giving them more competency in terms of using the technology that is out there today to rifle-shot rather than shotgun and go through the world scaring everybody. And I am looking to GMA to be helpful on that.

VOLUNTARY VS MANDATORY RECALL

Now, the other thing is—two more criticisms to my friends at GMA. You have an Orwellian statement in here that I have got to take exception to: "Give FDA mandatory recall if a company has refused voluntary recall." There is nothing voluntary about it if they refuse to do it and then they are going to have mandatory recall, right?

Mr. HENRY. Yes. According to the current programs, it is a voluntary action for a manufacturer to issue a recall. And at this particular time, except for infant formula, FDA does not possess the authority just to go in and execute on their own, so they take the next action, which is to put out an alert, and then work with the States to actually, if you will, control the distribution of that product in the marketplace.

So you are right, it is mandatory and voluntary in the same statement, but we are saying, Look, if the voluntary action, which is the option of the manufacturer, is not exercised and there is serious threat to human life, then FDA should have that mandatory authority where they can come in and say we are going to execute a full-blown recall.

Mr. KINGSTON. But I think we need to be frank and say that it is mandatory, rather than mandatory if they refuse the voluntary. Because it is just so Orwellian for us to be living in a government that talks like that.

Mr. KINGSTON. Last criticism. When you say you seek swift improvements, we all get frustrated when we want swift stuff, but swift action sent formaldehyde-laden trailers to the gulf. Swift action got us into a war looking for WMD. Swift action rushed a TARP program through that allowed AIG to have lots of bonuses and other unintended consequences. So sometimes slow deliberation is important.

An example, I think HACCP has worked actually fairly well on food safety, and that was a slow piece of legislation that went

through the process, but I think through that there was a lot of vetting.

But also, as Mr. Levinson has pointed out, technology is just moving at a remarkably fast pace, that there are so many more tools now that we would not have had 4 years ago. This Universal Products Code thing that I hadn't seen before, I don't really like those little stickers on my apples because I have got to peel them off, but this one kind of makes sense.

I know I am out of time and I yield back.

Ms. DELAURO. Thank you very much, Jack. I just think it is interesting, with your first comment with regard to the numbers, it winds up being about one out of four Americans who get sick when you take a look at those numbers and you try to break it down, which I think is significant. If you take a look at this, it is one, two, three, four, and you go down the list here, it goes through—and the other thing is I think your point is absolutely right about what has happened to the industries, which is why we have had such an outcry.

But when you think about the last peanut butter outbreak, nine people died. Some child, some mother, some relative of someone died because they ate some peanut butter-based product. Who could have thought that peanut butter would be an at-risk food, given the process. So it has very some very, very broad ramifications.

Let me look at the second recommendation. It has two parts. The first in the set is that each facility that handles a food product maintain records about every facility or farm that handled the product along with relevant lots. Typical information.

RECORDKEEPING REQUIREMENTS

To be clear, does your recommendation mean that the retailer would ultimately need to keep records about all the steps—growing, packing, processing, shipping—of every product that it sells? And since your report indicates that there are problems in implanting one-step-forward, one-step-back traceability, do you think that this is realistic? And which lot-specific information do you consider relevant?

Mr. LEVINSON. Madam Chair, I am going to ask my colleague to respond. She has done such extraordinary work on this and I want her to have an opportunity to inform you about this.

Ms. DELAURO. Okay, Jodi. Go ahead.

Ms. NUDELMAN. I think you are referring to our second recommendation where we are saying—beyond lot-specific information, we are saying more of a type of system where—and we are making suggestions for FDA to consider in this area, but to use the technologies we have been talking about, to have standards set where in electronic format there would be the type of information that could be standardized across industries so that could be eventually——

Ms. DELAURO. It would——

Ms. NUDELMAN. That is one of the possibilities we are offering.

Ms. DELAURO. It would appear that the proposal would seem to put the ultimate burden of traceability on the retailer. Is that accurate or a misreading?

Ms. NUDELMAN. That is not what we meant there. We had meant there for FDA to think about broader things here. So to go beyond the one-up/one-back rule, to talk about technologies that could be linked so that the product itself could be traced back through each stage of the——

Ms. DELAURO. But you are talking about the retailer keeping records, correct?

Ms. NUDELMAN. Correct.

Ms. DELAURO. Of all of the steps.

Ms. NUDELMAN. We are offering a couple of combinations here, so we are not being very prescriptive in this recommendation. We are saying that because we know that there are a lot of technologies out there, the industry has some new thinking. We are leaving this one open and saying, but it is time to think beyond keeping one-up/one-back. It is time to think of systems that could be interlinked, interoperable systems that would allow for traceability through each of the stages.

Ms. DELAURO. It just seems to me, though, that that does lead to the retailer in the way in which you would have to do all of that, and the retailer having that complete set of information. It almost appears to eliminate the need for traceback since the retailer would have that information.

But also I don't know what your sense was in terms of retailers. Are they adequately equipped to establish and to maintain the records? And I don't know what you turned up in your findings with regard to that.

Ms. NUDELMAN. Again, as you alluded to, though, the sample size that we were looking at was pretty small. But from that we could tell a number of the retailers weren't even aware of some of the requirements to maintain records just about their sources. So that was one of the things we brought to FDA's attention in this report; that they need to provide some further education in that sense.

TECHNOLOGY FOR RECORDKEEPING

Ms. DELAURO. Okay. The second recommendation is that the FDA should require facilities to use certain information technologies to help facilitate recordkeeping. Which technologies did you have in mind? Do they currently exist, or would we have to establish them?

Ms. NUDELMAN. Again, this is what I was alluding to in the first point where these technologies were referenced earlier that could—if you provide certain standards that could be in electronic format, which is one big jump here, because we did find a lot of paper-based records; so in electronic format, where people are keeping the same type of information and that information could then be linked across specific facilities here. So, again, we are not being overly prescriptive. We know that others have looked at it——

SAVED TIME

Ms. DELAURO. Just a final question. Do you have any estimate of how much time, in terms of what you looked at, the FDA might save in tracing products if you dealt with the new technologies?

Ms. NUDELMAN. We did not track the time of the products that we traced. At the same time, when facilities did have something electronic, they could immediately reference it and get to the source that we were asking for for a specific product. I mean, other just anecdotal evidence was that some facilities needed to look through stacks of paper or they would have part electronic, part paper, that didn't talk to each other. So I think it could be quite substantial.

Ms. DELAURO. I will just leave it with this. If you do have other approaches that you thought about besides what you have mentioned that you think would be beneficial, we would really like to know about what your views are on that.

Mrs. EMERSON.

Mrs. EMERSON. Thank you, Madam Chair.

Was it you, Mr. Henry, who mentioned that there really isn't any interoperability? You are the one who said that; that is correct?

Mr. HENRY. Yes.

COST FOR INTEROPERABLE SYSTEMS

Mrs. EMERSON. How much do you all anticipate it would cost to put together an interoperable system? No guess?

Mr. HENRY. No guess. It is a real challenge. And I think Tom's program that he has proposed lays the foundation and the system that could allow that to happen.

One of the things that I brought with me in anticipating that, this is an excellent support document to Tom's testimony. This was just released from GS–1, which is a standards organization for traceability, but this was released in February of 2009 that addresses the particulars on that.

Ms. DELAURO. Would the gentlewoman yield for one second, just to add, if you wouldn't mind, to your question about just sharing this issue of the lack of interoperability here. Just define that. That would, I think, be helpful to everyone.

DEFINITION OF INTEROPERABILITY

Mr. HENRY. Okay. The challenge when you develop a traceability program is there are a lot of interested parties or stakeholders there. You have the person that is supplying the ingredients, the person who is constructing the product, you have a distribution chain. You have got a first, second, or third-stage retail. Then you have got beyond what we would think to be the grocery store, down to other brokers, et cetera, et cetera.

Everyone has a different need for the information they are harnessing; therefore, they will develop their own coding system. They will adopt proprietary systems. GS–1 is a proprietary system. When they adopt that, it is only for their needs, not for everyone else's. So if I create a system that I manufacture a product for Tom, but Tom is going to retail that, if he doesn't have the scanning equipment, the databasing equipment to capture what I put on mine by electronic form, then he has to do it in written form. Which is exactly where the IG's report is going.

So when you do not have that interoperability—and I am only one supplier, so if everyone in this room was supplying Tom as a retailer with, let's say, 50,000 different products and we all were not unified in the coding system that we used, as well as the read-

ability of that code, be it electronic or even manual, now you can see where the problem develops.

Mrs. EMERSON. How does the EU do it?

Mr. HENRY. Pardon me?

Mrs. EMERSON. Does the European Union have traceability? I think that they do.

EUROPEAN UNION

Mr. HENRY. Well, they do. And this is one of the things—right now globally, and especially over in the EU, Kodak, of course, has traceability foundation and guidelines. Various countries, which some of those are enumerated in this report here, do speak to how they approach traceability. They are all still trying to struggle with the interoperability challenge and the cost. Especially when you really look at this, when we get down to traceability in the finest tune, we really are looking at the lowest common denominator.

Now, one of the things I was not able to ferret out from the IG's report, or the survey, was specifically at what level of the food chain were some of these facilities, in quotes, really affected? Was it, you know, the mom-and-pop operation who is doing a small operation where they don't have a lot of money. You know, they may all be paper based.

So we need to look at that level, because if we really want to improve recall and get the product out of the system, it has to be the lowest common denominator.

Mrs. EMERSON. I appreciate that. If we can't still get our first responders to be interoperable, I don't know how the heck we are going to get you all to be, but——

Mr. HENRY. I hope I didn't complicate that for you.

Mrs. EMERSON. No, you didn't complicate it at all. That is the bottom line. I appreciate your answer, although I guess it is just one more set of challenges with which we must deal. But thank you.

FDA AUTHORITY TO REQUEST RECORDS

Mr. Stenzel, I want to ask you about your comments regarding highly visible action when an outbreak occurs and companies aren't in compliance. Would you support increased authority for FDA to request facilities records at any time, as recommended by the IG? I mean, is there any reason that FDA should wait for an outbreak to determine compliance, or is it better just to perhaps do a spot check here, a spot check there?

Mr. STENZEL. Congresswoman, two parts to your question. If there is an outbreak and they find someone not in compliance, then that is the highly visible action.

On the former question, should they have access to records to see if people are having one-step-up/one-step-down compliance, we believe they should; that that is a rulemaking issue. It probably ought to be part of a standard FDA inspection when they are looking at facilities to check on their traceability compliance.

INDUSTRY EDUCATIONAL EFFORTS

Mrs. EMERSON. I appreciate that. Having worked myself at a trade association in my past life, one of the big components of that was doing an educational program to help the industry comply with different standards, FDA or OSHA or whatever. What educational efforts do you all do to raise industry awareness of their legal duties in this regard?

Mr. STENZEL. Well, we are certainly starting more in recent years than we used to do, quite frankly. And I think seeing the results of the IG's report, although only a few of those were produce items, it does make me think we have a responsibility to get out and do more education.

I mentioned in the whole chain traceability, the interoperability that our industry is launching, that is where we are putting most of our focus right now. But perhaps there is a remedial step as well on simply compliance with the current rules.

Mrs. EMERSON. Thank you. Thanks, Madam Chair.

Ms. DELAURO. Mr. Boyd.

Mr. BOYD. Thank you, Madam Chair, and thank you for holding this hearing. Ladies and gentlemen, thank you for being here.

First of all, I come from a place where I have long held the belief that we have the most adequate and safest and least-expensive food supply in the world. And there are some things that have happened, obviously, in the last several years that have begun to crack that belief of mine and go into it and make me doubt it.

First of all, I want to tell you that I come from an agricultural producing area and the last two most serious scares, the tomato industry—I have a major tomato industry in the district I represent that was literally destroyed. The industry, the farmers, were destroyed by that incident. And I also come from a large peanut producing area, which is now probably going to be seriously set back because of market effect of what has happened here. I think there are two reasons for the erosion of that confidence that I have.

Number one is that we have, as we have gone over the years to open our borders and rush to do trade agreements, that we have not kept our safety systems up with stuff that was coming in from other places, as well as we should.

And, secondly, this 24-hour news cycle. So when you have somebody that gets hurt, everybody knows, it and it just totally obliterates the market.

I am going to get to my question, but I want to set that up for you to tell you that the tomato issue, as I know it today, still has not been nailed down by the Food and Drug Administration as to where it happened and what the product was. As a matter of fact, they probably pretty much concluded that it was not tomatoes. It was peppers in Mexico; am I right or wrong?

Mr. HENRY. Yes.

Mr. BOYD. Okay. Now, I believe also that when you take a taxpayer's—the dollar out of his pocket and say you are going to protect the consumer with it, whether you do it at the local, State, or Federal level, that money comes from the same place. The most effective place to do all of this is closest to the consumer as you can get.

Every State, all 50 States, have a consumer advocate food safety component in their State bureaucracies, right? I assume there is nobody out there sent from a State agency on this issue that has jurisdiction over food safety.

INTERACTION WITH STATE AGENCIES

Now, Mr. Levinson, I have read your report or briefed it. I don't see anywhere in it where we have talked about interaction with the State agencies and use of their assets, their infrastructure, their people, their expertise, their knowledge. I have had several communications with my State agency folks, and not only did I find out that they weren't asked to be part of any of these investigations by FDA, in fact they were intentionally not shared information from the FDA. And they had access. My State agency had access to information which would help the FDA do the traceback.

Mr. Levinson, did you address this? Can you speak to it? And I would like for you to speak it and also maybe one of you folks from the private sector, too.

Mr. LEVINSON. Mr. Boyd, we have actually been asked by the Chair to look at the State inspection agencies, and we have work that we are in the middle of right now preparing for that specific request. This study is separate from that in the sense it was designed to see what the state of recordkeeping was pursuant to Congress' law back in 2002.

But you raise an important, valid, and a very timely issue; and we are actually engaged, per the Chair's request, in that specific project.

Mr. STENZEL. Mr. Boyd, if I could share a perspective also on behalf of those tomato growers in your district. There was a tremendous amount of information that was not brought to bear during the investigation that would have helped in the traceback. We think that is one of the most serious issues we have got here is just what the IG has done, is start these traceback exercises now. Let us do them now. Let us bring the State and locals and FDA and CDC together and learn the process, bring the industry into this process.

Very quickly, we knew that tomatoes were not the source. We knew they were tracking back to different farms. There wasn't a common point. But we couldn't move the agency away from that conclusion until very, very late in the game. But I think if we could do more of these traceback exercises today, we could bring some of that expertise you are describing that exists not only in State and local governments, but in industry.

Mr. BOYD. Thank you.

Madam Chair, I know that you are going to focus on this issue. You have, and rightfully so, and I assume you will continue to.

Can I request of you and the committee that we at least get some of those—I would like to have—since Florida, and now Georgia with your plant down there, your plant that buys my peanuts—it wasn't ours. It was the ones that you shipped in from China that caused the problem. I want everybody to understand that.

So if we could have some State agencies come in here, and FDA, and put them in the same room and maybe some industry folks, too, with them—have them talk to each other about their inability

to communicate with each other and to work together, share information; because, you know, Madam Chair, when you take the dollar out of the pocket of the taxpayer, he is funding both of those agencies and then didn't—not only did he not get his money's worth, it was counterproductive. They put him out of business for something he didn't do. So I would like to work with you on that.

Ms. DELAURO. I am more than happy to do that. I think it is just critical that wherever we move forward, that even with the State laboratory systems, the State agencies that have these responsibilities, they need to be looped into this; because there is a lot of expertise at that level which is now not being used.

I mean, quite frankly, Minnesota—the folks in Minnesota did an incredible job of identifying where the issue was and, unfortunately, with regard to tomatoes—and you were here, I think, at this last hearing that we had here, where they were still being let out on their own recognizance. Nobody has finished that up. So it continues to put the tomato industry in jeopardy. So I am happy to work with you.

Mr. BOYD. Thank you, Madam Chair.

Ms. DELAURO. Mr. Kingston.

INCREASE IN FDA FUNDING

Mr. KINGSTON. Thank you, Madam Chair. I wanted to first of all say for the record, particularly for my friends at GMA, that FDA since fiscal year 2008 has had a 19 percent increase. They have gone from a budget of about $1.7 billion to over $2 billion; $150 million in the supplemental in June of 2008 and $150 million-plus in the CR. If they needed—I mean, which is more than the money level you have been asking for. So I am not convinced money is their issue.

But I wanted to move in a different direction. Mr. Levinson, the 300,000 people who are hospitalized, I would like to know the breakdown of how much of that was in the commercial arena and how much of it happened at home in terms of when the food may have gone bad? Don't you think it is relevant to the discussion?

Mr. LEVINSON. That is a number from the Centers for Disease Control and Prevention.

Mr. KINGSTON. Can you get it?

Mr. LEVINSON. We will be happy to drill down as much as we can——

[The information follows:]

Response: I agree that this is an important part of the equation. The statistic you reference was contained in a CDC report entitled "Food-Related Illness and Death in the United States." In that report, CDC researchers estimated that there are 76 million illnesses, 323,914 hospitalizations, and 5,194 deaths attributable to foodborne illness each year. In order to arrive at this estimate, CDC researchers compiled and analyzed information from multiple surveillance systems and other sources.

In this report, CDC did not attempt to quantify whether any of those foodborne illnesses, deaths, or hospitalizations were linked to a contaminated food product or improper handling of the food. In addition, the study also did not quantify the number of illnesses caused by specific types of food. however, CDC is currently working on estimates for the number of foodborne illness that are attributable to different food types. These estimates are expected to be completed later this year.

Mr. KINGSTON. Don't you think that it is extremely relevant? Because if this is a food-handling issue, we need to know how much food-handling plays a part in terms of the homeowner.

The other thing is, do we have a breakdown of vegetable versus meat, or just the type of food, because there again I would think that would be extremely relevant. And would you agree with me that that is extremely relevant if we have 300,000?

Mr. LEVINSON. I think it is helpful to have more drilling down of the data than less, absolutely.

Mr. KINGSTON. My good Chair never misses an opportunity to plug a single food agency. This is why we need it.

And we may have a little overlap here, because what I do not like in this town that everybody is assumed guilty. And, you know, if we are talking 300,000 people a year being hospitalized, we should know a full analysis of where is it coming from. What if we found out it is 90 percent meat? What if we found out that it has happened because people are not washing the frying pan; the cold meat versus the cooked meat and things like that? That is extremely important.

IMPORTED FOOD

The other thing is—and Mr. Boyd touched on it—how much of this is imported food? Because I am a little concerned about some of the issues on imported food that we don't want to overreact and then have them shut down their buying our food from us; which, you know, in poultry country we are concerned about China and we are trying to balance that out. But I think we need to know that. And then in terms of if people are all complying by the—so let me conclude that.

You will get me those breakdowns, right?

Mr. LEVINSON. Yes.

Mr. KINGSTON. Okay. And then if everybody was playing by the rules now that are on the books, how much would this be solved, some of this problem? Do we know?

Mr. LEVINSON. If my colleague wants to venture an opinion, I am not sure we can necessarily provide some sure-fire conclusion as to a solution that obviously is aimed to such a large part of the economy and how that is going to be handled. I am not quite sure that anyone would be in a position to give any kind of final answer.

Again, this report is taking a snapshot of what happened when Congress decided, again pursuant to an antiterrorism law, to help ensure a safer food supply. And I think these results indicate that that kind of compliance regime has not revealed results. But I can't give you a going-forward conclusion as to what is going to work 100 percent.

Mr. KINGSTON. Okay. I know, Madam Chair, there are some people who haven't had a shot at the panel. So I am going to yield back.

Ms. DELAURO. Ms. Kaptur. We do have a total of seven votes. So Mr. Latham and then Ms. Kaptur. And I don't know how much time is left on the first vote. Ten minutes.

So, Ms. Kaptur, let us have you move forward. And then, Mr. Latham, let me see if we can get you in, and then others can go and start to vote, and then we will recess and we can come back.

I will be back and I am hoping others can come back.

FOOD IMPORTS

Ms. KAPTUR. Thank you, Madam Chair, very much.

Mr. Stenzel, can I ask you, in your association for all the food throughput that comes from United Fresh Produce, how much of it is domestic and how much of it is foreign—just ballpark—and which segment is growing?

Mr. STENZEL. The good news in fruits and vegetables are both are growing, and it is not through our organization but just in consumption in the United States. Imported products counter-seasonal to that grown in the United States have been growing in recent years. More than 35 percent of the fresh produce would be imported.

Ms. KAPTUR. Okay. In the community in which I reside, Toledo, Ohio, a number of our small markets go up to Detroit Farmers Market on any given day, purchase boxed items, and bring them back and distribute them.

What percentage of those in the winter months would be grown outside the borders of this country?

Mr. STENZEL. I would have to give you an estimate on that, but probably the majority.

Ms. KAPTUR. That is what I think. That is my take on it, too.

I wanted to ask a question about—I was reading in Mr. Levinson's testimony here a statement, "Only 5 of 40 products we purchased could be traced through each stage of the food supply chain back to the farm or border." And I wonder if you could comment on that, "or border"?

Mr. LEVINSON. Ms. Kaptur, we weren't looking at foods brought in from abroad, so the study does not include traceability, if you will, offshore or, for that matter, at the farm, at the source. We went as far as either the farm or the border, and then we looked at traceability domestically within that context.

Ms. KAPTUR. Didn't those jalapeno peppers come from Mexico? From everything you know, Mr. Levinson—is it Dr. Levinson or Mr. Levinson?

Mr. LEVINSON. It is mister.

Ms. KAPTUR. Mr. Levinson, okay. Could you please tell us what can we do about that? From everything you know, from what you have studied, what could have prevented that in terms of traceability systems that could be put in place?

Mr. LEVINSON. Ms. Kaptur, I guess that is why I am not a doctor. I really don't—I really can't answer that question in good faith and give you an answer that I feel in good conscience would be really responsive to what I think you are getting at.

EXCLUSIONS IN THE BIOTERRORISM ACT

Ms. DELAURO. Marcy, I just would make this point, in all fairness to Mr. Levinson. The rule which came out with regard to the Bioterrorism Act, all foreign persons except those transporting food in the United States were excluded. The original rule had them included. When the final ruling came out it was excluded.

So that is not—also, in terms of exclusion, farms are totally excluded. Foods under the jurisdiction of the USDA. Restaurants are

totally excluded as well. So there are certain categories of exclusion. And what the report reflects is what was included, in essence. So your question is very relevant and it is one to be asked about how to deal with this, but——

Ms. KAPTUR. It is so great that you are Chairwoman of this committee. It is just so great.

I am thinking back to the strawberry situation also. That was from Mexico, and all these kids in Michigan got sick in our neighboring State. It probably came from the Detroit market and was redistributed. So, you know, we have got to do something about this.

And the only comment, Madam Chair, as I end, is saying that the costs for some of this—also we have to think about how it impacts little local producers that are producing in our local communities and how we allow them to bring their product to market, and they are not a part of some big giant international corporation, and whatever regulations are adopted, how we have some sympathy for the small producer in all of this.

Thank you, Madam Chair.

Ms. DELAURO. Mr. Latham.

Mr. LATHAM. Thank you, Madam Chair. And welcome, everyone.

TRACEABILITY PRIORITIES

A consumer today can go to almost any grocery store in America and buy something that is ready to eat, made in China, and we really have no idea where that wheat came from, what kind of water was used in the cooking process there as far as the noodles, and they are in most of their ingredients.

Considering whether you are comparing food safety systems in the U.S. or in China, and if Congress increases funding for the FDA—as has been requested previously—which is the highest priority, do you think, as far as inspection of that foreign food or the traceability system in grain?

And I have got a question about traceability in grain, too. But where would you go?

Mr. LEVINSON. Mr. Latham, I sense that there is probably some good expertise within FDA, because I have had a conversation about this with Mr. Acheson himself, who handles this area, and he is very familiar with the international regimes that kind of exist to watch over the food supply in Europe and elsewhere. And I certainly am eager to offer the technical assistance of our office, because this study was done by some outstanding evaluators in our own operation. I think that really requires additional expertise that is not in this room right now.

COMMINGLED AGRICULTURAL PRODUCTS

Mr. LATHAM. Okay. Just coming from an agricultural area that produces huge quantities of grain—and apparently in your testimony you talked about how that, in a bag of flour, you can't trace where the wheat came from to individual farmers. I mean, have you ever seen how wheat is handled or corn is handled or whatever? It is virtually impossible to trace back——

Mr. LEVINSON. Right.

Mr. LATHAM. This would be extraordinarily expensive and unbelievably onerous.

Mr. LEVINSON. Mr. Latham, we are certainly keenly aware of the commingling challenge, if you will, and that when it comes to those kinds of foods it is really important. And, indeed, I think our recommendations reflect the need to work with industry to come up with a regime that isn't impractical, unrealistic; that takes into account the realities of how life works with respect to those kinds of foods. Absolutely.

Mr. LATHAM. Okay. I think we are very much out of time.

Ms. DELAURO. We are going to recess subject to the call of the Chair, but we will be back.

[Recess.]

Ms. DELAURO. I am going to proceed. I am going to assume that there will be others joining.

AUTHORITY TO REQUEST RECORDS

Very, very quickly, let me just say—because I think it was my colleague Mrs. Emerson who asked the question about FDA seeking statutory authority to request facilities records at any time, and currently they can only request the records if they have a reasonable belief that the food presents a serious threat to health. I think it was you, Mr. Stenzel, who said you believed they should be able to do this at any time.

Mr. STENZEL. Yes, Ma'am.

Ms. DELAURO. Mr. Henry.

Mr. HENRY. We would concur.

Ms. DELAURO. Mr. Levinson.

Mr. LEVINSON. Good. Sounds to me, Madam Chair, good——

Ms. DELAURO. That is what your recommendation——

Mr. LEVINSON. Yes.

Ms. DELAURO. Okay. I just want to make sure that we establish some principles. I will just try to put these things together.

You mentioned with regard to—I have got to be honest with you. When we encourage FDA to develop additional guidance on traceability, I understand the language but I am tired of guiding. I want to try to regulate here. There is nothing wrong with guidance, but I think we need to look at how we try to regulate.

THIRD-PARTY AUDITS

There was an issue about contracting with independent third-party auditors to monitor recordkeeping systems. I get a little bit nervous about that for self-serving reports and conflicts of interest. My view is that companies—why can't companies do this themselves? Mr. Henry?

Mr. HENRY. Yes, it can be done. The difference is in part there is what we consider first-party audits, which means I audit your own facility; second-party audits which I go, I am the buyer, and I audit my supplier, which has great value. There is value there.

Now, again going back to the lowest common denominator, a smaller operator here in the United States doesn't have certainly the wherewithal to send a member of their staff overseas to do those audits. The position GMA has tried to take on this, and working very closely with FDA on third-party certification, is that harnessing a third-party auditor—and, again, remembering the food protection program is focused on export to the U.S., or the im-

porter side—being able to use, if you will, a third-party auditor who has been properly certified, at arm's length, to evaluate accurately a foreign supplier has great value and great merit, especially for those manufacturers or buyers here that just do not have that wherewithal. And I think that is an excellent use of tax dollars because now you are having FDA at least bona fide the auditor who is executing as well as establishing some guidance for the criteria. Okay?

Ms. DELAURO. Well, I think that means that there has to be some real oversight of that process.

Mr. HENRY. I concur. And the oversight——

Ms. DELAURO. Otherwise——

Mr. HENRY. In fact, I have asked FDA in an upcoming Webinar we are going to do, the industry is very much interested to see how the shrimp pilot program works out, and we think that the walk-behind value is where the FDA, using their inspection which is part of the process to improve food safety, is able to back into that facility that, quote, is certified and confirm it, validate that it does meet the mark.

Ms. DELAURO. I think the most recent example which really wound up with this peanut butter salmonella thing being almost a perfect storm was because you had—I understand the contracting out to the States for inspection, but one has to have a set of criteria in which you ask them to do that. But then you have to monitor whether or not they are retaining that criteria, and then you have to have some reports back. So if you find something, it has got to come back in some way.

Tom.

TRAINING INSPECTORS

Mr. STENZEL. If I could just add another factor here that I think is going to be important is the training of the inspectors themselves. And that is one of the things that you support in terms of a consistent national training regimen. So whether they are State employees or local or even third-party private, that they would have the same level of qualification.

Ms. DELAURO. I think that is also true. I don't know you would concur with the laboratories. I mean, these are qualified people, but we have to make sure that we have very trained and qualified people in those labs. You find it in Minnesota but, you know, you don't find it someplace else and so forth. So my view is it ought to be looped into this process as well.

CHOICE OF PRODUCT SAMPLE

A quick question on the products. How did you choose the products? That is a question that I have. We have got ice, manufactured ice. Look, I am a novice at this. Manufactured ice, why was it chosen? Inclusion of flour. What was the criteria? Did you give FDA the criteria? Did they give you the criteria?

What was it with regard—because my colleague Mr. Kingston spoke about dealing with foods that have the highest risk as a way of trying to deal with this, and I think—were they considered with regard to their role in terms of causing a food-borne illness?

Ms. NUDELMAN. We developed a number of factors to pick—to select these foods in the end. We did consult with FDA, and so we were looking for relatively common sort of basic-type foods that had ingredients we could essentially trace, that weren't overly processed so it would complicate the study. But they did sort of gear us towards food products that they were interested in knowing more about, that they were unsure whether they were risky or not, and then asked us for—in the case of tomatoes, to look at something that they considered quite risky. So it does have a combination of factors that we looked at.

Ms. DELAURO. A final quick question with regard to that. If FDA did give you the list, did it include products that you did not trace? And if so, what were they and why did you not include them?

Ms. NUDELMAN. It was more of a discussion with them. They did not select specific products that we then chose from. We came together. We said that we were considering these types of products. They geared us towards particularly looking at the eggs. They had asked us to include that at the very end. So it was a consultation with them is how I would pose that.

Ms. DELAURO. Mr. Kingston.

Mr. KINGSTON. Thank you, Rosa.

COMPLIANCE WITH CURRENT REGULATIONS

Mr. Levinson, in your testimony in terms of records requirements, you said that 59 percent did not maintain the contact information required by FDA. Then you talked about some of it was logistics problem, paper records versus electronic records, but 59 percent basically were out of compliance. So if all these were in compliance, playing by the rules, how much would that reduce the problem?

The short of it is if we follow existing law, existing regulations, how much of this would be addressed and alleviated?

Mr. LEVINSON. Mr. Kingston, it would be hard to know exactly how much of whatever risk might remain would necessarily be alleviated. One of the requirements is to keep contact information. And we thought it was important to reveal that to the extent that we have, out of 118, something like 60 percent or 59 percent of those who were asked, not being able to have the information, and then one out of four not even knowing that there was contact information that was required just reveals, in effect, a flaw in the regime that was set up by Congress a few years ago.

As to whether if we had found that everybody had the contact information that that would resolve all safety-related issues, I guess that is something to look forward to another kind of study design.

OTHER RECORDS

Mr. KINGSTON. Well, now, let us say they didn't have the right FDA information or whatever but they did have some records of their own, maybe for product liability reasons or whatever. Did you ask them about that?

Mr. LEVINSON. One of the interesting things that was revealed in the study is that actually some of the distributors, wholesale and storage facilities and retailers, actually had lot-specific information.

It wasn't across the board everybody had a lack of information. There were actually some people who were not required to have lot-specific information who actually had it.

Now, whether that was either out of safety issues or, perhaps more likely, for business-related reasons, I mean there really wasn't a consistent pattern——

Mr. KINGSTON. I think if you were selling to Wal-Mart, they have a higher standard than, say, maybe the neighborhood grocer. I don't know. But I think that would be relevant to your whole investigation, study. And I use the word "investigation" loosely. But if we are trying to reduce the number of traffic accidents and you have got people going 90 miles an hour because they don't know the speed limit is 55, then we need to figure out how do we get you to comply with the existing law. Are you intentionally not complying or are you just totally ignorant, even though that is no excuse?

But it would appear to me that would be part of our mission here is to get people in compliance with existing law so that we can get an adequate data sample.

Mr. LEVINSON. Yes, absolutely.

COMMINGLED AGRICULTURE PRODUCTS

Mr. KINGSTON. And also I wanted to ask Mr. Stenzel, fruit and vegetable really has been kind of ahead of many products, and it might be because it is easier. But I would imagine it gets pretty difficult when you get a blended product outside of the bulk commodity and it is mixed in with something. The reason why we know about that is because the definition of organic food gets to be very complicated when you start blending products together and chopping them up and so forth. What are you guys doing on that sort of product?

Mr. STENZEL. I think you are right. I hope we are continuing to be out front on some of these issues. I think because we have fresh product that doesn't have a kill step, it is eaten fresh and wholesome, we are very sensitive to maintaining that integrity all the way through to the consumer.

For example, in a bag salad product today, or mixed vegetables, great, great care is taken to maintain records of the incoming sources. So if it has got a mix of lettuce and carrots in the same bag, that processor does keep lot identification records on where the carrots or the lettuce would have come from.

Mr. KINGSTON. On FDA, on spinach, tomato, you mentioned about the collateral damage, it certainly is very important to ensure the safety of people first. But along the way, it does seem like you can be counterproductive if you say that all the peanut butter, all the tomatoes, are tainted; because the next scare comes along and people aren't going to really believe you. So there is a danger of that.

What are your recommendations to make FDA more effective, again using a rifle-shot approach rather than a shotgun blast?

Mr. STENZEL. You are absolutely right, Mr. Kingston. I have called for in our industry for a total look at the way the FDA, the CDC, and State and local health departments cooperate in foodborne investigations.

Mr. KINGSTON. This might be the Chairman's opportunity to underscore one agency.

Mr. STENZEL. But that really is important. There is a diffusion of responsibility. There are different people going in different directions. And, really, we have seen in our industry in several of these outbreaks just how difficult it is to have—who is in charge. I have given the example of the National Transportation Safety Board; when there is an accident, that you know who is in charge. There is clear authority. The buck stops here. And we don't have that in any food-borne investigations.

MULTIPLE AGENCIES

Mr. KINGSTON. Madam Chair, I think this is my last question, but I want to make a statement. Following up on conversations you and I have had along the way, my concern about a single agency is that we will still have other agencies who won't give up their control. And then if I am a producer—and what I don't like is—you know, we need lots of small mom-and-pop producers. It doesn't just need to be the domain of giants who can afford to comply with anything.

What we want to do is make sure that for the mom-and-pops out there, you don't have 15 agencies that can come and harass them. Work with them, but not harass them and not make production impossibly expensive and prohibitive.

So I think talking amongst yourselves as food groups is very, very important in terms of recommendations to streamline this, and then also to take advantage of new technologies that really and truly were not out there 5 years ago.

The Chair and I came here when e-mail was not used in congressional offices. And I remember on 9/11 there were very few BlackBerrys. And now absolutely everybody has them, from the new staffer onward. But technology is evolving so quickly now that it is like telecommunications. We pass a law today, it is obsolete by the time the agencies flesh in the bones of it. So we need to be careful on the emerging technology.

Ms. DELAURO. Thank you, Mr. Kingston. And I think it is a point. And particularly with the mom-and-pop efforts, we now have 15 agencies that deal in some way with a food safety responsibility, and I don't know that there is anybody who has laid it out so that they don't overlap with one another.

Or talking about communication, which is what interoperability is about, it is about communication. If we think everybody is on the same wavelength and communicating, well, then we are just—I will show you a bridge you can buy maybe to nowhere.

But in any case, you recognize a concern about what happens here, and that is about giving up turf, and that is a very, very difficult thing to do. But I think we are looking at a new environment, and I am not just talking about a new political environment with a new administration. And I think for me that is particularly helpful in this regard. But I think the new environment is what has happened in the various outbreaks of food-borne illness, and then culminating with nine people dying and industries potentially going out of business, that people are now beginning to say my gosh, maybe there is some relevance here for all of us. And your

input into all of this is really critical for us to try to move forward in some way.

I have about three more questions or so, because I don't want you to have to be here all day.

This is about the Minnesota issue, because I think it is important in terms of what is in the public domain on that and what the findings are. During that investigation of salmonella in St. Paul last summer, there were a number of news stories about the process used in Minnesota to investigate food-borne illness outbreaks. Minnesota has seemed to pinpoint likely sources of contamination very quickly.

In the salmonella case in particular, it appears that the State identified jalopeno as the cause before the FDA did. They were also able to suggest that the shipper was in McAllen, Texas, and that the peppers came from Mexico.

In an AP story about the State's work, a representative of the State Department, of Agriculture, who did the actual traceback was quoted as saying, and this is a quote, "A few phone calls and you can work it fairly quickly back to the grower."

This seems to be at odds with your findings, and it may have been fortuitous in that case that the outlet from which the people contracted their illnesses was a restaurant that was supplied by a large local distributor.

So what I would like to have you do is for you to comment and for you gentlemen to comment as well. Minnesota and, you know, this comment about FDA.

DIFFERENCES IN MINNESOTA EXPERIENCE

Mr. LEVINSON. Well, Madam Chair, I would certainly ask my colleague to comment as well. But my first reaction is how much I think the report has tried to be crafted in a way to give a snapshot of a system, you know, so that we look across a variety of suppliers, manufacturers, processors, and the types of food. I think that, anecdotally, I think once you drill down, you can find very important fact patterns like the one you are talking about in Minnesota that add either a level of complexity or a level of simplicity, sometimes, to what a solution might look like.

And in a sense, I want to come back to your concern earlier about maybe the—what appears to be perhaps a weakness of the sixth recommendation; that FDA should conduct education outreach activities to inform the food industry about its records requirements. I do think that this is a terribly important area in which all of the key players—and the food industry is obviously a key player—and the FDA, I think, can hopefully craft an I&E effort that can really make a big difference in this.

But let me turn the mike over to my colleague.

Ms. NUDELMAN. I would just say that—I mean as we saw in our own study here, there is a lot of variability. And sometimes you can get back fairly quickly where there is one source to each piece. But I think what we try to do is make sure that you can trace that precise product back through each stage of the food supply chain. As many problems as you have back, you see a lot more problems going forward.

So as we saw in our study, facilities were a lot less likely to know their recipients, who they are sending the food to, and that you have seen the example of the peanut. Still right now, they are still identifying where that peanut paste went, who the recipients are, and that has, of course, a lot of impact on where to recall the product.

So I think there are a couple of answers to that—why the difference of their findings versus our findings.

Ms. DELAURO. Gentlemen? Tom.

Mr. STENZEL. I would comment on Minnesota. Certainly there is a degree of expertise and commitment and funding there for those investigators that is much above the bar, on average. I would also suggest, however, that there is an approach that is designed for public health first. That is, go as quickly as you can to find the source. And they are working through any of these variabilities. They are making those phone calls. They are asking questions. It is a very engaging process.

CRIMINAL LIABILITY-BASED INVESTIGATION

What we have found with FDA is it is a much more linear criminal liability-based investigation. They want the records. A number of our wholesalers and distributors through the summer were asked, send me all of your records of all the tomatoes you sold in the last 2 weeks. So, thousands of pages. Even companies who had electronic records were asked to print them out and fax them to the FDA. So we have a problem of a different intent, I believe, in the traceback.

Ms. DELAURO. In a paperless society, they are drowning.

Mr. STENZEL. There is a lot that needs to be fixed in this regard, but that is one explanation, I think, for why strictly on a health basis we can move a lot more quickly than on a records factual—criminal basis.

Ms. DELAURO. And particularly if you have identified foods that are at high risk, then you really—Mr. Henry.

Mr. HENRY. Yes. I think to echo part of what both of these gentlemen said, when you look at the State of Minnesota or other States, funding becomes a real issue. There are certain States out there that have almost a dearth of staff to take epidemiological reports on illnesses.

And now you look at Minnesota where they do have a Department of Health and a Department of Agriculture. If they are all on the same page, which is more aligned, if you will, with a single type of agency, now you are getting conveyance of information very quickly to get to the issue, as opposed to the linear relationship that we see between CDC and FDA.

CDC raises a red flag and says, hey, we think this is where it is; hence, the tomato issue. And I think that is where we need to have much more rapid transfer of information, not holding back, hopefully not worrying about litigation, et cetera, et cetera. Let us get to the source, let us get it off the shelf.

Ms. DELAURO. Sam, do you want to go now?

Mr. FARR. I will wait.

Ms. DELAURO. Jack, you are okay?

Mr. KINGSTON. I might need to make a motion that you guys can continue without me if you want.

Ms. DELAURO. Okay. That would be great. Thank you.

Mr. KINGSTON. So moved.

Ms. DELAURO. So moved. Okay. Thank you. The issue is that we need to have——

Mr. KINGSTON. We have a very conscientious Chair who does not want to appear to be doing it without equal——

Ms. DELAURO. I don't want to do it without——

Mr. KINGSTON. She is actually a closet Fox fan, fair and balanced. It would kill her if that word got out.

Ms. DELAURO. It is going to kill me now.

NEW STATUTORY AUTHORITY

Let me ask a question that has to do with an FDA legislative proposal. As part of the food protection plan that was released in November 2007, the FDA asked Congress to give it 10 new statutory authorities related to food safety. I am not endorsing each part of the request, but they are to be commended, really, and I will say in what was a regulation-averse administration for making this kind of a proposal.

ACCESS TO RECORDS

One of their proposals relates to access to records under the Bioterrorism Act, and there seem to be two parts of the proposal. Both relate to their activities in a food emergency. First is to allow the FDA to look at records about related articles of food, not just about the food in question. An example would be food produced on the same manufacturing line as the suspect food.

Second, in an emergency, allow FDA access to records without having to show that it believes the food is adulterated. FDA says the recent melamine situation, which FDA had early clinical evidence that a specific food was causing illness in pets, but did not have clear evidence of a specific adulteration. That is the example for the scenario. FDA says that this would not impose any new burdens on industry, presumably, since these records are already required. This proposal is more limited than the OIG recommendation that FDA have access to records at any time.

So I would love to have each of you to briefly comment on that.

Mr. Levinson.

Mr. LEVINSON. Madam Chair, I think that as you have explained, it would be a very helpful first step. But it would definitely be worth Congress' exploring whether something more consistent, with a more comprehensive approach recommended by the OIG, might actually be more effective.

Ms. DELAURO. Okay. Thank you.

Mr. Henry.

Mr. HENRY. Without question, if there is a regulatory mandate for records to be made accessible, as it is today in the Bioterrorism Act, or just to show that the lot coding is being managed by manufacturers, I think manufacturing entities would subscribe to that and will comply. That needs to happen.

There is certainly a challenge when it comes down to having access to all records at all times for any reason. FDA is very typical,

and even as we speak today will come in not only asking for records but also photographs and other things that are really quite invasive and it takes more time to get that. It is not mandated by regulation if there is real advantage.

And I think I would default back to Mr. Kingston's line of thinking there. Is there additional value in getting that information that is going to help improve food-borne illnesses or, as you just made comment a moment ago, Madam Chairwoman, about drowning in paper, you know. Because how much time are you going to spend at a facility when you can't deal with the paper that is already on your table at this particular moment?

Ms. DELAURO. Mr. Stenzel.

Mr. STENZEL. Both of those recommendations in the food protection plan we would support.

Ms. DELAURO. Mr. Farr.

Mr. FARR. Thank you, Madam Chair. I apologize for missing most of this hearing. I have been in other appropriations hearings. I really have a couple of questions. One is for United Fresh.

PROGRESS ON MANDATORY REGULATIONS

I was really impressed by your asking for mandatory regulations, and I just wondered what progress has been made on that.

Mr. STENZEL. Well, Mr. Farr, it has been a long time in coming. It is, as you know, a couple of years ago when our board of directors first made that call. I do believe that the FDA is much more intent now on moving forward with a regulatory standard particularly for those commodities when, based on science or risk, that they can say needs to have a specific standard set, the commodity-specific food safety standards.

We have always said that they had the regulatory authority to do that without increased statutory authority, but they have been reluctant to this point in time. Certainly Congress is now also considering a number of bills that would be very straight and plain in providing that statutory authority, if there is any question. And I would anticipate that that is going to move forward rather expeditiously.

Mr. FARR. As you know, the industry is really complicated in the sense of how many—from the field and the place in the field and where that field may be located geophysically to surroundings to—I have been very impressed in the Seines Valley how they are now mapping those fields, and can tell you with every box what—almost the exact spot of the field that that came out of. And those boxes are shipped all over the country.

SMALL, ORGANIC GROWERS

And, you know, you question what might happen in the transportation process or the unloading or putting the vegetables on the shelves. And I just hope that we don't create—because the backlash—I was on a talk show last weekend for small organic growers, and they are fearing that this whole thing is going to disrupt ability for them to grow in their garden and take it down and sell at the farmers market.

Mr. STENZEL. I think that is a valid point. We have got to be very careful that whatever regulatory requirements are put forward are not inhibitive or punitive to smaller growers or organic growers.

At the same time, food safety is not a scalable thing. You can't have E. coli in your food, no matter how small a farm you may have. So we have got to be consistent in that regard. That is where I do think FDA has got to use proper judgment, consultation with the U.S. Department of Agriculture, consultation with the State Departments of Agriculture and Industry.

In your own district, the California Leafy Greens Marketing Agreement has done a fantastic job at setting forth the standards that all of the growers should be complying with, and those are the standards that I think are appropriate for that sector of our industry across the board, no matter where that product is grown.

Mr. FARR. Do you think, as we develop the concept of regulations in these areas, that we are consistent with what industry thinks is practical and can be done?

Mr. STENZEL. For the most part I do. That is always the risk you run when you ask for regulation: Is it going to be wise regulation? Hopefully, we are not asking for something that doesn't make sense. But there is going to be oversight required of the FDA to make sure that they don't go too far in some of those areas; that they do recognize the difference in growing regions and what is necessary for safety and what might not be.

GOOD AGRICULTURAL PRACTICES

Thus far, I believe the guidance documents, the FDA revision of the Good Agricultural Practices that is coming, they are on target with what I think is the most responsible approach to growing fruits and vegetables.

Mr. FARR. I want to compliment you as a representative of your industry, because whenever we have had these crises in the past, I have never seen an industry step up and say we are ready to be supportive of regulation. And I think you are really to be commended for that in being a part of it.

Madam Chair, if I can, I have one more question and that will be it. And it is of the IG. You are the IG?

Mr. LEVINSON. Yes.

Mr. FARR. Sorry. I don't have my IG I.D.

Related to this recall—and I have gotten very interested in this issue. I never even knew. It was a little something that I saw with the E. coli recall, and then with the fires we had in Big Sur last year, and it is called crisis communication, and it is a whole developed field. I mean, medicine has always had it, and we remember the old adage to doctors: Don't alarm your patient. But we don't seem to be using that—and law enforcement is beginning to learn about it.

COMMUNICATION PROTOCOL FOR RECALLS

Did you look into communication, how professional or what they are doing to develop smart protocols for recalls?

Mr. LEVINSON. Well, in all candor, Mr. Farr, that is really beyond the study that we undertook here that is the focus of the hearing today. We have conducted several reviews of FDA work. And I

think the question that you are asking would really be of a more generalized nature than our specific work in OIG. But we have certainly identified FDA as—there is a major management challenge for FDA and the enormous jurisdiction that it has and the ability to align its work in a way that is effective and brings a high degree of confidence from the American people, from Congress. And I think that is reflected to a certain degree in our expression of concern over just the management challenge that FDA faces.

On the more law enforcement-specific ideas, we have looked closely at their own internal investigations process and have expressed concerns about how that works. And I think that kind of work should be—I would hope would be an important trigger in FDA revisiting or rethinking the way it handles things like recall.

Mr. FARR. Maybe you could help me understand. I sit on Homeland Security, which you would think would be the kind of area that would have that, but they don't have jurisdiction in this area, and they are just beginning to understand even questioning issues of food-borne biology that could lead to intentional food contamination or terrorist-type acts.

It seems to me that this is one of those areas that is emerging, particularly with the technology you have. We heard in the Virginia Tech shootings that the responders didn't have the information that the students in the classroom had, and they were text messaging on Facebook, and who was looking at that was the media. So here were the responders going through their responding channels that weren't accurate.

And so what happens is you arrive at a scene or you have an incident developing, and it is depending on how you handle that. You can take a problem and escalate it into a crisis because you haven't got the right people to respond to the crisis or you are not saying the right things and can develop a panic.

And it seems to me that all of us in government, because we are the authority, we have got to start figuring out how in a new Information Age that we are going to handle emergency communications—and I would imagine that all recalls are emergency communications or warnings—that we have got to do a much more—be much more sophisticated than we have traditionally been in just sort of leaving it up to the law enforcement speak, the police channels, and it includes regulatory agencies like the FDA. And if you have any idea, I don't even know how to start questioning all that.

Mr. LEVINSON. Well, I think you have outlined a lot of the most important concerns that should really be at the forefront as policymakers rethink, and especially Congress, rethinks, how it might want to align functions that historically have been buried in different departments or agencies. And of course, ultimately, it is the Congress' responsibility, authority to structure or restructure executive agencies and departments as it sees fit.

And I would certainly agree with you that historically this has not been viewed in a more wholistic way; and at this point, and especially given the progress we have with information technology, deserves a real revisit by people across a much wider spectrum of the national security picture than we have perhaps experienced before.

We have a piece of that at HHS and specifically at FDA, and I would hope that this is the kind of study that serves as a good example of the kinds of concerns that may be elevated to the Congress and to the Executive so that we can rethink how this actually works in practice.

Mr. FARR. It gives me something to think about. Thank you.

Ms. DELAURO. I just have two more questions.

ONGOING WORK WITH FDA FOOD ISSUES

Mr. Levinson, I am curious about your ongoing work with the FDA food issues. You indicated that you are conducting a number of audits, registration of food facilities with the FDA, FDA's inspection of food facilities and its follow-up on violations, and several audits on FDA's authority and procedures for recalls. Can you give us some additional detail on each of these reviews? Are there any preliminary findings that you can share with us?

I would just also add for fiscal year 2010, there is a bill moving forward, and we will see legislation—there is a major authorization in the Energy and Commerce Committee on the food safety issue. So I think your reports could be very very helpful in this regard, and if you can tell us when you expect to complete them. So any details, preliminary findings, when do you expect them to be completed?

Mr. LEVINSON. Thank you, Madam Chair. And really on behalf of an outstanding Office of Evaluations and Inspections and Audit Services as well, we do have within very limited kinds of resources, I might add, a fairly robust current and ongoing work in food safety. As you mentioned, compliance with FDA's food registry requirements, which we expect to be completed this fall; FDA's inspections of domestic food facilities, which we have a projected a completion date of 2010; imported foods, with a completion date sometime during this fiscal year; imported pet food and feed products, again to be completed toward the end of this fiscal year; human food and pet food recall procedures with a projected completion date of 2010.

We also have work on FDA's consumer complaint system process, medical devices, clinical trials and human subject protection due next year.

So this is a robust agenda. And without being able to provide really specific status of work at this hearing, I would certainly welcome the chance for our staff to be in regular contact with your staff so that you are kept very much current with where we are headed with this work.

Ms. DELAURO. I appreciate that and would like to keep in touch. I would also like to suggest, and I will make the suggestion, that Congressman Waxman's committee have the benefit of some of this information as well, and to loop their staff in.

So as we move forward, let us move forward with good, solid information, and not then have to backtrack because we didn't know about something or we thought we had looked at it but that we haven't. This is a question of the interoperability of our communication. And so I just think we are in an era, in a moment, when there is a spotlight on all of this, and I think we need to take advantage of that to its best results for the future.

SHARING RESPONSIBILITY FOR TRACEABILITY

Mr. Henry, let me just ask you a quick question, because in your testimony you said you call for the sharing of responsibility for traceability through office supply chain. Let me just ask you plainly, who is not carrying the load, the burden here?

Mr. HENRY. What we are really referring to there, as you look at the scope of the BT Act and who is required to participate, which is all those things that I think Mr. Levinson has already pointed out. So if there is a gap and the gap needs to be filled, then action has to be taken appropriately.

Ms. DELAURO. I just want to make this one comment. I wish Mr. Kingston was still here because I think it was Mr. Kingston who talked about the mandatory recall earlier on, and this is an article from today.

[The information follows:]

The New York Times

March 26, 2009

Investigators Find Source of Many Foods Untraceable

By GARDINER HARRIS

WASHINGTON — Most food manufacturers and distributors cannot identify the suppliers or recipients of their products despite federal rules that require them to do so, federal health investigators have found.

A quarter of the food facilities contacted by investigators as part of the study were not even aware that they were supposed to be able to trace their suppliers, according to a report by Daniel R. Levinson, the inspector general of the Department of Health and Human Services.

The report, expected to be made public Thursday, comes as President Obama and a bipartisan chorus of lawmakers have promised major changes to the nation's food-safety system.

And it may help explain why many small food makers continue to issue peanut-related recalls more than two months after the Peanut Corporation of America was identified as the source of a salmonella scare that has sickened at least 691 people and has been linked to 9 deaths. The New York Times obtained a copy of the report.

As late as Monday, the Food and Drug Administration formally asked Westco Fruit and Nuts Inc., based in Irvington, N.J., to recall all of its products containing peanuts made by the Peanut Corporation. Jacob Moradi, Westco's owner, could not be reached for comment, but he told ABC News that the F.D.A.'s recommended recall — the agency does not have the power to issue food recalls on its own — could ruin his company. "They are asking me to commit suicide based on presumption," Mr. Moradi said in a broadcast interview. "They have shown no proof."

An F.D.A. official said Mr. Moradi hid from investigators at his plant.

On March 14, Jay Robb Enterprises of Carlsbad, Calif., announced a recall of peanut-butter-flavored JayBars. Alana Weber of Jay Robb said in an interview on Wednesday that although the company knew the peanuts in

the bars came from the Peanut Corporation, it believed until recently that its bars were not part of the recall.

The inspector general recommended that the F.D.A. seek greater authority from Congress to require and ensure that food facilities maintain adequate records. In an official response in the report, the agency said that it largely agreed with the recommendations. Representative Rosa DeLauro, a Connecticut Democrat who is holding a hearing on Thursday where the report will be issued, said the recommendations would be included in reforms passed by Congress.

"Traceability is a critical tool in our ability to identify the source of a food-borne illness outbreak and locate where contaminated products were sold," Ms. DeLauro said Wednesday.

To test compliance with the rules, federal investigators bought 40 products — including tomatoes, oatmeal and yogurt — from retail stores in New York, San Francisco, Chicago and Washington and tried to trace them to farms or to the border. Foreign firms are not required to maintain supplier records.

Investigators successfully traced the source for only 5 of the 40 products, the report stated. Three of the traced products were egg cartons whose supply chain included only a farm and a retailer. For a tomato, a bag of ice, a bottle of fruit juice and a bottle of water, investigators were not able to even guess the product's supply chain. For 31 other products, investigators were able to identify only the likely suppliers.

The investigators contacted 220 food facilities to ask about their supplier records. But only 118 of these businesses were included in the study because the rest were not required under rules adopted by the F.D.A. in 2005 to maintain supplier and recipient records. Of those 118 firms, 70 failed to provide investigators with required information about suppliers or customers, with 6 of the companies failing to provide any information at all. One vendor told investigators that it kept no records of tomato purchases.

Tomatoes have repeatedly been implicated in nationwide food contamination scares, including one last year. Fifteen facilities told investigators they mixed raw products from more than 10 farms.

"According to an estimate from a manager at a grain storage facility, if grain from one farm were contaminated, millions of bags of flour would be at risk and might have to be removed from retail shelves," the report stated.

Ms. DELAURO. This is in the New York Times by Gardiner Harris. It is about this report. It says: "Investigators find source of many foods untraceable." That was the Gardiner Harris piece.

PEANUT CORPORATION RECALL

But this was very interesting to me. This was about the Peanut Corporation of America and the salmonella issue. It says, "As late as Monday, the Food and Drug Administration formally asked Westco Fruit and Nuts, Inc., based in Irvington, New Jersey, to recall all of its products containing peanuts made by the Peanut Corporation."

Now, I am surmising that the FDA was basing that on some reality here—you know, I have to—but how this thing is still ongoing.

"Jacob Moradi, Westco's owner, could not be reached for comment, but he told ABC News that the FDA's recommended recall—the agency does not have the power to issue food recalls on its own—could ruin his company. 'They are asking me to commit suicide based on presumption,' Mr. Moradi said in a broadcast issue. 'They have shown no proof.' An official said Mr. Moradi hid from investigators at his plant."

Now, I mention this because there are two pieces. I understand that Mr. Moradi is afraid that he is going to go out of business. But, again, we have to have a process at FDA which allows it to make a decision based on solid information that there is a problem here and therefore can say, you are shut down. You are shut down. But based on proof and data and science.

So we now are in the position where it is so tenuous that there is the view of oh, maybe they don't have any indication or proof or science. And on the other hand, my God, what is the product that these folks are dealing with that my family may have consumed and they won't recall their products? There is no—this is a no-win situation. A no-win situation because, in fact, it would appear that there is no one in charge here of making a determination.

Our goal here is not about—I mean this has been a terrific hearing. This is a complicated issue of traceability, and we need to do it. We need to do it right. We need to know where the first part is and where does it start and where does it end and how can we put in place a mechanism?

I think it is doable. I think you think it is doable. We are not in the 1930s here. There is technology. There are all kinds of ways for us to address this and deal with risk, deal with technology and inspection based on risk. But it is data that pushes us in that direction, so we can grant assurances on public health and assurances to a company that you are not going to go out of business here.

Mr. FARR. Madam Chair, if I can, my experience in that is when the government actually orders destruction of farm animals, the government will pay for it; so it is a takings issue. And I think a lot of this sort of gets into this tort liability issue of if we are not—like in the spinach, we didn't take it. We voluntarily asked people to take it off the shelves. And for that—and they did. They responded immediately.

VOLUNTARY RECALL AND REIMBURSEMENT

Many thought, well, I will get reimbursed for these costs. And as you know they didn't, and the insurance company said that was a voluntary recall. We don't ensure that. So you are in this gray area. And I think if we are going to resolve this question, it has really got to be the one of who is going to pay for it.

We have some of these protections under the Perishable Commodities Act, where if a buyer doesn't—if you buy wheat and you don't sell it in time, it is still good the next week. If you buy strawberries and you refuse to pay on them, they rot, and there is no secondary market.

So a lot of this is how you figure out the way to pay for it. Or if it is negligence, then the government shouldn't pay for it; the entity ought to be charged.

Ms. DELAURO. Well, I think that is a point and that is making the determination.

It is alleged that I am not going to deal with litigation, but we may be in a position with a company that knowingly sold a tainted product. Knowingly sold a tainted product. And we have to have the capability of making that determination, which means a number of enforcement tools and a number of strategies, enforcement strategies, that get at what happened.

Once you begin to put some pieces in place, people are not foolish; they say, why would I put myself in this position? But if we continue to just self-regulate and just turn a blind eye, well, then, hey, whatever the market will bear, and I am going to presume I am not going to get caught and I can just move on.

Not to be litigious, but we have got to have the full spectrum of tools available to be able to address what the current set of concerns are.

Thank you all very, very much. Obviously we look forward and we hope you will view that there is an open dialogue here about how we can try to move forward. I don't want to wait months. I think we need to move quickly and try to see how we can try to make some very strong recommendations about how traceability can work and what it could look like. So thank you all very very much.

This hearing is adjourned.

Questions Submitted by Congressman Kingston

Office of Inspector General
U.S. Department of Health and Human Services

Mr. Kingston: What discussions did you have with FDA in selecting the specific products to study? Do you know and can you tell us why FDA chose those specific products? Has there been a particular problem in the past with any of these products or the food industry's performance?

Response: We selected 10 different products for our study in consultation with FDA officials. We considered a variety of criteria, such as the products being commonly consumed within the U.S. and food products that contained a single primary ingredient. We then consulted with FDA officials to determine if there were any additional characteristics of food products that they believed would be important to consider when selecting our sample. Specifically, FDA officials wanted to learn more about foods with the following characteristics: foods with a short shelf life, unprocessed foods, liquids, unlabeled foods, and foods that are not governed by a safety plan (such as a HACCP plan). We took these characteristics into account when making our final selection of food products for the study.

Mr. Kingston: I would like to sort out the inability to trace the food products from the lack of adherence to existing regulatory requirements. Your testimony references both. How much less of a problem would you say existed if all the entities you visited had complied with all of the rules now on the books?

Response: Compliance with existing records requirements is necessary for FDA to identify the sources and recipients of contaminated food products. However, it is not sufficient. Our report found that even when facilities were in compliance with the regulatory requirements, the traceability of food products was limited by several factors. These factors included: (1) food facilities not maintaining lot-specific information, (2) products not being labeled with lot-specific information, and (3) mixing raw food products from a large number of farms. If FDA encounters any one of these factors, it will likely affect the speed with which FDA can trace food products through the food supply chain. Most commonly, these factors result in more facilities being implicated in an outbreak than necessary, and FDA must expend additional resources contacting these facilities and removing their products from the food supply.

Mr. Kingston: Your recommendations appear to apply to all foods over which FDA has responsibilities, as if the risk of food borne illness is the same in all processes. Would it not be far more efficient to target the regulatory requirements based on the potential risk of food borne illnesses for the products being manufactured or processed?

Response: One objective of our report was to assess food facilities' compliance with the records requirements set forth in the Bioterrorism Act. These requirements are designed to ensure that all foods under FDA's jurisdiction are traceable, regardless of risk. Traceability throughout the entire

food supply chain—which includes low-risk facilities as well as high-risk ones—is what enables FDA to remove unsafe food products from the food supply chain. Targeting only high-risk manufacturers or processors with regulatory requirements would not achieve a traceable food supply.

In our recommendations, we recognize that there are differences between industries, and therefore we did not recommend one-size-fits-all solutions or attempt to dictate specifics of how FDA should implement our six recommendations. Further, we encourage FDA to work with the food industry to develop guidance and regulations that are both targeted and effective. In particular, we recommended that FDA strengthen its existing records requirements by identifying additional types of facilities that need to maintain lot-specific information. We also recommended that FDA have access to facilities' records outside of a food emergency to ensure that all facilities are complying with the records requirements. Finally, we recommended that FDA consider seeking additional authority to enhance traceability, such as mandating interoperable recordkeeping systems or requiring food facilities to keep records beyond just their immediate sources and recipients. For each of these recommendations, we provided FDA with a considerable amount of latitude in terms of how it chooses to implement them.

Mr. Kingston: Your conclusion that many of the processers that you visited did not keep lot numbers because they did not have to do so and another that they only kept them if they existed. However, can you tell us if you requested or asked if those entities kept other information not required that enabled those firms to purchase insurance or protect them from liability?

Response: As noted in our report, facilities that process, pack, or manufacture food are required to maintain lot-specific information "to the extent that it exists." Our study found that 2 of the 38 facilities that labeled the food product with lot-specific information failed to meet this requirement. In addition, two other processors did not maintain lot-specific information because it did not exist. Further, most distributors, wholesalers, and storage facilities in our review did not maintain lot-specific information. Although these facilities are not required to do so by FDA, the lack of lot-specific information limits the ability to trace food products through each stage of the food supply chain back to the farm or border.

In addition to asking facilities about the extent to which they maintained lot-specific information, we provided several opportunities for facilities to discuss their record keeping practices. For example, we conducted extensive follow-up interviews with facilities where we asked about how they ensure traceability and how they keep their records. In these interviews, a number of facilities volunteered information about the beneficial practices they employ—such as mock recalls or third-party audits. We did not, however, specifically ask if facilities kept information that enabled those firms to purchase insurance or protect them from liability.

Mr. Kingston: Food safety is only one of the reasons for keeping records and keeping track of product origins and processing. Another major reason is product quality control, processing and distribution efficiency and product differentiation, to name a few. The studies done elsewhere demonstrate that private sector firms have developed a large capacity to trace products for those purposes. Do you think that these would be sufficient to meet the objective of food safety as well? Did you request any of that information in your survey?

Response: For our review, we collected all available information that the facility had about the food product we purchased, and its sources, recipients, and transporters to: (1) assess the traceability of the food product, and (2) to determine whether the facility was in compliance with the records requirements. The data we received from food facilities was likely maintained for a variety of reasons, such as quality control, processing and distribution efficiency, or product differentiation. In addition, several facilities we spoke with indicated that it was simply good business practice to keep records about their products.

In the majority of cases, this information was insufficient to allow us to trace the product through the food supply chain. Using all the records provided by the food facilities in our sample, only 5 of the 40 products we purchased could be traced through each stage of the food supply chain back to the farm or border. Additionally, 59 percent of the facilities that handled these food products failed to meet FDA requirements to maintain certain records about their sources, recipients, and transporters of food.

Mr. Kingston: Your recommendations, I think get to the heart of the issue. Should the government require that food borne illnesses be traceable or should they mandate how to do it? The government has many policy options for achieving its objective. Let me raise one that was highlighted by the researchers at ERS. What if the Government set standards for recalls that made firms prove (through mock recalls) that the firms could locate and remove hypothetically contaminated food from the food supply within a set period of time? But the Government would not specify how they would do that? Do you think that would meet your objectives as well as your recommendations for new legislative requiring more record keeping?

Response: The recommendation that is most directly related to your question is our recommendation that FDA consider seeking additional statutory authority to require food facilities to further strengthen the traceability of food products. As we noted in the report, this authority could include a variety of approaches such as requiring facilities that handle food products to maintain records about every facility or farm that handled the product, or requiring facilities to use certain information technologies to help facilitate recordkeeping. In our report, we left it up to FDA to determine the best approach for achieving the goal of traceability in the food supply chain.

Mr. Kingston: Wouldn't it make sense to require only that a firm's traceability system for pathogen control extend only back to the last "kill" step—where product was treated, cooked, or irradiated? Follow-up: And speaking of kill steps, wouldn't the introduction of kill steps, such as irradiation, in some products that are currently packed or processed without them, be a more useful tool for preventing food borne illness than traceability?

Response: There are a number of reasons why traceability should be extended throughout the entire food supply chain, not just back to the previous kill step. First, kill steps are not always effective at eradicating foodborne illness. Further, tracing food products back to the farm can provide FDA with valuable information that allows them not only to handle a food emergency in progress but can also help prevent future ones. For example, the E. coli outbreak of 2006 occurred after the chlorination of the spinach leaves – commonly considered to be a kill step; however, this was insufficient to ensure a pathogen-free product. Because the spinach could be traced back to the farm where it was grown, FDA was also able to identify certain agricultural practices that contributed to the outbreak.

As noted in our report, traceability requires the ability to trace food products throughout the entire food supply chain. This is what enables FDA to remove unsafe food products from the food supply chain. Omitting farms and other facilities that handle food products prior to a kill step from any traceability system would potentially limit the information available to FDA during a food emergency.

Mr. Kingston: One of the ways that industry has grappled with the legal threat associated with food borne illness outside of the regulatory process is third party safety audits and industry maintained standards. Did you review or assess the efficacy or adequacy of these actions on the part of the private sector in your study. Do you know of anyone that has at FDA in the past?

Response: Our study was limited to an assessment of the ability to trace selected food products as well as facilities' compliance with the records requirements. We did not assess the efficacy or adequacy of third party safety audits or industry maintained standards.

Mr. Kingston: The homogeneity of the products at the farm level has never warranted farm level detail. Instead safety and quality are best monitored at the elevator, including some product differentiation (genetically modified). Why do you think that farm level detail is needed and what do you think would be gained?

Response: Our report did not assess what specific level of detail may be needed at the farm level to achieve traceability. Our report did, however, note that commingling—or the mixing of raw products from a large number of farms—can potentially limit FDA's ability to trace a specific product through the food supply chain. For example, we found that 7 of the 40 food products that we traced contained raw products commingled from 100 or more farms. In the event of an outbreak of foodborne

illness, FDA would have to spend its limited resources contacting each of these farms and removing their products from the food supply. As noted in our report, this may affect the speed with which FDA could locate the source of a food contamination and remove contaminated products from the food supply.

We recognize that commingling is often a necessary industry practice. For example, some industries might need to mix raw food products from a large number of farms to create homogeneity within its products. In other industries, it might be possible to limit the number of farms that contribute to each food product in order to enhance traceability. Recognizing these differences between industries, we are not recommending a one-size-fits-all solution. Our report recommends that FDA work with the food industry to develop industry-specific guidance to address commingling.

THURSDAY, MAY 21, 2009.

FOOD AND DRUG ADMINISTRATION

WITNESSES

JOSHUA M. SHARFSTEIN, M.D., PRINCIPAL DEPUTY COMMISSIONER AND ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION
PATRICK McGAREY, DIRECTOR OF THE OFFICE OF BUDGET FORMULATION AND PRESENTATION
NORRIS COCHRAN, DEPUTY ASSISTANT SECRETARY FOR BUDGET, HEALTH AND HUMAN SERVICES

Ms. DELAURO. The hearing is called to order. Good morning. Let me welcome everyone this morning, particularly Dr. Joshua Sharfstein, who is the Principal Deputy Commissioner, Acting Commissioner of the Food and Drug Commission. I am pleased again to welcome all my colleagues. Our ranking member will be here shortly. Mr. Latham will make opening remarks in a moment. And I'm happy to continue with our efforts to move on with the budget hearings for the 2010 Agricultural Appropriations bill.

Dr. Sharfstein, let us just all welcome you here and congratulate you on your new position. Delighted to see you, so much look forward to collaborating with you and Commissioner Hamburg in the months and the years ahead. I had the opportunity to meet with and talk with Dr. Hamburg yesterday, and I'm looking forward to a—our conversation yesterday was just open and positive and productive, so, looking forward to that relationship.

I know that you agree that FDA's first responsibility is to the American people, to ensure the safety of food they eat, the drugs that they take and the medical devices that they rely on. That is the agency's most fundamental regulatory mission. The American people must be able to depend on the system, and the people in charge of protecting them.

I'm proud that since taking the chair of this subcommittee, we have begun to address that critical need for more resources. This committee and Congress have increased the FDA's total budget by more than $572 million since 2006. In 2009, FDA has 39 percent more in discretionary resources than it had in 2006, $572 million, despite overall spending limitations imposed by the previous administration. On top of that, a supplemental appropriation in 2008 of $150 million. I'm proud that since September 2008, the agency has been able to hire 1,500 new employees, scientists, inspectors, analysts who are doing critical work, a direct result of those increased resources.

Looking ahead to 2010, I am encouraged by the Administration's $2.3 billion request for discretionary resources provided by this committee, an increase of $299 million, almost 15 percent over last year. I believe this is a good start at giving FDA what it needs to get back on track. It represents a strong commitment to building

the historic levels of investment this committee has made over the last three years.

Dr. Sharfstein, I know you've already begun working to connect the recent increases in resources to concrete positive public health outcomes, and I encourage you to continue to make them a priority. But as you know, the problems at the FDA will not be solved simply with more funds and with stopgap measures. As you know, you are coming into an agency that is desperate, in my view, for fundamental reform. When we look at recent headlines, unsafe foods, dangerous medical products slipping through the cracks time and again, it is hard not to see a system in crisis and an FDA hobbled by a fragmented structure with outdated legal authorities in many areas and insufficient authority to protect the American people.

To restore the agency's gold standard mission and ensure the fundamental safety of the food and drugs that it regulates, I believe we must be guided by four principles: First we must increase funding to support the FDA's mission. Second, we must improve the management of the agency and hold it accountable. Third, we must push back against the influence of industries over the agency. And finally, and perhaps most importantly, we must let scientists do their work guided by science and not by political or ideological interference. These are the guideposts I will use in judging our progress as we move forward in a new Administration. This is our opportunity to get the big things right for the American people to make real changes that will affect their health and their safety every day.

With that in mind, let me raise a few issues that I imagine you will discuss in your statement, and I may ask you to elaborate on when we get to questions. In particular, I commend your decision to exclude from the budget fees from industry to finance the agency's direct to consumer television ads. I have always been of the view that having drug companies pay for the review of such ads and having reviewers' salaries dependent on drug company fees will further undermine the public's confidence in the FDA.

By the same token, I would like to hear more about your proposal to increase the number of generic drugs in the market and how you view the role of generic drug makers in this expansion.

I also know the FDA must frequently confront new and growing demands in a constantly-evolving public health environment. As you know, the House recently passed very important legislation giving the FDA responsibility for tobacco regulation. And the Senate is marking up their version as we speak. I look forward to hearing your strategy for implementing this regulation and discussing how you envision that responsibility fitting within the agency's overall public health and safety mission.

In the same spirit, I also know you will update us on FDA's approval of a new plant to make seasonal influenza shots that could also be used to make an H1N1 vaccine. Indeed, since the virus's outbreak, much of our public health infrastructure, including the FDA, has been put to the test. I want to commend you and all of the outstanding scientists and doctors for their quick and their thoughtful response. And I'm curious to learn what we are learning from this experience, what new demands has this outbreak created,

and how will our response going forward affect the agency's larger mission.

I thank you for joining us this morning, Dr. Sharfstein. I look forward to asking you about these and other efforts within the FDA. As I told Secretary Vilsack last week, our appropriations reflect the priorities of this great nation. We have big goals, and it is the details, the budget and the basics that we are discussing here today that get us to be able to reach those goals.

With that, let me recognize my colleague, Mr. Kingston, for any opening remarks that he may have.

Mr. KINGSTON. Thank you, Madam Chair, and I'm going to yield to Mr. Latham.

Ms. DELAURO. Okay. Thank you.

Mr. LATHAM. Thank you, Jack. Thank you, Madam Chair, and welcome, Dr. Sharfstein. The FDA is one of the most important agencies that this subcommittee has jurisdiction over, and as you can probably imagine, we've had a lot of people advocating for increased funding on your behalf, not just the agency itself.

I'm not aware of any other government agency probably outside of the CIA today that catches more grief from politicians and industry and others, and for as long as I've been in Congress, we've heard the same drumbeat about the agency being underfunded and understaffed. That said, there is much being asked of the FDA, and I would argue that as we try to achieve a risk-free society, we expect almost the impossible from your agency. So I think there needs to be some recognition that the FDA has challenges, but there is good work being done at the agency, and the folks on the ground really don't get the kudos that they deserve, and I think this committee would back that up.

The Administration or you're asking for a 19 percent increase in funding, and once again, much of that is based on the expectation of new user fees that Congress supposedly is going to create. I don't know what the prognosis for that is, and it's usually very difficult. So for today I hope we can have a productive conversation about these numbers, your priorities, and that we can draft a responsible spending bill that ensures that you can effectively do your job. So, with that, Madam Chairman, thank you.

Ms. DELAURO. Thank you. Mr. Kingston, would you like to make any remarks? Okay. Thank you.

Dr. Sharfstein, if you would please, we'll move to your testimony, and you can be assured that the full testimony will be made part of the record, so you're free to summarize as you like.

INTRODUCTORY REMARKS

Dr. SHARFSTEIN. Great. Thank you very much. Thank you Chairwoman DeLauro, Ranking Member Kingston, Congressman Latham, other members of the subcommittee. I am Dr. Joshua Sharfstein, the Principal Deputy Commission and Acting Commissioner, but not for very long, of the U.S. Food and Drug Administration.

I am pleased to present the President's 2010 budget request for FDA. For today's hearing, I'm joined by Patrick McGarey, the FDA's Director of the Office of Budget Formulation and Presen-

tation, and Norris Cochran, the Deputy Assistant Secretary for Budget at HHS.

In my testimony today, I will outline the Fiscal Year 2010 budget request and the policy initiatives that we are advancing in our budget. I will also summarize recent developments related to the 2009 H1N1 flu virus outbreak and describe how FDA is responding.

Let me start by thanking the subcommittee for exactly what you laid out, Chairwoman DeLauro, the historic investments at FDA that have been made over the last few years. I think these investments demonstrate the strong support of the subcommittee for the public health mission of FDA and the health of the American people.

When I came to FDA a few weeks ago, I asked each center to provide examples of how they're using these funding increases to promote public health in the United States. I believe a key goal of management for the FDA is to be able to connect the investment that you're making and the American people are making in the agency with clear public health outcomes. And I got some very interesting responses.

PUBLIC HEALTH OUTCOMES

I heard from the Center for Biologics that because of your investment, FDA is moving forward to be able to test the blood supply, and have the blood supply tested for rare and emerging strains of HIV. That we are now able to have trained many device regulators around the world so that the devices that we get are safer.

We are developing a Hepatitis A test for foods that had never existed before, so you could actually test a food to see if the Hepatitis A virus is there. We are developing rapid food safety diagnostics so we don't have to wait days for the results of salmonella tests. We're developing a system of coordinating with veterinarians so that pet food outbreaks can be identified quickly and stopped. And there's very interesting research going on that will lead to new ways in evaluating pediatric anesthesia, which is important for children and important to me as a pediatrician.

And of course there's flu. I think it's really important for you to recognize the investments that you made in FDA over the last couple of years are directly related to the nation's preparedness for flu. And the best example of that is right now we have six different companies essentially making flu vaccine for the U.S. market. In 2004, we were down to two, and it was only because of additional resources that FDA switched its model to proactively reach out to companies to try to engage them in the U.S. market, went out and inspected them and worked with them to develop their products for the U.S. market, and in the most extreme example, work with a factory that was just getting built and were able—which leading to the approval a couple of weeks ago what will lead to the doubling and eventually the tripling of the domestic manufacturing capacity for the injectable flu vaccine. And all that was really possible because of the investments that have been made over the last few years.

BUDGET REQUEST

So let me take it back up to the whole budget. The request overall includes $3.2 billion to protect and promote the public health through FDA's mission. This includes an increase of $510 million for FDA programs, which is a 19 percent increase compared to last year. This historic increase demonstrates this Administration's commitment to food safety, medical product safety and the health of the American public.

The increase includes $295 million in budget authority and $215 million in user fees. And this budget organizes these into two initiatives: Protecting the food supply and safer medical products. It also includes $74 million for statutory increases in user fees and for infrastructure to support FDA's mission. And I certainly would encourage everybody here to visit the White Oak campus if you haven't already. It's really remarkable and also demonstrates a tremendous commitment to the agency and public health.

This budget recommends four new user fees to facilitate the review of generic drugs, enhance FDA's ability to register and inspect food and feed manufacturing and processing facilities, allow FDA to reinspect facilities that fail to meet good manufacturing practices and other safety requirements, and allow FDA to collect fees when it issues export certifications for food and feed.

It also recommends new authority for FDA to approve generic—I would say follow on biologics through a regulatory pathway that protects patient safety and promotes innovation.

Finally, the budget also includes $5 million for FDA to develop policies to allow Americans to buy medications that are approved in other countries.

PROTECTING AMERICA'S FOOD SUPPLY

Let me go into a couple of details. First, I would like to talk about protecting America's food supply. For Fiscal Year 2010, FDA proposes an increase of $259 million for food safety activities. This includes $164.8 million in budget authority and $94.4 million in three new user fees that I described before.

This funding will allow the agency to hire over 600 additional staff to work on food safety. It will pay for cost of living increases. It will, through the staff, fund significant increases in domestic and foreign risk-based inspections, audits and laboratory analyses. The number of staff includes more than 220 additional investigators to conduct inspections, and we anticipate that when fully trained and deployed, this will lead to significant increases in the number of domestic and foreign food safety inspections.

More importantly in my mind than inspections, this will also fund an increase in—it will also fund FDA's ability to implement a strategic framework for an integrated national food safety system. And this includes working very closely with states and localities to integrate our efforts and develop preventive-based regulations and guidances that will shift our food safety system from what I think is now fundamentally an outbreak-focused food safety system to what should be fundamentally a prevention-focused food safety system.

These resources include money for the states, money to develop capacity around prevention, money for regulations. In addition, there's funding to better respond to outbreaks, which includes detecting contamination, quickly tracing contamination, and communicating risk during a food safety event. This funding will also support three new laboratories for chemical analysis.

And there's a major investment in information technology systems, including systems we use to screen, sample, detain and take enforcement actions against imported food and feed products that violate FDA safety standards.

SAFE MEDICAL PRODUCTS

As far as safe medical products, the budget proposes $166 million for medical product safety. This includes $120 million in budget authority and $46.6 million for a generic user fee program, and reinspection user fees related to medical product facilities. What this funding would accomplish is about more than 300 additional full-time equivalent staff. It would also fund the cost of living adjustment, and it would permit additional inspections of both domestic and foreign sources of ingredients, components and finished products throughout the drug and biologic and device supply chains.

Within the Center for Biologics, it would allow the hiring of additional safety experts for blood, tissue and vaccine safety teams, and would allow CBER to develop new screening tests for emerging blood-borne diseases, and additional work on identifying safety signals for both vaccines and tissue products.

For devices, it would allow the Center for Devices to implement safety requirements including in the FDA Amendments Act. This would include analyzing data relating to children's devices, conducting a medical trials workshop to address unmet pediatric device needs and hiring additional experts. There is also a special focus on eye medical devices that are included in the budget.

For CDER, the drug center, the budget increase would allow more work to be done on how to best use the risk evaluation and mitigation strategies to minimize drug risks and promote safe drug use. It also would allow CDER to conduct research on bioequivalent standards for generic forms of products such as metered dose inhalers, topical drugs and complex dosage forms, such as lipozone products. It will also expand enforcement against Internet sites that expose consumers to unapproved products and fraud.

For the Center for Veterinary Medicine, the funding will allow risk evaluation of animal biotech products and also expand efforts to create a safety system for animal drugs, and it will support research at NCTR on nanoscan materials and other important products. And there's a significant IT investment there.

LEGISLATIVE INITIATIVES

I should just briefly mention that there are legislative initiatives that are implied by the budget. These include support for generic drugs by developing a user fee program that would facilitate reduction of the backlog in generic drug applications. It also presumes a passage of legislation to permit follow-on biologics with a workable and scientifically sound regulatory pathway that could significantly reduce costs to the American people.

FLU OUTBREAK

Let me just briefly mention, if it's okay, how FDA has responded to the flu situation, because I think it really demonstrates how FDA is a public health agency working for the American people. Now this all happened really just a couple of weeks into my time at the agency, and I was really just getting acquainted. And I was just extremely impressed by how the agency responded, and I want to explain what happened.

As soon as we became aware of the outbreak, I asked Dr. Jesse Goodman, who is here today, the Acting Chief Scientist and Deputy Commissioner for Scientific and Medical Programs, to coordinate and lead FDA's efforts. And he oversaw a management structure that was different from the day-to-day management structure that FDA used. We established an incident command structure. We created teams around different topics, and they reported to Dr. Goodman. The substantive teams we created included the vaccine team, the anti-viral team, the in vitro diagnostics team, the personal protection team, the blood team, the shortage team and the consumer protection team. We also had other elements of incident command which include logistics support and communications, legal and worker safety.

So we actually shifted to a 24-hour move, because the CDC was interested in deploying products from the stockpile, and to do so, they needed some emergency approvals for things that were not approved by the FDA to that point. The team worked over the weekend, and at three in the morning, I signed several emergency use authorizations, which included the first dosing for Tamiflu for children under age one that CEDR came up with after extensive work over the weekend, and that was based on the tremendous amount of work they had done to that point on kids under age one. It also included approval for Relenza to be distributed by public health authorities, and it included the first diagnostic test for H1N1 which permitted CDC to distribute that test across the country and to more than a hundred countries around the world.

This team, this incident management team, has been meeting since then and has not slowed down even as the particular epidemic has taken its twists and turns. And I was just reading the most recent report from the team. And just to give you a sense of what's going on, the anti-viral team is aggressively looking at—and to take a step back, obviously the epidemic is not as virulent as initially feared at this point, but there is a lot of concern that when the fall flu season hits, it could come back and be quite significant, and certainly in this respect, when you're dealing a previously unseen flu virus, given the course of events in the 20th Century, it is definitely better to be safe than sorry. And so we have been working very aggressively to think about how we prepare for the worst case scenario even if we never need to use those preparations.

One of the things that CEDR is doing—sorry, the anti-viral team is doing is reaching out to manufacturers that have experimental or unapproved drugs for very severe flu, because there are no currently, for example, intravenous formulations of the flu drugs ap-

proved to see what might be made available if we really run into a problem this fall.

The shortage team is already contacting manufacturers of basic antibiotics, IV fluids and antivirals to make sure that they're increasing their supply in case of a big problem this fall.

The vaccine team is working full steam ahead on the preparations for a vaccine, and that includes growing the virus in the FDA's labs. There are sheep that have to produce antibodies to test the potency of the vaccine. The FDA is a pivotal player in approving and helping design the clinical studies that will be used for the vaccine when one is produced, and working with the manufacturers.

There's a blood team that's working in basically the supply of blood, which has been fine throughout this, and monitoring any questions of risk to the blood supply from the flu, of which there have not been any serious questions raised so far.

The diagnostic team is working very closely with CDC on the development of more additional rapid diagnostic tools for this particular virus.

And the consumer protection team is quite active now looking on the web to identify people who are really trying to defraud the American public. And I'll just read one website that recently got a warning letter and is shutting down from FDA. It said, "Independent tests show this product is hundreds of times more effective at killing the flu virus than the most potent antiviral prescription medications known, and it's the only one that actually kills the virus within a few hours and automatically eliminates all symptoms."

So FDA I think has taken several dozen enforcement actions through its consumer protection team to make sure that people are not misled. But my concern as a physician is that people would turn to products that clearly don't work instead of seeking medical attention, which is incredibly important when they're sick from the flu.

So I think I'll stop there. There's a lot more detail in the written testimony, and I look forward to your questions.

[The information follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT OF

JOSHUA M. SHARFSTEIN, M.D.

PRINCIPAL DEPUTY COMMISSIONER AND

ACTING COMMISSIONER

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT,

FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

U. S. HOUSE OF REPRESENTATIVES

MAY 21, 2009

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Chairwoman DeLauro, Ranking Member Kingston, and members of the Subcommittee, I am Dr. Joshua M. Sharfstein, Principal Deputy Commissioner and Acting Commissioner at the U.S. Food and Drug Administration. I am pleased to present the President's fiscal year 2010 budget request for the Food and Drug Administration (FDA). For today's hearing, I am joined by Patrick McGarey, FDA's Director of the Office of Budget Formulation and Presentation and Norris Cochran, Deputy Assistant Secretary for Budget at the Department of Health and Human Services.

In my testimony today, I will outline FDA's FY 2010 budget request and the policy initiatives that we are advancing in our budget. I will also summarize recent developments related to the 2009-H1N1 Flu Virus outbreak and describe how FDA's budget for pandemic preparedness allowed us to prepare for and respond to the 2009-H1N1 Flu Virus.

RECENT FUNDING INCREASES

The funding that this subcommittee appropriated to FDA for FY 2008 and FY 2009 demonstrates your strong commitment to the public health mission of FDA and the health of the American public. Thank you for your support.

When I arrived at FDA, I asked each FDA center to provide examples of how they are using the recent funding increases to promote public health and achieve mission priorities. A key goal for FDA is to directly connect the investment of Federal dollars to public health outcomes.

FDA 2010 BUDGET REQUEST

Overview

The President's FY 2010 budget request for FDA includes $3.2 billion to protect and promote the public health. The budget contains an increase of $510.6 million for FDA programs, which is a 19 percent increase compared to the FY 2009 budget. This is an historic increase in the FDA budget and demonstrates the Administration's commitment to food safety, medical product safety, and the health of the American public.

The FY 2010 increase of $510.6 million includes increases of $295.2 million in budget authority and $215.4 million in industry user fees. The FDA budget organizes these increases into initiatives for FY 2010. Our two major initiatives are Protecting America's Food Supply and Safer Medical Products. The budget also includes $74.4 million for statutory increases for user fee programs in current law and increases for infrastructure to support FDA's mission.

The FDA FY 2010 budget recommends four new user fees. The new user fees will facilitate the review of generic drugs, enhance FDA's ability to register and inspect food and feed manufacturing and processing facilities, allow FDA to reinspect facilities that fail to meet good manufacturing practices and other safety requirements, and allow FDA to collect fees when it issues export certifications for food and feed.

The FY 2010 budget also recommends new authority for FDA to approve generic biologics through a regulatory pathway that protects patient safety and promotes innovation. Finally, the budget also includes $5 million for FDA to develop policies to allow Americans to buy safe and effective drugs from other countries.

DETAILS OF THE FY 2010 BUDGET

Supply Chain Safety and Security

The globalization of the manufacturing and supply of foods and medical products that FDA regulates and Americans consume poses unique and demanding challenges for FDA. In the complex and rapidly changing environment driven by globalization, FDA cannot rely solely on traditional approaches – inspection and sampling at the U.S. border – to protect Americans and ensure the safety of foods. Rapid globalization requires that FDA implement new approaches and conduct a broader range of activities to effectively regulate the supply chain for foods and medical products.

Supply Chain Safety and Security is an overarching principle that applies to both food and medical products. Supply Chain Safety and Security holds all segments of industry accountable for ensuring that their products meet U.S. safety standards.

Key components of this initiative include: identifying products and processes at high risk for earlier and more comprehensive attention; establishing reasonable and effective regulations and other standards; increasing FDA inspections; increasing effective third-party inspections; and collaborating with local, state and international partners.

Protecting America's Food Supply

For FY 2010, FDA proposes an increase of $259.3 million for food safety activities. This increase includes $164.8 million in budget authority and $94.4 million in three new user fees: Food Inspection and Registration User Fees, Reinspection User Fees related to food facilities, and Export Certification User Fees for food and feed products.

To outline the key investments with the new FY 2010 resources:

- FDA will hire 678 additional full-time equivalent staff to expand programs and activities that protect America's food supply.

- FDA will fund the cost of living pay adjustment for FDA professionals that conduct food product program activities. (+$12.9 million)

- FDA will increase domestic and foreign risk-based inspections, conduct more audits of controls designed to prevent contamination, establish three additional high volume

laboratories, and conduct more food safety intervention, sampling and surveillance through our Office of Regulatory Affairs. The FY 2010 budget increase will allow FDA to hire more than 220 additional investigators. When fully trained and deployed, the new investigators will enable FDA to conduct the following additional field activities, based on the FY 2010 increases in budget authority and user fees proposed in this initiative:

4,000 additional domestic food safety inspections
100 additional foreign food and feed inspections
20,000 additional import food and feed field exams
3,000 additional samples for analysis in FDA laboratories.
(+$101.7 million)

- FDA will begin to implement a new strategic framework for an integrated national food safety system. Under this framework, FDA will build and expand existing programs and relationships with its regulatory partners: our federal, state, local, tribal and territorial partners. This will allow FDA to increase information sharing and improve the quantity and quality of food safety data that FDA receives from its food safety partners. (+$14.6 million)

- FDA will work with all stakeholders to better ensure that food protection is built into the complete lifecycle, from food production to food consumption. (+$6.0 million)

- FDA will improve its understanding of food and feed vulnerabilities and risks. This will include improving FDA's ability to use baseline data to measure the impact of food safety efforts and to track the status of foodborne illnesses in the United States. Achieving a better understanding of vulnerabilities and risks will allow FDA to adjust food and feed safety priorities and ensure that food programs achieve the best health benefit for the American public. (+$4.0 million)

- FDA will improve its ability to detect signals of contamination and also improve its ability to collect and analyze adverse events for food and feed. (+$9.8 million)

- FDA will respond more quickly to foodborne outbreaks and will improve its ability to quickly trace contamination to its source. (+$12.2 million)

- FDA will improve risk communication during a food safety event so that the public can respond promptly to FDA alerts and protect themselves from harm. (+$1.6 million)

- FDA will increase the capacity of the Food Emergency Response Network by establishing three new laboratories for chemical analysis. (+$3.3 million)

- FDA will further develop an integrated genomic data base for Salmonella and conduct research to reduce knowledge gaps. (+$0.8 million)

- FDA will charge fees to cover the cost of reinspecting FDA-regulated facilities that fail to meet good manufacturing practices or other FDA requirements. (+$15.3 million)

- FDA will charge fees to cover the cost of issuing export certificates for food and feed. (+$4.2 million)

- FDA will upgrade and integrate information technology systems, including systems that we use to screen, sample, detain and take enforcement actions against imported food and feed products that violate FDA safety standards. (+$49.9 million)

Safer Medical Products

There are three components of FDA's Safer Medical Products initiative. Like the food safety initiative, the first component relies on the principle of supply chain safety and security. The goal is to protect American patients from contamination or other manufacturing flaws that could harm patients. The second component will address patient-product interactions that generally do not relate to manufacturing flaws. FDA will improve the safety of human drugs, vaccines, blood and other biological products, medical devices, and animal drugs and medicated feed by hiring additional safety experts to analyze adverse events associated with these products. FDA will also identify safety problems through active surveillance of third party healthcare data. The third component focuses on increasing access to affordable generic drugs, granting FDA new authority to approve generic biologics, and allowing Americans to buy safe and effective drugs from other countries.

For FY 2010, FDA proposes an increase of $166.4 million for medical product safety. This increase includes $119.9 million in budget authority and $46.6 million for Generic Drug User Fees and Reinspection User Fees related to medical product facilities.

To outline the key investments with the new FY 2010 resources:

- FDA will hire 346 additional full time equivalent staff and expand programs and activities related to medical product safety.

- FDA will fund the cost of living pay adjustment for FDA professionals that conduct medical product program activities. (+$16.7 million)

- FDA will improve the safety and security of foreign and domestic sources of ingredients, components, and finished products throughout the supply chain–including their eventual use by patients in America–through increased inspections and through activities conducted by the Office of Regulatory Affairs. (+$12.2 million)

- FDA's Center for Biological Research and Evaluation (CBER) will hire additional safety experts for its blood, tissue and vaccine safety teams. This will strengthen the ability of safety teams to analyze emerging safety threats. CBER will modernize blood, tissue and vaccine standards to improve product safety

and quality. CBER will also provide increased training to support product development and improve product safety. (+$5.7 million)

- CBER will develop new screening tests for emerging blood-borne diseases. CBER will review vaccine and tissue data to identify safety signals. CBER will also develop quality systems for product testing and lot release of biological products and will provide additional support for safe development and manufacturing of cell, gene and tissue therapies. (+$2.3 million)

- CBER will provide increased technical support to FDA field operations as they conduct foreign and domestic inspections of biologic products. (+$1.3 million)

- FDA's Center for Devices and Radiological Heath (CDRH) will implement safety requirements related to the FDA Amendments Act (FDAAA). To support FDAAA safety activities, CDRH will collect and analyze adverse event information related to medical devices from pediatric hospitals. CDRH will conduct a pediatric medical trials workshop to address unmet pediatric device needs. CDRH will improve device safety by hiring experts to evaluate software used in medical devices. CDRH will hire staff to provide technical support to FDA foreign offices and to support FDA field operations as they conduct foreign and domestic device manufacturing inspections. (+$9.5 million)

- CDRH will develop new safety tests and strengthen postmarket safety reviews of ophthalmic medical devices. CDRH will also develop and validate new clinical trial methods for imaging devices. (+$1.7 million)

- FDA's Center for Drug Evaluation and Research (CDER) will evaluate how best to use Risk Evaluation and Mitigation Strategies to minimize drug risks and promote safe drug use. (+$3.4 million)

- CDER will also conduct research on bioequivalence standards for generic forms of novel products such as metered dose inhalers, topical drugs and complex dosage forms such as liposome products. (+$2.5 million)

- CDER will identify and improve enforcement against Internet sites that expose consumers to unapproved products and fraud. (+$2.0 million)

- FDA's Center for Veterinary Medicine will conduct scientific and risk evaluation of animal biotechnology products, regulate approvals for new animal biotechnology products, and coordinate U.S. and foreign regulation on animal health issues within FDA's jurisdiction. (+$0.5 million)

- FDA's National Center for Toxicological Research (NCTR) will conduct studies to analyze the consequences of human exposure to nanoscale materials. These

studies will provide the scientific basis for issuing FDA guidance on the safe and effective use of nanoscale particles in the products that FDA regulates. ($1.0 million)

- NCTR will develop noninvasive techniques to better understand the risks of anesthetic use in children. (+$0.2 million)

- FDA will develop policies to allow Americans to buy safe and effective drugs from other countries. (+$5.0 million)

- FDA will provide greater access to affordable generic drugs and improve the productivity of generic drug review through a new user fee program. (+$36.0 million)

- FDA will strengthen the safety of the supply chain through a new user fee program to charge fees to cover the cost of reinspecting FDA-regulated facilities that fail to meet good manufacturing practices or other FDA requirements. (+$10.6 million)

- FDA will modernize and enhance information technology, including systems that we rely on to collect, store and analyze the large volume of regulatory, scientific, and risk based information necessary to assure the safety and effectiveness of medical products. (+$40.1 million)

Legislative Initiatives for Safe, Affordable Drugs

The budget request supports greater access to affordable generic drugs, recommends new authority to approve generic biologics, and allows Americans to buy safe and effective drugs from other countries.

In the coming years, patents will expire on more than a dozen blockbuster brand-name drugs that account for tens of billions of dollars in prescription spending annually. Generic competition for these drugs will likely be very strong. It is imperative that FDA have the resources to ensure the safety, quality, and therapeutic equivalence of generic drugs and allow Americans to benefit from the savings from lower cost generic drugs. To meet this priority, FDA's FY 2010 budget includes $36 million in new user fees to support drug review for new generic products.

The Administration will also accelerate access to affordable generic biologics by working with Congress to establish a workable and scientifically sound regulatory pathway for approval of generic versions of biologic drugs.

Current Law User Fees

FDA user fee programs facilitate enhanced premarket review performance and the timely availability of safe and effective medical devices, human and animal drugs, biological products, and other FDA-regulated products. The FY 2010 budget request includes increases

of $74.4 million for existing user fee programs, as authorized by law. The increases expand the available options for treating and curing diseases and other health problems.

Annual Cost of Living Adjustment

FDA can only achieve its mission and fulfill its responsibilities if it has sufficient resources to pay the scientific, professional, and technical staff required to conduct food safety and medical product safety programs. The ongoing experience with the outbreak of 2009-H1N1 Flu Virus demonstrates the importance of maintaining pay rates to attract and retain top-notch scientists and professionals. The FY 2010 budget includes $29.5 million for the annual cost of living adjustment for employees in FDA's food and medical product programs.

Delivering the FDA mission is a personnel-intensive effort. FDA performs its public health mission through a highly trained professional workforce. Personnel and related costs account for 78 percent of FDA's annual expenditures. To maintain its strong science and regulatory capability, FDA must employ, train, develop, and retain highly trained professionals to perform the mission critical work of protecting public health.

Infrastructure to Support FDA Operations

Like the annual cost of living adjustment, the FY 2010 budget increase to pay higher rental costs and other costs for the buildings that FDA occupies will allow FDA to perform its public health mission. FDA's FY 2010 budget contains $14.0 million in budget authority for increased GSA rent and related costs of the space that we occupy.

FDA 2009-H1N1 FLU VIRUS RESPONSE

FDA plays a vital role in preparing for, and responding to, public health challenges such as the one presented by the 2009-H1N1 Flu Virus. FDA is part of the team led by the Department of Health and Human Services.

Since the beginning of the 2009-H1N1 Flu Virus outbreak on Thursday, April 23, FDA has worked closely with HHS, our sister HHS agencies, other U.S. government agencies, the World Health Organization (WHO), and foreign governments.

As soon as we became aware of the 2009-H1N1 Flu Virus outbreak, I asked Dr. Jesse Goodman, FDA's Acting Chief Scientist and Deputy Commissioner for Scientific and Medical Programs, to coordinate and lead FDA's efforts on the 2009-H1N1 Flu Virus. Dr. Goodman leads an incident management approach that includes seven substantive teams. The teams are cross-cutting and include staff from across FDA as needed. The teams include: Vaccine Team, Antiviral Team, In Vitro Diagnostics Team, Personal Protection Team, Blood Team, Shortage Team, and the Consumer Protection Team. These teams work with the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), other HHS agencies, and national and international partners.

FDA's management approach to respond to the outbreak is flexible and likely to change over time. It has already changed in response to evolving events.

Emergency Use Authorizations

Under the Project Bioshield Act of 2004 (Public Law 108-276), Congress added section 564 to the Federal Food, Drug, and Cosmetic Act. Section 564 establishes criteria that permit the FDA Commissioner to issue an Emergency Use Authorization, following a determination and declaration of a public health emergency. An Emergency Use Authorization allows the use of an unapproved product or of an approved product for an unapproved use.

On Sunday, April 26, 2009, the Acting HHS Secretary issued a determination that a public health emergency exists involving 2009-H1N1 Flu Virus. In the days that followed, the Acting Secretary issued declarations under section 564 justifying emergency use of certain antivirals, in vitro diagnostics, and personal respiratory protection devices.

Based on the Acting Secretary's actions, and using our authority under the Project BioShield Act, on April 27, 2009, FDA issued four Emergency Use Authorizations in response to requests from the CDC. Two of these Emergency Use Authorizations extend the circumstances in which two FDA-approved drugs, Relenza and Tamiflu, can be used to treat and prevent the 2009-H1N1 Flu Virus. A third Emergency Use Authorization makes available a test for diagnosing infection with the virus. The fourth authorizes the emergency use of certain personal respiratory protection devices, specifically certain disposable respirators certified by CDC's National Institute for Occupational Safety and Health, known as N95 respirators. The emergency use authorization for N95 respirators only relates to requirements under the Federal Food, Drug and Cosmetic Act, not other requirements such as the standards for safety in the workplace administered by the Department of Labor. On May 2, FDA issued a fifth Emergency Use Authorization for a first tier test for patient specimens with suspected 2009-H1N1 infection. Taken together, these authorizations allow CDC and state and local responders to take actions that help meet the medical and public health threat.

All seven of the FDA teams are working to ensure a comprehensive response to the 2009-H1N1 Flu Virus. I would like to highlight FDA's work in two areas, developing a vaccine and protecting consumers.

Developing an H1N1 Vaccine

FDA's Vaccine Team is working to facilitate the availability of a safe and effective vaccine to protect the public from the 2009-H1N1 Flu Virus as soon as possible, in the event that a vaccine is needed to protect the American public. Members of the team are working collaboratively with CDC and other partners in efforts to grow and genetically engineer the 2009-H1N1 Flu Virus in the laboratory for possible use in a vaccine. FDA is also beginning to prepare reagents that will be essential to help manufacturers produce and test the vaccine.

In a related development, on May 6, FDA announced that it approved a new manufacturing facility to produce influenza virus vaccines. The facility, located in Swiftwater, Pennsylvania, is owned and operated by Sanofi Pasteur and will greatly increase vaccine production capability. The facility is approved for seasonal influenza vaccine production, and the facility could also be used to produce vaccine against the new 2009-H1N1 influenza strain.

As we work to develop a safe and effective vaccine, FDA is also participating in the analysis of whether an H1N1 Flu Virus vaccine should be deployed later this year to protect the

American public. Decisions about whether to deploy an H1N1 vaccine will be independent of the decision to produce a vaccine.

Protecting Consumers

FDA's H1N1 Flu Virus consumer protection team works to safeguard consumers from fraudulent and potentially dangerous FDA-regulated products or other promotions for products that claim to diagnose, prevent, mitigate, treat, or cure the 2009-H1N1 Flu Virus. Deceptive products are being sold over the Internet take advantage of the public's concerns about H1N1 influenza and their desire to protect themselves and their families. The fraudulent products come in all varieties and could include dietary supplements or other food products, or products purporting to be drugs, devices or vaccines.

FDA has an aggressive strategy to identify, investigate, and take action against individuals or businesses that wrongfully promote products in an attempt to take advantage of this current public health emergency. FDA issued warning notices to more than 30 Internet sites that we believe are wrongfully promoting products to consumers. We have also invited the public to voluntarily report suspected criminal activity, Websites and other promotions for products that claim to diagnose, prevent, mitigate, treat or cure the 2009-H1N1 influenza virus.

FY 2006 Influenza Pandemic Funding

During FY 2006 this subcommittee had the foresight to appropriate $20 million to FDA for pandemic influenza preparedness in an emergency supplemental appropriation. FDA invested pandemic influenza supplemental funding in three key areas that are critical to America's preparedness for an influenza pandemic: strengthening our capacity to expedite the development of flu vaccines, conducting essential monitoring and inspection of flu vaccine manufacturers, and conducting FDA-wide pandemic planning and preparedness activities. This $20 million supplemental became part of FDA's base resources and allowed FDA to achieve a higher state of preparedness for events like 2009-H1N1 Flu Virus outbreak. Because of the work begun in 2006, FDA is better prepared for today's response to the 2009-H1N1 Flu Virus.

CONCLUSION

Our FY 2010 budget of $3.2 billion will allow FDA to strengthen the safety of the food supply and to anticipate and address safety signals that emerge from the use of the drugs, biologics and medical devices that FDA regulates. Our FY 2010 increase will allow the dedicated professionals at FDA to help ensure that Americans benefit from a safe and wholesome food supply and from medical products that sustain and improve their lives. Achieving our mission is possible because of your support for the work of the Food and Drug Administration.

Thank you very much for the opportunity to testify. I welcome your ideas and your questions.

Ms. DELAURO. Thank you for your testimony. Let me start with really a general question of many specific ones. As I outlined in my opening statement, I do believe that the agency is badly broken, and I think there are a number of surveys of employees who have found low morale, reflecting the efforts to muzzle staff, et cetera. I don't have to reiterate all of that. And you also commented and we have with regard to resources, and I am confident—I don't suspect—I'm confident we will make additional gains in terms of resources in 2010.

But what I would like to hear from you is about the other three areas: Management, industry influence and science. And what I'd like to know is how do—because these are the measures that we will return to in the future as to how we are really addressing these areas. If you can, tell us how you are approaching looking to improve the management of the agency, addressing the undue influence of the industry, and ensuring that the decisions are based on science.

FDA MANAGEMENT

Dr. SHARFSTEIN. Thank you. I think you're absolutely right that funding is just one part of the picture at FDA. And I think that management is extremely important. I'm very much looking forward to Dr. Hamburg. Both of our backgrounds are in running large public health organizations. Hers was much larger than mine. I was the health commissioner in Baltimore City. She was the health commissioner in New York City. But I think there are a lot of principles that are important from that experience that I think we both hope to bring to this.

It is very important that in every unit of an organization that people feel accountable for what they're doing and not just, you know, the kind of checking the box, of having kind of run through the motions of something, but actually moving a project forward that is clearly linked to public health. That's really what I think our management goals are going to be.

I think—and when I started by asking the different centers where did the increases go that really are directed to projects that are going to lead to improve public health, that was a message that we were able to send, and I think people have responded very well to that across the agency, that we really expect to be able to be accountable for where the resources are going and what the impact is going to be. And I think as we move forward and Dr. Hamburg starts, we have a few ideas for her to consider, specifically in how to move that forward.

But I think you'll see some specific mechanisms put into place in the management of the agency that will allow that to happen and will provide I think you and the subcommittee a lot more understanding of how the resources are used, and a lot more confidence in the management of the agency.

INDUSTRY INFLUENCE

To your second point on the influence of industry, I think that the credibility of FDA is absolutely critical, and I think one of the most challenging things externally and internally for people who worked at the agency were hits to the agency's credibility over the

last several years. And I think Dr. Hamburg and I plan to make that a major focus. And the question of industry influence is one element of that, but I think there are other elements, and I think the FDA's being more transparent about how it's making decisions and why it will be very important to addressing that.

SCIENTISTS

To your third point, letting the scientists do their work, I have been extremely impressed by the talent that's at FDA. I go to meeting after meeting where, you know, I kind of feel like I'm an imposter because around the room are twelve scientists through their careers are on a particular issue of the topic. And you really have to respect the kind of brainpower that exists at FDA.

And I think I've been very impressed by how positively people at FDA have responded to really how I open most meetings, which is, you know, I'm interested in hearing what you think should be done to move these issues forward, whatever the topic is. And I think it may be that one way to approach the fact that FDA has limited authority is to say, well, if we don't have authority there, then no reason for us to think about it.

But I'm really encouraging, and I think our approach is going to be that let's start with what the right thing to do is. If we can do it right away, then let's try to do it, because that's going to help American consumers, and I think along with consumers when people have confidence, it's going to help the industry, too. But if we don't have the authority, then we're going to talk about what we need to be able to protect the public. So I think that message has really resonated, and I think that's the start, and we'll have time to talk about maybe other elements of this. I think that's one part of changing the approach to science at the agency.

Ms. DELAURO. My time has expired, and I want to try to hold us to the five minutes so we can get as many questions as we can, but I thank you for that. Mr. Kingston.

Mr. KINGSTON. Dr. Sharfstein, let me ask you a couple of questions. I'm very concerned about the national debt, $11 trillion right now. And it seems to be something that we as a nation have chosen to kind of put on the back burner for the time being. But FDA often says they don't have the resources, but 2007, $1.97 billion. 2008, $2.269 billion. 2009, about—a little less actually, $2.667 billion, and now your proposal is almost $3.2 billion, which would be a 37 percent increase over the short 2½-year period of time.

Now it's interesting, you know, during that period there have been—your employee count has gone from about 9,500 with the proposal to go up to 12,000 employees. You know, when the private sector is cutting back, when households back home are cutting back, is it really fair for FDA to have a 37 percent increase? And I'm not aware—and I may be wrong but—of your suggested savings or cuts that you have proposed. And are there any?

Dr. SHARFSTEIN. In this budget?

Mr. KINGSTON. Yes.

Dr. SHARFSTEIN. Let me——

Mr. KINGSTON. Could you find anything to reduce, any duplicate—duplications or anything like that?

FDA'S BUDGET

Dr. SHARFSTEIN. I think it's a very fair question. And overall, given the state of the economy and the budget, I totally understand the question. I think it's important to put the FDA budget in two types of contexts. One is the years before the years that you mentioned. Because if you go back further, there was the erosion of FDA's budget considerably. It was held flat for many, many years, and the number of employees dropped considerably.

And I think the reason for the increase in the budget was the widespread understanding that the erosion of the FDA was hurting not only the health of people but the health of businesses as all sorts of problems were happening, and FDA was really unable to prevent them or respond in a way that people really felt confident about.

Mr. KINGSTON. Well, let me ask you that. What are those numbers in terms of—why you don't go back to say 2004, tell me what erosion specifically was.

Dr. SHARFSTEIN. I think you could go back even further. I don't know if I have them handy, but I would go back even to like the late 1990s and you could see—I think—I don't want to give you statistics I don't have right in front of me, but I think there was a considerable decline in the real budget at FDA, and there was a big drop in the number of employees in particular programs.

Mr. KINGSTON. Well, that's certainly relevant, and maybe—do you have your budget person here?

Dr. SHARFSTEIN. Yes. Patrick.

Mr. KINGSTON. Can you give me those numbers?

Mr. MCGAREY. What Dr. Sharfstein points out is consistent. Over about a ten-year period, with the recent increases brought in, we're about returning to where we were——

Mr. KINGSTON. So when were you at $3.1 billion?

Mr. MCGAREY. What our staffing will be?

Mr. KINGSTON. No. When were you there? Was that 2003?

Mr. MCGAREY. Excuse me. I apologize. We were never—I'm focusing on the number of employees that that money buys.

Mr. KINGSTON. Okay. So you were at 12,000 employees previously?

Mr. MCGAREY. We were just slightly below that if you go back a decade.

Mr. KINGSTON. Okay. Can you give me those numbers for the record?

Mr. MCGAREY. We'll get those for you.

[The information follows:]

FDA STAFFING

The table below displays a 20-year history of FDA staffing supported by budget authority, user fees, and the FDA total program level. The total program level includes budget authority and user fees. The proposed FY 2010 staffing funded by FDA's total program level is 12,340. This staffing represents the full-time equivalent staff or FTEs that FDA estimates will be on-board at the end of FY 2010. This FTE level is the highest staffing during the past two decades.

In the case of FTEs supported by budget authority, the proposed FY 2010 staffing funded by budget authority is 9,099 FTE. At two times during the past 20 years staffing levels supported by budget authority was higher than the level proposed for FY 2010: 1994, with a staffing level of 9,148 FTE and 1993, with a staffing level of 9,140 FTE.

FDA began receiving significant user fees for medical product review programs beginning in 1994. FDA projects that user fee-supported FTEs will raise to 3,241 in FY 2010.

FDA STAFING HISTORY
FTEs FY 1991 - 2010

Year	BA	User Fee	Program Level
1991	8,267		8,267
1992	8,824		8,824
1993	9,140		9,140
1994	9,148	204	9,352
1995	8,811	453	9,264
1996	8,487	685	9,172
1997	8,354	817	9,171
1998	8,083	821	8,904
1999	7,851	1,059	8,910
2000	7,728	1,102	8,830
2001	7,805	1,184	8,989
2002	8,311	1,157	9,468
2003	8,940	1,317	10,257
2004	8,567	1,574	10,141
2005	8,181	1,729	9,910
2006	7,893	1,805	9,698
2007	7,705	1,864	9,569
2008	7,678	2,133	9,811
2009	8,524	2,445	10,969
2010	9,099	3,241	12,340

*The total FTE level of 12,340 for FY 2010 includes the new hires for tobacco. This resolves the discrepancy between this response and the FY 2010 CJ.

Mr. KINGSTON. Because I'm very concerned about a 37 percent increase. And one thing to consider now versus ten years ago is that the national debt is so much higher, and I would also think that the FDA would be able to take advantage of some of the technology that's out there now that—you know, for example, what HACCP has done for USDA going from a carcass-by-carcass inspection to microbial inspection. I would think that the FDA would have the same sort of advantages with all the technology that might be able to be a savings.

Also, I wanted to talk to you about these user fees. Every Administration—and you have been on the Hill, and you know. You've seen—you were here when President Clinton was here and Bush, correct?

Dr. SHARFSTEIN. No. No. I started July 2001.

Mr. KINGSTON. Okay. Well, you know that every administration rolls out user fees. And yet rarely do user fees get beyond this hearing. And because I've just—I've never seen the Clinton Administration, the Bush Administration, I do not think the current new Administration is going to fight for user fees, but I could be surprised. Can you give me an indication of what you're hearing in your dying days as interim director?

[Laughter.]

USER FEES

Dr. SHARFSTEIN. My understanding is that this Administration is committed to the user fees as part of its plan to really support FDA. And, you know, we're kind of doing our best to make the case for them because we think that in order to transition to the system, the food safety system that you're talking about, and I agree with 100 percent on the HACCP and those principles and getting away from having to think of it in terms of how many inspections we're doing, and in terms of what standards are in place, whether the businesses have the responsibility to do it. We've got to get over that hump, and we need resources to put that system into place. And that's really our goal.

Mr. KINGSTON. Okay. Thank you. My time has expired.

Ms. DELAURO. Mr. Jackson.

Mr. JACKSON. Thank you, Madam Chair, and thank you Dr. Sharfstein, for your service to the nation. I have two questions, one regarding neuroblastoma, and the other regarding generic drugs.

Dr. Sharfstein, both the House and the Senate encouraged the FDA to prioritize review of new treatments and clinical trials for pediatric cancers in Fiscal Year 2009, particularly those related to neuroblastoma. It is clear to me that we can do better by young patients facing a dismal 20 percent survival rate from this terrible disease, a survival rate which, unlike other pediatric cancers, hasn't improved in decades.

New treatments and clinical trials that have the potential to help children with neuroblastoma should be reviewed with all due speed. This is particularly true of therapies for relapsed patients who face a survival rate of less than 5 percent. I guess I'm asking if you can please put neuroblastoma on your radar screen as an area, one, that needs attention, and can we work together to try

to make progress in this area so infants and toddlers battling this disease can access all promising treatment options?

Dr. SHARFSTEIN. And I would answer yes, I think it is very important, particularly as a pediatrician, I've actually cared for patients with neuroblastoma, and I've seen patients die from neuroblastoma, and it is just an incredibly difficult experience for everybody who is in contact with the child, as well as obviously the child.

I think one of the things that Dr. Hamburg and I strongly support is the FDA not just being passively sitting back waiting for applications to come in, but where we think there may be opportunities for innovation that can save lives, to really reach out and help researchers and industry think about what it would take to demonstrate that a product works and is safe for kids.

So I look forward to working with you and your office on identifying better treatments for neuroblastoma and other diseases affecting children.

Mr. JACKSON. Dr. Sharfstein, we also can agree that generic drugs can save patients substantial health care costs. However, hurdles still exist in bringing more affordable drugs to patients who desperately need them. As the number of generic drug applications rise, staffing at FDA has relatively stayed flat. What needs to be done to increase the amount of generic drugs being brought to the market, and are new user fees the only way?

GENERIC DRUGS

Dr. SHARFSTEIN. Thanks for that question also. I recently saw my uncle, who is a neurologist, who said that he has a lot of patients who skip doses of medicines and put themselves at risk for seizures because they can't afford their medicines. And generics are an extremely important way for people to get access to medications that are safe and effective.

I think that—and this reflects the previous question—I think there is reason to be optimistic about user fees. I think that the industry is open to that idea. I think the Administration is very interested in it, and I think, just like the user fee arrangements have been made in several other areas, I think that this is really important. I think more resources are critical, but we're also going to look to see whether there are other things we can do to streamline the approval process for generics.

Mr. JACKSON. Thank you, Dr. Sharfstein. Thank you, Madam Chair.

Ms. DELAURO. Thank you, Mr. Jackson. Mr. Latham.

Mr. LATHAM. Thank you very much, Madam Chairman. Doctor, the Administration is requesting an increase in the overall budget, $510 million. Just last year, the Administration came and asked for a $375 million increase, and I think it was Senator Kohl over in the other body asked the question to the administrator last year if the FDA could absorb that much money in one year, and it was just a flat no, we can't absorb that much money. It wouldn't be well spent. And I guess I would ask you the same question. How do you absorb an increase, $510 million in one year, to have the money to be well spent? Is it possible? Last year they couldn't absorb a $375 million increase.

Dr. SHARFSTEIN. You know, I'm going to probably turn to Patrick McGarey to talk a little bit about the process in place. I understand—my understanding is that FDA has been able to spend all the money that it has been given by Congress.

Mr. LATHAM. Are there any unobligated funds?

UNOBLIGATED FUNDS

Mr. MCGAREY. Well, in the current fiscal year, of course, we don't have that situation because it's available to obligation until the end of the fiscal year. We have an aggressive hiring plan because so much of our budget and our mission relates to our staffing, and we are about at 80 percent of our hiring targets for the fiscal year, and realizing of course we're between 60 and 70 percent through the fiscal year. So on our priority goal of hiring, we're meeting those targets. We're going to spend more than $400 million in the current fiscal year, and we feel in the coming fiscal year, we've poised ourself to make expenditures at the $510 million level.

Dr. SHARFSTEIN. Looking at that, there are chunks of money that are really for the development of IT systems, which we can obligate this year, and which aren't necessarily needed every single year, that amount of money. But that's what helps us get us over the hump to——

Mr. LATHAM. So how much of those funds are left unobligated?

Dr. SHARFSTEIN. I don't think there's an unobligated part of IT.

Mr. MCGAREY. Well, much of it is unobligated at this point in the fiscal year.

Mr. LATHAM. Well, he said he couldn't spend it this year.

Mr. MCGAREY. And we will spend it before the end of this fiscal year. Our major IT contracts, we're going to put money into those in the coming quarter.

Mr. LATHAM. And last year as far as food safety, you were granted authority to hire 161 new full-time equivalents in food safety. Do you know where you are on those hires?

Mr. MCGAREY. Again, we are at about 80 percent across FDA, and it's very similar to that in the food safety hiring goal that we have for that piece of our budget.

VETERINARY MEDICINE

Mr. LATHAM. The Center for—and in your testimony earlier you talked about working with the states and about surveillance and all that type of work. One of the key parts of it is the Center for Veterinary Medicine. And in the budget, it really only gets, what, $2 million, as far as an increase. And the GAO indicated in a Senate oversight hearing that the Center is in a state of crisis because there aren't enough vets out there working in the center.

I don't know, I wonder if there are some unobligated funds and you can tell me what the priorities are, but you know, if there's some funds, rather than worry about whether Cheerios are regulated as a drug, it might be a good idea to look at that as far as—the whole system out there is going to break down if you don't have these people out doing their job on the front lines. I don't know if you want to comment, or——

Dr. SHARFSTEIN. Sure. I think that—I'll turn at the end to Patrick on the increase in veterinary medicine. I think it may be more than $2 million. But to your general point——

Mr. LATHAM. As far as an increase? Okay. Go ahead.

Dr. SHARFSTEIN. How much is it?

Mr. MCGAREY. Between last year and this year, the increase for the program for animal drugs and fees, is 36.7.

Mr. LATHAM. But how about for hiring?

Mr. MCGAREY. Well, probably on average, 70 to 75 to 80 percent of that Center's investments will be in staffing.

Mr. LATHAM. Okay. My question then would be why the GAO says that the Center for Veterinary Medicine is in a state of crisis? Can you address that? Why and what are you doing about it.

Dr. SHARFSTEIN. Well, I think that—I wish I had a mental image of that GAO report, but I don't have it. But I do think that there are several very important——

Mr. LATHAM. You're not aware of a crisis at——

Dr. SHARFSTEIN. Well, I think that what my understanding of the situation in Veterinary Medicine is that—and if you can look back to the melamine pet food situation that happened, which I think people recognized as a major crisis. And not only that so many animals died, which was terrible, but that it took so long to really figure it out, and that the processes for fixing it were—where it took so long. And I do consider that a crisis. And I've been impressed that the Center now has a very strong plan to put in place, and I was mentioning that a little bit. This integrated system with the state, locals and veterinarians to identify problems in animal feed and be able to respond.

So that is something that is getting a lot of funding in this budget, and I think it's extremely important. As the health commissioner in Baltimore, I was the chair of the board of the animal shelter. And, you know, I think that there is tremendous importance to people and importance to the animals themselves of, you know.

Mr. LATHAM. How many more vets are you planning on hiring? I apologize, but I just—to close it off.

Dr. SHARFSTEIN. How many more vets are we planning to hire?

Mr. LATHAM. Yes.

Dr. SHARFSTEIN. I don't know that off the top of my head. We may have to get back to you.

Mr. MCGAREY. We would have to get that for the record. We certainly couldn't tell——

[The information follows:]

FDA HIRING PLANS FOR VETERINARIANS

FDA's Center for Veterinary Medicine plans to hire approximately 25 Veterinarians during FY 2009 and FY 2010, based on the FY 2009 enacted budget and the FY 2010 President's Budget.

Mr. LATHAM. Thank you, Madam Chairman.

Ms. DELAURO. Thank you, Mr. Latham. Mr. Farr.

LOUISVILLE INSPECTIONS

Mr. FARR. Thank you very much. Thank you for your public service with your incredible background, academic background, medical

background in pediatrics and so on, I just—I think it's nifty that you're dedicating your life to public service.

I have a question that arose from my—every year I visit the UPS centers in my district and talk to the drivers and learn a lot about how we transport things. And it came to my attention that the FDA has to inspect all the packages shipped out of country to ensure that there's no violation of U.S. health, food and safety laws. And the FDA provides inspectors to shippers like FedEx and UPS. But last year the FDA pulled its night inspectors from its UPS hub in Louisville, citing a lack of personnel, even though it had provided plenty of personnel to the same job for FedEx in Memphis. And I understand that UPS worked out a deal with FDA to undergo a six-week trial test to see if indeed UPS was handling the volume of packages that qualified for the nighttime inspectors, and it did.

The problem is that the inspectors haven't been provided, and this delays getting packages to consumers and creates an uneven playing field between UPS and FedEx. What's holding up the FDA from responding to getting those nighttime inspectors?

Dr. SHARFSTEIN. It sounds like a very fair question, particularly when it comes to the uneven playing field between different companies, and I don't know the answer to that, but I can promise to look into it and get right back to you. I think you deserve a good answer to that question.

[The information follows:]

UPS HUB AT LOUISVILLE

FDA recently completed a six-week pilot of entry reviews for the UPS Louisville hub location. FDA determined that the FDA Memphis Resident Post is the best location to review UPS entries. At this time, FDA is working with UPS on logistical issues and has begun identifying processes and procedures that need to be developed before FDA can review entries of UPS packages from the Memphis Resident Post.

IND APPLICATIONS

Mr. FARR. Thank you. I appreciate that, since you, you know, reviewed it and came to the conclusion that the volume is there. Another question came from visiting compounding pharmacists and learning a lot about compounding business. It's very interesting. And I'm very supportive of it, by the way.

The FDA banned the use of esterol, which is a natural occurring hormone in compound medicines to treat hormone replacement therapies. And I understand that a pharmacist can apply for a—file an IND, an Independent New Drug application?

Dr. SHARFSTEIN. Correct.

Mr. FARR. In order to do it. But this application process can be as many as up to 50 pages long, very complicated, costly to fill out. Consequently, doctors don't like to do it, pharmacists don't like to do it. And those who find—who have done it, find that their requests generally get denied. Is there any effort to simplify this process so the filing can be done in a—since you're not doing any test to decide whether esterol should be in compound medicines, that this is the only way one can get the exception, and is there anything going on to simplify this process, and at least give a decision up front?

Dr. SHARFSTEIN. Also a very fair question. You know, the big picture on compounding from my perspective—I'm a pediatrician. A lot of drugs are compounded for kids because they can't be made available another way. And so I've written for drugs that are compounded in clinical medicine, and I understand the importance of compounding to the practice of medicine in the United States.

I think the concerns comes when the agency thinks, or becomes concerned that compounding is at such a scale that it is sort of like drug manufacturing potentially for drugs that could be unsafe or not well presented to consumers. And my understanding of this particular issue is that there were some people who were selling this at a mass scale, a drug that's very similar to the approved estrogen, but with making claims about its safety that were almost certainly untrue, that it wouldn't have the adverse consequences, and that proved a risk to women's health. And I think that's what led to the action that FDA took.

Mr. FARR. Mm-hmm.

Dr. SHARFSTEIN. But FDA did provide, just as you are setting out, an option for people which allows some assurance that people will get more of the facts about this particular type of product and then would allow them to get it. But I understand that FDA is—has sought to meet with the compounding pharmacists to develop a quick way to get the IND going, and it has some trouble getting people to the table to talk about that. But in the absence of that meeting, that they did develop a website that explains exactly how to do it. But if that's not working for people, we want to know. And I'm sure FDA would be willing to sit down with the compounding pharmacists associations again to work on that. And I do know that some people have made it through the process.

So I think the thing to do may be to understand who is expressing that concern and offer to meet with them and see what we can do to make this particular pathway, which would allow people access to the medicines under conditions that they be going in with, you know, kind of both eyes open. If we could streamline that pathway, I think that would be something that could be mutually beneficial.

Mr. FARR. Okay. We'll follow up on it. Thank you.

Ms. DELAURO. Mr. Alexander.

FTE

Mr. ALEXANDER. Thank you, Madam Chairman. Doctor, I have a couple of questions for you, but first Mr. McGarey, going back to something that Mr. Kingston was talking about a while ago. You said that the lack of funding that you need goes back to the 1990s. That's the first time in a while that I've heard anybody not totally blaming President Bush for the problems that we have now. I'm certainly sure that he'll appreciate that.

But you said that at one point you were not at 12,000 but a little less than 12,000 employees. Is that correct?

Mr. MCGAREY. Well, we won't be at 12,000 in the current fiscal year. The target is to reach that at the end of Fiscal Year 2010.

Mr. ALEXANDER. But you said at one time you were almost at that——

Mr. MCGAREY. I know we were above 10,000.

Mr. ALEXANDER. Okay.

Mr. MCGAREY. At the end of Fiscal Year 2008, we were below 10,000.

Mr. ALEXANDER. Were conditions at that time better than they are today in your opinion?

Mr. MCGAREY. Well, I—my service doesn't go back that far, but talking to people who have been at FDA, conditions is a broad term, but there are many drivers our workload that are pressing now, and we deliver our mission with employees.

Mr. KINGSTON. Will the gentleman yield?

Mr. ALEXANDER. Sure.

Mr. KINGSTON. I want to make a clarification. This was your employee count in 1998, 8,841; 1999, 8,869; 2000, 9,406. So we're not talking about returning to a level that was over 10,000. I'm not sure what year you're talking about, but that's not accurate with what this is. Now maybe it dipped up in 2001.

Mr. MCGAREY. I would point out, the actual at the end of Fiscal Year 2008 was 9,811 employees. So we're in the year where we're seeing a lot of growth, and I guess I was looking at a ten-year span where we were——

Mr. KINGSTON. Well, I just want to clarify because my understanding from your answer to me was that you're returning, but you're not returning according to this.

Mr. MCGAREY. We would be happy to request a table that lays out the FTEs across those decades.

[The information follows:]

FDA STAFFING

The following table displays a 20-year history of FDA staffing supported by budget authority, user fees, and the FDA total program level. The total program level includes budget authority and user fees. The proposed FY 2010 staffing funded by FDA's total program level is 12,340. This staffing represents the full-time equivalent staff or FTEs that FDA estimates will be on-board at the end of FY 2010. This FTE level is the highest staffing during the past two decades.

In the case of FTEs supported by budget authority, the proposed FY 2010 staffing funded by budget authority is 9,099 FTE. At two times during the past 20 years staffing levels supported by budget authority was higher than the level proposed for FY 2010: 1994, with a staffing level of 9,148 FTE and 1993, with a staffing level of 9,140 FTE.

FDA began receiving significant user fees for medical product review programs beginning in 1994. FDA projects that user fee-supported FTEs will raise to 3,241 in FY 2010.

FDA STAFING HISTORY
FTEs FY 1991 - 2010

Year	BA	User Fee	Program Level
1991	8,267		8,267
1992	8,824		8,824
1993	9,140		9,140
1994	9,148	204	9,352
1995	8,811	453	9,264
1996	8,487	685	9,172
1997	8,354	817	9,171
1998	8,083	821	8,904
1999	7,851	1,059	8,910
2000	7,728	1,102	8,830
2001	7,805	1,184	8,989
2002	8,311	1,157	9,468
2003	8,940	1,317	10,257
2004	8,567	1,574	10,141
2005	8,181	1,729	9,910
2006	7,893	1,805	9,698
2007	7,705	1,864	9,569
2008	7,678	2,133	9,811
2009	8,524	2,445	10,969
2010	9,099	3,241	12,340

*The total FTE level of 12,340 for FY 2010 includes the new hires for tobacco. This resolves the discrepancy between this response and the FY 2010 CJ.

Mr. KINGSTON. I yield.

Mr. FARR. Thank you. Reclaiming my time. The reason I asked that is looking at data, CDC data, and I certainly don't want anybody to think that we're implying that they're misleading us, and for sure we don't want anybody to think we're calling them liars, but on this data sheet it says that 300 million Americans eat three meals a day. We know that's not accurate. Three hundred million people do not eat three meals per day. But even at that, they say that at 5,000 deaths, we have a 99.99 percent success rate. Five thousand deaths to me would seem like it would be a lot less than 99.9 percent success rate.

But getting to the question is when we had the number of employees that you would like to have, were we better than 99.99 percent successful?

Dr. SHARFSTEIN. Let me address that. I think that the number of employees is an important thing to follow up on, but it's one part of the complexity of the budget situation. And if you go back and compare a decade to now, the market for foods, the market for drugs, the complexity in the science has expanded tremendously.

Even if you just look at imports, number of imported foods, and the number of establishments importing to the United States has gone up tremendously. So the complexity of what FDA is dealing with sort of probably the best—and not just the complexity, but the amount of things that FDA is dealing with is also something you've got to factor into as you're looking at what the appropriate amount of resources for the agency is.

I think that 5,000 deaths is too many. And ideally, you wouldn't have people dying from the food that they're eating. Now do I think that the measures that we're going to be putting into place will reduce that number? I do. I don't think it's entirely based on the number of resources or the number of people, but what we do with that. And I think that the shift to what Congressman Kingston was talking about, a prevention-oriented system, is going to lead to reducing that. And ultimately, we have to measure our success by how many people are dying and how many people are getting sick, not how many people are we hiring or, you know, how many buildings are we building. And this gets to the management question that the chairwoman was raising, that if we can't demonstrate that you're getting important value for the resources at FDA, then we don't deserve the money.

IMPORTED SHRIMP

Mr. FARR. Just one more question. I wanted to ask about—we understand that only about 2 percent of the shrimp that are imported are tested. Do we know if that number is correct?

Dr. SHARFSTEIN. That's probably about right. I think for food in general, it's about 1 percent. So that may be a little high. I'd have to look exactly for shrimp, but.

[The information follows:]

SHRIMP IMPORTS AND FIELD EXAMS

The following chart displays the number and percent of shrimp imports where FDA conducted a physical analysis, a field exam, or a label exam during fiscal years 2006 through 2008.

A physical analysis is a laboratory analysis of a product to determine whether the product complies with the statutes and regulations that FDA enforces. FDA conducts the analysis in one of 13 FDA regulatory laboratories in United States.

A field exam is an examination of a product without a laboratory analysis to determine whether the product is complies with the statutes and regulations that FDA enforces. Field exams can include a can-by-can exam for defects, a quick test for the presence of lead, a bag-by-bag exam for filth, or an exam for decomposition.

A label exam is an examination of a product label by an FDA investigator to confirm that the label complies with the labeling statutes and regulations that FDA enforces.

An import line is a portion of an import entry that lists as a separate item on an import entry document.

SHRIMP IMPORTS:
PHYSICAL ANALYSIS, FIELD EXAMS, LABEL EXAMS
FY 2006 – 2008

	2006		2007		2008	
	Lines Examined	Percent of Total Lines	Lines Examined	Percent of Total Lines	Lines Examined	Percent of Total Lines
Import Lines	99,163		99,383		100,304	
Physical Analysis	944	1.0%	891	0.9%	808	0.8%
Field Exams	1,155	1.2%	1,068	1.1%	1,123	1.1%
Label Exams	252	0.3%	230	0.2%	218	0.2%

Mr. FARR. So since we import about 90 percent, we're told, of the shrimp that we consume, and we're only testing 2 percent, that should probably cause us concern, wouldn't you——

Dr. SHARFSTEIN. Well, I think this gets to the question of whether testing and inspections is the measure of safety or not. And, you know, FDA could show up with a budget request that is truly astronomical if the idea was that we should be testing all imports or inspecting all facilities annually. But we're actually trying to use the resources in a way to establish a system that doesn't require that kind of testing. So one of the things that FDA is doing on shrimp is, there's a pilot project to certify a program that would basically train auditors and inspectors to do prevention-oriented work with all the different foreign shrimp producers so that we have confidence that the foreign production of shrimp is done under a prevention-oriented system, then you're just using testing to kind of check. And two percent might be fine at that point. If you don't have a strong prevention-oriented system in place, then you're kind of stuck just thinking about it as testing, but that's something that turns very expensive very quickly.

So I think the principle is, we have to be assured that the system for production, both in the United States and internationally, is based around prevention, and then we do targeted testing to assure that rather than we have to test everything that's coming in, because even then you could miss stuff if the actual system isn't sound underneath that.

Mr. FARR. I know a lot of us have farm-raised fish farms in their districts, and we've been concerned about the increase in the number of imports fish, so-called catfish, from countries we're concerned about not only the processing the facilities, the cleanliness of them, but where those fish are raised, we're concerned about that. And then the other day we were told—we were talking about catfish—that we really have never even identified what a catfish is. So that really causes a lot of concern. We don't know whether some of those fish coming in from other countries can even be classified as a catfish.

Anyway, thank you for being here.

Dr. SHARFSTEIN. Thank you.

Ms. DELAURO. Then my colleague raises an interesting question, which I intend to explore further on, which is about the issue of equivalency and in standards. And having to do with FDA, which at the moment does not have any system of equivalency, though you have stopped a whole lot of product coming in from China just in January, probably within 800 or so different kinds of products have been stopped from coming in to China. And I'll just say to my colleague at the request of a number of colleagues move catfish to FSIS in the farm bill. It was of concern to me at that juncture. It was a concern to me right now. Mr. Hinchey.

Mr. HINCHEY. Thank you very much, Madam Chairman, and thank you very much, Commissioner Sharfstein.

It's interesting to listen to you. You seem to be dedicated to your responsibilities here with this job and that's very important. What you're doing is critically important to the health and safety and security of people all around this country, and that's something that we need very, very well. And the importance of the FDA is some-

thing that the chairman of this committee is focused on over the last several years in a very significant way, trying to make sure that this system works better.

GENERICS

So I just want to ask you a couple general questions, and thank you very much for everything that you're doing. One of them has to do with the generics, generic drugs, and the expense of these generic drugs and the ability of people to buy them. With the downturn in the economy it's making it increasingly difficult for people to be able to afford these generics and there is less and less generic options for a substantial amount of these drugs that are very important for people's safety and security. So I wanted to ask you. What is the generic drug backlog now, and how does it compare to the past. And, also, can we get a commitment from the FDA to ensure that there will be enough staff to always keep the generic drug backlog below a reasonable number so fewer people are inhibited by it.

Dr. SHARFSTEIN. Thank you. I think it's a very important question. Generics are extremely important in U.S. medicine.

Mr. HINCHEY. I can't hear you very well.

Dr. SHARFSTEIN. Oh, I'm sorry. Thank you.

Mr. HINCHEY. Thanks.

Dr. SHARFSTEIN. No problem. I was just saying that generics are extremely important in American medicine and to many, many, many patients. Many people in Baltimore where I was health Commissioner really relied on generics and we were active in working with certain companies making generics available very cheaply to make sure that that information was know to patients. I think that the fact that there's such a backlog, my understanding is that it's about 1300 applications is definitely of concern.

I don't think all of them necessarily are like ripe for approval right away, but that that's sort of what's in the pipeline and the need to increase resources and other types of measures is very important, and I think is something the President is counting on in part to reduce healthcare costs. And I think that's why we expect pretty strong backing for a user fee program for generics that would give considerable new resources, allow us to hire, I think, about another 60 or so people for the generic program and really make a dent in those numbers.

Mr. HINCHEY. So you are moving this in the right direction apparently and you are concerned about it, and you are trying to improve it as much as possible.

Dr. SHARFSTEIN. Yeah, this is very important, no question.

USER FEES

Mr. HINCHEY. Yeah, well, good, and look forward to working with you on that. One of the issues that we have dealt with over the course of the last several years if the Food and Drug Administration's dependence to a considerable extent financially on the drug industry, because of the financial interaction between the regulatory agency and the operations that are supposed to be regulated. In fiscal year 2001 the fees paid by the drug companies at that point funded 32 percent of the FDA's budget for drugs.

Last year those fees comprised almost 50 percent of the drug program's budget and nearly a quarter percent of the FDA's overall budget. And that, of course, is something that has been a great concern for a number of people on this committee, including our chairman and others. We've been trying to deal with that issue and make it work much better than it has.

So I'm wondering if you can tell us how much of the FDA's budget is expected to come from drug user fees in fiscal year 2010. Now, that may be down even though it stays at the same level. The percentage of it may be down, because of the fact that the budget is going up, and appropriately so going up. But I'm just wondering how much of the FDA's budget is expected to come from drug user fees in this upcoming fiscal year, and what steps are currently being taken to end the FDA's close financial ties to the industry that it oversees.

Dr. SHARFSTEIN. So I understand, if I am looking at this correctly, that the overall drug program is about—I'm going to have to make sure I get this right—an overall for the agency the total budget is $3.2 billion, and the number of user fees is 800 million; but, if you're looking particularly at the drug program—I don't want to get the number wrong—so I might ask about that.

Mr. HINCHEY. Yeah, the numbers are important, but I'm more concerned about what your attitude is going to be and what your plans are, the direction in which you are going to be moving.

Dr. SHARFSTEIN. Well, let me tell you my attitude about it. I think it's certainly true the percentage of FDA's budget that is comprised of user fees has been increasing, and I think that I understand the concern people have made or expressed that user fees create perception or a conflict with the agency's work. And, I think from my perspective, I think these concerns reflect a broader lack of trust in FDA that goes deeper than questions about the agency's sources of income.

And I think the most important thing that Dr. Hamburg and I can do is renew the public's confidence by acting with integrity and transparency by sending the signal inside and outside the agency that we will make decisions based on the best available scientific evidence and not on influence that's inappropriate and make sure decisions are not unduly influenced at any point, and I think that's something we are very interested in following through on, and we've already started some efforts in that regard.

As far as the user fees themselves, my view is it depends on the type of user fee and the rules about the user fee. I think that when I go to the MVA and I pay for a license, I am not getting a lot of consideration aside from the MVA in response to that. And I think that one of the things you see is you look back on the history of the user fee program at FDA is what the user fees have been allowed to pay for has changed, and I think that has moved in the right direction. So that money that comes with fewer restrictions and allows important safety work to happen is going to have less of the concerns.

Mr. HINCHEY. Thank you. I appreciate that. But what I am concerned about frankly is in the context of this operation the ability of the operation that is being overseen having an opportunity to influence the decisions that are being made based upon the money

that they are putting into the process. That's the important thing, and I am sure you will be focusing on it.

Dr. SHARFSTEIN. Right. I hear your concern.

Ms. DELAURO. Thank you, Mr. Hinchey.

I would just like to add to the conversation of my colleague, Mr. Hinchey, in this way. And that is I have always felt over the years that the user fees were never meant to outpace appropriations and that is in fact what exactly has happened. And it is not being part of the effort, but in effect in my view in control of the effort that I see compounded by a study by a Harvard Professor, "New England Journal of Medicine" in 2008, said that "Since 1993 the first year of PDUFA drugs approved closest to the review deadlines had higher rates of serious safety issues in later years than other drugs.

That was disputed by the FDA. Professor Reed checked his data. Months later he published his raw data in an 151-page memo where he made some corrections, but he stood by his original conclusion. And the most recent legislation, FDAAA, gave FDA long-needed power to order safety measures when approving drugs. But, before that, FDA reviewers with questions about safety issues could only request post-market safety studies, the large majority of which were never even started by the companies ordered to do them.

I think it's probably not surprising that we have serious safety issues emerging years later. I am going to ask for your thoughts and this is not where I was going in terms of a question, but I think it is appropriate at this juncture to lay that on the table and ask to get your thoughts about that before I move.

FDAAA

Dr. SHARFSTEIN. Let me respond in two ways. The first is the FDAAA legislation was extremely important. It came after a very important Institute of Medicine report when I was on the board. I joined the board that did that report after that report was done and I am very familiar with it. And I think it did give very important authorities to FDA when that legislation passed; not just require studies, but also to require label changes and to require risk management strategies for drugs that are marketed.

And I think all those things, plus the flexibility and the user fees to spend more on safety, is going to strengthen what FDA can do. And I do think there is—and I want to respond in a slightly different way also—which is I think ultimately if the history of the FDA—and I definitely would commend Phillip Hills' book "Protecting America's Health" on this—is that there is not such an opposition between a strong FDA and a strong industry.

In fact, if you look back on the history of the FDA, when FDA has had trouble with regulation or their having had authority and people have been injured and all sorts of problems have happened. It is undermining confidence in the industry, and the industry financially has suffered pretty dramatically. And if you look across the last century you see that when FDA does its job fairly and reasonably in the interest of public health, even if it is strengthening its oversight, the industry actually does well. And I think that, you know, we are going to do the best we can to make the right deci-

sions for public health, but I have every expectation that as we do that and as we are able to strengthen the credibility of the agency, that the industry in the long term will benefit too.

Ms. DELAURO. I would just say this to Dr. Sharfstein. It is not something I haven't said from this microphone over the last several years. I think what specifically happened with regard to the FDA, that it lost its mission; that it is a regulatory agency. It has not functioned as a regulatory agency. I would just submit to you that part of that problem has come from undue influence of an industry and I do believe that the user fee issues have had an effect on that process, have made it more difficult. I believe that is one of the single biggest efforts that you and Dr. Hamburg have to take a hard look at to restore the regulatory mission to this agency, self-regulation has failed. It has failed unmercifully in our financial institutions and we have been brought to our knees financially.

Now, that is one level of difficulty when this agency doesn't regulate the products that it is supposed to regulate, people die. That is the result; and, I believe on both sides of the aisle on this committee, we want to return the regulatory function to this agency. Let me just comment. Let me go back on the issue of budget increases and food, and taking a look at the testimony, I was a little bit concerned.

Lots of useful activities, stepped up inspections, honestly a lot sounds to me like buzz words from a prior administration working with stakeholders and probing risk communication. This is a real change, a real change from the past would be a plan on food safety that identify the foods at greatest risk, that dealt with enforceable performance standards on pathogens, E.Coli, salmonella, listeria, and those performance standards could be developed with industry.

Looking at a system akin to a HAACP system that allowed for sampling and contamination, and a requirement that that had to be reported back to the FDA to looking at how we do base facilities on risk and then developing a system for inspection, because we cannot inspect everything. But if we do not have data and information to base on that risk that which would seem to me that we are not going to get anywhere here and a strong certification process for imported foods, I don't see very much of that in testimony. I know you are there a short time.

Dr. Hamburg is not even there at the moment, but these are the kinds of changes that I am looking for with regard to the food safety aspect of the FDA. And, you know what my position is on where food safety ought to be. I don't have to repeat that here, but will we see these kinds of changes from the FDA? In the future I will make another point: Energy and Commerce is going to produce a piece of legislation in short order.

If we are to move in direction seriously on food safety are these kinds of requirements in that piece of legislation, and will you support these kinds of requirements in that legislation? The train has left the station on food safety and I need to know from FDA's perspective if you will support these kinds of efforts in a food safety piece of legislation.

Dr. SHARFSTEIN. Thank you. Excellent question, I think.

The budget testimony kind of runs down the general areas where the money is going to go. It's not oriented in terms of the priorities

for food safety, and I think my list of priorities for food safety would be very similar to yours. It's not about meeting with stakeholders. It is about putting in place a modern, regulatory system for food that's premised on prevention, and I think that is the gist of the Commerce Committee bill which I fully expect we'll be able to support.

I think the food safety working group, which I met the other day when you were there, talked about that. Those are the principles that we are going to support. There is a tremendous amount of new authority that FDA needs to be able to accomplish that, but at the same time we are proceeding as if, you know, we are going to get it. And, we are working very hard within FDA to develop regulations around GMPs that need to be revised, an approach to prevent good standards of the HASAP model and others that could be put in the enforceable.

And I met multiple times with industry groups and that's what they want too. You know, and I think if we don't see results in those ways, the FDA is not succeeding in food safety and I think Dr. Hamburg and I are going to make that an extreme priority. And our progress has got to be measured and the implementation of those things, not in the number of people hired necessarily. I mean those things we think are important to get there, but that's not actually progress, nor is the number of inspections progress. It is those other things that are going to represent progress.

Ms. DELAURO. Thank you.

I went over and I apologized to Mr. Kingston.

Mr. KINGSTON. Thank you, Rosa.

Dr. Sharfstein, I wanted to take in the numbers the CDC and Inspector General has given us. There are 76 million food borne illnesses reported a year; 300,000 hospitalizations; 5,000 deaths. Everybody on the same page on that?

Dr. SHARFSTEIN. Yes.

Mr. KINGSTON. Okay. 300 million Americans eating three meals a day, no snacks. It is 9 million meals eaten daily times 365 days a year. That's 328 billion meals a year and so if you divide that by the food-borne illnesses, you actually come up with a rate of safe food at 99.98 percent. Correct? I mean this me. I want to make sure that there's no editorializing or fudging here, so that is the mathematical model. I mean that's the mathematical reality. Correct?

Dr. SHARFSTEIN. The vast majority of food in the United States is safe. No question!

FOOD SAFETY WORKING GROUP

Mr. KINGSTON. Right. So where I am confused is with food safety being at 99.998 percent safe, is the goal of the FDA specific in terms of food safety or is it this general political where we need more food safety? And the reason why I say that to you as a scientist, how do we measure it? Will it be on, okay, we had less than 300,000 go to the hospital? Or do we have less than 5,000 deaths? I mean, where will the metrics be?

Dr. SHARFSTEIN. That's a very important question. The food safety working group or the President has identified that as one of the top priorities. And when the food safety working group comes out

with its report, you are going to see this is what we mean by progress and food safety, and it is going to be very specific.

I do think we want to see fewer deaths and fewer hospitalizations; and, you know, you can look at these numbers from different perspectives. As a physician, I have taken care of kids who have been very sick from food borne illness, and I will never forget a little girl I took care of who had hemolytic uremic syndrome from E.Coli 015787 and she was in renal failure. She was on a fluid restriction and she was begging for water, and her parents couldn't give it to her.

And I'll never forget that. And I think it's sort of like when you have that kind of thing that is preventable, and now I think if you get to a point where you decide, you know, there's just not more that you can do to make it preventable, then that's where you are. But when you have preventable illness.

Mr. KINGSTON. What I want to make sure is we have a specific goal in mind.

Dr. SHARFSTEIN. Yes.

Mr. KINGSTON. Because I do think that another thing we never talk about in this committee is the 300,000 hospitalizations or the 5,000 deaths. How many of those people actually had a broken immune system to begin with? Perhaps this little girl I don't know, and certainly wouldn't want to base decisions on anecdotal evidence any more than you would as a scientist.

But the other question is how much of this could be prevented with consumer education. You know, like we have always been told, do not put the cooked hamburger back on the same plate that you put the raw hamburger when you are taking it to the grill unless you have washed it. Do you know the breakdown of that 5,000, how much of this was in the household versus anything in the food processing commercial side of it?

Dr. SHARFSTEIN. My understanding, generally speaking, that about two-thirds of the illness are from FDA-regulated products and about a third from USDA; and, so, the meats would be about a third and the other types of food would be about two-thirds, but——

Mr. KINGSTON. So, I want to make sure I understand.

Dr. SHARFSTEIN. But don't stop me answering your question.

Mr. KINGSTON. Yeah. No, but what you are saying about a third of it is something that happened in the household that could not be regulated. Is that?

E.COLI

Dr. SHARFSTEIN. Well, no; not exactly. I think that for some problems that happened in food safety, you know, for example all E.Coli that's in meat, if the meat is handled with gloves and everything and it's cooked completely, that E.Coli is going to get killed by the heat, you know.

But that doesn't mean that you want to put people at risk by having a lot of E.Coli in the meat, because not everybody is going to be able to keep to that standard. So I think of it as a shared responsibility. I know that consumer education is an extremely important part of what we want to accomplish and USDA wants to accomplish, but that alone is not going to be sufficient.

And I think that you are raising a question, which is important, which is when we talk about food safety, are we dancing on the head of the pin. Are we talking about real things that can be done that can make meaningful improvements in food safety? And I think if you look back to say the PCA thing that just happened and the fact that you had a facility that was very——

Mr. KINGSTON. It was criminal actually more than process.

Dr. SHARFSTEIN. And, but the fact that you had hundreds of companies that were purchasing from that facility and not really aware of the conditions there, it suggests that there are things that could be done, processes that can be put in place, that can make the food supply a lot safer. It won't be perfectly safe at the end of the day, and I don't think perfection can be expected in this. But meaningful improvements that will reduce those numbers are what we are trying to find.

Mr. KINGSTON. Yeah. No. I am excited about it, but I also feel that FDA in the face of political pressure still has to be the adult in the room and say, you know, the food system is right here now, and we want to take it here, which means we are going to own up to this 300,000 number. We are going to reduce it to 150,000; and, I am like you. I don't want any deaths, whether they are food borne, you know, from the household issues or elsewhere.

Dr. SHARFSTEIN. So, your point is extremely well taken. I think the metrics and outcome have got to be a part of what we are doing.

Ms. DELAURO. Mr. Farr.

Mr. FARR. Thank you very much. I think the certification process really needs to be implemented, because I represent the most productive agricultural valley, maybe in the world, the Salinas Valley. And it was the center for the E.Coli breakout—not the Salinas Valley, but a valley near there—and it was isolated to one farm.

That E.Coli spinach recall had all kinds of unintended consequences for growers. One was that it was voluntary, so about a hundred millions dollars was lost in our county and not reimbursed in any way by any insurance. If it had been a taking, of course, it would have been some reimbursement for that.

I want to compliment you, because I have seen your budget. You are going to spend some money on it to improve risk communication during a food safety event so that the public can respond promptly to the FDA alerts and protect themselves from harm. I would like to make sure that you also include that to study the ways of improving the communication so that it's not just a scare tactic, because that's where I think, you know, the analogy given, "if an airplane goes down people don't stop flying."

But with this, the unintended consequences of just saying "Don't eat spinach," is to this day, leafy greens have never reached what they were at that point. And you know Mexico didn't say we're not going to buy any lettuce from the United States. The E.Coli was in spinach. But I think it is really important for the government in its ability to inform a constituency. I have seen this with fires this summer where—nothing to do with your agency—but law enforcement demanded that people leave, and they had all the information they needed, because they'd look on the Internet. And they'd say, "Why should I leave my house?"

You know, "The fire is 10 miles away. It is burning at a half a mile a day. It is not going to be here for days. I am not going to leave." And I think there is a whole new communication system out there that government hasn't really taken into consideration. It's the Internet, and Facebook, and so on. So I hope with this money that you're going to really work on what I call risk communication to make sure that the communicators think about what they're saying the consequences of that will be.

RECOVERY OF INDUSTRY

Dr. SHARFSTEIN. Let me respond in two ways. The first is I think that the response to these outbreaks is under-prioritized recovery. Recovery is a really important goal of food safety system, and I mean by recover, I mean recovery of the industry. And even from the beginning of an outbreak, that has to be a consideration; and, I'll give you a specific example of my short time with FDA how that's played out.

From the moment that we were engaged with the pistachio industry, we called in the leaders of the industry and talked to them, and asked them to see whether they would be willing to set up a website right away that would be the products that were not associated with the farm that had the problems. And they were maybe a little surprised to hear from us, but very interested; and they immediately set that up.

And we've had, you know, many, many hundred thousand—I don't know exactly how many—hits through our website. We link to it from the FDA website; the industry, you know, wanting to make clear right from the beginning which products were not associated with this particular farm that was the problem.

And, I think that's a very small step, but I think we have to think about from the beginning of these how we narrow the advice, and then what we do to permit confidence in the food, because people have to eat. And there are so many healthy foods out there, that's just extremely important.

RISK COMMUNICATION

On your point about risk communication I can tell you as a former local health officer in Baltimore that is the most challenging part of the job.

Mr. FARR. What you learned as a doctor, the first rule is don't alarm the patient?

Dr. SHARFSTEIN. Well, I think you're right. We don't want to alarm people. On the other hand, we want to give people the risk information that they need to protect them.

Mr. FARR. Exactly, but we have to be smart about it.

Dr. SHARFSTEIN. And what we're going to use the money for is in part to work with some researchers to hear how people are hearing the messages, because you can say the message and you can think you are getting it across; and people aren't hearing.

Ms. DELAURO. Thank you. We also want to prevent them and not react to them continuously. Mr. Latham.

Mr. LATHAM. Thank you Madam Chairman.

And I know we have votes on the floor here so I'm going to try to be brief. First of all, I want to associate myself with the previous

round, Mr. Farr's question about the disparity of inspections for express carriers, and that's a major issue; and, we need answers on that.

Talking about imported products; and, Ms. Emerson wanted me to ask some questions also about how the FDA proposals to rely on certification in order to obtain assurances that products comply with food safety standards, the certification, how would that work? Would it be used on domestic products only or on imports, or only for imports?

DOMESTIC PRODUCTS

Dr. SHARFSTEIN. So we are putting together the pieces of how we would approach this, and I will start with domestic products. I think the understanding is that we would have an integrated local, state-federal system where we would be working very closely with the states, localities, and there would be inspection through that system, not through third-party certification.

For imports, it's a different situation, and I think the best position you'd be in is where the country is doing such a credible job of inspections that you can rely on the country certification.

Mr. LATHAM. How do you assure that? I think that's the question. I think that's the question. How do you assure that the foreign country is credible. You've got people over the monitoring all the time? Or are there certification processes?

Dr. SHARFSTEIN. That hasn't started at FDA yet. USDA has the whole system of certification. We could probably learn a lot from how they do it, but we would anticipate that not every country is going to qualify for that, so then you've got to shift gears a little bit and you've got to say: "All right, if the country is not going to do it, could the country as a whole?"

THIRD-PARTY CERTIFICATION

Maybe the country's oversight of this particular crop will be sufficient. We'd have to create standards for that; and, if that's not sufficient, maybe there's a third-party certification process, internationally, like they are trying to do with shrimp that could have credibility. And with each of the steps you want to be checking more and more so that, you know, if the country standard is the best standard to have, you would have a certain level of checking.

But as you move towards other levels of standards that, you know, you are going to have enough confidence in, but you were going to have that confidence because you are going to be checking more and more, so we hope to be sharing. And I think, you know, an approach to this that will make sense and be able to answer some of those questions. In part, it is going to depend on whether and what kind of food safety legislation passes, because it gives us different authorities in that respect.

Mr. LATHAM. Now you've got a proposal that products that fulfill additional guarantees to exclude intentional contamination bioterrorism risks, maybe eligible for fast-track processing at the border. Are you going to have rules? Are you going to have guidance for the companies? Do you have any idea where that's going to come down?

Dr. SHARFSTEIN. I think that partly is going to depend on what passes in Congress. But the principle there is the more assurance we have that something is safe based on the rules that pertain to where it's made and who's overseeing it there, then the quicker it will be able to get into the country. The less assurance we have depending on the system, then the more we are going to have to do at the border for those products.

Mr. LATHAM. Do you expect to have fewer inspections under a system like that?

Dr. SHARFSTEIN. I think that what we expect to have to be able to target whatever number of inspections we have as effectively as possible. So I don't think that we are going to say. We'd like a system that doesn't have to be that we are inspecting 50 percent of the food, because that would be enormously expensive and not even as effective as having a better prevention approach in other countries.

Mr. LATHAM. Okay. I am going to stop there in the interest of time. I've got some questions for the record, but thank you, Madam Chairman. Thank you.

Dr. SHARFSTEIN. Thank you.

Ms. DELAURO. Thank you.

I will encourage my colleagues to go to vote. I just want to lay out something that we can come back to, but we will do that. I will be back and I think many of those who can will come back as well for additional questions. This has to do with counterfeit and contaminated products from China. A "Reuters" news story: "China State Food and Drug Administration counted 329,613 cases of the distribution of unlicensed drugs and medical products in 2007." Recent Op-Ed in the Asian section of the "Wall Street Journal," as many as five million Chinese citizens work in the counterfeit market, which includes fake drugs, patent infringement and trademark infringement.

While the Chinese government might not directly participate in drug counterfeiting, it certainly enables the practice at a minimum by looking the other way. Indeed, drug counterfeiting may be a significant part of the economy. The story also quoted a Chinese expert in counterfeiting who said: "Counterfeiting is now so huge in China that radical action would crash the economy over night and even destabilize a government or counterfeit factories and warehouses are often owned by local military and political grandees."

Five million people in China work at counterfeiting drugs; little enforcement by their government. What do you plan to do beyond—right now, as I understand, there are a couple of offices in China staffed by a few people in order to be able to safeguard the American people from dangerous drugs—Chinese drugs, drug ingredients and foods.

I clearly will come back with that, but I also have here a list of, you know, January 2009 listing all of the various products that have been stopped coming in from China as something as unsafe and we've got in the first four months of 2009 such practices as what the Chinese government is doing. The FDA rejected 839 shipments of Chinese products including fish.

Anyway, I have two minutes to go to vote, but I mean this is such a serious issue without any real infrastructure in place to deal

with it. Two percent of shrimp inspected, I mean, I think this is a crisis. I really do. And, today, 73 percent of people in this country are more fearful of the food they are eating in terms of food safety than they are in the war on terror, so I am going to ask you to address this when I get back. Thank you very much.

Recess subject to the chair. Thank you.

[Recess.]

Ms. DELAURO. I want to get the permission, which I have, of the Ranking Member. You usually cannot start with just one person. I apologize. It was longer than anticipated.

The hearing is called to order. I am not going to go through the commentary again, Dr. Sharfstein. This is on the counterfeit drugs, China.

Dr. SHARFSTEIN. I think this is an extremely important issue and one that Dr. Hamburg feels particularly engaged in. I think she is very aware of the statistics like this that show the increase in imports over time and reflect the incredible change in the world over the last decade in how products are coming to the United States.

COUNTERFEIT DRUGS

I think there are three separate issues. One is the counterfeit issue, which are drugs that are sort of purported to be a particular drug but are not that drug at all. That is very much an issue of global concern.

The World Health Organization is very engaged in it and there is going to be a lot of activity globally on it.

I think part of the solution to that one in comparison to the other two issues is that if we had a solid system for pedigree and tracking of drugs, then we know we are getting what we are getting. That is for that issue.

SUPPLY CHAIN SAFETY

Then there is a second issue of for what we are getting, are there safety issues. You have the not counterfeit, meaning a drug that is not sort of fake but the actual drug that has originated from another country where there are issues in the supply chain. The obvious example would be Heparin.

Ms. DELAURO. That is the thing that just came to my mind.

HEPARIN

Dr. SHARFSTEIN. That is in the second category. The Heparin problem was not a counterfeit problem. It was a problem that the actual raw ingredient was contaminated, and you have a situation where many raw ingredients for many drugs——

Ms. DELAURO. That appears to be intentional, the contamination of Heparin. No?

Dr. SHARFSTEIN. You have this issue of actual products that are legitimate products but may be unsafe because of problems in the supply chain.

Ms. DELAURO. That requires a tracking system.

Dr. SHARFSTEIN. I think the first issue, the counterfeit issue really is a solid tracking system, make sure you are getting the actual

drug you think you are getting in the sense that this is the company's drug. It is not someone purporting to be the company's drug.

The second issue is more complex because even a tracking system, you could be getting the drug you think you are getting but that drug can be contaminated in some way, and trying to figure out how to establish a system that is going to prevent that is much more complex.

Then there is the issue of foods, where you have hundreds of thousands of companies selling foods into the United States from different directions, all sorts of different foods, and it is not a closed system like the drug supply is.

Each of those are major challenges. I think this is going to be—you are putting your finger on one of the biggest challenges facing the food and drug markets, the biggest challenges facing the FDA, it is going to require a combination of approaches, but we are very much aware this is an important issue.

The approaches include, I think, responsibility at a lot of different levels. We have to hold the Government responsible in part, the Chinese Government, but in addition, the people importing the product have to be responsible. The companies that are—it is their supply chain, they have to be responsible.

There are major public health issues involved in this. There would be obvious public health issues like the food being unsafe or the drugs being unsafe, but then there are other public health issues.

The market for counterfeit drugs could mean a lot of people not getting treated with the right drugs, or for example, when you are dealing with anti-microbial drugs, like tuberculosis drugs, if somebody is making a poor quality tuberculosis drug, it is not even just that the patient does not get treated but that tuberculosis could become resistant.

Ms. DELAURO. Right, and that is a real problem.

Dr. SHARFSTEIN. That could swing back and hit the whole world. You have a series of overlapping challenges with imports that are going to be very important to address.

Ms. DELAURO. This is January 2009. Coca, melamine. Mixed mushroom, filthy. Frozen cat fish nuggets, Chloramphenicol. Chocolate candy, dark chocolate, all melamine. Dried mushrooms, filthy. Dried food, candy glaze, honey. Filthy.

It is staggering. This was stopped, fortunately. It is a large plate with a lot of things on it, but I think—vermicelli, filthy.

PUBLIC HEALTH

Dr. SHARFSTEIN. I take that personally.

Ms. DELAURO. Right, I take that very, very personally. Frozen white shrimp, unsafe animal drugs, fermented shrimp sauce.

Your business and my business is not trade. This is about the public health. We need to be able to rely on you to put the mechanisms in place. This is something that we will continue to talk about as you all move forward.

Mr. Kingston.

CIGARETTES

Mr. KINGSTON. Thanks, Rosa. Doctor, on the regulation of cigarettes, nicotine is carcinogenic, yes or no? What is carcinogenic in cigarettes? What ingredients?

Dr. SHARFSTEIN. Which ingredients? I think there are a number of them. I think there are more than 100 carcinogenic ingredients in cigarettes.

Mr. KINGSTON. Are you not in kind of an oddball philosophical position of having to come up with acceptable regulations of carcinogens?

Dr. SHARFSTEIN. You mean——

Mr. KINGSTON. Let us just say that was in cereal. You would not allow the cereal, right?

Dr. SHARFSTEIN. I think I understand what you are saying, that if the legislation that is moving forward now were to pass and FDA were to have regulatory authority over tobacco, would there be kind of a weird situation for FDA given that cigarettes are harmful, to regulate them.

I think it is a fair question to ask. I think the question that you have to ask with this is sort of the same question you have to ask with any kind of product or regulatory decision, which is do the benefits of doing it outweigh the risks.

I think the benefits of FDA regulation on tobacco could be quite considerable in terms of the public health. Tobacco is such a dangerous product and so unregulated right now.

At the same time, there are potential risks. One of the risks is that people may perceive why is FDA permitting something that is unsafe, as you put it.

I think on balance, there is no question in my mind that the benefits would outweigh the risks.

Mr. KINGSTON. What would you be able to do that would be different from what is going on now?

Dr. SHARFSTEIN. Under the tobacco legislation?

Mr. KINGSTON. Yes.

Dr. SHARFSTEIN. I think there is authority there that relates to the marketing of tobacco products as well as the composition and performance standards that would be for the manufacturing of tobacco products.

Mr. KINGSTON. What would you do different in the advertising?

Dr. SHARFSTEIN. We do not have authority over it and it is not something the agency has really thought of, but it would be—the one thing I would say is part of the legislation does implement the 1996 rules, which was proposed and does have some advertising related provisions in it.

I do not know if I could tell you all of them exactly. If you went back to that, you could see some of the things that the bill——

Mr. KINGSTON. Maybe if you could give me something for the record. I would love to know what you would do different in advertising and then what you would do different in the regulatory structure, and the big question that everybody hates to ask, you know, what is the safe level of nicotine.

Are you going to tell me I can go to three cigarettes a day and that is better than ten? Once you have that FDA stamp on there, you are telling a whole bunch of kids, hey, the FDA approves it.

[The information follows:]

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) amends the Food, Drug, and Cosmetic Act (FDCA) to give FDA authority over tobacco advertising in several respects, including, principally:

- Under FDCA Section 906(d), FDA may impose restrictions on the advertising and promotion of a tobacco product as appropriate to protect the public health.
- Under FDCA Section 903, a tobacco product is misbranded: (1) if its advertising is false or misleading in any respect (Section 903(a)(7)(A)); (2) if it is sold or distributed in violation of regulations prescribed under Section 906(d) (Section 903(a)(7)(B)); or (3) unless its advertising and other descriptive printed material includes certain information (Section 903(a)(8)).
- FDCA Section 911 contains several provisions relating to advertising for modified risk tobacco products, which give FDA some administrative responsibilities, rulemaking authority, and enforcement authority.
- Section 201 of the Tobacco Control Act directed FDA to reissue final regulations issued in 1996 that restrict access and certain marketing practices, including certain advertising practices, to protect children and adolescents. These regulations, 21 CFR Part 1140, were reissued on March 19, 2010 (75 FR 13225).
- Section 201 of the Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act and Section 204 amends the Comprehensive Smokeless Tobacco Health Education Act of 1986 to give FDA administrative responsibilities, rulemaking authority, and enforcement authority over the statutory health warnings on cigarette and smokeless tobacco packages and in advertisements.

Dr. SHARFSTEIN. I could tell you that three cigarettes a day is probably better than ten because there is a dose response, the more people smoke, the more dangerous it is for them.

I do hear your point. I know it is something the bill tries to address. I think it is something that has to be taken into account as you move forward so people do not get the idea that a product is safe just because the FDA regulates it.

FDA regulates other things that may not be so safe also, and has to deal with that same balance.

Mr. KINGSTON. Do you regulate things that have carcinogens in them?

TANNING BEDS

Dr. SHARFSTEIN. Yes. For example, tanning beds would be an example, and can promote skin cancer. There are actually a lot of drugs that can cause cancer.

Mr. KINGSTON. Let me ask you this, another philosophical question. Do you think FDA should regulate cigarettes?

Dr. SHARFSTEIN. Yes.

CIGARETTES

Mr. KINGSTON. Do you think cigarettes are bad for you?

Dr. SHARFSTEIN. Yes.

Mr. KINGSTON. Do you feel—I am going to kind of assume you do feel a little bit of queasiness in that there is an endorsement side to this; correct?

Dr. SHARFSTEIN. I think you have to look at it as a benefit of regulation versus the risk, just like any kind of balance.

Mr. KINGSTON. You have an opportunity to control it a little better and kind of accept, you know, you cannot outlaw tobacco smok-

ing but FDA involvement might come up with better results, philosophically.

As I understand it, menthol cigarettes are exempted. Is that correct or am I wrong on that?

Dr. SHARFSTEIN. I think the current version of the bill prohibits certain flavorants right off the bat.

Mr. KINGSTON. I think they are exempted.

Dr. SHARFSTEIN. What menthol is—menthol is not listed as one that by statute is prohibited, but the FDA would have authority to take action on menthol under the current version of the bill.

Mr. KINGSTON. The menthol language, you think is fine and acceptable, or would that be something you would not wish necessarily was in there?

Dr. SHARFSTEIN. I think the menthol language is fine. I think the President has made it clear that he supports the legislation.

TOMATOES

Mr. KINGSTON. I want to get back to Mr. Farr's question earlier in terms of the health benefits of eating peanuts, spinach or tomatoes. When the FDA sounded the alarm on those three products, there were a lot of people who were unable to buy these products or they could buy them but basically, it was very risky.

Dr. SHARFSTEIN. They were told not to eat them in some cases.

Mr. KINGSTON. Mr. Farr's analogy, and I think it is a good one, it is almost like there is a plane crash and we have gone out and told people do not fly, planes are unsafe.

That absolutely was not the case with many of the products that are out there. You had said to him that is where the trace back becomes important, so you do not just say okay, nobody eat tomatoes for the next three months until we get to the bottom of this, but you could pinpoint what farm or what production shop or whatever.

There would be a data bank of information. Who keeps that information and for how long and who would have access to it?

Dr. SHARFSTEIN. That is an excellent question. I think right now, FDA is working on guidance for the industry on how to keep information. Ideal would be that the companies would keep the information.

Mr. KINGSTON. I just want to interrupt real quick. I may have misunderstood you but I thought you said to him that the stakeholders would not be in the room, that you would do this kind of by yourself or something.

Dr. SHARFSTEIN. No, I do not believe that at all.

Mr. KINGSTON. There was some statement. I want to make sure I have a clarification.

Dr. SHARFSTEIN. I think that working with industry in these—

Mr. KINGSTON. As you did. I think you pointed out with pistachios, you did bring in—that was a different model than these other commodities.

Dr. SHARFSTEIN. I started the day the pistachio thing happened. It has been said no matter how long I last at the agency, whether it is a month or ten years, my good-bye present is going to be a bag of pistachios.

That is where we started and I thought it was very important to reach out to the industry.

The other area in food that we have dealt with is alfalfa sprouts. That was very challenging. We had extensive conversations with industry from the beginning. It is only at the point where we realized it looked like 70 percent of the seeds could potentially be involved, the industry understood the predicament.

It is challenging. When I was the health commissioner in Baltimore, you get called in the middle of the night. There are 100 people that are sick in the hospital. You show up.

This is a true story. I went to the hospital. They said there had been a wedding and someone had driven a pig down from New York, from New York to Baltimore. People had eaten it after it had been sort of at lukewarm temperature.

Clearly, you knew exactly what made people sick. Now you have the situation where you know probably thousands of people have gotten sick and you do not know the cause. It is a real challenge.

I think that when we are in that situation, we want to protect people, but we do not want to scare people and destroy industries that are very important to the United States.

I think we have been trying to do this a lot more, or I have been trying. It is one of my goals since I have been there, to get everybody who is engaged and knows information to the table, figure out how we can best make a tough judgment under the circumstances to protect people and balance that against the other issues that are involved.

It may be that what we did with pistachios is we made a pretty broad announcement and then narrowed it very quickly, and the same thing with alfalfa sprouts, a pretty broad announcement but we told people we think we are days away from getting it more narrow, and we were days away, and we were able to narrow it. It was by working in large part with the industry that we were able to figure that out.

INDUSTRY

I met with the industry several times already. They have been very open to it, even on peanuts. We are working with them to try to get the messages out that they are interested in getting to their growers. They have been incredibly supportive of the FDA doing more.

I think there is a lot to be done in concert with industry that is going to make the food supply safer.

Mr. KINGSTON. Thank you.

Ms. DELAURO. I think it is true about industry. We were both here when the western growers told us that what we needed were mandatory enforceable standards because they were going out of business. Spinach has not come back to what it was. Tomatoes, lettuce, peppers, the whole business.

I think industry is very, very much interested in making sure that the product is safe and there is an opportunity to work with them.

USER FEES

I want to ask about the food registration and inspector user fees. There are a few references in the budget document which you estimate in terms of food registration, an inspector user fee, $75 million in 2010.

At one point, the document says the fee would allow FDA to collect fees to register food facilities and conduct safety and good manufacturing practices, inspections of food manufacturing and processing facilities.

How would the fee be assessed? Are you proposing a single fee for registration, that is conducting the safety, the good management practices? This fee would fund inspections or are you planning to charge both a registration fee and a fee for the cost of inspections?

If you are planning a fee for inspections, would that be assessed on a per inspection basis or would it be a general fee paid by the facility?

Frankly, I would be concerned about the potential for a conflict of interest in a per inspection fee.

Dr. SHARFSTEIN. I understand that. I am going to ask Patrick to tell me whether I am wrong on this. I may just have him answer that question. I know there is a registration fee and I think there is a re-inspection fee, which is a separate fee.

Ms. DELAURO. That is a different issue. That requires legislation.

Dr. SHARFSTEIN. Right. I think this also would require legislation, the food registration fee.

Ms. DELAURO. That is right.

Dr. SHARFSTEIN. I know at a minimum it would be a fee upon registration. I do not know whether it is contemplated, I have not heard, that it would be a per inspection fee.

Mr. MCGAREY. I have not heard any discussions on it being a per inspection fee.

Ms. DELAURO. It would be important to know. If you could get back to us on that. That is something we would just like to get some clarity on.

[The information follows:]

FDA USER FEES

FDA's FY 2010 budget includes $75,000,000 for user fees to register food facilities and conduct safety and good manufacturing practices inspections of facilities that manufacture and process foods that Americans consume. The Food Registration and Inspection User Fees recommended in the FY 2010 budget would be paid annually by each registered food facility, whether the facility is inspected that year or not. FDA will use the fees to pay for inspections of food facilities and other food safety activities that FDA conducts.

Dr. SHARFSTEIN. Okay. No problem.

Mr. KINGSTON. Rosa, would you mind yielding?

Ms. DELAURO. Not at all. Go ahead.

GENERIC DRUGS

Mr. KINGSTON. I think this Committee really is philosophically in support of generic drugs, and what we might be interested in from you is what can we do to accelerate them getting to market. There are a lot of obstacles that are out there. We would not mind stray-

ing into the authorization territory. Appropriators do not authorize unless you have everybody who wants to authorize, have 51 percent agree.

I think we would be interested in hearing from you on suggestions to get them out there.

Dr. SHARFSTEIN. Yes.

I think there is obviously a goal of getting the user fee program off the ground. I met with the generic drug industry. They seem quite open to the idea of this. I think if everybody who is engaged in it seems supportive of it, you have at least the basis for it actually happening.

I would be pretty optimistic just going in that it could be worked out that way, but I do think if that path does not pan out, we are going to need more resources to be able to get more generics to the market.

Ms. DELAURO. The control measures for all levels of food production and processing, the budget again says "FDA will improve its ability to protect American consumers, strengthen safety and secure the supply chain by working with domestic and foreign industry to develop new control measures for all levels of food production and processing.

"FDA will also verify that these control measures are effective when implemented."

This ties in with what we were talking about before in terms of the imports. What exactly are these control measures? Will they be enforced, and if so, how?

Further on control measures, I have two more specific questions on this and your views on moving to an equivalency system for FDA regulated food imports.

My understanding is this was proposed during the Clinton Administration but never implemented. While I believe that there are gaping holes in how FSIS has administered equivalency, I am not using that as the standard.

A properly administered equivalency system can be an important help for protection.

Second, what about enforceable HACCP sanitation and pathogen standards?

CONTROL MEASURES

Dr. SHARFSTEIN. To your first question about control measures.

Ms. DELAURO. What are the control measures; right.

Dr. SHARFSTEIN. The big picture is we really need a new food safety system that is premised on prevention, and in order to get that, and what we have heard very clearly from industry and consumer groups and you and others and all the experts we have consulted is we need clear regulations that establish the basic approach to prevention, that include things like performance standards where they are appropriate.

That is something that we hope to get out of the legislation in the Commerce Committee. If we do not get that, we will see what we can do under the current law.

That is what is needed. The entire system is probably not going to be put into place by the time we meet again next year, but we want to see a lot of progress towards that. We want to see many

different things moving forward that are going to do that and over the next several years, we want to see that system put into place.

On the question of equivalency, are you talking about third party certification equivalency or are you talking about international equivalency?

Ms. DELAURO. I am talking international, government to government.

Dr. SHARFSTEIN. Government to government. I think something like that has got to be part of the import system. It is inconceivable that FDA could be inspecting 200,000 facilities. There has to be some other way to approach it.

Equivalency is going to be something that we will have to look at, the strengths and weaknesses of the USDA system will be something we will have to take into account in doing that.

EQUIVALENCY

I think we are open to the idea of equivalency overall, and then equivalency for particular products. If a particular country import a lot of a particular food or something, that particular food is done well and we know it is done well, and we have confidence that they can oversee it, and that is good enough.

The key in my mind is that we have different tools to balance it. The more confidence we have in that system, the easier it is for the products to come in, the less confidence maybe the more assurance we need from that system, then our approach at the border can change.

We are not saying that everything is exactly the same. We have the ability to kind of modulate what our response is at the border based on our level of confidence about what is going on overseas, and in the end, those two things have to add up to an acceptable level of confidence or else we cannot import it.

HACCP

That is what we need to get to.

Ms. DELAURO. And HACCP?

Dr. SHARFSTEIN. We are in favor of HACCP. It has to be adapted to the products appropriately. One good thing about HACCP is it gives a lot of flexibility to the companies to innovate as long as they are hitting their safety targets.

You do not want to lock people into an old way of doing business, but you want to hold them accountable. I think what you see in the wake of some of the food safety problems are businesses and industries really stepping forward and doing an awful lot.

I think it is just critically important if you think about how much testing is going on in the private sector, we want that to be as high quality as possible. I really do believe that the companies, particularly the big companies, have such an incredible interest in the safe food supply that they really are allies in how we move forward.

Ms. DELAURO. Mr. Kingston, would you mind if I ask one more question?

Mr. KINGSTON. No, not at all.

Ms. DELAURO. I will just ask this one and then turn to Mr. Kingston and then hopefully we can try to wrap up.

STATE INSPECTIONS

This is about the review of state inspections of food facilities. Budget again will allow "FDA to expand state capacity for risk based inspections by increasing the number of cooperative agreements and partnerships with states."

Peanut Corporation of America is the case in point here. Just having state inspections is not enough if FDA does not do anything to ensure that the state inspections are competent and thorough.

We have a news story that ran on Monday that says "The FDA told several minority members of the Energy and Commerce Committee that it did not even know if it had done any reviews at all in 11 states in 2007 and 2008, including Texas and Georgia, where salmonella was found in peanut plants this year."

The story said that an FDA official wrote to those members and said the recent salmonella outbreak, and I quote, "Has highlighted limitations in our current approach and has prompted internal discussions on potential enhancements to the audit program."

I am a little tired of seeming to look at failures and think about improvements after people die. That is not a standard I think we ought to adhere to here.

The stories have identified numerous holes in the state inspection system operated by FDA. What is particularly troublesome is that the gaps in the system were identified in 2000 by the IG and little has been done to address them.

What specifically is FDA doing now to improve the quality of state inspections? What are you going to do in 2010? What do you believe is the purpose of these contracts? How should FDA oversee the work of the states and are our states now required to report their findings to the FDA?

Dr. SHARFSTEIN. Let me take that on in a couple of ways and I might ask Mike Chappell from the Office of Regulatory Affairs to answer some of those, give his perspective.

I think the approach—I think your point is very well taken that this is not about modest improvements in the system. This is about really changing the system.

Ms. DELAURO. I would just say this, I believe we do not have all the resources to do what we need to do.

Dr. SHARFSTEIN. But even with that, I think the right question is not how we are going to audit a little bit better, that is not the right question. It is how are we going to really integrate the Federal, state and local food safety systems.

There was a very good report that was done for the Robert Wood Johnson Foundation by Mike Taylor at G.W. that I would definitely commend to you. It is something that the FDA has been engaged in and FDA has been meeting with the states around food safety, David Acheson and Steve Sunlof are both here.

The idea is not to think of the states as contractors any more. I think there is $15 million in this budget to start this transformation, but to really be a partner with the states.

STATE PARTNERSHIPS

FDA really does not have the kind of training capacity that it needs, that we would be at a point that when the state goes out,

we feel like it is FDA going out, and we have confidence in their inspections. We have confidence in their labs. That is the goal.

I was just at a meeting where a business said I know we hear there are not enough inspections, but we could have a week where a Monday, it is the Federal inspector. On Tuesday, it is the state inspector. On Wednesday, it is the local inspector. Sometimes, they are all the same person. They just put on a different hat and they are filling out different forms. Does that make any sense at all. How can you say that makes sense.

In order to jump to that system that is envisioned in the Robert Wood Johnson report, there is going to be an up front cost of developing the capacity to really retrain the states, invest in the states.

I can tell you this for Maryland, this is not an area—the states are having economic problems. This is an area where a Federal partnership that comes with money, I think, would be very much appreciated because then it would give them a big incentive also to participate and develop the capacity we want to see in the states.

AUDITS

I think there is an issue with the audits under the current system, but I think the right question is not are we going to get 60/70/80 percent of the states audited, it is are we going to really change our relationship with the states, change the system, so we are able to genuinely feel like they are partners and not sort of hired hands to deal with inspections.

Mr. CHAPPELL. I think that is fair.

Ms. DELAURO. You have to identify yourself.

Mr. CHAPPELL. I am Mike Chappell. I am the acting associate commissioner for Regulatory Affairs.

I think as Dr. Sharfstein said, we are really going to approach it a little bit differently. Frankly, we really have not put the resources into what was our typical audit program. We are looking at it totally different, rather than trying to audit inspectors per se, look more at state programs holistically. Integrate training. Integrate audits, the whole process.

I think we are moving forward in that direction, and certainly in the manufactured food standards, where we are trying to look at standards for programs rather than auditing individual investigators or states.

Ms. DELAURO. Thank you. Mr. Kingston

Mr. KINGSTON. I do not know if the FDA has this model, but with USDA, with many processing plants, you can be inspected by state inspectors or a USDA inspector, but you can actually choose which one you want. You do not choose the easier one necessarily. There is some reason that some prefer Fed and some prefer state.

Have you looked at that kind of model to stop that Monday, Tuesday, Wednesday, which inspector is going to walk in the door and what hat is going to be on his head?

Dr. SHARFSTEIN. I think we should look at that model. I think we are in the process of setting up and moving forward, particularly in fiscal year 2010, a system like this, and I think that is very fair.

Mr. KINGSTON. There is a reason that some prefer state and some prefer USDA, and it may be because of interstate commerce or something, one checks more boxes on the list.

It would appear that you do not have to re-invent the wheel because there is something out there that could be helpful.

Rosa, I am actually finished, unless you say something that peaks my interest.

[Laughter.]

Ms. DELAURO. Then just interrupt, Jack.

We are going to have votes within the next 15 minutes. I would like to try to get in the last couple of questions and I know you have to go to the other side or maybe to the dark side. I am sorry. I had to say that.

OFF LABEL MARKETING

Off label marketing. This is a guidance issue that at the end of the Bush Administration, one week before it ended, issued guidance to facilitate off label promotion of drugs, medical devices, by drug and medical device companies.

It allowed the drug companies to distribute reprints of medical journal articles on off label use of products with only minimal guidance on the quality of the studies and the journals themselves.

A news story reported that Bush/FDA issued new guidance over the objections of Bush's Department of Veterans' Affairs, which pays for drugs taken by its health system patients.

"We urge the FDA to withdraw the proposal. The VA wrote FDA last year. It will not improve drug safety. It could very well result in a decline in drug safety."

Among other things, the VA said "Second rate studies published in journals with questionable peer review processes will be used to convince physicians to use drugs for an ever-increasing number of unapproved uses."

What are your views on the policy and will you move to revise it?

Dr. SHARFSTEIN. Thank you for asking that question. Let me start by backing up a step. FDA does not regulate the practice of medicine and physicians are free to prescribe drugs for unapproved uses generally speaking.

As a physician, I have prescribed drugs for unapproved uses and particularly as a pediatrician, because there are a lot of drugs that are not approved in kids, and it is really your only option.

That problem is being addressed and thanks in large part to Congress, over time, that will be addressed. It is important to the practice of medicine that the physicians have that capacity.

At the same time, when there is promotion of unapproved uses that is excessive, you have the potential problem that the particular uses may not be actually safe and effective because they have not been reviewed by FDA, and you also have the fact that companies may have less of an incentive to ever seek approval if they can go ahead and promote it without approval.

As a result, I think you have to draw the difference between the use of medicines for unapproved uses on the one hand and the promotion of medicines for unapproved uses on the other.

I am aware of the guidance that was issued. I think like many different things going on, it merits looking at. It is part of the bigger picture of how do you strike a balance with unapproved use that respects both the importance in many cases of unapproved use but at the same time, not wanting to permit promotion that could have adverse health problems.

Ms. DELAURO. You are going to address that issue?

Dr. SHARFSTEIN. Yes, the issue of unapproved use is something that is very much on our minds.

FOOD SAFETY

Ms. DELAURO. I will not go through all the commentary here. I think you have heard me say before there is no one official in FDA who is responsible for overseeing food safety, that the functions are spread out and scattered across it, OBM and ORA, toxicological research, et cetera.

It has been suggested that the President could administratively create a new position of FDA deputy commissioner to the Secretary for Food Safety, directly accountable to the Secretary.

This would create within the FDA a virtual food safety agency, if you will, and give the person authority over the food safety effort.

I do not know what your thoughts are about that, which I would like to get. My question is would you move to support legislation that would get us moving toward consolidating food safety functions of FDA?

I am going to pose my question this way because I think you probably know where I am going with this question.

You may have to hedge your response because of the food working group and in any case, I do want your views on a single food agency, and is the Administration with regard to FDA opposed to a single food agency?

Dr. SHARFSTEIN. Sure. To the first part about a position within FDA, I would split your statement into two parts. One is does it make sense to have somebody in charge of all food activities at FDA, and I would say that is a suggestion we are taking very seriously at this point, and we will be happy to update the Subcommittee on where that goes. I definitely understand that perspective.

Where that person reports is the other half, and you mentioned reporting to the Secretary. I will just tell you personally, that does not make sense to me. If it is within FDA, it should report to the FDA Commissioner, as to maintain a good management structure and not create a lot of confusion, people have to know who they are reporting to.

I think both Dr. Hamburg and I are extremely committed to food safety. Both of us have experience as local health officers managing outbreaks. I think we are going to be very focused on it and I think we will be able, as you can tell from the level of interest in this discussion, this is a very high priority for us.

SINGLE FOOD AGENCY

As far as the single food safety agency, the big picture is I am not aware the Obama Administration has a position on this at this point.

My view is this is an opportunity for major progress on food safety in the United States as we switch to a prevention oriented system, and there is a lot of ground that we can gain very quickly if we are really focused on moving forward, and that is the right thing to be doing now.

The longer term discussion on how best to organize things, I think that is something Dr. Hamburg and I are going to be willing to engage in, but without sort of a pre-conceived notion of what the right thing to do is.

Right now, we think it is very important for FDA to get these resources and to get the authority and then to make a difference and create a better system.

Ms. DELAURO. I appreciate that. I also would just comment, I still think that getting to where we need to go with regard to food safety means food safety out of FDA and the two agencies within HHS, as I have suggested and others, seems to be a good idea as well.

MEDICAL PRODUCT INSPECTIONS

Quickly, it looks as if the $12.2 million for medical product inspections both domestic and foreign seems low. It seems to me to be very low in terms of your budget.

I think it was Dr. Woodcock who testified last year at Energy and Commerce that it would cost an estimated $225 million to inspect foreign drug plants as frequently as U.S. plants are inspected.

This seems very, very similar to the past here. As you begin to take a look at the problems here, are you open to advising us on the redirection here?

Am I wrong that in terms of this changing what we deal with in terms of inspection of drugs, both domestically, and medical products, both domestically and foreign, does that seem low to you, $12.2 million?

Dr. SHARFSTEIN. It is hard for me to answer that question in terms of whether it seems low or not. I think there is a lot of work that has to be done internationally, and that work may require more resources for FDA than is in this budget over time.

I totally accept that premise. I think it cannot be a model that every country sends inspectors to everyone else's plants. There has to be a better system of oversight where we have confidence in plants that maybe we ourselves have not inspected.

I think that is why FDA has started some cooperation with Europe and Australia to kind of split up the inspections. There are a whole bunch of things that I think Dr. Hamburg is going to be very interested in looking into in this regard.

As we dig into it and we figure out—I will tell you one of the things from my perspective in the budget is that things are measured by what the increase is as opposed to where are we compared to the goal.

I think that ultimately, we want to understand for imports what is the goal system we are getting to, what does it take to get there, both in terms of policy and resources. That, I think, is eventually how we will want to present the budget as well.

DIETARY SUPPLEMENTS

Ms. DeLauro. The last two questions, this has to do with dietary supplements as it deals with health risks of conventional hormone therapy, and when there were risks associated with the therapy, people started to look at natural alternatives, such as the dietary supplements.

The products are heavily marketed to women at or around the age of menopause. The Dietary Supplement Act limits FDA's authority over the supplements. You are responsible for the safety aspects of the products and what is the adequate oversight of these efforts.

How are you going to move the agency to develop a very robust safety program for dietary supplements within the current structure?

Dr. Sharfstein. Excellent question. You may be aware that FDA recently was involved in a voluntary recall of the largest dietary supplement used for weight loss in the United States.

That was the result of work within the agency and a lot of work from external doctors who were publishing papers and being concerned about what was happening to their patients. That product was able to be removed. It was a relatively rare side effect that was identified, but a very serious one, and one that had the product come off the market.

The challenges to FDA include the fact that we are not told what is being sold, let alone reviewing for safety prior to marketing.

Within the context of FDA's role, I think we have the manufacturing standards that are being put into place and we have the required adverse event report, reporting for serious adverse events that is being put into place, and we have to make as best use of those as possible.

I think we have to be prepared if we are identifying risks, that are really putting people at risk, to not be shy about talking about them. I think that is in the best interest of public health but it is also in the best interest of the industry, which I do not think wants to put its customers at risk.

I think using the data that we get, hearing from doctors who are concerned, hearing from patients who have had problems.

The other thing that I think is important that we can look at is when companies are making claims that are inappropriate, we can crack down on that right away. Even if we do not have good data on safety, if people are making claims and are leading people to believe they can get something treated without appropriate evidence, we can stop them from making those claims and that could be helpful on safety, even without doing a full safety review.

Ms. DeLauro. That means there is going to have to be funding attached to that, and adequate funding.

Dr. Sharfstein. I think that is true and there is a good group within FDA and I think one of the things we will want to do is assess how that is compared to the need. I think this recent withdrawal demonstrates that FDA can do things.

I would commend the health hazard evaluation on this particular product. It very clearly walked through the evidence and when you

see that kind of evidence, you can understand why the company looked at that and did the right thing.

MEDICAL DEVICES

Ms. DELAURO. My last question, and we will submit questions for the record, this has to do with medical devices, and you review medical devices, thousands of them every year.

Ninety-eight percent are cleared through the 510K process, a less vigorous process than prescription drugs go through. Again, as is my understanding, FDA does not require clinical trials for 90 percent of medical devices that are sold in this country.

Again, my understanding is this was a process that was supposed to be for minor changes in simple devices. GAO recently reported that it is inappropriately being used for implanted medical devices and life saving medical devices.

The New York Times report has been used for diagnostic tools used to diagnose cancer. If the devices are not safe or accurate, people die.

My question is should not the FDA always require clinical trials to prove that implanted medical devices are safe and effective and should not clinical trials be required to prove diagnostic accuracy of devices used to detect cancer and other life threatening diseases?

510K PROCESS

Dr. SHARFSTEIN. Those are two excellent questions and I think the 510K process has obviously been subject to a lot of different reviews and questions. I think it is something that both Dr. Hamburg and I are going to want to understand pretty well.

I know FDA has started the process of making sure the products that should go through the pre-market approval process are going through it and a whole bunch of products that had been put in the 510K pile or I should say were sort of grandfathered out are now getting pulled back in.

In terms of what actually should require clinical trials, I think that has to be a judgment call based on the particular product. I will give you an example.

If there is a product, even if it is implantable, say there is a very clear improvement that you could prove in the lab, in other words, internal to the device, that made the device more stable say, and you could prove that in a million different ways in the lab, that it is clearly more stable and it is all internal to the device, it may be a scientific judgment that you do not have to randomize people to the old version, which we think is less stable, if you have a ton of evidence, and it is evidence. It is just not in people, that it is going to be better.

You would not necessarily need a clinical trial for that. For a cancer diagnostic, I think it also might depend. If you have confidence in the approach based on a whole bunch of other science that this worked for these other four tumors and you know this is the same basic concept, you might want some clinical data but whether you would want a clinical trial, I am not sure.

I think it is not so much the—the law gives FDA considerable flexibility. The key is for FDA to be making good scientific decisions. I think one conclusion that I have kind of drawn in my lim-

ited time at the agency is that a lot of—it is very important for FDA to explain its decisions.

If FDA is going to put a device in the 510K pile because they think it is equivalent to a previous device, why, what is the basis for that decision. What can FDA do to explain that and then people can agree or disagree.

Ms. DELAURO. Make a judgment.

Dr. SHARFSTEIN. It is right out there. I think some of the reason for the concern over the 510K process may be that FDA is doing it wrong or it may be that people do not really understand what FDA is doing.

I think that is an important more general issue for us to tackle. This is an area that people feel like to a certain extent is behind the curtain, and when making decisions on things like this, FDA should be explaining itself.

Ms. DELAURO. Thank you. That is my last question. We will submit some for the record. I thank you for your time, your patience, for your commitment to this effort.

I will end with where I started. I am very, very much looking forward to working with you and collaborating on an area and an agency that I have the utmost regard for and respect, and it has a function in our society which I believe is very, very critical to the health and safety of the people of this country.

I want to also say you have a number of your folks with you today and I will continue to say to them, many of them have been here in the past and have spoken up, but I will ask the same questions of the people who are currently in charge as I asked of the people who were previously in charge.

I am excited, quite frankly, I would be less than honest if I did not say, of a new environment, an environment which I think can help us to go back to the mission of the agency, which is regulation but founded on sound science.

I look forward to that and am encouraged by our conversation. Thanks very, very much.

Dr. SHARFSTEIN. Thank you.

Ms. DELAURO. The hearing is adjourned.

1. National Antimicrobial Resistance Monitoring System (NARMS)

Background

FDA along with CDC and USDA tests bacteria collected from food animals, retail meat, and sick humans for antibiotic resistance under the National Antimicrobial Resistance Monitoring System (NARMS). NARMS provides important public health surveillance of enteric pathogens including Salmonella, Campylobacter, and Escherichia coli.

Questions on NARMS

Mr. Farr: How has funding for surveillance of antimicrobial resistance through NARMS changed over the last 5 years?

FDA Response: FDA recognizes the public health value of the NARMS program. The funding level for the NARMS program has remained consistent for the last four fiscal years, from 2006 through 2009. Between fiscal years 2005 and 2006, the NARMS program, like all other programs, reflected budgetary reductions such as management savings, administrative efficiencies, rescissions, and full coverage of pay raise.

The following table displays FDA appropriation amounts, including the amount that FDA allocated to USDA and CDC for the NARMS Program for the past five fiscal years.

NARMS Funding FY 2005 – 2009

	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
USDA	$1.6M	$1.4M	$1.4M	$1.4M	$1.4M
CDC	$2.0M	$1.8M	$1.8M	$1.8M	$1.8M
FDA*	$3.7M	$3.5M	$3.5M	$3.5M	$3.5M
Total	$7.3M	$6.7M	$6.7M	$6.7M	$6.7M

* Included in this figure are lab supplies FDA purchases for USDA and CDC

Mr. Farr: In 2007, the FDA's Science Board made specific recommendations on steps to strengthen the NARMS surveillance system. What progress has FDA made in implementing these recommendations?

FDA Response: In 2007, the FDA Science Board subcommittee evaluated NARMS. The main findings related to concerns with sampling strategies and conducting more extensive research studies, collaborating with international partners, improving data harmonization across the three federal partners, and ensuring timely reporting.

NARMS has evolved into a mission-critical tool for FDA. New pilot projects have proven worthwhile and merit further development. For example, FDA has a pilot study with the University of Maryland testing retail meat samples for Methicillin resistant Staphylococcus aureus, or MRSA. FDA will use the results of the study to determine the correlation, if any, to clinical cases of infection. NARMS plans to expand MRSA surveillance of retail meat in 2010 in collaboration with CDC and select FoodNet laboratories.

NARMS scientists continue to address and implement many FDA Science Board recommendations. FDA working groups are addressing specific challenges in sampling, research, international harmonization, and data management and reporting. FDA is working with USDA to investigate options to overcome limitations of the current sampling scheme.

FDA expanded support for international capacity building in surveillance of antimicrobial resistance in foodborne pathogens through the World Health Organization. FDA significantly improved reporting timelines from 3.5 years to 14 months and launched a user friendly data query tool on the web.

In 2009, FDA and CDC committed resources to establish an integrated NARMS database. The business plan, tactical plan, and harmonized data dictionary are complete. FDA has dedicated resources to developing data intensive testing methods, also known as microarray technologies, to more rapidly and comprehensively characterize strains of foodborne bacteria. FDA held a strategic planning meeting August 5-7, 2009, to focus on progress made implementing the FDA Science Board recommendations, address new priorities, and further develop the strategic plan. The FDA Center for Veterinary Medicine is also reaching out to other FDA Centers to determine how NARMS can support their specific regulatory responsibilities.

Mr. Farr: What would FDA need in support from Congress to fully implement the recommendations of the FDA Science Board on NARMS?

FDA Response: FDA appreciates the support Congress has given to maintain the mission-critical NARMS program. FDA continues to address and implement many of the FDA Science Board recommendations with its annual appropriations, in an effort to maximize the leveraging of resources between FDA, USDA and CDC.

Mr. Farr: Does NARMS have adequate resources to respond to emerging threats such as livestock associated MRSA and imports of food and feed?

FDA Response: Current NARMS funding permitted FDA to leverage its resources and scientific staff with partners at the University of Maryland to conduct a pilot study testing retail meat samples for Methicillin resistant Staphylococcus aureus, or MRSA. FDA will use the results of the study to determine the correlation, if any, to clinical cases of infection. NARMS plans to expand MRSA surveillance of retail meat in 2010 in collaboration with CDC and select FoodNet laboratories.

2. Non-Therapeutic use of Antibiotics

Background

The FDA has had long standing concerns about the non-therapeutic use of antibiotics in farm animals. In 1977 the FDA proposed withdrawing approvals for non-therapeutic uses of penicillin and tetracycline. In 2004, FDA wrote letters to the sponsors of non-therapeutic uses of penicillin asking the companies to address the safety issue. In 2008, the FDA told Congress that it had completed its review of the "scientific literature for microbial food safety information for penicillin-containing products" and that it "continues to have safety concerns regarding the non-therapeutic use of antimicrobial drugs in food-producing animals."

Questions regarding non-therapeutic use

Mr. Farr: Did drug sponsors respond to FDA's concerns raised about their products?

FDA Response: FDA received limited information from one sponsor, but the information did not address FDA concerns.

Mr. Farr: What were the results of the FDA's safety reviews of penicillin?

FDA Response: FDA reviewed all available information relevant to assessing the safety of using the penicillin class of antimicrobial drugs in the feed of food-producing animals. FDA is also reviewing information about other classes of antimicrobial drugs because of concerns about the use of medically-important antimicrobial drugs for non-therapeutic, production purposes in food-producing animals. FDA continues to have safety concerns regarding the non-therapeutic use of antimicrobial drugs in food-producing animals and is committed to pursuing the appropriate action to address those concerns.

Mr. Farr: What action has FDA taken or is taking to respond to the safety concerns regarding non-therapeutic use of antimicrobial drugs?

FDA Response: FDA is reviewing all available information relevant to the use of medically-important antimicrobial drugs for non-therapeutic, production purposes in food-producing animals. FDA has engaged in wide public outreach to discuss the public health concerns associated with the use of antimicrobial drugs in animal agriculture. The outreach activities provided an effective means for stakeholders and other members of the

public to directly engage FDA in constructive dialogue about strategies for addressing this important public health issue.

FDA's ongoing efforts to address potential human health risks associated with the use of antimicrobial drugs in food-producing animals include using risk assessment methods, such as Guidance for Industry #152, during the new animal drug evaluation process. FDA also is actively conducting research to advance our understanding of antimicrobial resistance mechanisms and to support our regulatory decisions. FDA is participating in educational outreach activities to strengthen and promote science-based approaches for managing the potential human health risks associated with the use of antimicrobial drugs in food-producing animals. FDA is also assessing relationships between antimicrobial use in agriculture and subsequent human health consequences through the National Antimicrobial Resistance Monitoring System--NARMS. Finally, FDA is participating in international dialogue on the use of antimicrobials in animals, including the World Health Organization and the Codex Alimentarius *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance.

3. Methicillin-resistant Staphylococcus aureus (MRSA)

Background

Methicillin-resistant Staphylococcus aureus (MRSA) is a serious public health threat leading to an estimated 20,000 annual deaths. Recent evidence has revealed that farm animals can act as a reservoir of MRSA that is then readily transferred to farm workers, veterinarians, and their families.

Questions regarding MRSA

Mr. Farr: What actions has or is FDA taking to ensure that antimicrobial use in food animals does not lead to the spread of MRSA in food animals and their handlers?

FDA Response: FDA is reviewing all available information relevant to the use of medically-important antimicrobial drugs for non-therapeutic, production purposes in food-producing animals to identify the development of antimicrobial resistance in human bacterial pathogens, including MRSA. FDA has engaged in wide public outreach to discuss the public health concerns associated with the use of antimicrobial drugs in animal agriculture. These outreach activities provide an effective means for stakeholders and other members of the public to directly engage FDA in dialogue about strategies for addressing emerging pathogens, including MRSA.

Mr. Farr: Has FDA taken any steps to determine the extent to which MRSA is present in food animals in the US?

FDA Response: Both human-to-animal and animal-to-human transmission of MRSA are known to be possible. However, it has not yet been adequately determined whether animals are an important primary source of MRSA infections for populations other than

high-risk exposure groups such as swine farmers and veterinarians, or if most animals acquire the bacterium after contact with human carriers.

In 2010, NARMS plans to expand MRSA surveillance of retail meats in collaboration with CDC and select FoodNet laboratories. This work will help FDA make science-based policy decisions on the nature of this potential hazard and the need for mitigation strategies if warranted.

Mr. Farr: Does FDA consider MRSA when making decisions about the safety of animal drugs?

FDA Response: FDA recognizes that foodborne human exposure to antimicrobial resistant bacteria is complex and often involves contributions from other sources of exposure, for example, direct contact between animals and humans or introduction of resistant bacteria into the environment. However, FDA believes evaluating antimicrobial new animal drug safety relative to the most significant exposure pathway, the foodborne pathway, is the best way to assess the risk of antimicrobial drug use in food-producing animals. Nonetheless, as FDA stated in Guidance 152, non-traditional foodborne pathogens such as MRSA may be considered when deemed necessary.

4. Questions Regarding fire retardants in Plastic Pallets

Mr. Farr: To what extent does the FDA train its field inspectors to look for contamination of food that results from hydro-cooling and wet room cooling of fresh fruit and vegetables? For example, plastic pallets that are used in these food cooling operations are often dripping wet and may be leaching deca-bromine. Do inspectors receive training that enables them to spot this potential unapproved food contact?

FDA Response: FDA's Division of Human Resource Development, DHRD, within the Office of Regulatory Affairs, ORA, delivers a one-week training course called "FD150 Food GMPs 110" that covers "Current Good Manufacturing, Packaging or Holding Human Food." This course is targeted to FDA investigators and state inspectors and addresses the proper use of equipment and utensils, including design, construction, cleaning, and preclusion of contaminants. The course also addresses the fact that food contact surfaces should be made of nontoxic materials and maintained to protect food from contamination and unapproved indirect food additives. The course covers a variety of examples of compliant and noncompliant equipment surfaces in the manufactured food industry. Currently the course covers a multitude of unapproved and approved food contact surfaces and materials, but it does not specifically emphasize plastic pallets used in hydro-cooling and wet room cooling of fresh fruit and vegetables. As this is a new concern, DHRD plans to add this topic to our FY 2010 FD150 Food GMP courses beginning early in FY 2010.

There is an article in the May 7th issue of *Food Packaging Insights* that quotes an individual who states that the FDA has evaluated the safety of plastic pallets and found the amount of deca-bromine that leaches onto food as part of hydro-cooling occurs at levels deemed to be safe by the FDA. FDA relies upon data provided to it by petitioners

regarding the safety of food contact substances, and any food contact substances require pre-market approval through a public comment process. Additionally no amount of deca-bromine is currently allowed as a food contact substance and any such leaching onto food is therefore illegal.

Mr. Farr: Will the FDA confirm whether it has conducted any testing regarding the safety of deca-bromine, and provide any results of such testing to this committee? Will it also confirm the current status of deca-bromine as a food contact substance and identify what if any levels of deca-bromine contamination are currently permissible under the FDCA?

FDA Response: FDA's Center for Food Safety and Applied Nutrition recently had several exchanges with a manufacturer of plastic pallets containing decabromo diphenyl ether, or DECA, to communicate FDA's concern that DECA is not authorized for any food contact use and that DECA would require premarket approval for uses in hydrocooling produce where it would be reasonably expected to migrate to food. It is the responsibility of the manufacturer to conduct any testing necessary to demonstrate the safety of the use of DECA in such pallets. FDA has not conducted such testing. CFSAN is considering regulatory action regarding unauthorized uses of DECA.

5. Questions Regarding Food Safety User Fees in Budget

Background

The Administration's 2010 budget includes $75 million in new user fees to offset the cost of routine food safety inspections by the Food and Drug Administration. Additional FDA user fees (+$25 million) are also included in the Budget for re-inspection costs (when a food company requires more time and services from FDA because of poor performance).

Taxpayers have always funded government mandated food safety inspections both at FDA and at the U.S. Department of Agriculture's Food Safety Inspection Service (FSIS). For over a decade, Congress has rejected user fees for food safety inspection in previous Budget requests for FSIS. Food safety inspection is a requirement that protects the public at large, and is not a special service or benefit to the food industry.

The OMB manual on user fees ("Circular A - 25) requires that fees provide "special benefits derived from Federal activities beyond those received by the general public." Many of FDA's activities on the drug approval side provide such benefits; however, routine food safety inspection does not fall into this category.

When a food company does get special benefits, such as for accelerated import approvals, or re-inspection services because of poor performance, user fees are justified. The Budget proposes such "performance and service fees" for FSIS ($4 million); and FDA re-inspection ($25 million).

The food industry opposes any new industry fees that would fund routine FDA inspection costs, but accepts performance-based fees and fees for accelerated FDA services that are consistent with government wide user fee requirements.

Questions:

Mr. Farr: Why does the Budget propose inconsistent treatment of food safety inspection at FDA and USDA, by proposing new user fees to partially cover inspection at FDA? ($75 million in so-called "registration fees")

FDA Response: For FY 2010, FDA is proposing $75 million for Food Registration and Inspection User Fee and $25.8 million for Reinspection Fees. These user fee programs advance the Administration's priority of establishing a food safety system focused on prevention. In the case of Reinspection Fees, the fee amount related to food establishments is $15.3 million. The balance of the $25.8 million is for reinspection activities related to medical product programs.

We do not believe that there is an inconsistency in FDA proposing these two user fees. One important goal of these fees is to establish a food safety system focused on prevention. Achieving FDA's prevention goal offers important benefits to industry as well as American consumers.

The registration of a facility is a benefit to the registrant. The registration fees will pay for registration as well as food safety inspections and other food safety activities, which will reduce foodborne illness outbreaks. This "provides business stability or contributes to public confidence in the business activity of the beneficiary" as identified in OMB Circular A-25, 6.a.1(b).

Mr. Farr: Significant increases in funding for FDA has allowed growth in the number and frequency of field inspections at FDA. How much will FDA derive from "performance fees" or fees that provide a special service, such as re-inspection, export certification and import approvals?

FDA Response: The FY 2010 proposed Food Registration and Inspection User Fee will fund approximately 2,050 additional domestic and foreign food and animal feed inspections. The proposed Reinspection User Fee will fund approximately 630 domestic and foreign food and animal feed inspections.

Finally, in the case of Export Certificate User Fees, this program does not pay for the cost of inspections. This program will fund the cost of issuing export certificates for manufacturers of food and animal feed.

Mr. Farr: Does the Administration believe that there should be a consistent approach in how food safety inspection costs are funded at FDA and USDA?

FDA Response: Although consistency is an important principle, there are significant differences between the factors that determine the costs of FDA and USDA inspection programs. These differences are primarily due to the differences in the underlying statutory authorities of FDA and USDA.

The Food Safety and Inspection Service provides continuous or daily in-plant inspection of domestic plants under its jurisdiction. FDA's Office of Regulatory Affairs (ORA) performs risk-based inspections of the domestic as well as foreign food establishments that FDA regulates. Examples of ORA food inspection activities include domestic food safety, imported and domestic cheese, domestic low acid canned foods, domestic fish and fishery products HACCP, import seafood HACCP, juice HACCP, and interstate travel sanitation.

The Food Safety and Inspection Service inspects more than 6,000 production facilities. Based on the number of facilities that have registered with FDA, the inventory of food facilities under FDA's jurisdiction includes more than 150,000 domestic and 225,000 foreign food facilities.

FDA and FSIS are partners in food safety. However, the significant differences between the volume, type, and location of food establishments that are subject to FDA and FSIS inspection, as well as the differing statutory authorities, require different approaches to funding these inspection programs.

Mr. Farr: Many States have fees for inspection services? Has FDA looked at whether state inspectors can conduct inspection service for FDA?

FDA Response: FDA works closely with its State partners on food safety issues. For example, FDA funds state contract and state partnership inspections of foods establishments on an annual basis. Inspections conducted by our State partners are important to achieving FDA food safety program goals, and FDA plans to expand these inspection activities with the states under the FY 2010 budget. We will continue to evaluate the best way of expanding State inspections, which may include FDA's proposed user fee programs.

Mr. Farr: How do you expect small businesses to handle these users fees?

FDA Response: We believe that a consistent high standard should apply to food establishments that are subject to food safety standards under the Federal Food, Drug, and Cosmetic Act and the implementing regulations under the Act. Similarly, we believe that the size of a business should not be the basis for determining whether a business should pay user fees for food safety inspections. The FDA inspections funded by the Food Registration and Inspection User Fee and Reinspection Fee help assure the business and American consumers that the facilities that FDA inspects comply with food safety requirements.

6. Salmonella and egg Farms

Mr. Farr: You have been working for several years on a regulation to prevent Salmonella on egg farms. Many states, like California, have not waited on the federal government but already have highly effective Salmonella programs in place that have strong producer support. The Centers of Disease Control found that these programs reduced foodborne illness. Can you assure me that when your federal regulation goes into effect, producers who are complying with a state plan like California's will also be considered to be in compliance with federal requirements?

FDA Response: FDA recognizes that existing voluntary egg quality assurance programs, or EQAPs, have been successful in reducing *Salmonella* Enteritidis, SE, contamination in poultry houses in certain states. However, these programs are not uniformly administered or equally comprehensive in their prevention measures. In addition, currently the EQAPs that exist are voluntary for shell egg producers. Although the existing EQAPs all have some similar requirements, they vary in how those requirements are implemented. FDA's final rule establishes uniform, nationwide requirements to prevent SE in shell eggs during production, storage, and transportation. FDA believes that these requirements will further reduce SE illness and deaths associated with egg consumption.

Because all EQAPs are different, we cannot say for certain that a producer complying with a certain EQAP will be in compliance with FDA's rule. Rather, if an EQAP contains at least the same provisions as our rule, then producers complying with that EQAP would be expected to already be in compliance with our rule.

Finally, we want to mention that FDA is enlisting the assistance of existing EQAP organizations and officials in implementing our regulation. The rule provides that a state or locality may, in its own jurisdiction, enforce the rule by carrying out inspections under §118.12(c) (21 CFR 118.12(c)) and by using the administrative remedies in §118.12(a) unless FDA notifies the State or locality in writing that its assistance is no longer needed. FDA plans to provide guidance to states and localities through an enforcement and implementation guidance to be published later this year.

QUESTIONS SUBMITTED BY REPRESENTATIVE BOYD

ON-FARM PROCESSES

Mr. Boyd: One of the problems Florida has encountered with the FDA is a lack of understanding of on-farm processes or an appreciation of the voluntary approaches of the fruit and vegetable producers.

As we saw with our tomato industry last year with the salmonella outbreak, what incentives or reasons do these tomato producers have to bear the increased expenses of on-farm and packinghouse protocols to minimize food borne illness risks—like Florida's Tomato Good Agricultural Practices Program? Especially if, at the end of the day, the FDA does NOT take these kinds of programs and the regions where they are implemented, into consideration when telling the public what products to avoid during a food borne illness outbreak?

Response: While FDA believes that it is ultimately the industry's responsibility to produce safe products, we have worked closely with the produce industry to ensure we are aware of current on-farm practices and conditions. This spans from the earliest stages of developing the 1998 Good Agricultural Practices—GAPs—guidance to our more recent produce safety initiatives. Some of these initiatives involve conducting assessments in tomato and leafy greens fields in collaboration with growers and university extension agents.

FDA encourages and supports industry and states to be proactive in implementing preventive programs to minimize the risk of foodborne illness. FDA is providing significant technical assistance during the development of the industry-led Tomato Supply Chain Guidance, Florida's Tomato GAPs, and the Tomato Metrics. During the *Salmonella* Saintpaul outbreak, FDA involved the tomato industry at an early stage in the outbreak investigation. In order to lessen the economic impact, FDA posted a list of states on the web that were not associated with the outbreak, based on information provided by industry and the state authorities. This represented a new approach by FDA in response to comments received during a government and industry conference held to improve communication and response.

FDA has undertaken projects to improve the speed and accuracy of tracebacks in outbreak investigations. These efforts involve industry, including the Florida tomato industry, government, and academia. Improved tracebacks will aid in limiting the adverse economic impact by getting to the source quicker and in a more targeted way. FDA has held meetings internally, with other agencies, and with industry to discuss lessons learned from this outbreak and ways to move forward. There may be other ways to recognize food safety programs by states and industry that might lessen the economic impact and FDA is actively exploring those avenues.

Mr. Boyd: The way FDA handled last year's outbreak had a lot of our tomato producers asking myself, and Florida Agriculture Commissioner Bronson, why they should continue to participate when they suffered the same market loss damages as other tomato producers who do not participate in these programs. FDA dismissed this program as having no bearing on food borne illness risks so they completely discouraged participation in it. If these programs have no

bearing on how FDA handles outbreaks and who they tag as "suspect", then why should any producer participate in them?

Response: FDA supports industry and state efforts to be proactive in implementing preventive food safety programs to minimize the risk of foodborne illness. It is our understanding that the Florida state program was only recently enacted at the time of the outbreak and that the first year of the program was to be educational. Given the scope of the outbreak and the number of illnesses, our public health charge required us to use more definitive criteria for our list of states not associated with the outbreak, such as states that were not in production at the time illnesses occurred and therefore could not have been the source of contaminated product. FDA is exploring ways to recognize food safety programs by states and industry that might lessen the economic impact when outbreaks occur.

FDA's first responsibility is to protect public health. We respond to foodborne disease outbreaks based on the epidemiologic information received from the Centers for Disease Control and Prevention—CDC, state and local health departments. We are working on efforts to improve surveillance, detection, and investigation of outbreaks. These efforts can make the process more effective which will result in quicker and more accurate investigations and responses. A challenge we encounter is the level of resources available to CDC, and state and local health departments for them to carry out their epidemiology roles, which is critical for long-term consumer confidence.

QUESTIONS SUBMITTED BY REPRESENTATIVE LATHAM

LAB DEVELOPED TESTS

Mr. Latham: The FDA currently has the authority to regulate all types of clinical laboratory tests. With limited exception, the FDA has not exerted its authority over lab developed tests (LDTs) except in cases where problems have been found after the tests have been administered to patients. Laboratories themselves must meet GMP standards set by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CLIA also requires that makers of LDTs register and list their products and that the labs are inspected regularly. However, the premarket safety and efficacy of the tests themselves are not independently reviewed by the FDA. And there is no postmarket safety reporting requirement for LDTs. Do you intend to exercise your authority over all clinical laboratory diagnostic tests, including laboratory developed tests?

Response: While FDA implements premarket and postmarket requirements related to devices, including in vitro diagnostic tests, FDA developed a policy of exercising enforcement discretion over LDTs, which are developed and used within single clinical laboratories that have certificates under CLIA to perform high complexity tests. However, as FDA has explained in the "Draft Guidance for Industry, Clinical Laboratories, and FDA Staff - In Vitro Diagnostic Multivariate Index Assays," advances in diagnostic technology may indicate that it is time to revisit this approach. FDA will consider these issues in the coming months.

Mr. Latham: Do you need additional regulatory authority to ensure the safety and efficacy of all clinical laboratory diagnostic tests, including LDTs? If so, what specific legislation is necessary to provide you with that authority?

Response. The Federal Food, Drug, and Cosmetic Act currently Provides premarket and postmarket requirements for devices. The definition of device includes *in vitro* diagnostic products such as LDTs. As we continue to evaluate issues related to LDTs, FDA will also identify whether there is a need for specific legislative authority.

Mr. Latham: Understanding the limited resources available to FDA to undertake the review of so many new and existing tests that have been unregulated for so long, would you seek to adopt a risk-based approach to regulation of all lab tests, including LDTs?

Response: FDA currently applies a risk-based approach to its regulation of devices, including in vitro diagnostic devices, as required by the Federal Food, Drug, and Cosmetic Act, which establishes a risk-based classification system: class I, II, III. FDA intends to continue to consider relative risks in making regulatory decisions applicable to devices.

DRUG APPROVALS

Mr. Latham: FDA is now facing enormous challenges, especially given the outbreak of H1N1 and recent food safety threats. What is your proposed approach to addressing these challenges while also maintaining as a priority the important work of protecting Americans by approving new medical products expeditiously?

Response: Despite the challenges that FDA faces, the agency nonetheless succeeded in delivering more new and innovative drugs, in the form of new molecular entities to patients in 2008 than the previous year. In response to the H1N1 pandemic, we issued five Emergency Use Authorizations with minimal interruptions to our normal review work. We successfully hired additional review staff, and continue to implement efforts intended to improve the efficiency of our drug review process.

Mr. Latham: Last year, the FDA stated that it had missed 20% of its approval deadlines for new medicines. How can we bring new cures to our citizens when the FDA seems to be slowing the pipeline?

Response: The PDUFA deadlines are decision deadlines, not approval deadlines. FDA shares the goal of bringing new safe and effective medications to market as quickly as possible. Whether decision deadlines are met is a poor measure of whether the agency is succeeding. The best measure is whether novel drugs are being approved. A table listing the drug approvals from January 2008 through May 2009 follows:

CDER New Molecular Entity (NME) Drug and New Biologic Approvals				
JANUARY 2008 - MAY 2009				
Proprietary Name	Established Name	Review Classification	Approval Date	Indications
INTELENCE	ETRAVIRINE	P	18-Jan-08	Provides in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced adult patients, who have evidence of viral replication and HIV-1 strains resistant to a Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) and other antiretroviral agents.
ARCALYST	RILONACEPT	P,O	27-Feb-08	Provides treatment for Cryopyrin-Associated Periodic Syndromes (CAPS).
PRISTIQ	DESVENLAFAXINE SUCCINATE	S	29-Feb-08	Provides treatment of major depressive disorder.
TREANDA	BENDAMUSTINE HYDROCHLORIDE	P	20-Mar-08	Provides for the treatment of patients with Chronic Lymphocytic Leukemia (CLL).

LEXISCAN	REGADENOSON	S	10-Apr-08	Provides for the use as a pharmacologic stress agent for radionuclide myocardial perfusion imaging 0.4 mg/5 ml (0.08mg/ml).
CIMZIA	CERTOLIZUMAB PEGOL	S	22-Apr-08	Provides for the treatment of reducing the signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease that have an inadequate response to conventional therapy.
RELISTOR	METHYLNALTREXONE BROMIDE	S	24-Apr-08	Provides for the treatment of Opioid-Induced Constipation in patients with advanced illness who is receiving palliative care, when response to laxative therapy has not been sufficient.
ENTEREG	ALVIMOPAN	S	20-May-08	Provides treatment of for the acceleration of time to gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis.
DUREZOL	DIFLUPREDNATE	P	23-Jun-08	Provides treatment of inflammation and pain associated with ocular surgery.
EOVIST INJECTION	GADOXETATE DISODIUM	S	03-Jul-08	Provides treatment for use in Magnetic Resonance Imaging (MRI) of the liver in adult patients to provide contrast in the T1 weighted images to aid in the detection and characterization of focal liver pathologies in pre-surgical evaluation.
CLEVIPREX	CLEVIDIPINE BUTYRATE	S	01-Aug-08	Reduces blood pressure when use of oral therapy is not feasible.
XENAZINE	TETRABENAZINE	P	15-Aug-08	Provides treatment for the chorea of Huntington's disease.
NPLATE	ROMIPLOSTIM	P,O	22-Aug-08	Provides treatment for Idiopathic (Immune) Thrombocytopenic Purpura.
ADRE VIEW	IOBENUANE	P	19-Sep-08	Provides for the detection of primary or metastatic pheochromocytomas.
RAPAFLO	SILODOSIN	S	08-Oct-08	Provides treatment of the signs and symptoms of Benign Prosthetic Hyperplasia
VIMPAT TABLETS	LACOSAMIDE	S	28-Oct-08	Provides adjunctive therapy treatment of partial onset seizures in patients with epilepsy.
TOVIAZ	FESOTERODINE FUMARATE	S	31-Oct-08	Provides for the treatment of overactive bladder.
BANZEL ORAL TABS	RUFINAMIDE	S,O	14-Nov-08	Provides for the treatment of seizures associated with Lennox-Gastaut Syndrome

PROMACTA	ELTROMBOPAG OLAMINE	P,O	20-Nov-08	Provides for the treatment of short term Idiopathic Thrombocytopaenic Purpura (ITP)
TAPENTADOL	TAPENTADOL	S	20-Nov-08	Provides for the treatment of moderate to severe acute pain
LUSEDRA	FOSPROPOFOL DISODIUM	S	12-Dec-08	Provides for sedation in adult patients undergoing diagnostic or therapeutic procedures
MOZOBIL	PLERIXAFOR	P,O	15-Dec-08	Provides for stem cell mobilization
VASOVIST	GADOFOSVESET TRISODIUM	S	22-Dec-08	Provides for magnetic resonance angiography
DEGARELIX	DEGARELIX	S	24-Dec-08	Provides for the treatment of Prostate Cancer
SAVELLA	MILNACIPRAN HYDROCHLORIDE	S	14-Jan-09	Provides for the treatment of Fibromyalgia Syndrome
ULORIC	FEBUXOSTAT	S	13-Feb-09	Provides for the chronic management of hyperuricemia in patients with gout
AFFINITOR	EVEROLIMUS	P	30-Mar-09	Treatment of Advanced Renal Cell Carcinoma
COARTEM	ARTEMETHER/ LUMEFANTRINE	P,O	07-Apr-09	Provides for the treatment of infections due to Plasmodium Falciparum or mixed infections including Plasmodium Falciparum
PHYXXLICE	BENZYL ALCOHOL	S	09-Apr-09	Provides for patients infected with Pediculus Humanus Capitas (head lice) of the scalp hair
SIMPONI	GOLIMUMAB	S	24-Apr-09	Provides for the treatment of Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis
DYSPORT	ABOBOTULINUMTOXIN A	S	29-Apr-09	Provides for the treatment of Cervical Dystonia (Spasmodic Torticollis)
FANAPT	ILOPERIDONE	S	06-May-09	Provides for the acute treatment of Schizophrenia in adults
SAMSCA	TOLVAPTAN	S	19-May-09	Provides for the treatment of Clinically Significant Hypervolemic and Euvolemic Hyponatremia including patients with the Syndrome Of Inappropriate Antidiuretic Hormone Secretion (SAIDH), heart failure, and cirrhosis.

To facilitate the development of effective novel drugs, FDA is meeting with industry on drugs in development, publishing new guidance on drug development issues, and is continuing its efforts on the Critical Path Initiative.

Mr. Latham: Last year, Congress provided the FDA funding to hire approximately 1300 new scientists and others—with about half going to the Center for Drug Evaluation and Research. However, there have been claims from within the drug review center that the agency does not have the resources to meet their review deadlines. What is your plan to reinvigorate the FDA so that we can get the agency focused on meeting its drug review deadlines and assuring that the American public has a growing supply of safe and effective medicines?

Response: We are continuing to implement and refine our "21st Century Review" process – an effort that will make the new drug review process more organized and more integrated among the numerous offices and technical disciplines. The process is built upon a team-based approach with mutual accountability by all members of the team. We are also incorporating the concept of "Equal Voice" throughout the Center for Drug Evaluation and Research, or CDER. The teamwork embodied in Equal Voice fits perfectly with the 21st Century Review initiative to meet CDER's timeliness goals in an environment of enhanced communication and closer collaboration.

TUESDAY, JULY 28, 2009.

PROTECTING THE PUBLIC HEALTH IN A GLOBAL ECONOMY: ENSURING THAT MEAT AND POULTRY IMPORTS MEET U.S. STANDARDS

WITNESSES

WENONAH HAUTER, FOOD AND WATER WATCH
LORI WALLACH, PUBLIC CITIZEN
KEVIN BROSCH, DTB ASSOCIATES, ON BEHALF OF AD HOC COALITION FOR SOUND SCIENCE AND TRADE

Ms. DELAURO. The hearing will come to order. Good morning. Thank you all for attending today. The subject of today's hearing is Protecting the Public Health in a Global Economy: Ensuring That Meat and Poultry Meet U.S. Standards.

I particularly want to say a thank you to Kevin Brosch, Lori Wallach, and Wenonah Hauter for coming to speak with us today.

One of our core responsibilities on this committee is to ensure that the agencies under our purview safeguard America's food supply. Not all the dangers that threaten the health and safety of American families can be found in airport, border checkpoints, or harbor containers. Sometimes they lurk in our fridges and on our kitchen tables. And protecting our food supply is not just a crucial matter of public health, it is vital to the success of our farmers and our ranchers.

With that in mind, today we will review the process used by the USDA, the United States Department of Agriculture, to determine equivalency between the food safety systems of different countries.

Specifically, I have concerns about the granting of equivalency for processed poultry from China, processed poultry being the chicken that ends up in chicken soup, canned chicken, breaded chicken tenders, and a host of other products on the American market.

To use the exact USDA language, processed foods, which I believe is important to note, are exempt from country of origin labeling, our retail items derived from a commodity that has undergone specific processing, such as cooking, curing, smoking, or restructuring, or that have been combined with another food component.

It is my belief and my concern that this granting of equivalency to China was extremely flawed and based on trade promotion rather than public health concerns.

Decisions about the importation of food products from China or anywhere else are a public health issue that cannot and must not be entangled in and subordinated to trade discussions.

In its 2005 audit report on its inspections of several plants in China, USDA found disturbing, unsanitary conditions, such as grease, blood, fat and foreign particles being observed on product contact areas of conveyer belts. Yet despite these findings, USDA

found that the food safety system in China was equivalent to ours in the United States. And once this equivalency was granted, we ceded much of our ability to ensure the safety of these poultry products to the country in question, in this case China.

This experience with Chinese processed poultry raises troubling questions about the equivalency process, which I hope this hearing explores today. As I see it, there are four main questions which this hearing should attempt to address, and which we should take as a guideline for equivalency reform in the future.

First, can we come to a conclusion on whether the declaration of Chinese equivalency by the USDA was valid and well-founded according to the standards of equivalency already outlined by the agency?

Second, if not, why not? Is there a way or process we can establish equivalency, using the standards that are currently in place?

Third, do we know how to correct the problems that arose with China's equivalency based on how we currently determine equivalency with other countries such as Chile, Canada, Australia, to name a few?

And finally, what do we need to change about the equivalency process more broadly, independent of the example of Chinese processed poultry here?

We intend in this hearing to undertake a thorough review of the USDA equivalency process. Quite frankly, that may necessitate further hearings, until it can be established that the process used for determining equivalency is focused primarily on protecting the public health rather than facilitating global trade, and that it is based on sound, scientific assessments, rather than business-minded, wishful thinking, or political considerations. We need to tread carefully.

Particularly given the contaminated food outbreaks we have experienced in our own country of late, the continuing concerns about the safety of other products coming out of China, such as toys, and the relative lack of transparency in the Chinese safety system, we need to make absolutely sure that we do not open the door to potentially unsafe processed meat and poultry imports from China or anywhere else around the world.

We all believe in the value of trade. However, we also believe that the health and safety of American families are nonnegotiable. It is our charge and that of the USDA to ensure that consumers do not have to worry about the safety of processed poultry products on the market. And we are here today to ensure that the USDA is living up to its most important responsibility and is always putting the public health first, above considerations of global trade.

To discuss the question today we have three panelists with us. We have Kevin Brosch. Kevin Brosch is a cofounder of DTB Associates, LLP, an international policy and agricultural policy consulting firm. Between 1989 and 1999, he served as Deputy Assistant General Counsel for International Trade in USDA's Office of the General Counsel. Mr. Brosch also served as legal adviser to the USDA team negotiating the agriculture and sanitary and phytosanitary agreements in the WTO Uruguay Round, and he supervised and participated in the negotiation of the agricultural portion of the Northern American Free Trade Agreement.

I should also mention that my staff asked a coalition of industry groups to send a representative to today's hearing to discuss their views on this matter, and they said that Mr. Brosch's testimony would speak for them.

Lori Wallach is Director of Public Citizen's Global Trade Watch Division, a Harvard trained lawyer. Wallach has testified before more than 20 U.S. Congressional committees on trade and globalization matters. She has served as a trade commentator on numerous domestic and foreign news outlets. Her most recent book is Whose Trade Organization: A Comprehensive Guide to the WTO. She has also contributed to numerous anthologies, including the International Forum on Globalization's Alternative to Economic Globalization: A Better World is Possible.

Wenonah Hauter is the Executive Director of Food and Water Watch, a nonprofit consumer organization founded in 2005. She has worked extensively on energy, food, water, and environmental issues at the national, State and local level. From 1997 to 2005, she served as Director of Public Citizen's Energy and Environment Program, which focused on water, food, and energy policy. From 1996 to 1997, she was Environmental Policy Director for Citizen Action, where she worked with the organization's 30 State-based groups.

I want to say thank you all for attending. We look forward to your testimony. Before you start your testimony, and I will ask you now and also again before you begin, your entire testimony will be in the record and we will ask you to summarize and speak between 5 and 7 minutes. I know the staff will kill me, but it is 5 and 7 minutes to get out what it is that you want to get out.

With that, let me yield to my colleague, the ranking member of the committee, Mr. Kingston from Georgia.

Mr. KINGSTON. I thank the chairwoman for yielding, and I thank you for holding this hearing today.

We have a great number of very good, very fruitful hearings in this committee and we have a great atmosphere of agreeing to disagree. I would really thank the Chair for having this hearing today, because so many in Congress will make a stand but then they won't defend the stand. The Chair has taken a position and, by proof of this hearing, is letting it be challenged, and rather than hiding in the shelter of the majority, which unfortunately both sides are guilty of in the past, I think it is very good to have this hearing today.

I also agree with the Chair that food safety is paramount to trade, and I can say that as somebody who voted against GATT, somebody who voted against NAFTA, and somebody who voted against most favored nation status for China. I think that we have to be very careful when we are dealing with trade partners and some multi-trade agreements, if not all of them. We have to be very cautious. I think safety does have to take precedent over trade.

Now, I do think there are three points we want to make as we start this hearing that are very important. Number one, while we do have the industry groups represented, we do not have USDA or FSIS here, and I feel that we maybe should consider having further hearings in which we get to cross-examine them on equivalency, because certainly they would have the opportunity as people who

are on the ground to let us find out did you rush this through under political pressure or do you really feel that the Chinese-re-imported poultry is safe?

So I do think it is a missed opportunity not having FSIS here, but perhaps in a second hearing we can do that.

The second point I want to make is there is sometimes in Congress, in political bodies, an assumption that if we don't prevent something happening then other groups are going to let it happen. And in this case, there is almost a subtle message that we may inadvertently be sending that American industry is more concerned about the profit than food safety. And I don't think that is the signal we want to send. I believe that American corporate citizens are good citizens and don't want to, in fact, poison their own people.

I will point out, as I have many other times, the U.S. food safety success rate. According to the CDC, 76 million food-borne illnesses are reported a year. That is a big number: 76 million. 300,000 hospitalizations, 5,000 deaths.

Now, we who study this know that there are preexisting illnesses and immunity problems in terms of some of these deaths. But putting that aside, 5,000 is a very serious number of deaths. 300,000 hospitalizations. We all take these numbers to heart.

Taking a step back, though, if you have 300 million Americans, which we have more, and we have visitors all the time, and they eat three meals a day, which they eat more than that, and they have snacks. Multiplying that times 365 days a year, you are looking at 900 million meals, without snacks, eaten by 300 million people. That comes out to 328 billion meals a year.

Doing the math by that, 76,000 divided by 328 billion, you get a food illness rate of .0002 percent, or a success rate of 99.98 percent.

Now one of the things that our witnesses and I share in common is that the FDA doesn't do a good job, and the USDA doesn't always do a good job. But if the food safety record is this, according to the CDC, then who would we attribute that to? We would attribute it to the private sector and American industry. Then obviously if you are a food processor, you don't want to put poisoned food out on the marketplace, even if you don't care about people, because you don't want them to get poisoned. You want them to come back next week and buy more of your stuff so you can make more money.

But these are important statistics to keep in mind if we feel that the FDA and the USDA do not do a good job on food safety because you have to come to the conclusion that there is another factor out there worrying about food safety, and I would say that it is the private sector.

The third point I want to make in terms of our trade with China is we are picking winners and losers. Case in point, these are some goods that we are importing right now from China.

Seafood medley, and it says, "For fast, easy, fun seafood dishes." Thank you, Mr. Latham.

Grilled wheat cakes with real octopus. No meal would be complete without this. Imported from China.

Organic—some kind of beans.

Mrs. EMERSON. Edamame.

Mr. KINGSTON. Edamame. Is that Chinese or is that a Missouri word?

Ms. DELAURO. Soybeans.

Mr. KINGSTON. Maybe I am more careful here. But organic. Now the question would be, we go over what is the definition of organic? I am wondering how they earned that organic label? Is there an organic equivalency? I would say there is not.

Okay, Ms. Emerson, kamame? Noodles.

Mrs. EMERSON. Those are just noodles.

Ms. DELAURO. Who does the grocery shopping in your house, Jack?

Mr. KINGSTON. I do it, but I go straight to the poultry.

Raw and unsalted sunflower seeds. I always think of that as being Kansas.

Shelled edamame. Here it is again. It is very popular somewhere.

No Thanksgiving dinner would be complete without dried seaweed.

I am not sure how to pronounce this particular word, but again imported from China.

Now Mrs. Emerson is going to talk about that product.

Mandarin oranges from China.

Mrs. EMERSON. They are scary.

Mr. KINGSTON. This is floating in some sort of syrup, I am not sure what. In light syrup.

Smoked oysters in sunflower oil, salt added.

Straw mushrooms, whole peeled.

Bumblebee smoked oysters.

Stir fry sauce, simply Asian.

Water chestnuts. And this was just one quick shopping trip. This wasn't let's go out on a Chinese survey and try to find things. These are products right now that we can import from China.

So my question is: Should we not also be having a ban on these things, or are we sure that the FDA does it a little bit differently than the USDA, that we do not trust the USDA but we do trust the FDA? And I think that if we were going to be maybe philosophically honest here that we should either ban them all or review them all or treat them the way that we are treating poultry. I ask that question because I think sometimes government can pick winners and losers and inadvertently you can do a disservice to our consumers out there, the public that we want to serve.

I will close with this. We are very interested in this hearing today. Again, I thank the Chair for having it. I want to know all about it, but keep in mind that my position and others on the committee is not saying let's import Chinese chicken as much as it is let the process work. Apparently the process works for this through the FDA. We should let the process work through the USDA.

Thank you.

Ms. DELAURO. I thank the gentleman. Let me actually make three points.

One, I would have loved to have had the new Undersecretary from the USDA be here today. But in fact there isn't an Undersecretary yet for the FSIS, Food Safety Inspection Services. So it may be we do, as I said at the outset, Congressman Kingston, that we may want to do further hearings.

I would also like to introduce Dr. Richard Raymond, who is here and who is a former FSIS Director, and welcome. I am not sure where you enjoy being seated more, where you are now or here, but you have always been very up front and candid, and I enjoyed working with you, Dr. Raymond. Thank you very much.

Before we begin testimony, I would like to say what an array of products, Jack. But you should know in February of 2009, FDA's import actions with regard to these Chinese products stopped: Frozen pollack, filthy; breaded shrimp, unsafe animal drug; rice stick, filthy; dried mandarin peel, maybe from those mandarin oranges, filthy; frozen squid tube and tentacles, filthy; breaded shrimp, unsafe animal drug, nitrofuron; soy protein powder; poisonous frozen tilapia, unsafe animal drug; frozen frog legs, salmonella. Oyster flavor sauce. Anyway, the list goes on and on and on. And that is February of 2009.

With that, I am going to ask Mr. Brosch if you will begin the testimony for us today.

Mr. BROSCH. Thank you, Madam Chairman. I have my full testimony here for the record.

Ms. DELAURO. Yes.

Mr. BROSCH. Thank you, and I ask that it be accepted.

Good morning, Madam Chairwoman and members of the committee. My name is Kevin Brosch. I appear today on behalf of the Ad Hoc Coalition for Sound Science and Trade. With me is Mr. Bill Roenigk, the Vice President of the National Chicken Council. The Coalition appreciates your invitation to present its views.

The Coalition consists of 39 trade associations and companies engaged in domestic production and international trade related to meat and poultry products, including trade with China. Its members are listed in the attachment at the end of my testimony.

The Coalition urges Congress to reconsider section 723 of H.R. 2997, the House version of the 2010 agricultural appropriations bill. Section 723 would continue to prohibit USDA's Food Safety and Inspection Service from implementing or advancing any regulation regarding potential imports of Chinese poultry products. The Coalition has two simple points.

First, public health and safety are paramount considerations in the production, processing, and distribution of the food supply, and we need effective FSIS regulation of meat and poultry products to ensure public safety and public confidence.

For companies in the food business, food safety is an everyday preoccupation. They have a legal and moral responsibility to place a safe, wholesome, properly labeled product on the market. And they also live with this simple marketplace imperative: If the public even perceives that a product is unsafe, the public will stop buying it.

It is not enough that your product is safe, your competitor's product must be safe, too. USDA has a long successful history of ensuring the safety of imported meat and poultry through a stringent, comprehensive process of determining regulatory equivalency and approving individual plants. U.S. standards are very high and very tough to meet. Many countries have applied to ship poultry to the United States over the years, but only five are approved and ship

here now. Accordingly, all meat and poultry products, domestic or imported, must meet our national standards.

Second, the United States should apply its food safety requirements to imports in a manner consistent with international trade rules, and in particular with our obligations under the WTO agreement on sanitary and phytosanitary measures. The United States insists that other countries abide by SPS rules, and we must treat our trading partners, including China, as we want them to treat us.

Any WTO member country that applies to ship meat or poultry products to the United States can have the safety of those products determined on the basis of science and risk assessment. Only China has been singled out for different and less favorable treatment.

China has invoked its right to WTO dispute settlement. It asserts that current U.S. law contravenes WTO obligations to afford China Most Favored Nation treatment, and that that law is inconsistent with SPS articles 2 and 5, which require that SPS measures be based on sufficient scientific evidence and appropriate risk assessment.

The Coalition is very concerned by these developments, and apparently we are not alone. Recently, the Obama administration in its comments on H.R. 2997 also noted its concerns regarding the consistency of section 723 with U.S. International obligations.

Section 723 sends the message, perhaps unintended, but nonetheless grave, that U.S. food safety regulators cannot be trusted to do their job. The confidence of the U.S. consumers and the safety of meat and poultry is based, to a significant degree, on their trust that FSIS is an effective regulator. Also, most other countries accept our exports based on FSIS certification. What does section 723 say to our consumers and our trading partners about our food safety system?

Second, the United States regularly invokes SPS rules to nontariff barriers and to maintain market access for U.S. products. U.S. Trade Representative Ron Kirk recently announced the Obama administration trade policy emphasizing enforcement, particularly in the SPS and TBT areas. This administration's policy to enforce U.S. trade rights will be severely undermined if the United States itself is held to maintain WTO inconsistent policies.

Third, section 723 is eroding our trade relations with China. Importers applying for permits to enter U.S. poultry products are being told that the permit office is closed for the holiday, even when there is no holiday. China can use these or other tactics to shut U.S. poultry products out of its market when it considers that it has been unfairly treated.

China is a $700 million market that the U.S. poultry industry has worked long to develop. It is now at risk.

I would say in conclusion that this Coalition does not advocate any specific result. It advocates for a process that is consistent with our WTO obligations. It does not prejudge the outcome of any risk assessment that FSIS may conduct with respect to Chinese poultry. FSIS may determine that Chinese product meets U.S. standards and may be safely imported. Or, FSIS may conclude that that product does not meet our standards and therefore cannot enter the

market. The Coalition simply asserts that the process of science-based risk assessment, inherent in both our national legislation and in international trade law, must be respected and that our interests in a safe and reliable food supply, and fair and predictable trade rules and in sound U.S. trade policy are best served by allowing FSIS to proceed in the case of the Chinese application, as it does in all other cases.

Thank you, Madam Chair.

[The statement of Mr. Brosch follows:]

Before the Committee on Appropriations

United States House of Representatives

Testimony of

Kevin J. Brosch

DTB Associates, LLP

Washington, DC

On behalf of

The Ad Hoc Coalition for Sound Science and Trade

Madam Chairwoman and Members of the Committee: My name is Kevin Brosch. I am a lawyer who specializes in international trade law and agricultural trade, and a partner in the international trade consulting practice of DTB Associates, LLP here in Washington, DC. I am here today on behalf of the Ad Hoc Coalition for Sound Science and Trade. The Coalition very much appreciates your invitation allowing me to appear before the Committee today and to present its views.

The Coalition is a group of approximately 39 trade associations and companies who are engaged in international trade around the globe, including with China. Most of the associations and companies in the Coalition are involved in trade in the meat, poultry, and related businesses in the protein sectors of the economy. The coalition members are listed in the attachment at the end of my testimony.

The Coalition includes companies that produce both for the domestic and export markets. Indeed, it is true to say that many of the members of our Coalition are engaged, first and foremost, in producing and processing the high quality meat and poultry products that are consumed every day by the nearly 300 million citizens of the United States. Our Coalition members are extremely proud of what they do and are actively engaged every day in making sure that the food and food products that Americans eat are as safe as humanly possible.

The Coalition formed in response to shared concerns regarding section 727 in the Omnibus Appropriations Act of 2008, and the implications of that provision for U.S. food safety policy, U.S. trade policies, and for bilateral trade relations with China. An identical provision – now known as section 723 – has recently been included in H.R. 2997, the House version of the 2010 Agricultural Appropriations Act. This continues to cause Coalition members the same concerns.

The Coalition's views can be stated simply and succinctly in two points. First, public health and safety are paramount concerns in the production, processing and distribution of the food supply. Accordingly, whether produced domestically, imported, or even exported, meat and poultry products should comply with the strict science-based regulations and food safety standards enforced by the United States Department of Agriculture's Food Safety and Inspection Service as well as other agencies with food safety regulatory responsibilities. Secondly, where international trade in concerned, the United States should apply our food safety requirements to imports in a manner consistent with our international obligations

and, in particular, with the World Trade Organization Agreement on Sanitary and Phytosanitary Measures. These are the principles that the United States insists be applied by other countries to our exports, and are the principles that allow us to obtain and maintain access to other markets. In other words, the United States should treat our trading partners as we want them to treat us.

We know that the members of the Committee are very interested in food safety and that a primary reason for today's hearing is to ensure that the food Americans consume is safe. For companies in the food business and for their trade associations, food safety is much more than just an interest; it is an every day preoccupation. Food safety has to be the foundation of every successful food enterprise. Companies in the food industry have a legal and moral responsibility to place a safe, wholesome, properly labeled product on the market. They also must live with a simple marketplace imperative: if the public perceives that a product that they are selling is somehow unsafe or that it presents a health risk, the public will stop buying it.

And, it is not enough that the product that you produce be safe; it is crucial that the product that your competitor brings to market also be safe. Just recall the Alar scare some years ago. The public did not distinguish between those companies whose products were implicated with the use of Alar and those companies whose products were not: the public simply stopped buying apples and apple juice altogether. There have been more recent examples with food products that have

been implicated in food borne illness outbreaks with similar commercial consequences.

For these reasons, the members of our Coalition support strong and effective regulation that ensures the integrity of our food system. U.S. food companies, and in particular meat and poultry processors, are subject to the laws that Congress has passed, and to the requirements and regulatory oversight of several federal and state government agencies. For meat and poultry companies regulated by FSIS, this includes compliance with strict Hazard Analysis and Critical Control Points programs and related pathogen control regulatory requirements as well as continuous government inspection. Imported food is expected to be subject to the same rigorous standards. And USDA has a long, successful history of ensuring the safety of imported meat and poultry through a stringent, comprehensive process by which the Department must determine that an exporting country's inspection system is equivalent to the U.S. system before approving that country for export to the United States. Beyond that, any plant seeking to export meat or poultry to the U.S. after this equivalency determination has been made must demonstrate its compliance with the U.S. requirements. This approval process can take many years, and it should; it is the way USDA protects American consumers from unsafe products. While nothing in life is perfect, the Coalition believes that the U.S. food safety system is among the best, if not the best, food safety system in the world.

The Coalition agrees that considerations of public safety are always paramount whether the food that Americans buy is produced domestically or is

imported. With respect to the issue presented by section 723 – i.e., access for Chinese poultry to the U.S. market – the Coalition is not here to advocate for any specific result – either that poultry from China be permitted into the U.S. market, or that Chinese product be excluded. We are here to advocate that Congress allow the determination whether poultry from China is safe and meets U.S. requirements to be made in the same way that decision is made for our domestic product and for product from every other country – through risk assessment and the comprehensive science-based approval process that has been established under our laws and regulations.

We do not prejudge the outcome of that process and we respectfully suggest that this Committee should not either. U.S. standards are very high and only some countries have been able to meet them. Although many countries have applied for approval to ship poultry to the United States, our regulators have, over many years, approved only 5 countries as eligible to ship product to the United States. The USDA approval process is exceedingly rigorous. For example, Mexico, our NAFTA partner and one of our largest trading partners, has been discussing the possibility of shipping poultry products to the United States for nearly 15 years, but has yet to formally submit an application. Although Chile and the United States entered into a free trade agreement nearly 20 years ago, Chile did not receive approval to ship poultry to our market until last year. We entered into the Central America Free Trade Agreement five years ago, but most CAFTA countries do not have permission yet to ship poultry to the United States. Our standards are very high and the approval process is very tough.

The United States does, however, have the obligation under international trade law to consider requests from our many trading partners for access to our market, and to make the judgment whether to permit access on an objective and scientific basis. For the past 15 years, since the conclusion of the Uruguay Round negotiations, the United States has been an adherent to international trade rules governing the application of health and safety requirements to food and food products in international trade. I am referring specifically to the World Trade Organization ("WTO") Agreement on Sanitary and Phytosanitary Measures ("SPS Agreement"). The SPS Agreement does not dictate specific food safety requirements; rather it permits a WTO Member country to set its own health and safety standards, to chose any level of health protection that it deems appropriate. However, the SPS Agreement requires that any measure chosen to implement that level of protection be based on sound science and risk assessment; and that, the measures be applied in a non-discriminatory fashion, i.e., that the measures be applied no less favorably to imported product than to product of domestic origin, and no less favorably to imports from one WTO Member country than from another.

Section 723 is, in the view of the Coalition, inconsistent with these obligations. First, U.S. law currently allows any other of the 152 WTO Member Country to apply to ship meat and poultry products to the United States and to have the safety of its products determined on the basis of a science-based risk assessments conducted by agencies of the U.S. Department of Agriculture. Only China has been singled out for different treatment. Because section 727 denies funding to FSIS even to consider the Chinese request for market access, China is

being treated less favorably than any other WTO Member country, a situation that contravenes both our SPS obligations and our obligations under Article 1 of the GATT – the "most favored nation" provision – which is the most fundamental tenet of WTO law. In addition, section 723 would continue the prohibition on FSIS conducting a risk assessment with respect to Chinese poultry, and therefore appears to be at odds with our obligations under SPS Articles 2 & 5 to base our SPS measures on sound science and appropriate risk assessment.

The Coalition is not alone in its concerns. Recently, the Obama Administration submitted to Congress its comments with respect to H.R. 2997, and in those comments noted its concerns that section 723 was inconsistent with our international obligations.

We will not be able to avoid a serious trade confrontation with China if Congress does not reconsider section 723. China has raised this issue at the World Trade Organization, first seeking consultations pursuant to Article XXIII, and more recently invoking its rights to dispute settlement in this matter. The coalition is concerned that the U.S. government will face a very serious challenge in attempting to defend section 727 in the WTO, and that section 723, if enacted by Congress, could be determined by the WTO to be inconsistent with our international obligations. This would have very serious consequences both for our food safety policy, our trade policy and our bilateral trade with China.

First, section 723 sends the message, perhaps unintended but nonetheless grave, that U.S. food safety regulators cannot be trusted to do their job to assure the

safety of the food entering our market. Recall that the confidence of our own consumers in the safety of meat and poultry on our market is based to a significant degree on their confidence that FSIS is an effective regulator. Moreover, when we negotiate market access with other countries, we have traditionally been able to convince our trading partners that they can depend upon FSIS certification. How can we expect our consumers and our trading partners to rely on FSIS when section 723 indicates that our Congress does not trust their ability or judgment?

Second, the United States regularly invokes the provisions of the SPS Agreement to convince our trading partners to dismantle non-tariff barriers disguised as SPS measures, and to permit market access for U.S. products based on sound science and risk assessment. The United States will only be able to maintain the moral high ground in the court of international opinion if it is perceived by the international community that the United States adheres to those principles itself. The Coalition notes that U.S. Trade Representative Ron Kirk has recently announced that the emphasis of the Obama Administration will be on trade enforcement, i.e., bringing dispute settlement cases against those trading partners who are failing to live up to their WTO obligations. The Coalition respectfully suggests that Ambassador Kirk's efforts to enforce our trade rights will be severely undermined if the United States itself maintains WTO-inconsistent policies.

In this regard, some of the Committee may recall the problems that the United States encountered during the 1980's in enforcing its trade rights after one of our own laws, section 337 of the Trade Act, was determined to be inconsistent with

provisions of the General Agreement on Tariffs and Trade ("GATT"). When U.S. officials in Geneva demanded that other countries implement GATT rulings in our favor, they were consistently asked in return: "When does the United States intend to implement changes to section 337." Ultimately, The United States did not get effective implementation of cases that it had won until it made conforming amendments to section 337 in the course of implementing the Uruguay Round results.

Third, section 723 will have very significant impact on our trade relations with China. Already, the Chinese have reacted unfavorably to continuation of section 727 of the 2008 Appropriations Act, and its likely renewal by the House as section 723 of H.R. 2997. Recently, importers applying for permits to enter U.S. poultry products into China have received responses that the permit office was "closed for holiday," even though there was no holiday. Although Chinese officials have denied that there has been any change in policy, anyone familiar with the situation – both U.S. government officials and private sector participants in the Chinese market -- know differently. China can use its permit system or other indirect tactics to shut U.S. poultry product out of its market if its chooses to do so, and indications are that it will. This is a $700 million market that the U.S. poultry industry has worked long to develop. It is now at risk, even before the WTO case has run its course.

The Coalition can only note the irony of this situation. The U.S. Congress has long supported market development for our agricultural products, providing

funding mechanisms for programs like the Foreign Market Development Program (FMD) and the Market Access Program (MAP). Over the years, the United States has spent hundreds of millions of dollars assisting U.S. agriculture and food companies to obtain markets in countries such as China. Section 723 threatens to undo what our government has spent many years, and very significant amount of taxpayer dollars, trying to accomplish.

I want to reemphasize here that while the Coalition urges Congress not to enact section 723, it does not prejudge the outcome of any risk assessment that FSIS may conduct with respect to Chinese poultry. FSIS may, based on the scientific evidence, determine that Chinese product is produced and processed in a manner that meets all U.S. standards and may be safely imported; or it may decide that it does not meet those standards and therefore cannot enter the market. We simply believe that the process of science-based risk assessment, inherent in both our national legislation and in international trade law, must be respected; and that our interests in a safe and reliable food supply, in fair and predictable trade rules, and in sound U.S. trade policy are best served by allowing that FSIS to proceed, in the case of the Chinese application, in the same manner that obtains in all other cases.

Attachment

Membership of

The Ad Hoc Coalition for Sound Science and Trade

Advanced Medical Technology Association
AJC International, Incorporated
American Meat Institute
Animal Health Institute
Butterball, LLC
Cargill, Incorporated
DGM Commodities, Corporation
Elanco
Fieldale Farms Corporation
Grocery Manufacturers Association
Grove Services, Incorporated
Hormel Foods Corporation
Interra International, Incorporated
JBS S.A.
Limited OK Foods, Incorporated
MetaFoods, LLC
Monsanto Company
National Cattlemen's Beef Association
National Chicken Council
National Foreign Trade Council
National Meat Association
National Pork Producers Council
National Retail Federation
National Turkey Federation
New Orleans Cold Storage and Warehouse Company
Pilgrim's Pride Corporation
Sanderson Farms, Incorporated
Seaboard Corporation
Sellari Enterprises, Incorporated
Shelf-Stable Food Processors Association
Smithfield Foods, Incorporated
Tyson Foods, Incorporated
USA Poultry & Egg Export Council
U.S. Dairy Export Council
U.S. Chamber of Commerce
U.S.-China Business Council
U.S. Hide, Skin and Leather Association
U.S. Meat Export
U.S. Poultry & Egg Association

Ms. DELAURO. Thank you very much, Mr. Brosch.

Ms. Wallach.

Ms. WALLACH. On behalf of Public Citizen's 100,000 members, I want to thank the chairwoman and the committee for the opportunity to discuss this problem of ensuring that consumer safety is protected in the context of America's increasingly globalized food supply.

Since NAFTA and the WTO, there has been a rapid growth of imported food coming into the U.S. Our current trade pact rules prioritize the expansion of food trade and literally limit countries' domestic food safety policy space, which gets to the question about whether we need to change some of the WTO rules as compared to focus on whether or not our current practices, which promote safety, comply with the existing rules.

Finally, the way that some U.S. agencies have applied the trade rules; for instance, with USDA and meat and poultry equivalence, have resulted in U.S. consumers increasingly being forced to rely on foreign governments to regulate the safety of the foods purchased and consumed here.

Unfortunately, our recent experience, the headlines we all see in the news have shown that quite frequently other governments are not up to the task. We still have improvements in this country after all the infrastructure, experience, and years of fighting for food safety. Relying on foreign governments and their food safety systems to protect Americans' health is a recipe for disaster, and it must be changed. There is a way to get the benefits of trade and still ensure food safety for U.S. consumers. However, under our current trade rules, this is difficult.

I am going to summarize the six points that are in my testimony for the record. The first point is the fact of the increasing share of Americans' food coming from or being processed or grown in other countries. In the 15 years since the implementation of NAFTA and WTO, what was a trickle of imports became a flood. So now, $80 billion in food are imported into the U.S. Annually. That is over double the level when NAFTA and WTO went into effect.

Number two, this shift has occurred following U.S. entry into particular trade agreements that contain trade, investment, and deregulatory rules and standardization requirements explicitly designed to increase the volume of food trade.

So NAFTA in 1993, WTO in 1994, these agreements enforced systems of rules. WTO has 17 different agreements. These agreements prioritize expanding volume of ag trade over food safety. I am not saying that is a theory, it is explicit in the rules. Number one, the WTO tariff rules require that you set your tariffs low enough that every country is importing at least 5 percent in each tariff line. Even if you are exporting, that is about increasing the volume, that is not even about rational efficiency.

Number two, the agreements contain new foreign investor rules that safeguard and in fact incentivize relocating production and processing offshore.

Number three, the rules in these agreements facilitate trade expansion by limiting the kind of import safety terms and inspection rates that can be applied on the return. The specific rule is all countries shall ensure the conformity of all laws and regulations

and administrative procedures, which is to say we are supposed to change our domestic laws to meet the trade rules.

Finally, the trade pacts provide a mechanism for exporting countries to challenge domestic food safety laws in other countries and seek their elimination.

One of the 17 WTO agreements is the agreement on sanitary and phytosanitary measures, the so-called SPS agreement, and in the name of facilitating trade, that agreement, in sum, does the following 4 things: Number one, it sets a ceiling on food safety standards.

Countries are to use, number two, international standards whenever possible, and any standard providing a higher level of protection is subject to challenge. There is no floor, it is only a ceiling.

Number three, it requires that domestic food safety measures be constructed in the least trade-restrictive manner, which is to say trade comes first, and then you figure out what also works for safety.

Number four is a requirement that other countries accept imports that meet other country safety standards but not the importing country's safety standards. Taken in combination, the agreements effectively are deregulatory superstructure, which undermines our strong domestic policies to protect the food safety.

Now I found the Obama administration comments on the chicken measure extremely worrisome because the issue here, as President Obama said as a candidate, is how to make sure our trade agreements, as he noted, which might need renegotiating, make sure we have product safety, and that as a priority, as compared to criticizing whether a product safety measure meets a trade agreement, should be our focus.

We have to ask how we got these rules. My testimony goes into more detail on this, but when NAFTA and WTO were negotiated, there were 500 corporate representatives on the official U.S. Trade Advisory Committee System. There was not a single consumer, public health, or safety organization. So under the theory of he who writes the rules rules, we got rules that satisfied the advisers. And, in fact, agribusiness firms have been openly interested in trade rules that would facilitate the ability to have a global single marketplace with production overseas.

A recent APHIS report talks about companies such as Perdue, Tysons, Smithfield, ConAgra all relocating plants abroad, many in order to send products back under U.S. equivalency standards.

Now these equivalency standards, the basic question that neither USDA or any government agency engaged in trade related equivalency has answered, is the fundamental paradox, which is how can something that is different be the same? Which is to say we expect U.S. consumers expect that the food that comes to their plates, regardless of where it is grown, processed, or comes from is going to meet U.S. standards. And if the basic rule of equivalence is that you must accept things that do not meet your standards, it begs the question of how we can satisfy U.S. consumers because the basic rule for trade equivalence is that it is a process where the exporting country gets to show you that their system, which may be substantially different, is good enough, meets your goals, even though it may be very different, and then you are required to take

the food under their system and treat it as if it was under your system.

Now, different WTO signatory countries have implemented this in different ways, some of them with more focus on safety than the way USDA has done it in the U.S., and in fact FSIS brags it has gone the furthest in trade facilitation equivalence in its own materials. The trade agreements don't define what equivalence means, and therein lies the space for USDA to create a new equivalence policy that can increase the public health focus. There is more room to put focus on public health. But regardless of what it could mean in the U.S., during the Uruguay Round Act implementation the U.S. previous standard which required sale of meat in the U.S. from foreign countries to be "equal to" all U.S. safety standards was switched to "equivalent to." This change in language from "equal to" down to "equivalent to" was done in the Meat Act and in the Poultry Act.

As a lawyer I would say it was actually not necessary to make that weakening. There was nothing in the WTO agreement that would define it downward. However, whether or not it was necessary, that is what was done.

USDA at different times has stated that they will only accept food under the system that meets U.S. standards, and alternatively, in issuing the regulations, have said they can no longer require that food meets U.S. Standards. This is something that needs to be clarified. All food sold here must meet U.S. standards. But instead of FSIS staff going to other countries and explaining how to meet U.S. standards so that we can have the benefits of trade and food safety, now FSIS staff spend a lot of time discussing amongst themselves whether varying technical standards and different foreign regulations are close enough to be able to rely on them for U.S. consumers.

Bottom line is that now the meat industry in foreign nations who have different standards certify their own plants where the USDA used to certify plants under their own systems, and it comes in. This gets to Congressman Kingston's point about the market incentives, which has repeated violations by foreign plants of U.S. law, do not, as it would in the U.S., result in them being shut down so that they need to actually follow the rules.

Instead, it is a two-tier system where the U.S. plants have to meet the U.S. law, the foreign plants can meet their own law, and they are supposed to compete in the same market. And as consumers, we are supposed to rely on them. That in a way gets to the chairwoman's number three question, which is it is not just the practice, it is the policy. The actual USDA equivalence policy needs to be reissued.

Perhaps the bottom line evidence of that is the fact that under that policy it would be even vaguely possible to determine equivalence for the Chinese chicken system. Now I am talking about an analysis based on science and an inspection of the actual circumstances. So you would hope that there would be rules such that, given what we know of the record in China, not just in the chicken plants, but systematically of the government covering up safety problems, of people not only being fired but being jailed for actually reporting safety problems, of absolutely no culture of ac-

countability in that government for prioritizing safety of their own citizens, much less for the export market citizens, the notion that that system, given under the current equivalence formula—USDA is in the business of approving countries, not plants, not safe meat. So the notion that that culture of non-regulation could possibly fit under the current policy is evidence that the policy itself needs to be changed. That is an equivalence that never should have been found.

And I want to conclude by saying that it is not just China, because we found equivalence with Canada, despite the fact that the E. coli standards are fundamentally different, and for 15 years we have been fighting about whether they are safe, and it stayed in place.

Public Citizen did a 2002 report listing all of the equivalency problems with Chile and other countries that list systematic, clear violations, and equivalence has been left in place.

So we have three key fixes that we recommend. The details are in my written testimony. Number one is for USDA to do a new rulemaking to create a new equivalence policy and one that prioritizes public health. And we recommend that in doing so, USDA consider how NHTSA at the Department of Transportation did their rules, as it is a very much public safety-oriented priority standard.

Number two, that the operation of equivalence be tightened up to those regulations as specific recommendations. For instance, what happens with audits, how often, what happens when there is a failure that should be shut down and equivalence determinations should end at a certain point, have to be redone to keep the countries on their toes to stay with the standard.

Finally, we need to fix the trade agreement rules that in their first instance would even call for the prioritization of trade expansion, volume expansion, over standards. There is a way to have both, and I would recommend a review of the Trade Act, H.R. 3012, as a system for how to review and renegotiate some of the food safety provisions. Those provisions were negotiated amongst farm and consumer groups.

Thank you very much.

[The statement of Ms. Wallach follows:]

Auto Safety • Congress Watch • Energy Group • Global Trade Watch • Health Research Group • Litigation Group

Testimony of Lori Wallach
Director, Public Citizen's Global Trade Watch

Hearing on Protecting Public Health in a Global Economy

Subcommittee on Agriculture, Rural Development and FDA
House Appropriations Committee
July 28, 2009

On behalf of Public Citizen's 100,000 members, I want to thank the Chairwoman and members of the subcommittee for the opportunity to discuss the problem of ensuring consumer safety in the context of Americans' food supply increasing coming from countries around the world without strong domestic food safety systems. Public Citizen is a nonprofit research, lobbying and litigation group based in Washington, D.C. Founded in 1971, Public Citizen accepts no government or corporate funds. The mission of Public Citizen's Global Trade Watch division is to ensure that in this era of globalization, a majority have the opportunity to enjoy America's promises: economic security; a clean environment; safe food, medicines and products; access to quality affordable services such as health care; and the exercise of democratic decision-making about the matters that affect their lives. This Global Trade Watch monitors the outcomes of the current globalization model and its implementing mechanisms, including the World Trade Organization (WTO) and North American Free Trade Agreement (NAFTA) with respect to their effect democracy, economic and social justice, public health and safety, and a healthy environment.

At issue with today's increasingly globalize food supply are critical public health and safety issues. However, because of the inappropriate invasion of domestic food safety and public health regulatory space by 'trade' agreements, perversely much of my testimony today will focus on trade agreement policy.

Indeed, the rapid growth in imported food, the current trade pact rules prioritizing expansion of food trade volumes by limiting countries' food safety policies, and the way that some U.S. agencies have applied these trade rules means that U.S. consumers are increasingly being forced to rely on foreign governments to regulate the safety of foods sold and consumed here. Unfortunately, our recent experience has highlighted that many foreign regulatory systems are simply not up to the task. Thus, relying on foreign governments and their food safety systems to protect Americans' health is a recipe for disaster -- and must be changed.

In this testimony, I will focus on six key issues:

- **An increasing share of Americans' food is being grown and/or processed in other countries.** Nearly $80 billion in food goods are imported into the United States annually – more than double the level when NAFTA went into effect in 1994.

- **This shift has occurred U.S. entry into agreements such as WTO and NAFTA that contain trade, investment and safety deregulation and standardization requirements designed to expand the volume of agricultural trade. These pacts prioritize expanding trade volumes over the goal of consumer safety and contain rules to constrain signatory countries' food safety requirements.** For instance, the pacts require signatory countries to set their tariff levels so as to facilitate imports of at least 5% of each agricultural tariff line, even if the country is also a major exporter of the same products. The pacts also require that to facilitate such trade expansion, countries conform their domestic food safety regulations to certain limits. The trade pacts provide new rights for exporting countries to challenge domestic food safety laws in foreign tribunals to seek their elimination if such laws extend beyond the trade agreement-imposed constraints. Yet, there is no similar mechanism for challenge of trade rules that undermine critical food safety and public health goals. As a result, some targets of such attacks, such as the European Union with respect to its ban on artificial growth hormones in meat; have paid millions in trade sanctions to maintain their important consumer health protections.

- **One particularly dangerous trade agreement limitation on food safety involves obligations related to "equivalence" – the requirement that countries may no longer require imported food to actually *meet* their domestic standards.** Trade agreement equivalence rules involve a process under which an exporting country requests to show that its own, different safety system provides an equivalent level of food safety protection to U.S. policy and then the United States must accept imported food that meets the exporting country's laws, even if such food does not meet U.S. safety laws' requirements. However, the term equivalent is not defined in the trade pacts, providing U.S. agencies more authority than is now being employed by some U.S. agencies to ensure the safety of imported food.

- **Americans expect the food they eat meets U.S. safety standards. This is not the case with respect to some imported meat and poultry under current U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) equivalence policy.** USDA has used various trade pact rules and related U.S. statutory changes to establish an equivalence policy that shifts away from explaining to other countries how to comply with U.S. standards and instead FSIS staff now spend their time discussing whether or not other countries' varying technical standards and differing rules and regulations are "close enough" to U.S. rules to provide the same level of protection for U.S. consumers as the domestic system. As a result, U.S. consumers increasingly are being forced to rely with respect to meat and poultry purchased and consumed in the United States on the food safety systems of foreign countries whose regulatory systems are simply not up to the task. Meat and poultry that does not meet U.S. safety standards is being allowed entry into the United States under such USDA "equivalence" determinations. The increasing level of food imports combined with equivalency determinations, different foreign standards, the inadequate auditing of foreign plants and minimalist border checks has resulted in a broad abrogation of U.S. food safety standards.

- **USDA has found equivalence and sought to force U.S. consumers to rely on the food safety systems of countries known for widespread and deadly safety failures.** Consider China: how could U.S. consumers ever be left relying on a system which is responsible for a chain of deadly food and product safety problems domestically and internationally and where a absolute lack of government accountability and transparency and have been steady international news headlines – from the early H5N1 avian influenza outbreaks and their suppression of this information and associated human illnesses and deaths as only one prominent example.

- **Changes are needed to the relevant U.S. laws and regulations implementing trade pact food safety-related policies, notably including meat and poultry equivalence policy.** The fifteen year track record through Democratic and Republican administration that the U.S. Department of Agriculture has had in implementing WTO equivalence rules shows U.S. law and agency regulations and practices must change – as well as trade agreement constraints on food safety. It is not only a matter of the agency 'doing better,' but changes to underlying policies.

1. An increasing share of Americans' food is being grown and/or processed in other countries.

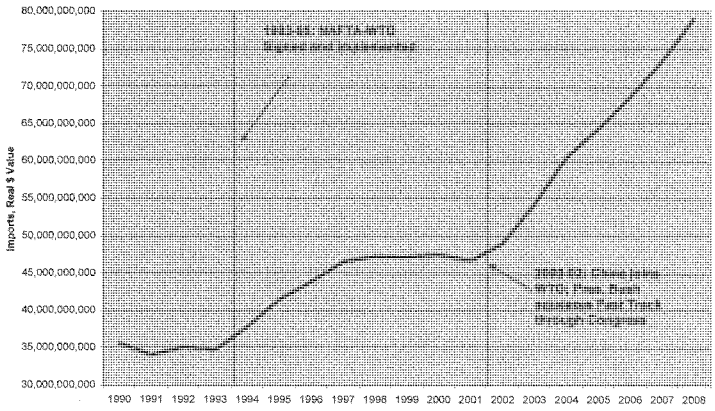
In the decade-plus since the implementation of the WTO, NAFTA and other U.S. Free Trade Agreements (FTAs), food imports have risen from a trickle to a flood. Figure 1, below, shows that nearly $80 billion in food goods are imported here annually – well over double the level when NAFTA went into effect in 1994.

The CDC estimates that some 76 million people a year suffer from food-borne illness. An estimated 325,000 are hospitalized and an estimated 5,000 die.[1] It is impossible to estimate what percentage of the cases of serious dollar levels, it is safe to say that the numbers of food illness attributable to food imports is on the rise.[2] As the *New England Journal of Medicine* argued succinctly, "with a global food supply, we worry less about the possibility that Grandmother's potato salad will affect 80% of the people attending a church picnic than about the prospect that hundreds of thousands of people in many countries will be exposed to a single contaminated product."[3]

American farmers were told by NAFTA and WTO supporters that the pacts would increase exports and thus provide a new path for struggling farmers to succeed economically.[4] In fact, U.S. agriculture exports increased, but food imports skyrocketed. Thus, from 1993 to 2005, the United States went from a $24 billion food surplus to an $840 million food deficit. While this has improved somewhat in recent years, the fact remains that food imports grew 128 percent over the 1993-2008 period, while exports only grew 86 percent. Nearly 300,000 U.S. family farms have gone under since NAFTA and the WTO went into effect[5] and net farm income (minus government payments) declined 13 percent for family farmers.[6] These food trade shifts impact the environment as well. The United States is now importing massive amounts of the grains and foods it also exports, with tons of redundant trade being shipped in and out simultaneously.[7] A recently leaked United Nations study found that carbon emissions from merchant shipping are nearly three times greater than previously estimated, or an estimated 4.5 per cent of global carbon emissions.[8]

FIGURE 1

U.S. Food Imports Explode During NAFTA-WTO Era



Source: USDA's FATUS Aggregations, authors' calculations

2. Agreements such as WTO and NAFTA prioritize expanding trade volumes over the goal of consumer safety and contain rules to constrain signatory countries' food safety requirements.

The pressure for globalized agricultural trade is largely being driven by the transnational agribusiness and shipping companies. These interests played a disproportionate role in establishing U.S. trade policies and agreements such as WTO and NAFTA. Such firms were heavily represented among the 500 corporate representatives comprising the U.S. trade advisory committee system while not a single consumer, health or safety organization was included. Many of these agribusiness firms were interested in 'trade' rules that would facilitate their desire to relocate production and processing to other nations because of cheap labor and production costs and weaker food safety and environmental regulations while still being able to sell such food back here in the key U.S. market.

As a publication by the U.S. Department of Agriculture's Animal Plant Health Inspection Service states, "International commerce is increasingly the result of more commercial activities than just exporting or importing. Most of the top-ranked U.S.-based meat corporations are also investing overseas in processing or production. Market access, lower production costs, growth opportunities, and regulation drive international location decisions."[9] The agency specifically points to lower labor and environmental compliance costs in nations like Mexico.[10]

Meat and poultry industry giants such as Perdue Farms, Inc., Tyson Foods, Inc., Smithfield Foods, Conagra Foods, and Cargill, Inc. have all located plants abroad, many in order to send product back to the U.S. market under the equivalency system.[11] The increasingly international nature of the enterprise is leading meat processing interest to push for weakening of governmental regulation of slaughter and processing of meat and poultry products at home and abroad.

In 1993, Congress passed NAFTA, a comprehensive international investment, deregulation and trade agreement covering Canada, the U.S. and Mexico. In 1994, Congress passed the Uruguay Round Agreements Act making the United States part of the now 153-member WTO which enforces seventeen major agreements, many of which have little to do with trade per se, but rather require the conformity of signatory countries domestic non-trade regulatory policies to various constraints. Indeed, a key WTO and NAFTA provision requires each signatory country "to ensure the conformity" of all of its "laws, regulations and administrative procedures" to the agreements' expansive terms.[12] Domestic policies that fail to conform to NAFTA or WTO constraints can be challenged by other agreement signatory countries as barriers to trade in the built-in dispute resolution bodies established in these agreements.

Among the common provisions of varying strength in these pacts and other U.S. FTAs are those that establish new 'foreign investors' protections that, by eliminating certain costs and risks previously associated with the offshoring of U.S. investment and production to developing countries, incentivize and protect such relocations.

Meanwhile, the actual agricultural trade provisions of the WTO eliminated quotas that many countries, including the United States, once used to manage food supplies – often with formulas designed to modulate imports levels based on the actual gap in supply provided by domestic producers. That is to say, many countries only imported food that their domestic producers could not adequately supply until the WTO eliminated such policy options. And, the WTO, NAFTA and the FTAs also decreased tariff rates. For instance, the pacts require signatory countries to set their tariff levels so as to facilitate imports of at least 5% of each agricultural tariff line, even if the country is also a major exporter of the same products.

Finally, the WTO includes as one of the agreement it enforces an Agreement on Sanitary and Phytosanitary Standards (SPS) – which is incorporated into and in some instances expanded on in various U.S. FTAs. In the name of facilitating expanded volumes of agriculture trade, the SPS agreement sets criteria

that WTO nations must follow regarding their domestic policies designed to protect human, animal or plant life from pests, diseases and toxins in food, beverages, or animal feed. In sum, this agreement establishes a ceiling on food safety standards, but no floor; requires that domestic regulations should be constructed in the least trade restrictive manner possible to facilitate trade; and, as discussed below, requires countries to use uniform international standards when possible and to accept other countries' different safety policies as equivalent in the name of trade facilitation.

Taken in combination, the agreements constitute a deregulatory superstructure which undermines strong domestic policies to protect the food supply and consumers from pathogens and contaminants. Consider the bottom line established through these agreements: foreign governments – and the export interests they represent including U.S.-brand-name agribusiness corporations who have relocated production offshore - that are unhappy about U.S. food safety laws can now challenge such laws as 'illegal trade barriers' in a regime where losing countries have the choice of either changing their policy or paying trade sanctions.[13] This regime obviously puts trade expansion above consumer safety: decisions by U.S. government officials about food safety are now subject to oversight by trade tribunals operating behind closed doors whose goal is to facilitate trade, not to safeguard the interests of U.S. consumers – while obviously there is no mechanism to challenge the ways in which trade expansion had exposed U.S. consumers to new safety threats - must less an obligation to remedy that conflict in favor of safety.

When NAFTA's implementing legislation and the Uruguay Round Agreements Act passed Congress in the early 1990s, huge swaths of U.S. domestic laws and policy were rewritten in one fell swoop. Because the agreements were passed under the extraordinary limits on Congress' normal committee and floor debate functions provided for in special requirements of the "Fast Track" trade agreement voting procedure (no normal mark ups, no amendments, limited debate), many in Congress had only the vaguest sense of what was contained in these bills. Because no amendments are allowed to Fast-Tracked trade bills, even the members of Congress who noticed and understood the arcane details (such as the regulatory roll backs enacted in the name of "trade" agreement food and product safety harmonization and equivalency requirements) had no ability to fix the provisions that troubled them.

3. One particularly dangerous trade agreement limitation on food safety involves obligations related to "equivalence" – the requirement that countries may no longer require imported food to actually *meet* their domestic standards.

Trade agreement equivalence rules involve a process under which an exporting country requests to show that its own, different safety system provides an equivalent level of food safety protection to U.S. policy and then the United States must accept imported food that meets the exporting country's laws, even if such food does not meet U.S. safety laws' requirements. Thus, once another country's food safety system or an individual foreign standard is declared "equivalent" to a U.S. domestic system or standard, products produced under that system must be treated as if they were produced under the U.S. domestic system or standard, even though the two systems may differ in significant ways.

This notion stands in sharp contrast to U.S. policies to ensure the safety of imported meat and poultry that were in place before WTO and NAFTA. Under that safety system, foreign meat inspection systems were required to produce meat destined for export to the United States utilizing sanitary and quality standards *the same as* those of the United States. U.S. government inspectors had to certify that foreign processing plants met U.S. standards in order for such a facility to send food to the U.S.

NAFTA and the WTO both oblige member governments to make equivalency an aspect of their domestic regulatory systems. For instance, Article 4.1 of the WTO Sanitary and Phytosanitary Agreement, states that, "*Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product if the exporting Member objectively demonstrates to the importing Member that its measures achieve*

the importing Member's appropriate level of sanitary or phytosanitary protection."[14] Similarly, Article 2.7 of the WTO Technical Barriers to Trade (TBT) Agreement, which sets parameters for WTO signatory countries' domestic standards not related to food safety or animal or plant health (but sometimes applying to food) states "*Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own...*"[15]

Various WTO signatories have implemented these rules in differing ways. Indeed, various U.S. agencies have taken different approaches. And, the trade agreements do not include a definition of equivalency. However, with respect to U.S. meat and poultry safety, the 1995 Uruguay Round Agreements Act rolled back pre-existing safety standards. The WTO implementing legislation changed the Federal Meat Inspections Act and the Poultry Products Inspection Act so that the words "equal to" were replaced with the word "equivalent."[16]

Whether that statutory change was even necessary is questionable given there is no definition of equivalent in the trade pacts that would call for such a change. Indeed, the USDA FSIS' latest equivalence policy report notes that under WTO rules: "Meat, poultry and egg products exported from another nation must meet all safety standards applied to foods produced in the United States. The burden for demonstrating equivalence rests with an exporting country. The importing country has a sovereign right to set any level of protection it deems appropriate to eliminate or abate a food safety hazard within its territory."[17]

However, whether or not the statuary changes in the Uruguay Round Act were indeed required, USDA has used the WTO SPS Agreement and the statutory changes to establish an equivalence policy that shifts away from explaining to other countries how to comply with U.S. standards and instead FSIS staff now spend their time discussing whether or not other countries' varying technical standards and differing rules and regulations are "close enough" to U.S. rules to provide the same level of protection for U.S. consumers as the domestic system.

As a result, the meat industry in foreign nations could maintain *differing* standards, certify their own plants for export, and still be eligible to export into the United States.[18] As explained by FSIS officials: "since 1995 the United States, along with other members of the World Trade Organization, has shifted its emphasis from 'compliance' with importing country inspection requirements to 'equivalence' in conformance with our obligations under the [WTO Sanitary and Phytosanitary] SPS Agreement," which governs trade in food.[19] Another official states, "if you revert to 'the same as,' then there's even arguably a higher standard and a more difficult challenge to meet to gain entry [into U.S. markets]."[20]

The result has been FSIS repeatedly authorizing meat imports from nations whose standards did not meet U.S. regulatory requirements.[21] In a 2002 review of the FSIS system audits of countries that FSIS found to be "equivalent" systems, Public Citizen found sanitary measures that not only dramatically differed from FSIS policy, but in some cases, actually violate the express language of U.S. laws and regulation.[22] This included:

- The U.S. law requiring meat to be inspected by independent government officials was violated by plants in *Brazil and Mexico.*

- U.S. regulations requiring monthly supervisory reviews by foreign government officials were violated by *Argentina, Brazil, Canada,* and *Mexico.* Canada and Brazil are requesting an equivalency determination on this core requirement of U.S. regulation. Monthly reviews are vitally important to remind the meat industry that the meat inspector who works the line in the plant is backed by the weight of the government and to double check the work of meat inspectors on a regular basis.

- Even though U.S. regulations require that a government official and not a company employee sample meat for *Salmonella* contamination, USDA approved company employees performing this task as part of equivalency determinations with *Brazil and Canada.*

- Even though U.S. regulations require government samples to be tested at government laboratories, the U.S. approved testing by private labs as part of the equivalency determinations with *Brazil, Canada and Mexico.*

- USDA's sanitary and zero tolerance policies for contaminants including feces, urine, and ingesta (stomach contents) was violated by *Australia, Canada* and *Mexico.*

- Unapproved and/or improper testing procedures and sanitation violations have been re-identified by FSIS year after year for *Australia, Brazil, Canada* and *Mexico*, but the countries have retained their eligibility to export to the U.S.

- After its regulatory system was designated equivalent, *Mexico* began using alternative procedures for *Salmonella* and *E. Coli* that had never been evaluated by FSIS.

- *Australia* and *Canada* were allowed to export to the U.S. while utilizing their own methods and procedures for such matters as *E. Coli* testing, post-mortem inspection, monthly supervisory reviews and pre-shipment reviews while awaiting a decision from FSIS on a request for an equivalency determination on these standards.

- FSIS auditors and Canadian food safety officials continue to disagree about whether or not particular measures have already been found "equivalent" by FSIS, yet Canadian meat exports to the U.S. continued uninterrupted.

- The regulatory systems of *Brazil and Mexico* were rated equivalent even though the countries pleaded insufficient personnel and monetary resources to explain their inability to carry out all required functions.

Post equivalence determination, when problems have been discovered, FSIS has given countries seemingly time-unlimited opportunities to try to address them. As noted above, many of the problems identified had been reported before. For instance, in violation of U.S. requirements for government meat inspection, Mexico was allowed to have company-paid meat inspectors year after year. Canada and the United States still have not agreed that differing sanitary standards, such as those governing *E. coli* testing, are in fact equivalent. Yet, Mexican and Canadian meat still flows into the U.S. and is stamped with the USDA seal.

Not surprisingly, the very notion that trade pacts require that goods be allowed entry if they meet the *exporting* country's laws and regulations but not the standards of the *importing* country has been broadly criticized by consumer and health organizations and experts. For instance, consider the conclusion of the Transatlantic Consumer Dialogue, the network of all major U.S. and European consumer organizations: "The very notion of equivalence allows for imprecise, subjective comparisons that are not appropriate when dealing with issues as important as public health and safety."[23] According to the Center for Science in the Public Interest, "Equivalency is a method by which nations can create exemptions to each other's food safety laws to advance trade."[24]

Under WTO use of equivalence is mandatory. A WTO member country "shall accept" another member country's food safety measures if the exporting country demonstrates that its standards achieve the importing country's appropriate level of protection.[25] However, most interestingly, what exactly equivalence

means is not defined. This provides discretion that other countries with strong domestic systems have employed to safeguard their consumer protections, In contrast, as discussed below, the USDA's FSIS has set up equivalence policies and procedures seemingly aimed at always finding equivalence when asked by another country. Indeed, USDA has issued equivalence determinations allowing reliance on the domestic food safety systems of countries in which visiting American tourists are extremely cautious about what foods they can safety consume.

Yet, once "equivalence" is agreed to, the standards of the exporting party apply and U.S. consumers purchasing food here are forced to rely on the other nations' policies and their implementation. In other words, different regulatory standards for the same food product exist at the same time, both of which are considered legal in the United States. One set of standards has been adopted by a U.S. regulatory agency to implement a U.S. law enacted by Congress. Citizen input into these standards has been assured by an array of U.S. laws including: the Administrative Procedure Act,[26] requiring public notice and opportunity for public comment on proposed regulations or regulatory changes; the Freedom of Information Act,[27] permitting citizen access to the records of government agencies; the Government in the Sunshine Act,[28] ensuring that important agency meetings are publicly noticed; and the Federal Advisory Committee Act,[29] requiring balanced representation on government advisory committees. Compliance with the U.S. standards is secured through the monitoring and enforcement mechanisms of U.S. law.

In sharp contrast to this consultative democratic process, an "equivalent" set of standards has been agreed to by the U.S. regulatory agency at the request of a foreign country on the basis of a claim that the foreign country's standards promulgated under its own domestic procedure achieve the same level of protection as the standards that the U.S. agency itself has selected after consideration of the opinions of its own experts, representatives of public interest groups, industry and academia, and the affected public.

Equivalency is a fairly new concept in U.S. domestic law, but it has a track record elsewhere. The notion first arose in Europe in the context of the Common Market integration where the principal of mutual recognition ensures the free flow of goods across borders based on the recognition of differing national regulations as being equivalent to each other.[30] Notably, these issues still remain controversial in Europe and generate frequent lawsuits between nations. This is true even though the Common Market countries also provided a significant amount of financial and technical assistance to nations which needed to elevate their standards to achieve a comparable level of protection to other EU nations. This is particularly striking considering the relatively small gaps in levels of development and the strength, robustness and funding of safety regulatory systems between the European countries compared to the differences between U.S. standards and those of many of the nations from which it imports meat.

Given the vast discrepancy in resources and infrastructure between the 153 member nations of the WTO and the discrepancies even within the three NAFTA nations, it is becoming abundantly clear that the concept of equivalence does not translate well. Yet, highlighting the perils inherently involve in the equivalence concept, are continuing issues related to Canada, a country with a level of economic development and development of its regulatory infrastructure the same as that of the United States. The first U.S. meat safety equivalence program was with Canada under the 1989 Canada-U.S. Free Trade Agreement. Two decade later, after considerable turmoil and numerous investigations and programs reversals and changes, the equivalence concept has resulted in entry into the United States of Canadian product produced under *E. Coli* testing and other policies different from U.S. policy that U.S. consumer groups believe fail to meet U.S. protection levels.[31]

But then consider the practical implications of relying on the food safety systems of developing countries with extremely limited safety infrastructure and experience, no funding for or culture of enforcement and uneven records with respect to the most basic rule-of-law issues. Just consider the funding issues. For instance, the U.S. food safety budget is close to a billion dollars.[32] By contrast, in 1992, Mexico's spending on food safety inspection was $25 million. Three years later, with food exports soaring under

NAFTA, but with Mexico reeling from the peso crash and obligated by new loan agreements to implement further "structural adjustment," Mexico's food inspection funding was slashed to $5 million.[33] By 2001, Mexico's total food safety and animal and plant health budget had returned to the $25 million level – half a percent of Mexico's agriculture ministry budget and less than one dollar per Mexican citizen.[34] Yet, over the years since NAFTA went into effect, the real dollar value of Mexico's exports of FSIS-regulated foods to the U.S. (meat, poultry and eggs) has risen 3525 percent, from $4.7 million in 1993 to $170 million in 2008.[35]

4. Americans expect the food they eat meets U.S. standards. Given this is not the case under current USDA equivalence policy, changes are needed to the relevant laws and regulations.

Although the American public has every reason to assume that they are protected by laws enacted by their elected representatives and enforced by administrative agencies in a publicly transparent and participatory fashion, this is not necessarily the case. U.S. consumers increasingly are being forced to rely with respect to food purchased and consumed domestic on the food safety systems of foreign countries whose regulatory systems are simply not up to the task. Meat and poultry that does not meet U.S. safety standards is being allowed entry into the United States under various USDA "equivalence" determinations.

FSIS, which regulates meat and poultry products, has pushed the equivalence concept the furthest, a fact FSIS itself touts: "FSIS' process for evaluating the equivalency of foreign meat and poultry food regulatory systems is both path breaking and precedent-setting. No other food regulatory system in the world, to our knowledge, is actively engaged in applying the concepts of equivalence to the degree and extent as is FSIS. The matter of exactly how an importing country judges, and determines equivalence is controversial. The world is watching how FSIS carries out its equivalency process."[36] These equivalency decisions are being made by a small number of officials with extremely limited information available about how these decisions are made.

Thirty-seven countries that had previously been found to meet the U.S. meat and poultry import "equal to" standard were grandfathered in and immediately declared "equivalent."[37] When the HACCP and pathogen reduction regulations were adopted in 1996, FSIS became responsible for determining these 37 countries' "equivalent" with regard to the new HACCP program and this was done without public notice or an opportunity to comment.[38]

By 2002, 43 countries had been granted equivalency status by FSIS for exports to the U.S. of meat and meat products from cattle, sheep, swine and goats:[39] Argentina, Australia, Austria, Belgium, Belize, Brazil, Canada, Costa Rica, Czech Republic, Denmark, Dominican Republic, El Salvador, England and Wales, Finland, France, Germany, Guatemala, Honduras, Hungary, Iceland, Ireland, Italy, Japan, Mexico, Netherlands, New Zealand, Nicaragua, Northern Ireland, Norway, Paraguay, Poland, Republic of China, (Taiwan), Republic of Croatia, Republic of Slovenia, Romania, Scotland, Spain, Sweden, Switzerland, Uruguay, Venezuela, and Yugoslavia. Five had been granted equivalency status for poultry exports: Canada, France, Great Britain, Hong Kong, Israel and Mexico.[40] Currently, in 2009, the FSIS lists Australia, Chile, China, Costa Rica, and New Zealand as additional countries having equivalence status for poultry.[41] Not surprisingly, the amount of imported meat and poultry has grown under the equivalence regime – which no longer requires that exporting countries take special care to meet U.S. standards.

Moreover, the American consumer cannot distinguish these imports from meat produced under U.S. standards. Unbeknownst to consumers, in the meat sections of grocery stores all over the United States, there are packets of beef and poultry bearing the USDA seal that were produced in slaughterhouses and processing plants abroad that are not required to obey the same rules as U.S. facilities and in which no U.S. government inspector may ever have set foot. Yet, the appearance of the USDA grade stamp (which marks beef "choice," "prime" or "select") on certain meat packages as well as the inspection stamp for certain meats processed in the United States misleads many consumers to believe that the meet is homegrown.[42] One hamburger sold in the U.S. could potentially contain a veritable United Nations of meat as processors may mix beef from many

nations in one batch. This is a cause for concern that the new country of origin labels take some critical first steps in addressing.

Prior to adoption of the 1994 Uruguay Round Agreements Act, FSIS had detailed procedures in place governing eligibility to export meat to the U.S. Foreign meat inspection systems were required to have laws and regulations, and sanitary and quality standards, identical to those of the U.S., including those requiring government meat inspectors.[43] In addition, all foreign inspection systems were required to conduct "supervisory" visits to each establishment certified as eligible to export meat to the U.S., no less frequently than once a month as a backup check to ensure that the regulatory requirements were being met.[44] To ensure compliance with U.S. standards, FSIS itself conducted the actual audits of foreign slaughter and processing establishments certifying them as eligible to export to the U.S.,[45] and FSIS staff was frequently stationed in the other countries.[46]

However, shortly after the passage of the Uruguay Round Agreements Act, in 1995 FSIS amended its meat and poultry import regulations stating that "[u]nder this new law, drafted to comply with GATT, the United States can no longer require foreign countries wishing to export meat and poultry products to have meat and poultry inspection systems that are 'at least equal' to those in the United States...."[47]

Instead of directly inspecting foreign establishments as it did before the 1995 adoption of the "equivalence" mandate, FSIS now relies on "system audits" to determine whether an exporting country's regulatory system can be declared "equivalent" to that of the U.S. FSIS auditors, who are veterinarians, are responsible for conducting all foreign country audits. Each audit can take from two to six weeks.[48] In conducting annual "system audits," FSIS auditors translate and analyze documents and data, meet with exporting country inspection officials, and accompany the foreign country officials on-site as they inspect usually a small sample of the plants that are approved by foreign governments as eligible to export to the U.S.[49]

Once a system has been declared "equivalent," FSIS relies on the *other country's* regulatory officials to conduct the ongoing inspection and monitoring of the establishments in which animals are slaughtered and meat is prepared for export to the U.S. The number of eligible plants that are actually visited by an FSIS auditor as part of the annual system audit varies widely and can be as few as nine out of 513 certified establishments, which was the case for Canada.[50] As explained by Sally Stratmoen, Acting Director, Equivalence Division, FSIS' Office of International Affairs: "We used to approve plants. Now we approve governments."[51]

In order to be classified as "equivalent," a country must be found by USDA to have a regulatory program administered by its national government that implements standards equivalent to those of the U.S. meat inspection system in the following areas: uniform enforcement; ultimate control by the national government; competent, qualified inspectors; authority to certify or refuse to certify meat intended for export; adequate technical and administrative support; and inspection, sanitation, quality, species verification, and residue standards.[52] The country's legal authority must impose equivalent requirements for antemortem and post-mortem inspection; official control of establishments; direct and continuous official supervision of slaughtering and preparation of product; separation of certified establishments from uncertified ones; sanitation requirements; control over condemned product; and HACCP system.[53]

According to the regulatory requirements, maintenance of eligibility is dependent on the results of periodic reviews conducted by FSIS.[54] In order to ensure that its requirements are being met, the regulations require that foreign regulatory system must conduct supervisory inspection visits to establishments eligible to export least once a month (these are the so-called "monthly supervisory reviews") and write up the results and must perform random sampling in accordance with sampling and analytical techniques approved by FSIS.[55] Moreover, once a country's system is declared equivalent, that nation's government becomes responsible for approving plants interested in exporting to the U.S., not U.S. auditors. U.S. auditors will then

annual inspect only a small sample of these plants as part of the systems audit they are supposed to conduct on an annual basis.

The policies FSIS established to implement "equivalence" and their practices alike have been extremely problematic. The first report on the extent of the problems was produced by the USDA's own Office of the Inspector General in 2000. The unusually harsh report described a meat and poultry inspection system in chaos. The report noted that:

- FSIS granted equivalency status to six countries for their HACCP program without conducting onsite reviews;[56]
- Seven foreign establishments that had lost their eligibility to export to the U.S. were found to have shipped 4,625,363 pounds of meat and poultry into the U.S.;[57]
- Nineteen plants that had not been re-certified as meeting U.S. standards were allowed to continue to export meat to the U.S.;[58]
- Procedures for determining equivalency were not detailed enough to ensure that all aspects of a country's regulatory system were reviewed in accordance with applicable regulation and equivalency determinations were based on insufficient documented analysis and support;[59]
- Regulatory requirements that countries provide annual certifications of plants and residue test plans were not enforced;[60]
- FSIS had no clear procedures for determining if another country's alternative testing methods were equivalent;[61]
- FSIS was underutilizing technical experts of the Technical Services Center and over utilizing program analysts of the Equivalency and Planning Branch. In astonishingly severe language, the Inspector General wrote "We question whether the Equivalence and Planning Branch, collectively, has the technical expertise to make equivalency determinations;"[62] and
- Violations by certain countries were tolerated, while the same violations by other countries were not tolerated. The fact that FSIS had no written procedures for terminating eligibility raised the specter of arbitrary decision-making.[63]

The USDA Inspector General followed up with a 2003 report. Eighteen of the recommendations in the June 2000 Inspector General's Report concerned port-of-entry re-inspection. Yet, amazingly, in a report released in February 2003, the Inspector General found that FSIS had taken "adequate action" on only four of these 18 recommendations.[64] Although the need for increased management oversight had been one of the major findings of the June 2000 report, the Inspector General found in 2003 that "inaction occurred because no one was held accountable for implementing these recommendations and no mechanism was established to alert top FSIS management officials that this work was not being done."[65] The report revealed that between January 1999 and March 2001, over seven million pounds of meat which had entered the U.S. market came from 37 foreign establishments whose eligibility in the computerized information system was contradicted by other documents.[66] Because of FSIS' laxity and failure to take corrective action after the June 2000 report, the Inspector General concluded that it was not possible for the agency to ensure that all meat entering the U.S. market was produced in plants that were eligible to export to the United States. In a January 2003 interview with Public Citizen, one FSIS employee confirmed the confusion and lack of good processes in the equivalency division of FSIS, by describing incomplete files, lengthy delays in responding to a request for an equivalency determination, and pressure from supervisors to declare a file complete even though many documents had not yet been translated into English.[67]

Public Citizen's 2002 review of the FSIS equivalence audits of five countries, Argentina, Australia, Brazil, Canada, Mexico, and Argentina, reveal a significant degree of confusion about the application of "equivalence" in practice and an alarming gap between decisions made at the policy level and information used for equivalency determinations acquired in the slaughterhouses and processing plants. In these countries whose regulatory systems have been declared equivalent to that of the United States, U.S. officials

documented significant violations of all of the core protections of the U.S. meat safety laws. Sanitary standards have not been met; required testing has not been performed or has been performed improperly; continuous inspection and required supervisory oversight have not been provided; and the key safeguard of direct inspection by impartial publicly-paid inspectors has been disregarded. And yet, current policy allowed FSIS to continue to rate these country's meat inspection standards as "equivalent" and U.S. consumers continue, unknowingly, to purchase and eat meat that has not been produced in compliance with their democratically enacted laws:

- Systems with sanitary measures that differ from FSIS policy, and in some cases, actually violate the express language of U.S. laws and regulations, have been declared "equivalent;"[68]
- Improper and/or unapproved testing procedures and sanitation violations have been re-identified by FSIS year after year and are not remedied, but the countries have retained their eligibility status to export to the U.S.;[69]
- After their regulatory systems have been designated "equivalent," countries have altered their methods and procedures or adopted new ones that have never been evaluated by FSIS, which FSIS has only discovered when later conducting an on-site audit;[70]
- Regulatory systems have been rated equivalent even though sufficient personnel and monetary resources are not available to carry out all required functions;[71]
- Countries continue to use their own methods and procedures while awaiting a response from FSIS to a request for an equivalency determination, but are treated as equivalent while they wait for a response;[72] and,
- FSIS auditors and foreign food safety officials disagree about whether or not particular measures have already been found to be "equivalent" by FSIS.

Finally, USDA's focus on facilitating expansion in agricultural trade volumes rather than public health has meant that rather than requiring the exporting country to provide equivalence assessment documents in English, the agency was spending vast sums on translation costs.[73] Other federal agencies, such as the FDA in the context of similar multinational agreement (the U.S.-EU Mutual Recognition Agreement for pharmaceuticals and medical devices), have insisted that nations requesting equivalency bear the burden of translation costs.

Given the results of the current USDA policy, a new approach is needed – one that focuses on public health, not only trade facilitation.

The equivalence polices and practices of the department of Transportation's National Highway Traffic Safety Administration (NHTSA) could provide useful information in this respect to USDA. NHSTA is the only federal agency to have performed formal rulemaking to establish its harmonization and equivalency procedures. After soliciting public comment and responding to it on the record, it issued a final rule in May 1998 which incorporates a number of helpful elements.[74]

First, the NHTSA policy clearly states that its practice will be to identify and adopt those foreign vehicle safety standards that "clearly reflect best practices i.e., that require significantly *higher* levels of safety performance."[75] Second, "if resource limitations make it necessary to choose between competing petitions [for amendment of standards], the agency will give priority to granting a petition asking the agency to *upgrade* one of its standards to the level of a superior foreign standard over granting another petition simply asking the agency to add a compliance alternative."[76] Third, every petition to amend a NHTSA vehicle safety standard must be accompanied by appropriate data and an analysis of the relative benefits of the NHTSA and foreign standards meaning that NHTSA places the burden of proof on the petitioner by requiring the petitioner to supply the data and analysis to support the petition.[77] Fourth, if the agency tentatively decides that a foreign standard is functionally equivalent or better than a NHTSA standard, the agency will issue a notice of proposed rulemaking and request public comment on the tentative determination and the proposed amendment.[78] Finally, the agency explicitly affirms that any final rule to amend a NHTSA

standard will be made in accordance with the applicable law of the United States and "only after careful consideration and analysis of the public comments."[79]

That is to say that the process is designed to implement U.S. trade obligations in a manner that prioritizes consumer safety. If a foreign system does not meet U.S. safety standards, then it is not determined to be equivalent. Thus, under this process, NHTSA has already turned down a number of equivalency petitions, such as one for windshield wipers that they believe were an unacceptable abrogation of a U.S. standard. This stands in contrast to the current USDA policy under which countries which clearly do not provide reliable safety protections, much less those meeting U.S. levels of protection, such as China, can be found to be equivalent. That there is any possibility, regardless of the vagrancies of political will and staffing, that China's food safety system could be found equivalent to the U.S. system highlights when the USDA policy itself must be changed.

5. USDA has found equivalence and sought to force U.S. consumers to rely on the food safety systems of countries known for widespread and deadly safety failures.

As repeated incidents of import safety breakdowns have demonstrated, the People's Republic of China's (China) food safety standards are neither adequate nor enforced properly. China's food safety problems are well documented. With respect to the products that already are imported from the PRC that fall under the jurisdiction of the Food and Drug Administration (FDA), 12 of the 18 current Import Alerts listed for China are for food items -- with the most recent alert covering products that contain dairy powder that might be adulterated with melamine.[80] In just the past four months, 467 different human food items imported from the PRC – from seafood to candy – were refused entry by the FDA. The reasons cited included: filth; illegal animal/veterinary drugs used; suspected contamination with melamine; unsafe food additives; unsafe color additives; lack of labeling; salmonella contamination; packed in unsanitary conditions; unsafe pesticide residue; poisonous; unfit for food; and failure to register process. And, people in scores of countries have suffered the deadly consequences of China's exports of contaminated cough syrup, toothpaste and pet food. Yet, even China could obtain a USDA food safety equivalence determination under the current policy.

That the current USDA policy could lead to a finding of "equivalence" is made even more horrifying when considering the recent comments from China's own Health Ministry. He described the food safety situation in the country as "grim, with high risks and contradictions."[81] This unusually candid statement makes it clear that China's regulatory system cannot adequately enforce food safety standards for domestic, much less exported, food products.

The recent melamine scandal is a perfect example of how China's food safety system is unable to prevent even *intentional* contamination of the food supply or detect widespread problems. It is also an example of the Chinese government's extreme lack of transparency with respect to its food safety regulatory system and that system's frequent failings. Indeed, the Chinese government systematically suppresses news of major food-borne illness outbreaks, including the extreme steps it took to prevent news of illnesses and infant deaths caused by this mass food adulteration from being made public because it would have conflicted with the staging of the Beijing Olympics in August 2008. China's food safety system cannot protect its own people, yet under USDA's equivalence policies Americans were to be forced to rely on this system? That the underlying USDA policy must be changed is also highlighted by the fact that the evidence provided by a major food safety scandal that called into question every fundamental critical aspect of China's safety system did not result in revocation of the USDA equivalence determination. Under the current policy, Americans would have been exposed to food imports whose only safety assurance would have been the obviously inadequate Chinese system had Congress not intervened.

Further, consider the PRC's handling of the early H5N1 avian influenza outbreaks in the PRC and the associated human illnesses and deaths from those outbreaks. The Chinese government lowered a veil of secrecy, denying critical information to its own citizens and the world at large. China has been one of the

epicenters for H5N1 avian influenza that has impacted both poultry and humans. According to the World Health Organization, there have been twenty-three H5N1 avian influenza outbreaks in the PRC that have afflicted birds and poultry since 1996,[82] with 38 reported human cases and 25 deaths.[83] Obviously, this is a significant animal health issue that impacts public health, which needs to be addressed before the United States can even consider importing any poultry products from China – a fact that again highlights the critical need for USDA equivalence policies to be reformed given under current policy it was *possible* to force U.S. consumers to rely on this Chinese system for our safety.

The bottom line is clear: under current USDA policy that it was even *possible* to find China's system equivalent shows it is not only the past practices, but the underlying policies that must be altered. And the China case is only the most extreme example of the limits of the notion of equivalence: the appropriateness of relying on the regulatory authority of other nations is called into question every time another cover-up hits the papers, from Britain's mishandling of the "mad cow" crisis to Argentina's delay in reporting a foot and mouth disease outbreak to the Belgian government's cover-up of dioxin-contaminated chicken.[84]

However, the case of China is perhaps the poster child for the inherent limitations of the equivalence concept. It is simply impossible for the U.S. government to shift responsibility for U.S. consumers' safety into a government that has repeated demonstrated that it will not and cannot ensure the safety of its own citizens' food – and in fact does not put emphasis on that goal. It is impossible for the U.S. government to shift responsibility for U.S. consumers' safety into a government that has shown repeatedly that it will not even provide basic information about problems. Thus, an appropriate USDA equivalence policy would NOT find equivalence between the U.S. and Chinese systems.

6. Changes are needed to the relevant U.S. laws and regulations implementing trade agreement food safety-related policies, notably including meat and poultry equivalence policy.

Neither USDA, nor any other U.S. government agency engaged in trade-related equivalency decision-making, has answered the fundamental paradox posed by the equivalence concept: how can something that is different be the same? When it comes to important public health and safety standards, most Americans would argue that "close" is simply not good enough.

And, when it comes to the safety of food – and the threat of deadly food borne illnesses – most Americans would not even contemplate putting their families' wellbeing second to corporate-inspired "trade" agreement rules. Given the beating the concept of "free trade" has already gotten in the public mind thanks to being associated with corporate-managed-trade agreements like NAFTA and WTO, one could only imagine the level of backlash that would be generated by a public airing of the notion that a trade agreement required the United States to permit imports from, say, China based on reliance on a domestic 'safety' system that the American public is only too well aware had led to the deaths of scores of Chinese babies, cough medicine consumers in Latin America and thousands of American pets.

Whenever new leaders arrive at FSIS, consumer groups are told that the past equivalence disasters have been the result of bad practices or past staff. Yet, on a bipartisan basis through numerous staff turnovers, implementation of the current FSIS policy has resulted in imports of unsafe meet and poultry that clearly do not satisfy U.S. food safety protection standards. It may be the case that the past China poultry equivalence assessment was done in a slipshod manner, but the bottom line problem is the underlying policy that could ever result in China's system being considered equivalent given an array of obvious structural issues, not the least of which is a record of the government covering up severe food safety problems, not seeking to avoid them.

- **The USDA should conduct a rulemaking to establish a new process for determining standard for meat and poultry imports.** To date, USDA's policy for equivalence assessments and determinations has

been focused on trade facilitation rather than U.S. consumers' food safety and American public health. A new policy is needed that establishes public health based standards and processes for reviewing existing meat and poultry import equivalence determinations and issuing future ones. The basic principles of such a new policy must be that the safety and inspection laws and systems of another country can only be found equivalent when the relevant foreign laws, standards and procedures either are the same as U.S. standards or function to deliver the same or higher level of public health protection, enforceability, and effectiveness of the comparable U.S. laws, standards and procedures in all respects – as actually applied and implemented. That is to say that some countries will be required to modify their policies and practices with respect to food they seek to prepare for export to the United States – in contrast to the past policy which resulted in systems with vastly different standards and outcome being declared equivalent to the U.S. system.

- **Equivalence determinations must be conducted through formal rule making so that all interested parties can participate.** To ensure that all potentially interested parties have an opportunity to review the analysis of whether a foreign country's food safety and inspection laws and systems are the same as U.S. standards or deliver the same or a higher level of public health protection, enforceability, and effectiveness, equivalence determinations must be conducted through on-the-record notice and comment ruling-making similar to the practice of NHTSA.

- **Equivalence determinations should be granted for set periods of time with reauthorizations based on reassessments of not only the food safety laws in question, but their application, enforcement and future funding levels.** Existing equivalence determinations must be reassessed under the new policy noted above given the extended audit record of problems within the system previously determined to be equivalent.

- **USDA auditors should resume the practice of inspecting and certifying every foreign plant shipping product to the U.S. on an annual basis.** First, there is no requirement in the WTO or other trade agreements that requires that this vital function be outsourced to foreign governments' officials. Second, given the lack of whistle blower and other government employee protections in numerous countries, it is critical that U.S. officials have the power to make these determinations and that they do so through careful written reports of their findings with respect to specific facilities.

- **USDA and FDA must be given more money for conducting rigorous overseas audits and the follow-up that is necessary to instruct foreign regulators on U.S. food safety policies and procedures.**

- **Equivalence status and the right to export must be terminated promptly upon audit findings of problems.** The only way to ensure that other countries' law continue to meet U.S. standards is to hold them accountable to such standards by conditioning their continuing right to export to the United States on such compliance. If an audit finds that the exporting country is not fully implementing and enforcing the laws, standards and procedures that were found to be equivalent, the equivalence determination must be suspended and not reinstated until USDA re-inspection verifies that the implementation and enforcement problems are remedied.

- **Congress must act to substantially increase border inspection activities.** Even if the system of U.S. officials certifying which foreign plants may export to the United States was restored as it must be, increased border inspection is a critical tool in ensuring continuing compliance of such facilities. It is unconscionable – and dangerous – that the U.S. inspection rates for produce and seafood is less than one percent and meat and poultry inspection is only 11 percent. In contrast, the European Union physically inspects many high risk imports, such as seafood, at a rate of 20-50 percent.

- **Trade should not trump public health: trade agreement need rebalancing.** A thorough review is needed now of our existing trade agreements – including NAFTA and WTO - to carefully identify the provisions that are causing problems. The Trade Reform Accountability Development and Employment (TRADE) Act H.R. 3012 provides a process for doing just that and sets a new road map to allow trade expansion under rules that also ensure food safety. We must fix the existing agreements by renegotiating problematic provisions – and do better in the future. If we are to enjoy the benefits of trade – and also reverse the trend of growing public opposition to trade expansion- the non-trade limits on our basic health and safety that have been inserted into recent trade agreements must be removed. Indeed, there is a growing international call for a paring back of the key WTO agreements like the WTO TBT and WTO SPS agreements that inappropriately delve into regulatory issues via such trade promotion mechanisms as harmonization and equivalency. Not only do such provisions establish new means to attack public health, consumer protection, and food safety regulations at barriers to trade, but they inappropriately elevate the expansion of trade volumes over all other public policy concerns, including that of ensuring a safe and wholesome food supply. If the same domestic regulatory standard is applied to both domestic and imported food, the level of protection or enforcement is something those living with the results must decide. That is to say that there is no trade issue if there is no discrimination and trade agreements must be renegotiated to roll back the inappropriate limits on legitimate food safety and other public health protections. Specifically, our current trade agreements must be modified to remove provisions that:

  → Limit the level of food or product safety protection countries choose to implement. We must be free to set our own level of desired safety and environmental protection.

  → Limit countries' rights to inspect imports at a more intensive rate than similar domestic goods. We must be free to inspect imports at the rate government safety agencies determine is needed to ensure safety.

  → Require the United States to allow imports of food and non-food products from foreign countries that use "equivalent" and often lesser safety standards. We must be free to require that only goods that meet our U.S. safety and environmental standards can be imported.

  → Include trade agreement harmonization requirements that give primacy of internationally harmonized rules relative to domestic law. Unless they are designed with the *intent* of discriminating against foreign goods, our domestic safety standards and the level of safety protection we desire are not a trade issue.

- **Restore meat and poultry acts to 'equal to' standard.** Congress must intervene to change the underlying law and regulations so to clarify that only food that meets U.S. safety standards is eligible for sale in the United States.

ENDNOTES

[1] The Centers for Disease Control and Prevention, "Foodborne Illness, Frequently Asked Questions," U.S. Department of Health and Human Services website. Available at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm.

[2] Roughly 20 percent of the foods we eat are now imported. Number derived from the ratio of the dollar sum of Foreign Agricultural Service's Agricultural (Food) Import Commodity Aggregations to the dollar sum of food expenditures calculated by the U.S. Department of Agriculture's Economic Research Service.

[3]. Michael T. Osterholm, Ph.D., M.P.H., "Emerging Infections: Another Warning," *New England Journal of Medicine* editorial, Vol. 342, No. 17, Apr. 27, 2000.

[4] Charles Conner, "Agribusiness Food Producers Back NAFTA," *Memphis Commercial Appeal,* Aug. 15, 1993; Jennifer Lin, "In Texas, High Noon over NAFTA," *Knight-Ridder Newspapers,* Oct. 31, 1993.

[5] From numbers for the USDA's "limited resources," "farming occupation – lower sales," and "farming occupation – higher sales" farm typology categories. *See* USDA's Economic Research Service's "Farm Business and Household Survey Data: Customized Data Summaries for Agricultural Resource Management Survey," for numbers after 1996, and "Farm structure: historic data on farm operator household income" data tables for numbers prior to 1996.

[6] This figure is the sum of the average net cash income for both limited resources and farming occupation farms, minus government payments, and is inflation adjusted, for years 1996 and 2005, the most recent comparable data. For 1996, the average inflation-adjusted net cash income for limited resource, low- and high- sales farming occupation farms were -$3,721, -$979, and $35,947, respectively; while the comparable 2005 figures were -$4,245, $1,538, and $29,354.

[7] The food items with the highest volume of highly redundant trade include rice, tomatoes, potatoes, watermelon, onions, and beef cuts. *See* Public Citizen, forthcoming, 2009,

[8] John Vidal, "Shipping boom fuels rising tide of global CO2 emissions," *The Guardian*, Feb.13, 2008.

[9]. USDA, Animal Plant Health Inspection Service, "Overseas Investments by U.S. Meat Corporations: What's the Future for U.S. Exports?" Changing Times in Animal Agriculture, Jul. 2000, available at, www.aphis.usda.gov/vs/ceah/cei/chtimes0700.htm

[10]. Id. at 4.

[11]. Id. at 3.

[12] See e.g. Agreement Establishing the WTO, Article XVI-4.

[13]. USDA, Public Meeting: FSIS Equivalence of Foreign Meat and Poultry Food Regulatory Systems, Washington, D.C. Apr. 14, 1999, Transcript, at 167, on file with Public Citizen.

[14]. World Trade Organization, Agreement on Application of Sanitary & Phytosanitary Measures, [WTO SPS Agreement], Articles 4.1, available at www.wto.org/goods/spsagr.htm.

[15]. World Trade Organization, Agreement on Technical Barriers to Trade, [WTO TBT Agreement], Article 2.7, available at http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

[16]. 60 Fed. Reg. 38667, Jul. 28, 1995.

[17] USDA FSIS, "Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems," Oct. 2005 at 5. (http://www.fsis.usda.gov/regulations/Equivalence_Process/index.asp)

[18]. 9 CFR §327.2.

[19]. Dr. John Prucha, Asst. Dep. Administrator for Int'l and Domestic Policy, USDA, Public Meeting: Equivalence Evaluation of Pathogen Reduction HACCP Requirements, Transcript, Washington, D.C. Dec. 14, 1999 at 15, on file with Public Citizen.

[20]. Mark Mannis, Int'l Policy Development Division, USDA, Public Meeting: Equivalence Evaluation of Pathogen Reduction HACCP Requirements, Transcript, Washington, D.C. Dec. 14, 1999 at 170, on file with Public Citizen.

[21] Just one obvious example: in its 2000 report on equivalency, the USDA Office of Inspector General determined that 19 plants that had not been certified were allowed to ship meat to U.S. and that the U.S. had granted 6 countries equivalency status without first conducting on-site reviews. USDA, *Food Safety and Inspection Service, Imported Meat and Poultry Inspection Process, Phase I*, Report No. 24099-3-Hy, June 2000, Section III at ii-iii.

[22]. Public Citizen, The WTO Comes to Dinner: U.S. Implementation of Trade Rules Bypasses Food Safety Requirements, 2002. For instance, in its 2000 report on equivalency, the USDA Office of Inspector General determined that 19 plants that had not been certified were allowed to ship meat to U.S. and that the U.S. had granted 6 countries equivalency status without first conducting on-site reviews. USDA, *Food Safety and Inspection Service, Imported Meat and Poultry Inspection Process, Phase I*, Report No. 24099-3-Hy, June 2000, Section III at ii-iii.

[23]. The Transatlantic Consumer Dialogue, formed in 1998. is comrpised of the largest consumer organizations in the U.S. and Europe and provides consensus recommendations on trade and consumer matters to the U.S. and European governments. Transatlantic Consumer Dialogue, Principles of Harmonization, Feb. 2000, at 2, available at http://www.tacd.org.

[24]. Silverglade, Bruce, "The WTO Agreement on Sanitary and Phytosanitary Measures: Weakening Food Safety Regulations to Facilitate Trade?," *Food and Drug Law Journal*, Vol. 55, No. 4, at 517.

[25]. WTO SPS Agreement, Articles 4.1.

[26]. 5 U.S.C. §551.

[27]. 5 U.S.C. §552.

[28]. 5 U.S.C. §552b.

[29]. 5 U.S.C. Appx. §1.

[30]. The Riksdag (Swedish Parliament), "EU Information: A Common Market, Fact Sheet 3," Aug. 29, 2001 at 3.

[31] The two nations' meat inspection systems were declared equivalent and a "streamlined" border inspection system was implemented. In February 1990, the two countries announced that they would take this new system one step further and proposed a one-year experiment with an "open border" which would eliminate all border inspections for meat imported from one country to another.(See GAO, "Issues USDA Should Address Before Ending Canadian Meat Inspections," Jul. 1990, GAO/RCED-90-176, at 1.) At the time, some FSIS officials interviewed by the GAO questioned whether this move was in compliance with U.S. law on import inspection or whether it needed an act of Congress to drop all border controls, but the experiment proceeded. (GAO, "United States-Canada Open Border Proposal for Meat and Poultry Inspection System," Testimony by John Harman, Director GAO Food and Agriculture Issues before the Subcommittee on Agriculture Research

and General Legislation, Senate Committee on Agriculture, Nutrition and Forestry, GAO/T-RCED-90-96, Jul. 12, 1990, at 10.) Shortly after U.S. and Canadian officials touted the agreement as "the first time in our countries' history that we have been able to open our borders for food safety standards," alarming warnings reached Congress about the results. Bill Lehman, a U.S. meat inspector with 26 years of experience blew the whistle on USDA for allowing contaminated Canadian meat into the country unchecked. (David Lapp, "Return to the Jungle," *Multinational Monitor*, May 1990.) Jack Perrault, director of the International Import Inspection Service, condemned USDA for "giving up consumer protection for free trade." (Id) The brouhaha generated bad press and congressional investigations, prompting USDA to abandon its "open border" with Canada. Yet, a streamlined inspection system remains in effect between the U.S. and Canada to this day despite significant differences with respect to *E. Coli* testing and other matters that U.S. consumer groups believe fail to meet U.S. protection levels.

[32] USDA, Office of Budget and Program Analysis, FY10 Budget Summary listed the budget authority for FSIS programs at $981 million, at 68. Available at: http://www.obpa.usda.gov/budsum/FY10budsum.pdf. Accessed July 27, 2009.

[33]. OECD, *Examen de las Politicas Agricolas de México* (1997).

[34]. Steve Suppan, Institute for Agriculture and Trade Policy, speech before the conference "Legal Platform for Consumer Concerns and International Trade in Food and Agriculture," July 2002.

[35] Data for red meat & products; eggs; mutton, goat & lamb; pork; poultry meat; fresh or frozen variety meats. Extracted on July 27, 2009, from USDA's Economic Research Services FATUS system for FATUS Commodity Aggregations. Available at: http://www.fas.usda.gov/ustrade/USTImFatus.asp?QI= . Adjusted for inflation using CPI-U-RS from Congressional Budget Office, extracted on July 27, 2009.

[36]. Undated FSIS document quoted in USDA Office of the Inspector General, *Food Safety and Inspection Service, Imported Meat and Poultry Inspection Process*, Phase I, June 2000 USDA/OIG-A/24099-3-Hy, Section III, at 65.

[37]. USDA, Office of Inspector General, *Food Safety and Inspection Service, Imported Meat and Poultry Inspection Process, Phase I*, Report No. 24099-3-Hy, June 2000, Section III, at 2, available at http://www.usda.gov/oig/webdocs/imported.pdf.

[38] At a public meeting on December 14, 1999, with no prior public notice of its intentions to declare nations equivalent, FSIS announced that 32 of the 37 countries already approved for shipping meat products to the U.S. had been determined to have "equivalent" pathogen reduction and HACCP systems in place. (USDA, Public Meeting; Equivalence Evaluation of Pathogen Reduction/HACCP Requirements, Transcript, Washington, D.C. Dec. 14, 1999 on file with Public Citizen.) FSIS announced that 36 countries had adopted FSIS' Sanitation Standard Operating Procedure (SSOP) requirements; that 32 had adopted FSIS' HACCP requirements; that 18 had adopted FSIS' *E. coli* testing requirements, with 13 adopting different testing requirements, which FSIS had found to be equivalent;[38] and that of the 27 countries to which the *Salmonella* testing regulations were applicable, eight had adopted FSIS' requirements, with 19 adopting different measures which FSIS had found to be equivalent. (Id. At 78.) In addition, it is notable that one country, the Netherlands, decided to use an altogether different microbiological indicator of contamination, testing for enterobacteriaceae not *Salmonella*. This departure from U.S. regulation was also defined as "equivalent" by FSIS staff. (Id at 82.) Although the federal regulations require that FSIS employees conduct *Salmonella* testing and send the test samples to government labs, FSIS revealed at the meeting that other countries' export establishments could use private laboratories for this purpose if the laboratories met certain criteria.[38] This departure from U.S. federal regulatory requirements did not go through notice and comment rulemaking prior to its adoption by the agency. Ten countries allow their meat processing establishments to take samples, 12 countries' systems use private laboratories. (Id. At 91.) FSIS explained at the meeting, "We don't, or we are not in a position to, dictate that you must [use a government laboratory]. That is the way we operated before 1994. If we had these requirements prior to then, it would have been rather simply put, it's got to be government labs, its got to be government people selecting the samples." (Id at 112) FSIS staff had undertaken a massive comparison of nations for pathogen reduction and HACCP with no public notice or opportunity for comment. Yet, FSIS' own policy is to give public notice regarding renewals of nations' declared equivalent when nations make changes to their system. It is difficult to imagine a more significant change that required for each nation to develop a fully functioning HACCP system. Secondly, FSIS also revealed that rather than requiring the exporting country to provide documents in English, the agency spent over $550,000 on translation costs. (Id. at 63.) Other federal agencies, such as the FDA in the context of similar multinational agreement (the U.S.-EU Mutual Recognition Agreement for pharmaceuticals and medical devices), have insisted that nations requesting equivalency bear the burden of translation costs.

[39]. 9 CFR §327.2(b). Because of endemic disease conditions, some countries, including Brazil, are eligible to export only cooked and canned products. 9 CFR §94.1. An outbreak of disease can cause a country to lose its eligibility, as happened to Argentina at the beginning of 2001 when foot and mouth disease was brought in by animals from a bordering country. 66 Fed. Reg. 29897 (Jun. 4, 2001).

[40]. 9 CFR §381.196(b). Mexico is eligible to export only process poultry products from poultry that has been slaughtered in the U.S. or another country eligible to export to the U.S.

[41] http://www.fsis.usda.gov/pdf/Countries_Products_Eligible_for_Export.pdf Accessed on July 22, 2009.

[42]. Noel C. Paul, "Where is the beef (from)?" *Christian Science Monitor*, Apr. 14, 2003.

[43]. 9 CFR §327.2; 35 Fed. Reg. 15610 (Oct. 3, 1970).

[44]. 9 CFR §327.2(a)(2)(iv)(A); 35 Fed. Reg. 15610 (Oct. 3, 1970).

[45]. Clark Danford, USDA, Public Meeting: FSIS Equivalence of Foreign Meat and Poultry Food Regulatory Systems, Apr. 14, 1999, Transcript, at 90, on file with Public Citizen.

[46]. Winifred DePalma, Public Citizen telephone interview with Sally Stratmoen, Acting Director, Equivalence, Office of International Affairs, FSIS, Nov. 22, 2002.
[47]. 60 Fed. Reg. 38667, 38668 (Jul. 28, 1995).
[48]. *Id.*
[49]. FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems, Mar. 1999, at 9-10, on file with Public Citizen.
[50]. Audit Report for Canada, June 11 through July 6, 2001, USDA, available at http://www.fsis.usda.gov/OFO/TSC/foreign_country_audit_reports.htm. In approximately half of the countries that are eligible to export to the U.S., because comparatively few plants are certified, 100% are visited by FSIS. Dec. 5, 2002 Winifred DePalma, Public Citizen telephone interview with Don Smart, Director, Review Division, Technical Service Center, FSIS.
[51]. Winifred DePalma, Public Citizen telephone interview with Sally Stratmoen, Acting Director, Equivalence Division, Office of International Affairs, FSIS Nov. 22, 2002.
[52]. 9 CFR §327.2(a)(2)(i).
[53]. 9 CFR §327.2(a)(2)(ii).
[54]. 9 CFR §327.2(a)(2)(iii).
[55]. 9 CFR §327.2(a)(2)(iv).
[56]. USDA, Office of Inspector General, *Food Safety and Inspection Service, Imported Meat and Poultry Inspection Process, Phase I*, Report No. 24099-3-Hy, June 2000, Section III, at iii, available at http://www.usda.gov/oig/webdocs/imported.pdf.
[57]. *Id.*, at Section III, at 37.
[58]. *Id.*, at Section III, at ii.
[59]. *Id.*, at Section III, at ii, 26.
[60]. *Id.*
[61]. *Id.*, at Section III, at 31.
[62]. *Id.* at 63.
[63]. *Id.* at 28-29.
[64]. USDA, OIG, Food Safety and Inspection Service, Imported Meat and Poultry Reinspection Process, Phase II, February 2003, Audit report No. 24099-04-Hy, at iii-v, available at usda,gov/oig/webdocs/24099-04-Hy.pdf.
[65]. Id., at 6.
[66]. Id., at ii.
[67]. Winifred DePalma, Public Citizen telephone interview with USDA employee, Linda Lewis, Jan. 14, 2003.
[68]. *See*, Argentina, Australia, Brazil, Canada and Mexico, below.
[69]. *See*, Australia, Brazil, Canada and Mexico, below.
[70]. *See*, Mexico, below.
[71]. *See*, Brazil and Mexico, below.
[72]. It is FSIS policy to continue to allow trade while an equivalency request is under review. FSIS claims that it will suspend eligibility if a country does not provide satisfactory documentary evidence of an equivalent sanitary measure. 64 Fed. Reg. 70690, 70692 (Dec. 17, 1999). However, as the cases below demonstrate, this is not practise. *See*,, Argentina and Mexico.
[73]. USDA, Public Meeting; Equivalence Evaluation of Pathogen Reduction/HACCP Requirements, Transcript, Washington, D.C. Dec. 14, 1999 at 63, on file with Public Citizen.
[74]. 63 Fed. Reg. 26508 (May 13, 1998).
[75]. 63 Fed. Reg. 26508 (May 13, 1998), at 26509.
[76]. 63 Fed. Reg. 26508 (May 13, 1998), at 26509.
[77]. 63 Fed. Reg. 26508 (May 13, 1998), at 26512.
[78]. 63 Fed. Reg. 26508 (May 13, 1998), at 26513.
[79]. 63 Fed. Reg. 26508 (May 13, 1998), at 26513.
[80] http://www.fda.gov/ora/fiars/ora_import_country.html
[81] Shanghai Daily, "New Law Fights Grim Situation in Food Safety," March 3, 2009, see http://www.shanghaidaily.com/sp/article/2009/200903/20090303/article_392914.htm
[82] See http://www.who.int/csr/disease/avian_influenza/ai_timeline/en/index.html
[83] See http://www.who.int/csr/disease/avian_influenza/country/cases_table_2009_04_23/en/index.html
[84]. The 1999 Belgian dioxin scare brought down the Belgian government when it was revealed that the government knew as early as mid-March 1999 that it had a problem with dioxin contaminated animal feed which spread to chicken and eggs, but failed to notify the public until May 1999. (Coric Lok and Douglas Powell," Belgian Dioxin Crisis of the Summer of 1999, a case study in crisis communication and management," Department of Food Science, University of Guelph, Ontario, May 2000.) In 2001, Argentina's neighbors blasted the government for not promptly notifying them of an outbreak of foot and mouth disease in that country. ("South Americans Call on Governments to Come Clean on Foot and Mouth," *Agence France Presse,* Mar. 14, 2001). News reports indicate that Chinese officials suppressed news and accurate statistics about the SARS epidemic for months. In April 2003, Chinese officials announced the country harbored 10 times the number of previously disclosed SARS infections. ("China Admits SARS Cover-Up," Seattle Times, Apr. 21, 2003.)

Ms. DELAURO. Thank you, Ms. Wallach.

Ms. Hauter.

Ms. HAUTER. Chairwoman DeLauro, Ranking Member Kingston, and members of the subcommittee, thank you for the opportunity to testify today. I think most Americans would be shocked to know that every year since 2006 during the annual appropriations process, that Congress debates whether to continue to forbid funds from being used to implement the rule allowing China to import poultry products into the U.S. Most people would use their common sense and determine that it doesn't make sense to import a risky food like poultry from a country with a food safety record like China, from a country that is almost 7,000 miles on the other side of the world.

I will note that we agree with Congressman Kingston that we should also look at the FDA process and that the same thing is true for FDA and all of these other products. We just happen to be talking about poultry today.

It was politics that determined China was eligible to import poultry into the U.S. There was no honest process based on the evaluation of risk. The inadequate process ignored major problems, and approval was rushed through.

Let us review the events that have brought us here today. In November 2005, FSIS published a proposed regulation listing China's eligibility to export processed poultry products. Food and Water Watch was among the groups that raised serious concerns during the public comment period. We pointed out that the 2004 FSIS audit of seven Chinese poultry and slaughter processing plants was problematic. The three slaughter plants failed the audit, two of the four processing plants failed. And we believe that a sample of only four processing plants was insufficient anyway given that the proposed rule indicated that more than 25 processing facilities would be eligible for export.

It is important to note here that in an August 2008 USDA Office of the Inspector General audit report, that inspectors from FSIS visited China again in 2005 and conducted another audit. The four facilities failed. But there was no publicly visible regulatory activity on the proposed rule until April 18th, 2006, when the final rule was sent to OMB. Normally I think everybody is aware that a review of this nature takes up to 90 days. Today, 32 countries are eligible to export meat products to the U.S., and eight are eligible for poultry products. These countries had to go through a very lengthy review. And while it was imperfect, it was many, many, many times more rigorous in terms of regulatory hurdles than what China was required to do.

So the rule was announced on April 18th. Stunningly, on April 20th, 2 days after the rule was sent to OMB, the final regulation was announced at the White House because Chinese President Hu Jintao was visiting then-President Bush. The rule limited exports to the U.S. to shelf-ready poultry products. The rule was clear it didn't include birds slaughtered in China, but USDA officials continued to push for equivalency, even in the face of overwhelming evidence that China's poultry slaughter and processing facilities are not really equivalent.

To its credit, this subcommittee has been responsible for raising issues that have led Congress to prohibit expenditures of funds by USDA on this rule. Without the committee's vigilance, Americans would now be exposed to dangerous contaminants and bacteria. Lurking in the background is a trade issue that seems to be tied to the equivalency of status of China for proposed poultry products. China refuses to import beef products from the U.S., ostensibly because of concerns about mad cow disease. But really, China is willing to reconsider beef imports if it can export poultry to the U.S. In fact, the Chinese press reported just before the April 2006 visit by President Hu Jintao that a beef for chicken deal was being negotiated.

There was an April 12, 2006, article that appeared in China Daily entitled, Chinese Poultry to U.S., U.S. Beef to China, that strongly suggested that a quid pro quo agreement had in fact been struck.

While USDA officials have stated that no such understanding was ever reached, opening up beef trade with China seems to be a very high priority for the USDA. Although some of our domestic agribusiness trade associations are using their considerable political power to push for a swap, it is the National Cattlemen's Beef Association who has been very vocal in pressing for a removal of the ban on the importation of processed poultry products from China. They view it as an impediment to the export of U.S. beef to China.

But we should be clear, imported food from China is not safe. Their own government officials have admitted that openly. In March 2009, when their food safety law was unveiled, officials in the Chinese Health Ministry described the food safety situation in their country as grim, with high risks and contradictions.

The new law which took effect on June 1, 2009, is designed to address the problems that arose from the intentional contamination of milk, which caused over 300,000 Chinese citizens to be hospitalized with acute kidney disease and 13 infants to die. I think everyone is aware, because milk powder is used in various baked goods and candies, hundreds of products were impacted.

Other imported food products from China have been the source of recalls, import alerts, and detention. And since January 2009, the FDA has stopped 545 shipments of Chinese food items that fall under FDA jurisdiction from being imported. Among the reasons cited, illegal veterinary drugs, suspected contamination with melamine, unsafe food additives, unsafe color additives, lack of labeling, salmonella contamination, listeria contamination, unsanitary packaging conditions, unsafe pesticide residue, poison, unfit for food, and failure to register a food process.

In addition, currently there are 12 FDA import alerts for various Chinese foods, and there have been several U.S. recalls of imported Chinese food products such as seafood, candy, baked goods, and pet food ingredients.

We should really wait and see how the new food safety law works and whether the government of China can enforce it before we allow them to export any more food to us. We believe that the equivalency approval process for China was deeply flawed, and the

process needs to be started anew, and this should include revoking the April 2006 rule.

Our regulatory agencies must maintain the integrity of the food safety system, and regulations must be based on science, not politics. Trade should not trump public health. And while China might view this as a quid pro quo, the welfare of U.S. consumers should not be sacrificed so that we can open up new export markets.

[The statement of Ms. Hauter follows:]

Statement by
Wenonah Hauter
Executive Director, Food & Water Watch
Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Committee on Appropriations, U.S. House of Representatives

July 28, 2009

Chairwoman DeLauro, Ranking Member Kingston and members of the Subcommittee, my name is Wenonah Hauter and I am the executive director of Food & Water Watch, a non-profit consumer organization that was founded in 2005. I welcome this opportunity to testify on the safety of imported meat and poultry and the equivalency process at the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA).

Food & Water Watch has worked extensively on the issue of food safety and in particular we have focused much of our efforts on the safety of imported food. It has been estimated that approximately 15 percent of American diets[1] now comes from imported food products and the import share is growing each year. For some food products that fall under the jurisdiction of the Food and Drug Administration (FDA), the numbers are even higher. We are now importing over 80 percent of seafood and are witnessing an exponential growth in the volume of imported produce. Food & Water Watch has published several reports on seafood and produce imports that are accessible on our website.[2] As you know, FDA has furnished this Subcommittee with data that show that in FY 2008 FDA was capable of inspecting only 1.31 percent of the imported food products from over 150 countries that fall under its jurisdiction because of the agency's

[1] Statement of David W.K. Acheson and Margaret O'K. Glavin before the Energy and Commerce Subcommittee on Oversight and Investigations, U. S. House of Representatives, October 11, 2007, p.1.
[2] Food & Water Watch, "Import Alert;" "Laboratory Error;" and "The Poisoned Fruit of American Trade Policy" http://www.foodandwaterwatch.org/food/pubs/reports/

almost exclusive reliance on port-of-entry inspections.[3] In documents that we have obtained from the FDA, its Office of Regulatory Affairs has made the observation that "half of the foods that have been associated with food borne illness have been imported."[4]

For meat, poultry and egg products regulated by USDA's FSIS, the volume of imports has remained fairly steady in recent years – between three and four billion pounds of meat and poultry products (most of the imports are meat products and a negligible amount of poultry is currently imported, primarily from Canada) and about 21 million pounds of egg products annually.[5] Recent food borne illness outbreaks have been associated with imported meat products, most notably the 2007 Topps Meat Company recall in which 40 consumers became ill from eating hamburger patties contaminated with *E. coli 0157:H7*.[6] The source of the contamination was eventually traced back to beef trimmings imported from Canada.[7] There is also increasing concern that strains of food borne pathogens not common in the United States are contaminating meat and poultry products that are being imported.[8]

The FSIS System of Equivalency Determination and Enforcement

Unlike FDA, which has no formal approval system for the food safety programs of exporting countries before their products can be imported into the United States, FSIS does have

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[3] FY 2010 Justification of Estimates for Appropriations Committees, Department of Health and Human Services, Food and Drug Administration, p. 75
[4] FY 2007 Food and Drug Administration, Office of Regulatory Affairs Work Plan, p. 03-20.
[5] Food Safety and Inspection Service, "Quarterly Enforcement Reports," http://www.fsis.usda.gov/regulations_&_policies/Quarterly_Enforcement_Reports/index.asp
[6] Centers for Disease Control and Preventions, "Multistate Outbreak of *E. coli 0157:H7* Infections Linked to Topp's Brand Ground Beef Patties, see http://www.cdc.gov/ecoli/2007/october/100207.html.
[7] Food Safety and Inspection Service, "FSIS Provides Update on Topps Meat Company Recall Investigation," October 26, 2007, http://www.fsis.usda.gov/News_&_Events/NR_102607_01/index.asp
[8] The Food Safety Group, U.S. Meat Animal Research Center, USDA-ARS, "Non-0157 Shiga Toxin-producing *E. coli* and Relevance to Food Safety, " October 9, 2007.

a fairly extensive evaluation and enforcement system in place for imported meat and poultry products.

Before a country can export its meat, poultry, or egg products to the United States, it must first file with FSIS a request for an equivalency determination. There is a document review conducted by FSIS staff to determine whether the exporting country's food safety laws and regulations meet our standards. If the country passes that hurdle, then FSIS conducts on-site visits to the country to determine whether the food safety system in operation meets our food safety and inspection standards. If after the on-site review FSIS is convinced that the exporting country can meet our standards, then FSIS proposes a regulation for the country to be added to list of countries eligible to export products to the United States (9 CFR 327.2 (b) for products from cattle, swine, sheep, and goats; 9 CFR 381.196 (b) for poultry products). FSIS solicits public comment on the proposed regulation. If after the public comment period FSIS remains convinced of its recommendations, then the country is added to the appropriate section of the Code of Federal Regulations list of countries eligible for export.

Foreign food establishments wishing to export their products to the United States must be certified by the exporting country as to their ability to meet U.S. food safety standards. To ensure that our food safety and inspection requirements are being met, FSIS dispatches audit teams to the exporting country on annual basis to conduct on-site reviews of laboratory procedures and to a sample of the certified plants. If problems are found and are not corrected, food establishments can be de-listed and will no longer be eligible to export to the United States. In addition, FSIS has a re-inspection program at the ports of entry. A team of 74 FSIS import inspectors assigned to some 100 import inspection houses conducts 100 percent visual inspection of shipments and they do a more thorough inspection of about 10 percent of the imported

product. About half of that receives microbiological testing.[9] Furthermore, it is our understanding that products from newly certified plants receive heightened scrutiny at the ports of entry, as do products from exporting establishments that have failed previous re-inspection procedures.

There are currently 32 countries that are eligible to export meat products to the United States; eight countries are eligible to export poultry products; and one can export egg products.[10] There are approximately 1000 foreign establishments eligible to export meat, poultry and egg products to the United States.

The 2006 Equivalency Determination for the People's Republic of China

Food & Water Watch believes that FSIS' processes provide better safeguards for U.S. consumers on imported foods than what FDA currently does. However, it is in the execution of its import food safety program that FSIS falters. The 2006 processed poultry equivalency determination for the People's Republic of China (PRC) is a case in point.

As you know, FSIS published a proposed regulation on November 23, 2005 to list the PRC under 9 CFR 381.196 (b) as being eligible to export processed poultry products to the United States provided that the slaughtered poultry came from an approved country (70 FR 70746-70749). Because FSIS was not prepared to make an equivalency determination on the domestic poultry slaughter facilities in China, the proposed rule would only permit the PRC to export processed poultry provided that the raw product came from either the United States or Canada.

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[9] Testimony by Food Safety and Inspection Service, USDA, before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations, U.S. House of Representatives, April 19, 2007, p. 332.
[10] Food Safety and Inspection Service, USDA. "Eligible Foreign Establishments," http://www.fsis.usda.gov/Regulations_&_Policies/Eligible_Foreign_Establishments/index.asp

The public comment period for this proposed regulation ended on January 23, 2006. The majority of comments were opposed to the proposed rule. Food & Water Watch was among them for several reasons:

1) In the 2004 FSIS audit of seven Chinese poultry slaughter and processing facilities, most of the facilities did not meet U.S. food safety standards. Of the four processing facilities audited, half did not meet U.S. standards;

2) We believed that a sample of four establishments was insufficient given that the proposed rule indicated that more than 25 Chinese facilities would be eligible to export processed poultry products to the United States;

3) Several outbreaks of H5N1 avian influenza in the PRC illustrated the importance of the origin of the birds, yet without constant surveillance by U.S. inspection personnel there is no guarantee that only U.S. or Canadian poultry would be used;

4) We believed that FSIS had underestimated the economic impact of new imports on the U.S. poultry industry in the proposed rule;

5) In December 2005, the USDA Office of Inspector General (OIG) issued a scathing audit report regarding FSIS enforcement of its equivalency agreement with Canada. The OIG found that FSIS did not have written protocols or guidelines for evaluating an exporting country's inspection system.[11] We voiced our concern that if FSIS could not enforce its equivalency agreement with Canada, just north of the border, how could it possibly handle an agreement with the PRC, 7000 miles away?

6) While FSIS argued that consumers would be able to discern the difference between processed poultry products from the PRC from those produced domestically, we

[11] Office of the Inspector General, USDA, "Audit Report: Food Safety and Inspection Service Assessment of the Equivalence of the Canadian Inspection System," Report No. 24601-05-Hy, December 2005.

contended that FSIS was factually incorrect on this point because there was no country of origin labeling requirement at the time

There was no public activity on the proposed rule until April 18, 2006, when the final rule was transmitted to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) for its review under Executive Order 12866. Normally, the review for a major rule can take up to 90 days. But in this instance, OIRA cleared the rule in one day.[12] On April 20, 2006, PRC President Hu Jintao visited then-President George W. Bush at the White House where the final regulation was announced. The final rule was eventually published in the April 24, 2006 Federal Register.[13] The rule was very clear that products from Chinese poultry slaughter facilities were not eligible for export to the United States. The rule limited exports to fully cooked shelf-stable poultry products. The PRC could have started to certify plants under the rule beginning in May 2006. It chose not to do so. [14]

In the meantime, discussions continued between USDA officials and the PRC about extending the equivalency determination to Chinese poultry slaughter facilities so that the PRC could begin exporting processed poultry products of Chinese origin. On January 4, 2007, a news report from India revealed that a commitment was made by then-Undersecretary for Food Safety Richard Raymond that the PRC would be eligible to export processed poultry products from birds slaughtered in the PRC.[15] It would require another rulemaking to change the April 14, 2006 rule. Apparently, FSIS had already completed its equivalency determination for poultry slaughter facilities in June 2006 based on a 2005 audit, according to an August 2008 USDA

[12] Office of Information and Regulatory Affairs, Office and Management and Budget, "Executive Order Reviews Completed January 1, 2006 through December 31, 2006," Regulatory Information Number 0583-AD20.
[13] 71 FR 20867 – 20871.
[14] See http://www.fsis.usda.gov/PDF/China_establishments.pdf
[15] "United States to Allow Imports of Chinese Processed Chicken," Newswiretoday.com, January 4, 2007.

Office of Inspector General audit report. [16] That FSIS audit revealed that none of the four slaughter facilities visited would have been eligible to export to the United States because they did not meet our inspection standards. [17] A rule was never proposed. Even if a rule had been proposed, the OIG report also revealed that the Animal and Plant Health Inspection Service would have also prevented importation of poultry products of Chinese origin because of H5N1 avian influenza concerns.[18] But it is also incredible that FSIS was prepared to move forward with approving Chinese slaughter facilities to export poultry products of Chinese origin less than two months after it had made it abundantly clear in its April 24, 2006 Federal Register Notice that Chinese slaughter facilities did not meet our standards.

In two successive fiscal years, the U.S. Congress passed prohibitions on the expenditure of funds by the USDA to establish or implement a rule to permit the importation of poultry products from the PRC.[19] To its credit, this Subcommittee has been especially engaged in this issue from its inception. Many of you were here in 2006 when Congresswoman DeLauro, Congresswoman Emerson and former Congressman Virgil Goode expressed their opposition to USDA officials about moving forward with the 2006 rule.[20] During the mark-up of the FY 2007 Agriculture Appropriations bill, an amendment was unanimously adopted in Subcommittee to prohibit the use of funds to implement a rule to permit the importation of poultry products from the PRC. That provision never made it into law because an omnibus continuing resolution was passed that did not contain the provision. It was not until December 2007 that the prohibition

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[16] Office of the Inspector General, USDA, "Audit Report: Follow-up of Review of Food Safety and Inspection Service's Controls Over Imported Meat and Poultry Products," Report No. 24601-08-Hy, August 2008, p.15.
[17] Food Safety and Inspection Service, "2005 Audit Report for China," http://www.fsis.usda.gov/OPPDE/FAR/China/China2005.pdf
[18] Ibid., p. 16.
[19] H.R. 2764, Division A, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act for FY 2008, Section 733; H.R. 1105, Division A, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act for FY 2009, Section 727.
[20] Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations, U.S. House of Representatives. Hearing transcripts for February 15 and March 8, 2006.

became law for FY 2008. From May 2006 until December 2007, the PRC failed to certify any plants and FSIS chose not publish a proposed rule to permit the PRC to export processed poultry products of domestic Chinese origin to the United States. After December 2007 the agency was prohibited from doing so.

The Beef for Chicken Swap

Lurking in the background has been a trade issue that seems to be tied to the equivalency status of the PRC for processed poultry products. The PRC has refused to import beef products from the United States because of concerns about bovine spongiform encephalopathy (BSE) or mad cow disease. However, the PRC position is tempered when they attempt to link beef imports with poultry exports to the United States. In fact, the Chinese press reported just before the April 2006 visit by President Hu Jintao that a beef for chicken deal was being negotiated. In fact, there was an April 12, 2006 article that appeared in *China Daily* entitled, "Chinese Poultry to U.S., U.S. Beef to China" that strongly suggested that a quid pro quo agreement had in fact been struck. While USDA officials have stated that no such understanding was ever reached, opening up beef trade with the PRC remains a high priority for the USDA.

Some of our domestic agribusiness trade associations seem to think that there is linkage between the status of poultry imports and beef exports. The National Cattlemen's Beef Association has been very vocal in pressing for a removal of the ban on the importation of processed poultry products from the PRC because they view it as an impediment to the export of U.S. beef to the PRC.[21] Trade should not trump public health. While the PRC might view this

[21] National Cattlemen's Beef Association, "Agriculture Appropriations Bill Could Impact U.S.-China Trade," Cattlemen's Capitol Concerns, June 25, 2009.

as a quid pro quo, the welfare of U.S. consumers should not be sacrificed so that we can open up new export markets.

The Chinese Food Safety System Today

The food safety system in the PRC is in disarray. Their own government officials admit that openly. In March 2009, at the unveiling of their new food safety law, officials in the PRC Health Ministry described the food safety situation in their country as "grim, with high risks and contradictions."[22] The new law, which took effect on June 1, 2009, is designed to address the problems that arose from the intentional contamination of the Chinese powdered milk supply with the industrial chemical melamine during the summer of 2008. While the outbreak of illnesses associated with this contamination was not made public until September 2008, illnesses began to surface in May and June – just before the Beijing Olympic Games. According to PRC officials, over 300,000 Chinese citizens were hospitalized with acute kidney disease and 13 infants died from consuming the contaminated milk powder. Because milk powder is used in various baked goods and candies, hundreds of products were impacted that caused some countries, including our own, to issue recalls of scores of Chinese food products that had been imported.

Other imported food products from the PRC have been the source of recalls, import alerts, and detentions. Since January 2009, the FDA has stopped 545 shipments of Chinese food items that fall under FDA jurisdiction from being imported. Among the reasons cited: filth; illegal animal/veterinary drugs used; suspected contamination with melamine; unsafe food additives; unsafe color additives; lack of labeling; *Salmonella* contamination; *Listeria*

[22] "New Law Fights Grim Situation in Food Safety," Shanghai Daily, March 3, 2009.

contamination; packed in unsanitary conditions; unsafe pesticide residue; poisonous; unfit for food; and failure to register a food process.[23] In addition, there are currently twelve FDA Import Alerts for various Chinese food products that place severe restrictions on the importation of those items. There have been several U.S. recalls of imported Chinese food products, such as seafood, candy, baked goods, and pet food ingredients in recent years.

The food safety track record of the PRC is not good. We should wait to see how their new food safety law works and whether the government of the PRC can enforce it before we allow them to export any more food to us. We believe that the PRC equivalency approval process was flawed and that the process should start anew. This should include revoking the April 2006 rule.

Thank you for your attention and I will be happy to answer any of your questions.

[23] Food and Drug Administration, "Import Refusals for China," January –May 2009, http://www.fda.gov/ora/fiars/ora_import_country.html

Ms. DELAURO. Thank you very much, and you all very much.

If I may start, I would like to, Mr. Brosch, ask you a question.

Mr. BROSCH. Certainly.

Ms. DELAURO. First of all, I am just reading your testimony and you say we are here to advocate that Congress allow the determination whether poultry from China is safe, meets U.S. requirements, to be made in the same way that decision is made for our domestic product and for product from every other country, through risk assessment, comprehensive science-based approval processes that have been established under our laws and regulations. I concur. I agree with you, and I applaud the commentary.

Further in your testimony you say, Imported food is expected to be subject to the same rigorous standards. USDA has a long successful history of ensuring the safety of imported meat and poultry through a stringent, comprehensive process by which the Department must determine that an exporting country's inspection system is equivalent to the U.S. system before approving that country for exports to the United States. Beyond that, any plant seeking to export meat or poultry to the U.S. after this equivalency determination has been made must demonstrate its compliance with U.S. requirements. This approval process can take many years, and it should. It is the way USDA protects the American consumers from unsafe products.

You go on to talk about the approval process, which is rigorous.

Let me ask this question because there was a declaration by USDA of equivalency with China. But this is what was in the inspector's reports. And while you can't read anything that is up there, but you have at your desk the inspection documents.

Mr. BROSCH. This document?

Ms. DELAURO. Yes. It is a summary of the document which I believe is worth reading. This is what the auditor found. This was for four processing plants. Keep in mind the notion was that there would be between 10 to 25 processing plants in China. So this was four processing plants that China selected. They selected the processing plants and, quite frankly, the three slaughtering plants. We didn't go in and randomly select. They selected the plants for us to look at.

Sanitation control. In one establishment during pre-operational sanitation, grease, blood, fat. Pieces of dried meat and foreign particles were observed on product contact areas of conveyer belts and plastic containers. In one establishment, over product dripping condensation was observed in several areas.

In two establishments, edible and inedible containers were not segregated in the cut-up area.

In three establishments there was inadequate light at the reinspection stations.

In one establishment, tables were missing at the inspection station.

In three establishments, the conveyer belt used for edible product transfer had several deep cuts.

In one establishment, a rusty pipe with flaking paint was observed over the exposed chiller.

In one establishment, product contact areas were continuously wiped off by a dirty cloth that was not cleaned.

In one establishment, non-food contact surfaces of processing tables were observed with heavy grease in the raw meat area.

In two establishments, employees designated the floor duties were handling edible product duties.

Slaughter processing controls. In one establishment, monitoring activities were not adequately addressed in the HACCP plan.

In one establishment, generic E. coli testing on the whole birds was not being performed.

In one establishment, no testing for salmonella species on whole birds was performed.

In two establishments, there was no pre-chill or post-chill operation performed by the establishment employees or inspection service.

Now, there was, based on this audit, a determination and a declaration of equivalency with U.S. standards. Now if in the United States, Georgia, Iowa, an inspector went into the plant, in inspecting U.S. plants, and found—I could repeat them, but I will not—if they found all of these circumstances, would they be declared safe in the United States?

Mr. BROSCH. Of course not. They would be delisted.

Ms. DELAURO. They would be delisted. Okay.

Now, I am all—this is science, this is science. This is not ad hoc legislation. Science. But there was a declaration of equivalency based on these findings. Your comment, just to say back to you, in the United States they would have been delisted.

Mr. BROSCH. Yes.

Ms. DELAURO. Where do we then provide the same standards that we ask of U.S. plants, we ask of foreign plants?

In addition, I might add—I want to talk about—I believe in what the U.S. domestic market is doing. And I do have here the U.S. Department of Agriculture, FSIS quarterly enforcement report from January 2009 through March 31st, 2009. And it says here on average with regard to compliance rate that it is 98.8 percent. So we are dealing with compliance. This is not compliance, nor is it equivalency.

Let me make one more point. The issue is why we have singled out. Your point here where you talk about the USDA approval process is exceedingly rigorous, and the approval process can take many years, and it should. Let us talk about the approval process here. Essentially if I take an October 2004 letter from the Chinese Government to Dr. Murano, and they were asking for poultry, domestic Chinese poultry to be let into the country, and I believe they asked at that time that we bypass any inspection process. Fortunately, that didn't happen.

But let's go from October of 2004 to—we are talking—what did you say, Ms. Hauter—June 1 of 2006, and a determination of equivalency in that period of time.

I would like to ask you why China was singled out for preferential treatment versus any other country. What is that, a year, 6 months, a year, 7 months, in terms of making that determination?

I have to make one more point to you, that during this period of time, and if you go back, this was, I think the rule was—the discussion about it was November 23rd, 2005, November 21st, was it

Detroit operation, Newark, Detroit? Newark. I will get the precise citation, in Newark Operation Foul Play. This was U.S. Customs that stopped a million pounds of poultry products smuggled in from China; smuggled in illegally from China.

At the same time, going back, June 2004, outbreaks of highly pathogen avian flu strains of virus found among poultry flocks in eight Asians countries, Cambodia, China, Indonesia, Japan, Laos, South Korea, Thailand, and Vietnam.

June 2005, more human and poultry cases of H5N1 influenza are coming to light in Southeast Asia. Human illness in Vietnam and the second poultry outbreak in China.

August 10, 2005, Chinese authorities say they have identified the virulent disease that appeared in Sichuan Province in late June. Sickened a suspected 212 people so far; killed 38.

Streptococcus suis, a bacteria in pigs. The 16th to 21st of January 2006, European Health and Consumer Protection Commissioner Markos Kyprianou will visit the People's Republic of China. He is interested in avian flu and human influenza.

I will just say that is the atmosphere in which all of these deliberations are being discussed. How we could have provided equivalency in this period of time, given what USDA auditors talked about, the amount of rigorous time involved in being able to declare a country equivalent, and the incredible health circumstances at that time when we should have cut off negotiations, in my view, and said we have to really take years to figure out whether or not we will allow chicken to be processed in China or slaughtered in China to come back here.

Mr. Brosch.

Mr. BROSCH. Thank you, Ms. Chairman.

I guess first of all I would say with respect to the smuggled poultry, the million tons, our Coalition or any company of course is not in favor of anything that would be smuggled or brought in illegally. We want things to go through the process. That is what this is all about. With respect to that, we are in total agreement with you. That was outrageous. What companies were involved with smuggling should have been brought before the law and punished for that. So we don't have anything to say about that certainly.

With respect to the sheets that you have put out here, I would just note that what you see here, I think, you know, you see a lot of bad situations, but you also see FSIS doing its job. What you have is FSIS out here, and they are observing and reporting all of these things. And at the conclusion of the pages, they are saying, if approved, this establishment—the equivalency was approved, this establishment would be delisted. And they say that on the second page and on the fourth page.

Now, we have circumstances where we have approved other countries or we have approved plants in our own country who get delisted, because even though the decision has been made on the equivalency of the system, something goes awry and something goes wrong. And our people are on the spot, and they take care of it.

For example, the United Kingdom right now has been approved but it is currently suspended. And it is suspended because our in-

spectors, doing their job, found something wrong, and they took care of that. And they now have that suspension.

We have companies in this country that are suspended. We regularly have companies—and I am sure Dr. Raymond has told you about that on many occasions—from other countries where those plants are delisted on a regular basis, have to go through some process to get back on.

So these are unacceptable situations——

Ms. DELAURO. But you went and—not you, but the agency—based on that data—and believe me, this was done in 2006. Our ban, the limitation, did not go into effect until 2007. Between 2006 and 2007, I don't know of any going back and saying that this has been corrected, that has been corrected. And, by the way, China never certified any plant during that period of time.

But this is not someone that you approved based on good data. This is someone that you approved on problems. Wasn't somebody who came through the process, you said it was okay, they had a problem, and then you addressed that problem. This was from the get-go. This was, day one, you knew of all of these difficulties.

Mr. BROSCH. Yes. Well, obviously, I left the Department of Agriculture in 1999, and I can't respond for the Department of Agriculture. I think those are questions they are going to have to respond to, your questions. But I can't answer that question.

Ms. DELAURO. And allowing a year and 5, 6, 7 months in order to do this progress, does that meet the standards that you have laid out in your testimony?

Mr. BROSCH. You know, I would have to know more facts to be able to say that. I mean, you have brought a lot of facts out here on the table. I haven't had a chance to discern those, "Here are the responses," I really can't answer that.

Ms. DELAURO. And you also—I just want to repeat your answer early on—if you found these circumstances in U.S. plants, you would delist them.

Mr. BROSCH. I would think they would be delisted.

Ms. DELAURO. Okay. Thank you.

Lori, Ms. Wallach, do you have a comment? Quickly, because I am well over and my colleagues are bearing with me. They will take me to task later.

Go ahead.

Ms. WALLACH. I just wanted to speak to what those inspections were about, because prior to the WTO and the change in the law, U.S. officials had to go into each plant and inspect and then decide that particular plant was equal to U.S. and certify that plant.

Now, under equivalence, under the existing rules that need to be changed of USDA, they do what is called a paper audit, where they look at what the system is supposed to be. But then the plant inspections go to whether or not it is actually being enforced or implemented.

So, particularly when you have a developing country that hasn't the budgetary or infrastructure or culture of enforcement, those inspections, when you see the catastrophe, are not just about whether or not the plant itself is approved, but rather it is the evidence of whether what is on paper is what is in reality.

So it was an abomination that that equivalence determination was issued. And we thank the chairwoman from saving us for that, though it is a scary fact that it was necessary to intervene to stop it, which, in a way, gets to one of the structural problems that has to change, which is: It is not a matter of what would be delisted. We don't get to pick that. We can go in and audit and see repeated problems we don't delist, because our report from 2002 shows repeated problems in Brazil and Chile and other places. But they get to pick.

So it is the actual country, once you certify equivalence, it is the country that picks the plants. And so, it is not even that we would be looking at them like we used to once they had been picked as an okay plant to say they were no longer okay, which makes that set of disgusting information even more horrifying.

Ms. DELAURO. Uh-huh.

Mr. BROSCH. Just for the record, we don't import anything from Brazil. Brazil is not approved to ship to the United States.

Ms. WALLACH. That is not true.

Mr. BROSCH. Not for poultry.

Ms. WALLACH. For beef.

Ms. BROSCH. Not for poultry at all.

Ms. WALLACH. Right, for beef. Our report in 2002 looked at beef and poultry in the equivalence system. So let me clarify: Brazil was beef. And they had company-paid inspectors year after year, and we allowed it.

Ms. DELAURO. They do beef, they do mutton, and they do pork from Brazil, and not poultry.

Mr. BROSCH. Not poultry.

Ms. DELAURO. I just want to make one other point. I think it is important. These plants were selected by China for us to look at. Two of the four processing plants failed. Three out of three of the slaughtering plants failed.

When you deal with equivalency, we don't get to pick and choose what plants. The Chinese Government, the Brazilian Government, the Canadian Government, they pick the plants. We, in essence, lose our ability—we are supposed to do a yearly audit, assuming we do a yearly audit. We go back and we take a look. But we don't certify, we don't select the plants, we don't do the inspection of those plants.

Mr. Latham.

Mr. LATHAM. Are we going in order?

Ms. DELAURO. I thought you were representing Mr. Kingston. I am sorry. I thought that was the case, but it is up to you guys. You tell me what you want to do.

Mr. LATHAM. Okay. Thank you very much, Madam Chairman.

And welcome, the panel.

Some of the correspondence that has been shared with me and some of the testimony that I have read today, proponents of the ban have, in all intents and purposes, accused American farmers of putting sales ahead of public concerns, public health concerns.

And, in your letter, it says here, "I was disappointed to read that the producers of virtually all meat products in our Nation's grocery shelves would place a higher premium on the benefits of the mar-

ketplace than maintaining the safety of our food and protecting public health."

I am sure we are going to hear today that trade should not trump public health. And I will tell you, if you put yourself in the shoes of an Iowa farmer, there would be absolutely no disagreement with that, because only one food safety incident can put that farmer out of business.

And I will tell you that statements like that are absolutely offensive and to my constituents are very offensive. The idea, somehow, that they would place sales above the public health I think is shameful and has no place in this debate at all. Ensuring the safe food supply is absolutely critical to the success or failure of all of the agricultural economy. And I really ask people to stop painting farmers as the bad guys.

And it seems to me—and if you look at this, when you look at different initiatives that are here, whether it be the indirect land use, that farmers are, you know, the cause of all environmental problems, that there is in this Congress today a real war on agriculture and the family farm operations. And it simply is wrong, and it has to stop. And to keep painting them as the bad guys I think is, again, very, very offensive, as far as I am concerned.

I really wonder why, if proponents of the ban feel as strongly as they do about China's food safety, why haven't they supported a ban on all food products coming from China?

And it is really frustrating today that we don't have a representative here from USDA. This is what this is all about. We have no one here. We have gone through the whole spend bill this year, the ag appropriations bill, and not had any oversight into these agencies. I really wonder why they are absent here today. They should be here to defend themselves and provide information. And I have questioned, you know, whether we are doing any oversight, as far as the Department itself is concerned, with the funding that has already been put forth this year.

But I think a lot of us that represent agriculture and represent family farmers are extraordinarily frustrated when we hear them being blamed for the type of problems that are certainly in the system.

Ms. Hauter, you indicate in your testimony that the FSIS has a fairly extensive evaluation and enforcement system for meat and poultry products and that your organization believes that the process provides better safeguards for consumers.

Why don't you advocate a similar funding limitation on foods imported under the FDA jurisdiction?

Ms. HAUTER. Sir, we have supported a ban on all Chinese food products coming into the U.S.

And, just for the record, I would like to say that our organization works very closely with family farm organizations.

Mr. LATHAM. Such as? Who?

Ms. HAUTER. And I am actually married to a full-time family farmer on my family's farm 40 miles from Washington, D.C. So we would never make an attack on family farmers.

We work with the National Family Farm Coalition and all of its affiliates from several States, from the Alabama Contract Poultry

Growers Association. I can list—would you like me to list the groups?

Mr. LATHAM. No, no, that is fine.

How can you, you know, say—and this is horrible, all these findings. And I will note that they are back from 2004, the most recent one, 2005. How do we know that things haven't gotten any better, when you have the prohibition from doing inspections?

Ms. HAUTER. Well, sir, I, the past 2 years, had the opportunity to go to China and attend a food safety meeting. In fact, I will be going again at the end of September. And it is a trade show that is put on by the proponents of food trade. Dr. Raymond was there last year and spoke at the conference.

And I had the opportunity to speak to any number of Chinese people about the food safety system, heard about the problems that the government is having from the government officials' own mouths, and, in fact, have lots of concerns about a whole range of products, especially organics.

And I think that we need to really look at the equivalency process again, and for all countries, not just China. Because I think China is probably the most dramatic example of problems, but I know that when we have looked at other countries from Latin America, even Australia, there are major problems—Canada.

Mr. LATHAM. But if you have the funding prohibition in place, how are you ever going to know, on a science-based inspection, whether or not there are improvements? Again, this is 4- and 5-year-old information. I mean, have they done nothing since then? We don't know, because we can't inspect them.

Ms. HAUTER. I think that we need to wait and see how many recalls we have on other products and what happens in China with food safety issues. I know that we are monitoring the Chinese press.

Mr. LATHAM. How are we going to know that if we don't have the ability, don't have the funding to be able to inspect it?

Ms. HAUTER. Because there are many very dramatic food safety problems that have occurred in China——

Mr. LATHAM. That were at the trade show?

Ms. HAUTER. Well, not that were just at the trade show. I think the melamine—the press. I mean, the melamine crisis was occurring when I was in China last August. The Chinese people that I spoke to were actually outraged, and I think that they are very concerned about their own food safety issues. And we need to give it some time to see if the government can become accountable to its own citizens on food safety and a range of other issues.

So, what is the rush? We have enough poultry products in this country. Why would we put our own citizens at risk just so that we can import processed chicken from China? I don't understand why that is such an imperative that we would actually risk our citizens' health.

Mr. LATHAM. Are we out of time?

Ms. DELAURO. Look, I went over——

Mr. LATHAM. I enjoyed yours though.

Ms. DELAURO. If you have another question, please go ahead.

Mr. LATHAM. Well, just kind of that point, in your testimony you said, "Some of our domestic agribusiness trade associations seem to

think that there is linkage between the status of poultry imports and beef exports." Are you questioning whether there is a linkage?

Ms. HAUTER. No, I believe there is a linkage when you look at the evidence. It is a quid pro quo. And I don't think that that is how we should make public policy decisions on the food that our citizens eat; that, so that we can export beef to China, that we allow imported pork products into the country.

Mr. LATHAM. Okay.

Ms. Wallach, in your testimony you talk about NAFTA and the WTO for the explosion of U.S. food imports that gives the impression that, you know, U.S. farmers are hurt by it. In fact, U.S. food exports have gone from $37 billion in 1991 to $115 billion last year. You know, you are saying that they doubled as far as imports. But doesn't that kind of counteract what, you know, you are saying about the negative impact of free trade?

Ms. WALLACH. Sir, the food import growth rate is 128 percent since NAFTA and WTO until the last set of data. And the food export rate is 86 percent. So it makes my point that the volume overall has gone up.

But the reason why the U.S. trade surplus in agriculture has declined—and, in fact, in 2005, the United States was a net food importer for the first time since 1955—relates to the fact that our import growth is expanding much more quickly, almost double, than our export growth.

Mr. LATHAM. And why is that?

Ms. WALLACH. I would argue that, under the rules of the trade agreements, a lot of production, particularly processing—because if you look in the processed lines of tariff lines, that is where the biggest increases are—has shifted offshore to take advantage of lower wages and lower safety standards. So, with the equivalent measures, the producers don't have to meet our standards anymore.

Mr. LATHAM. But artificial trade barriers of products wouldn't have any effect on that?

Ms. WALLACH. Well, the areas where we are basically still exporting a lot are areas where, theoretically, that would be the case still, in grains. But in the processing and the human value added, more expensive, additional value added goods is where we are now becoming a net importer. Which gets to—if you look at the tariff lines, it looks like the agribusiness companies are shipping the human cost to cheaper venues.

On your question of how we could ever find out if things are better in China, I mean, practically, an approach would be—and this gets to the problem with the existing equivalency rules at USDA. Right now, if there is a problem, the equivalency isn't listed, and you go back and reassess.

So what I would suggest is that, for instance, the past determination, which seems on all grounds to have been done terribly—even if the rules were right, it seems pretty slipshod—to be to lift that assessment and to start over, number one, to get the underlying rules correct, so that, for instance, we go back to a system where the U.S. inspectors picked the plants. There is nothing in the sanitary and phytosanitary agreement that would require us to give us that right. That would help, particularly in the culture of

a regulatory system like China that has so many problems in its own system. So that might be a way to try and make it work.

But also, you know, other elements of improvement, not the least of which would be to make very clear on the record that, to find equivalence, you need to find the system really does provide the same level of protection in every regard, which is to say some places are going to have to clean up their act if they want to be able to send food here versus we just let it come in. And then you would go through the process, having gotten rid of the old equivalence determination, fixing the system, and then using the new system of determining equivalence to figure out if whether or not, in fact, practically, in this day, if things have gotten better. And under a proper system, you could find that food can come from China in a safe way.

It is an assessment that you have to do. I am skeptical because, with your colleague's grocery bag of delectables, I actually look at the country of origin labeling, and I avoid stuff made in China, food, that has any potential contamination, like the Mandarin sauce, et cetera. The dried stuff I am less worried about. But it is a pretty severe problem. I mean, if we have had staff who read Chinese, who read the Chinese press—because it is only when people start to die that you see in the foreign press coverage of the food safety problems—but it is endemic. I mean, it is like the jungle. And so if you can read the actual Chinese language press, there is coverage of horrible problems that just don't get bad enough to kill people all the time.

So it needs to be redone.

Mr. LATHAM. Okay.

Mr. Brosch, do you have any comments?

Mr. BROSCH. Well, I guess I would just reiterate what I said earlier, which is that we are not here to advocate for any particular result; we are here to advocate for a process.

And the process that we are here to advocate is the one that we have committed to, which is to allow each country to apply and to be evaluated on the basis of risk assessment and science. And to simply shut out one country seems to me to be inconsistent with the application that we have taken.

And I think that we owe that to all—now, if the decision is taken, that they are not sufficiently safe or their product doesn't meet our standards, so be it. But I think it is the process that we are here to advocate for.

Mr. LATHAM. All right. And I appreciate that, that no one is advocating that we need to bring safe products in here. You know, when we have funding prohibitions, we will never know.

Mr. BROSCH. Mr. Latham, in my testimony, my longer testimony, I mentioned—I think all of us can remember alar from years ago and its effect on the apple market. And I think it is a good example of the kinds of situations that our members, the members of our coalition, face, which is: The market is sensitive to these kinds of issues, so if you have a situation where there is an unsafe product on the market, the consumers are not sitting there saying, is that an apple from Washington State or is that an apple from France or wherever. They are saying they are afraid of apples.

So it is in our interest and all off our interests, probably more than anyone else's, not only because we are consumers and our children are consumers and our relatives are consumers, but also our businesses depend upon the perception of the American public that things be safe.

So we are very much with the chairwoman. We are very much with everybody here who has indicated their interest in safety of food product. But we think that there is a process that we have put into place that is part of our law for everyone else, that is part of our international obligations, and that has to be respected.

Mr. LATHAM. Right. And that is exactly why I find it very offensive when people make statements that the producers put marketplace over safety. Because that is simply—if you want to be out of business tomorrow, if you are—and to sell an unsafe product to what is probably your own family knowingly, for profit, that charge is—I am very frustrated by it and I am very offended by it. And I appreciate it.

Mr. BROSCH. I have the privilege of, besides working for this coalition, of working very regularly for the National Milk Producers Federation, and I go to their meetings. I am their outside general counsel. And I can tell you, at the meetings I have had in the dairy industry, I have heard more discussion among dairy farmers about this issue, how they can improve, how they can be more safe, somatic cell count, everything else. Because they are living right there, they are living right there in those circumstances. They don't want to live in something that is unsafe.

So I applaud your statements. I think that is the way farmers and food industry people think in this country; it is just not well-known. And, unfortunately, they get a bad rap.

Mr. LATHAM. Right.

Thank you very much.

Ms. DELAURO. Let me just, before I yield to Mr. Sanford—because my colleague from Iowa is referencing the letter that I wrote to the groups who wrote to me. And I would ask him to take a look at the letter that they wrote to me and what they stipulate.

And now, we are not talking about—and, Mr. Latham, you began talking about small farmers. Well, as far as I know, Cargill, JBS, Monsanto, Tysons, and several others, these are not exactly small farmers.

I have a high regard for small farmers. I spent a lot of time and have for almost 15 years on this subcommittee, not as its Chair but as a member of this subcommittee, and now as its Chair, providing enormous resources in order that small farmers might be successful.

And I have dairy farmers. And not that long ago at the Greenbacker Farm in Wallingford, Connecticut, and trying to find out how it is, because of melamine in China and children dying in China, that the Chinese people do not want to drink milk anymore, whether it is milk produced in China or milk produced in the United States. And our folks are having a very difficult time with that because of the drop.

So this is not about small farmers. This is about large agribusiness and large producers, who have a very big interest, and some, quite frankly, who years ago when this first came out—and

the National Chicken Council—who said this would be the wrong direction to go in. Tunes have changed.

Mr. Bishop.

Mr. LATHAM. Would the gentlelady yield just a second?

But this letter you write, I mean, you are talking—the response is to Cattlemen's Beef Association, Chicken Council, Pork Producers, the Turkey Federation. You are accusing them of putting the sales or trade above food safety. Those are all the small farmers in Iowa and throughout——

Ms. DELAURO. I am saying that food safety is to be uppermost. It is good to think about trade. There are ways in which we are going to be able to deal with this.

And I would like to ask Mr. Brosch, if I can: Ms. Wallach and Ms. Hauter, both talked about a way to start over, to revoke the current rule, start again, so that we have an inspection process and can move forward to see—in fact, I think it is clear, based on evidence. I am not a scientist. I take advantage of the science that the agency has in place.

Should we start this over again?

Mr. BROSCH. Are you talking about the USDA rule?

Ms. DELAURO. I am talking—yes.

Mr. BROSCH. Well, I think that is a question—the USDA and you can have that discussion. I don't——

Ms. DELAURO. You don't have an opinion on whether we should do that. Do you have an opinion on whether we should start over? You represent all of these groups. What——

Mr. BROSCH. Well, obviously, we are going to have to start over or start at some point, because the current legislation has blocked any movement on a rule for a number of years now. So I don't know where we are at here, given that situation. So I think that discussion would have to have USDA in the room.

Ms. DELAURO. Fine.

Mr. KINGSTON. If the gentleman would yield, basically you would have to start all over. Because if you jump in halfway, you have to make sure it is from A to Z safe. And so you sort of have to start all over, by definition.

Mr. BROSCH. Well, it looks to me like—the data, for example, that has been presented here today is from 2004. That seems to be a bit dated. I would think——

Ms. DELAURO. That is the date, that is the time period on which equivalency was determined on that data. Between 2006 and 2007, there wasn't any visits or re-audits or anything of the current state of affairs, in terms of correcting deficiency.

Mr. BROSCH. I am not offering any criticism, Madam Chairman. I am just saying, in response to your question whether you would have to start all over, since this process has been essentially blocked by legislation for several years—and this data goes back to 2004. I don't know what the newest data is, but of course you want to make your decisions on current data. So USDA would have to do something of that sort. And, again, we don't have USDA in the room, so I would think——

Ms. DELAURO. I want to address that again. I want to address that again. There is no individual at USDA who was head of FSIS.

That is not your problem. It is a problem for us, because we can't get the appropriate person up here to be able to ask questions.

Clearly, as well, this was not the USDA that made this determination. It was a prior USDA. So we are waiting very patiently for the new head of FSIS, and then, boy, do I have a series of questions for that new Secretary.

Mr. BROSCH. Again, Madam Chairman, I wasn't offering any criticism of your comments. I was simply saying that, in order to answer this properly, somebody from USDA would have to be in the room.

Ms. DELAURO. Sure. Okay.

Mr. Bishop.

Mr. BISHOP. Thank you very much.

Let me join Mr. Latham and Mr. Kingston, Mr. Brosch, in suggesting that I think it is obvious that safety has to be first and foremost for our producers, for our farmers, for our processors, for our wholesalers, and for our retailers. Because, obviously, if the consumer feels that the food is not safe, they are not going to buy it. And if it is not bought, it means that all of you, everybody in that process, is going to suffer. And, Mr. Brosch, I was happy to hear you suggest that, perhaps, as Mr. Kingston suggested, we do have to start over with USDA to make sure that our food is safe.

But I want to just ask this question to all of the panel members. Getting back to Chinese chicken, according to the Chinese Government, their poultry industry complies with the international standards and practices with respect to their inspection of meat and poultry and that it currently exports poultry to other developed markets, including Japan, the European Union, and Switzerland.

I want to ask the panel members, all of you, if you will, to your knowledge, is there any evidence that those other developed nations who currently import Chinese meat and poultry products have encountered or experienced any significant issues or problems with those products that they have imported from China?

Mr. BROSCH. Well, Mr. Bishop, I asked that question just the other day in preparation for this. My understanding is that the current volume of poultry shipped from China to Japan is about 10,000 tons a month, which is a fairly significant volume. And, for the European Union, which I believe approved shipments from plants about a year and a half ago, my understanding is, for the first half of this year, there is something on the order of 1,500 tons total to Europe, which is not as big a number.

I asked about the question of food safety problems. I am unaware of any. I mean, I don't have comprehensive knowledge, but I am not aware of any, at this point, in those markets. But that is all I know at this point.

Mr. BISHOP. Ms. Wallach.

Ms. WALLACH. I tried to figure out the same question. I found two things, although I am still snooping around.

One thing is that, for Japan and Europe, which is the information I could find—I couldn't find out Switzerland—the countries have inspectors from their own food safety systems in the plants so that——

Mr. BISHOP. In China.

Ms. WALLACH. In China. And so they won't rely on the Chinese system, and they run a separate line—there is a day when the guy from Japan is in a particular plant, and that is the day that they can actually run the line——

Mr. BISHOP. Are they signatories to the same agreement that we are?

Ms. WALLACH. Yes. That is how they have interpreted it. That was my reference to the notion that there are different ways to interpret how you can do it. So that is number one. That is how they have interpreted making sure it is safe; they put their own people there.

And so then they have to live up to the actual standard, and they are applying their standard. So it is, like, a different day. And, apparently, the way they staff it is they have the inspector moving around. There is a particular day or 2 days that it is running the Japan line, and then it goes back to what we would otherwise have to accept.

The second thing is that they have a much higher rate of reinspection at the border, which is the second thing I found out. Japan and Europe, with respect to high-risk foods, which they characterize a lot of meat and poultry products from China, inspect between 50 and 70 percent. That is, you know, numerous times over what we do, which is, what, around 11 percent now.

So those are the two things I could figure out of how they are dealing with the problem.

Mr. BISHOP. So you would then suggest, I would imagine, that we look at the approach that they take to try to make sure that ours is safe.

Ms. HAUTER. Yes, the EU has restricted poultry imports from one region of China that doesn't have avian flu. And China has a very decentralized way of addressing inspection issues. It is not centralized in the same fashion as ours. There is a lot of discretion at the regional level.

Mr. BISHOP. Through your research, have you determined also that they have the people on site?

Ms. HAUTER. Yes. And they do microbiological testing, as well.

Mr. BISHOP. On site?

Ms. HAUTER. Yes.

Mr. BISHOP. And we do not?

Ms. HAUTER. No. I mean, one of the things that we would like to see is, rather than our current recall system, that we actually do testing on site and we get the results immediately, so that we don't need to have recalls.

Mr. BISHOP. So you are suggesting a more proactive approach?

Ms. HAUTER. Yes.

Ms. WALLACH. When I was discussing generally revisiting our rule for finding equivalence and I had mentioned that other countries, under the same exact international trade rules, have done different things, some of the best practices have been things like a more prophylactic "let's avoid the stuff coming in" versus "we pick up what is left later," but also only this notion of actually not only picking the plants but having your people there and having your standards being applied by your people.

Mr. BISHOP. How do you feel about that, Mr. Brosch?

Mr. BROSCH. Well, I think USDA would have to respond to that better than I, because that is a question of resources. I mean, that may be a question of resources in terms of being able to put——

Mr. BISHOP. Well, we are responsible for the resources.

Mr. BROSCH. Yes, sir.

Mr. BISHOP. But we could, with resources and with direction, force them to do it. But I want to know how you feel about whether or not that is something that we ought to do.

Mr. BROSCH. You know, that really——

Mr. BISHOP. How you think that the processors in our country would feel about making sure that they had on-site inspection——

Mr. BROSCH. I will be honest with you, Mr. Bishop. I don't know. I really don't know.

Ms. DELAURO. Could you yield for a second, Mr. Bishop?

Mr. BISHOP. Yes, ma'am.

Ms. DELAURO. I just wanted to ask another question.

In our process before, because earlier in your testimony or in commentary, that when we were equal to, did we have on-site inspections? What did we have in the past, before the rules changed, in terms of some of the facilities? What kinds of inspection regimen did we have, in terms of determining equivalency and those kinds of things?

Ms. WALLACH. Even then, we didn't have people in all the time doing continuous on the line that was the U.S. line.

Ms. DELAURO. Right. But what we do have——

Ms. WALLACH. We had USDA inspectors go first pick the plant, decide if they met our standards. And then they did audits. There were complications. I am not saying that was a blessed system, but that sure as heck was better than the current system.

Now, China and Europe have gone one better, and they have actually figured out ways—and, by the way, this is also—I am sorry, Japan and Europe have gone one better. And this is not only in China, which is how I threw China in the wrong part of the sentence, they do that also in Latin America. So if you basically want to send food there, they make sure that it is going to be safe.

And, as I understand it, but this—I couldn't get to the bottom of it, contradictory information—they actually have user fees as part of how they—because why should—if the company on site should have some contribution to how—and it is a sum fee, the way some of the new food safety bills have been, where you are not paying for a service which you could capture but rather register, you pay a fee, and then that is part of getting the inspection.

Mr. BISHOP. Mr. Brosch, do you have some further information?

Mr. BROSCH. Mr. Bishop, I wanted to consult with Mr. Ronick from the National Chicken Council because I felt bad about not responding to your question, and I wanted to get a little bit more information so that I could.

In response to the question about how I would feel about having U.S. inspectors in plants overseas, the reason I think it is a complicated question is because we ship poultry—we, the United States—ship poultry to about 60-some countries. So we are talking about not just China, we are talking about Russia and the Ukraine and substantial numbers of countries and a substantial resource

issue that you would have to address. But, certainly, we are cognizant that it would be an issue.

But the second is, we do import meat and poultry from a number of countries now. I have the list here. I think it is about, oh, maybe 20 or 30 countries, something like that. And then we have this question about whether or not we are going to have 20 or 30 different inspectors from 20 or 30 countries in our plants, as well. Because they may say, "Well, you know, you send inspectors over, we will send inspectors." And maybe that——

Ms. DELAURO. 98 percent compliance.

Mr. BROSCH. Well, I know, Madam Chairman, but that is something we would have to consider, that is something we would have to think about and how that would work itself out. But, you know, we are talking about a very complicated problem.

Mr. BISHOP. Yeah, it is a very complicated problem, but, at the same time, it is one that would be in the best interest—in order to lift the prohibition, it would be in the best interest of American consumers. It seems to me it would be in the best interests of our American processors if we had a level playing field across the globe.

Mr. BROSCH. It may be. I am just trying to give you the best information I know at the current time. And that may be a discussion that has to be——

Mr. BISHOP. And I want to be very helpful, because, you know, I have processors that you represent in my district. And I want to make sure that they are able to export, that we don't have this quid pro quo thing and the leveraging that apparently is happening. We want to level the playing field because we believe that you have the best products and that we have the safest, the highest quality, most economical anywhere. But let's demonstrate a level playing field.

Mr. BROSCH. Well, we appreciate your support, Congressman. We do.

Ms. DELAURO. Mr. Kingston.

Mr. KINGSTON. Thank you, Rosa.

Ms. Wallach, you had testified that we have $80 billion in food goods that are imported to the United States annually. Of the $80 billion, which ones do you feel safe with and which ones are you more uncomfortable with?

Ms. WALLACH. I, actually, on that question, being more of a trade person than a food safety person, though I am in the nexus, would defer to my friends at Food & Water Watch.

Mr. KINGSTON. Okay. Well, it came out of your testimony, the statistic.

Ms. WALLACH. Well, I can give you the general answer to that, which is the answer that is common sense, and that is from countries in Europe, from the European Union member countries, from Japan, the countries that have advanced food safety systems that have been invested in a lot, we are less concerned. Those might literally honestly be equivalent in certain respects to what we are trying to do, number one.

Number two, things that aren't subject to spoilage through long transportation, things that aren't temperature-sensitive. So, for instance, with chicken and the idea of what temperature you have to

keep to keep E. coli from growing, et cetera. Processed foods have more of a risk than those that are not processed, except for potential chemical contamination of pesticides, et cetera.

I mean, what I am saying—I am familiar with all of that. I am not familiar with the last data set. I haven't done a study looking at the last set of recalls except for China, which is a lot of the FDA recalls are China.

Mr. KINGSTON. Okay. Then let me ask the question maybe for both of you. Do you feel that there were politics involved in the approval of the USDA rule in 2006?

Ms. WALLACH. Yes.

Mr. KINGSTON. And that was Ms. Hauter's statement also. I had wondered, since Dr. Raymond is here, to put him on the spot and the whole committee—I feel like Perry Mason. Why don't we pull him up here? And could we swear him in and ask him? You know, he is a freelance guy now. Could we ask him if he felt pressured? He might choose this moment to run, go outside, and make a phone call. Is that—can't do that?

But I think it is important that we have—yeah, I think we should have him come back. Because I am not sure that that is an accurate statement. I am not sure that it is inaccurate. I will say that trade agreements do tend to have politics involved in them. However, I wouldn't think the USDA would put food safety secondary to trade for the myriad of reasons we have already discussed.

But what I am also concerned with, Ms. Wallach, is, again, having voted against GATT, WTO, NAFTA, most favored nation status, you know, you now have cream in the coffee, and you can't separate it.

And we are at $80 billion in imported food. Are we not looking backwards, are we not sticking our head in the sand by saying, let's put this band in place without letting the science rule the day and without letting the process move forward?

And the reason why I say that is, if you look at CAFTA, which I think your groups were against—you have been critical of CAFTA, which is fine—but it has been in effect for 5 years, and not one of those countries has been approved to import food to the United States. Chile is still, I think, even though finally we had a trade agreement with them, only 2 years ago have they been approved for meat. And, so, you know, that is the process at work.

Rosa had listed off a myriad of products which the FDA pulled off the shelf in February of 2009. Is that not the system at work? Is that not the healthy thing? Do you want to—well, I don't know if you want to talk or not. You are welcome to. We are family here.

Ms. HAUTER. Okay, I will go.

It is what basically is being caught. And a lot of the contaminants that are being caught may be things that make people sick today. But there are other contaminants that, on a long-term basis, could be very detrimental to people's health.

And I think we need to look at our globalized food system generally and what it means. And it is a larger issue than just food coming into the country and safety issues. I mean, we were talking about small farmers earlier today and the impact of global food trade on small farmers, so that they are not able, basically, to com-

pete or to get their product on the market. So we have most garlic, for instance, being produced in China.

I mean, I think that there are a lot of reasons that we need to look at this system and that one of the reasons is food safety.

Mr. KINGSTON. Reclaiming my time, that is not really what the issue is here. I mean, what you are talking about is their inability to compete. That is a trade issue; that is not a food safety issue.

And, really, what I am trying to say is you and I lost on NAFTA and WTO, and we can't go back. Now, going forward, shouldn't we lift the ban? And, if there is a problem with USDA and politics, was that not settled in November of 2008?

Ms. HAUTER. Well, it is never too late to have the food safety regulations that we need and to look at a process that has been flawed from the beginning. And the equivalency process and the problems are a lot bigger than with China. And so, I don't think it is too late.

And I do just want to say that I spoke with Dr. Raymond at that food safety meeting in China that I mentioned. He gave a speech, and he was rushing out of the room. And I said, "Do you support Chinese chicken coming into the U.S.? Are we going to have Chinese processed chicken?" And he was on his way to a poultry conference in Beijing, and he said, "If I have anything to do with it."

And so, you know, I think there were politics, and I don't think that they were secret.

Ms. WALLACH. What we are talking about is going forward based on the current reality. And so, the reality is these trade agreements passed. We now have a much more globally integrated food sourcing system. But we don't have food safety systems and rules that actually are up to that reality.

Mr. KINGSTON. Well, we actually do for FDA, I think you would agree. Or maybe you would say FDA is totally flawed and we shouldn't be importing. I mean, do you——

Ms. WALLACH. There have been some improvements made with the bill last year, but, no, they are not actually in a situation where one should feel particularly safe about their import safety. I mean, you either——

Mr. KINGSTON. Well, let me ask you, on a scale of one to 10, 10 being safe, where are the FDA products, in your estimation?

Ms. WALLACH. Before I do the math on that, because it depends on the product—for instance, some of the seafood I would say is like a one—what is the bottom? One? Zero? I mean, some of the seafood is horrifyingly not safe.

And some of the other products, such as fruits and vegetables, I am less worried about.

Mr. KINGSTON. So you would support a similar ban on the FDA products?

Ms. WALLACH. Until we come up with a system to ensure they are safe? Yes, of course.

Mr. KINGSTON. So you feel like the USDA and FDA systems are so——

Ms. WALLACH. Dropping the ball.

Mr. KINGSTON [continuing]. That lifting this ban—is that a delay tactic, or is that a, "Hey, can we retool this?"

Ms. WALLACH. Well, you were out of the room, I think, when I proposed that what we need to do is basically revoke the current

rule, get the actually USDA equivalence determination policy right——

Mr. KINGSTON. Okay, let me ask you this——

Ms. WALLACH [continuing]. And then redo it to figure out.

Mr. KINGSTON. But, now, you are a lawyer. Isn't that against GATT? I mean, wouldn't that open up an entire can of worms, in terms of trade agreements, if we said, "Okay, we are going to change it"? I don't know.

Ms. WALLACH. What the WTO requires is that when a country petitions us, we go through a process to determine whether or not their system is equivalent, not defined, to our system. And then if we deny it without a basis, they can challenge that.

But if we go through a new process now and we have a basis, we determine through the legitimate process this is not up to snuff, or if you want to do it, here is what you want to do. That process—and, again, the determination based on the criteria we set—is what our obligation is. So if we started over, that is not a trade violation. We basically have the obligation——

Mr. KINGSTON. But we can't start all over with this ban in place.

Ms. WALLACH. Well, we have to get rid of the current equivalence determination. I mean, it was an abomination that it was made that way. And we need to start over and figure out if we can do one that is actually kosher, so to speak.

Mr. KINGSTON. To mix meat terms.

Ms. HAUTER. Could I add one thing? China never actually certified any plants under the April 2006 rule. And they could have because the ban wasn't in effect until December of 2007.

Ms. WALLACH. One other thing on the looking forward versus——

Mr. KINGSTON. Mr. Brosch? He has, kind of, been champing at the bit.

Mr. BROSCH. No, no, that is all right. I was just going to say, I am not sure that that point supports the idea of banning. I mean, what that basically says is that China didn't feel that it could certify any plants. And that seems to be part of the process——

Mr. KINGSTON. That would be like the CAFTA countries.

Mr. BROSCH. Yeah. In fact, we have that situation——

Ms. DELAURO. Why? Why couldn't they certify?

Mr. BROSCH. Well, they took a look at what they had, and they decided they wouldn't meet our standards, and they didn't certify them. If we have a plant——

Ms. DELAURO. They thought they couldn't, but we thought they could. Is that right?

Mr. BROSCH. I don't think that had any—the question was whether they had a system in place which seemed to be equivalent. And the question is, that doesn't presuppose that you can certify a specific plant under that. You may look at the plant and say it is not up to snuff, we can't do that. And we have had lots of situations like that. There are two steps to this.

Ms. DELAURO. So, because of that, I mean—excuse me, Jack—we should then allow this to go—because they didn't feel that they were up to snuff or they didn't have a system in place to deal with this, then we should allow it to happen. We should allow it to happen. I mean, that is a little bizarre here.

Mr. BROSCH. Could I make one statement?

Ms. DELAURO. Could I just make one statement? I don't understand, as well as that, this was a prelude. I mean, ultimately, as in my understanding—and I have a concern about this with regard to our domestic industry, and that is that China's ultimate goal is, really, they want to get a domestic Chinese poultry, the ability to export that into the United States.

And, in fact, there was an equivalency determination based on slaughter, but they had to backtrack on that given the unbelievable conditions. But all of the press commentary at the time was that we were on our way to looking at—the process piece was a prelude to the domestic Chinese poultry coming into the United States, which would, in fact, mightily compete with our small producers, the way it has with our seafood industry.

Mr. KINGSTON. Well, but that gets back to trade and deviates from safety. I mean, if they can compete against this garlic thing, it is not a safety question; that is a trade issue.

But Ms. Wallach is now champing at the bit.

Ms. WALLACH. Just factually, both Honduras and Nicaragua are determined equivalent, I believe, for meat, not for poultry. But they are both on the list. So those are your CAFTA countries. They are actually determined equivalent.

Mr. KINGSTON. Then why aren't they importing?

Ms. WALLACH. That would be a Tony question, about what in particular. He is a meat man.

But on the question going forward versus looking back, I mean, we have a system of rules; that is the WTO's non-tariff barrier rules. We have now had 15 years to see how they work. And even when this was negotiated, I don't think anyone contemplated we would be as integrated as we are now.

So taking the incoming data of how it is working, different countries have done different things to make it so that they can have the benefits of trade and still have safety. So you have, for instance, the European Union and Japan doing their in-site inspection thing. You have different countries that have just said, "We can't afford it; we are not going to certify as equivalent." There are a lot of countries that have denied equivalence determinations.

We need to keep up with the times.

Mr. KINGSTON. So if we had, say, an amendment in committee that said we would have a system similar to Japan, you would be comfortable with it?

Ms. WALLACH. I would like to look at specifically what you had in mind with the details, but I would suspect we would be a lot more happy than that than our somewhat what appears to be a blinded dartboard approach.

Mr. KINGSTON. I know I am way over.

Ms. DELAURO. No, we all are.

Mr. Hinchey. And then Mrs. Emerson.

Mr. HINCHEY. Rosa, thank you very much for—this has been a fascinating experience. And it is fascinating primarily because it is so important. I mean, it is something that is terribly significant, and important and significant to all the people of our country and a lot of other people around the world. So it is important for us to try to understand this better and to do whatever we can to make it more effective.

We are importing and exporting food materials. Is there any clear understanding of the rationale between exports and imports of specific elements of the food? In other words, we are importing poultry, but we are exporting poultry. Are we exporting more than we are importing, or is it the other way around?

Mr. BROSCH. Well, I can answer that. We are the largest exporter of poultry in the world. We export about 3.3 million tons a year.

Mr. HINCHEY. Yes, that is what I thought. So the fact of the matter is that we don't really have an internal need to export poultry. We produce all the poultry we need.

Ms. WALLACH. To import it.

Mr. HINCHEY. And more, actually. We are exporting a lot of it.

So much of these trade relationships that we have and these so-called free trade agreements that have been put into play over the course of years, particularly the most recent, fairly recent ones, over the last couple of decades, say, for example, are a little longer even, are focused on the level of profits that can be made by the people who are engaged in these trade operations.

So the trade agreements that we have are not really trade agreements any longer, even if they ever were. They are really investment agreements now. They are so-called trade agreements which encouraged the investment of finances out of the United States in order to maximize the profits that can be made by the importation—manufacture or creation, in some way, and then importation of those materials from those other countries here into the United States.

So, apparently, based upon this conversation here and your brilliant answers to these questions and intriguing answers to these questions, it is pretty obvious that that is the same kind of thing that is happening here.

Who are the major corporations that are importing food from other countries, particularly now, say, China? What are the names of the major corporations that are involved in the importation of food, poultry and other food, from China to the United States?

Ms. WALLACH. Well, right now, no poultry is being imported from China.

Mr. HINCHEY. Pardon me?

Ms. WALLACH. Right now, no poultry is being imported from China, thanks to the intervention of the committee.

Mr. HINCHEY. Okay. Who was doing it before it was excluded?

Ms. WALLACH. The firms that I understand were interested in having this capacity and were looking towards China included Perdue and Tysons. Those were the two U.S. companies who were seeking this equivalence determination for this particular commodity in that particular country.

If you look more broadly, you will see that Cargill, Archer Daniels Midland, and a couple of other of the major processors have used the trade agreements to relocate processing offshore to lower environmental health, OSHA-type standards and lower wages and have set up in a variety of other countries——

Mr. HINCHEY. Yes.

Ms. WALLACH [continuing]. To send back to the U.S. market.

Mr. HINCHEY. Yeah. Well, that is exactly the point that I am making. We are dealing with a situation here that is not in the

best interests of the people of the United States or people of other countries, as well. It is in the best interest of corporate profits for people who are in the process of manipulating these trade agreements for their own benefits. That is basically what we are dealing with here.

What are the food imports that are coming in from China right now? Any?

Ms. HAUTER. There is a wide range, a long list——

Mr. HINCHEY. Long list. Okay, who are the corporations that are involved in that importation of those long list of foods from China? Do you know offhand?

Ms. HAUTER. Not offhand. Major seafood—we can get that list to you.

Mr. HINCHEY. Okay. Okay. I would like to see it, because that seems to me what is really happening here. And it is intriguing why our country is allowing or even encouraging these kinds of things to take place.

Ms. WALLACH. I think when you look at the trade agreements, there are different sets of rules to consider. The investment rules have to do with those investment and competition questions and offshoring. But then, in addition, the sanitary and phytosanitary rules have to do with the food safety issue. So, even as Mr. Kingston described, you separate out what is the trade issue, you also have these food safety rules in the trade agreements that limit your domestic food safety enforcement capacity and standards.

So not only do you have the investment rules taking away a lot of the risks and costs that used to be associated with relocating to a poor country, but then you reduce the import safety you can apply, so that even if you weren't looking at the economic issue, you now have also the penalty on the safety side, which, from a U.S. producer perspective, is pretty catastrophic.

Because if you are the actual grower, the farmer, the rancher, as compared to the agribusiness company who is the processor, and you actually are going to produce, you know, for instance, the milk, when there is a crisis someplace internationally, it is the desire and the demand for the actual commodity that crashes.

And so it is the actual producer that gets clobbered by what is sometimes a greedy investment decision by the processing firm that then exploits the holes in the rules that they helped write in the trade agreement that limit the ability to implement the same domestic standards on imports.

Mr. HINCHEY. Yes. Exactly. Right.

Ms. HAUTER. From USDA's own reports on value of U.S. food imports from China by category, juices and products of fruits and vegetables are 24 percent. In fact, most apple juice is now produced in China, not in the United States.

Food ingredients and preparations, 8 percent; fruits, vegetables, and nuts, 10 percent; and fish and shellfish imports account for 41 percent of value of food imported from China.

And Food & Water Watch did a report on food safety violations of fish, where we found that only 1.3 percent of fish coming from China, which is about 32 percent of the fish that we get into this country, actually was inspected.

Mr. HINCHEY. Well, again, very interesting. And this is something, obviously, that we have to deal with, both from the perspective of the agricultural operation here and the way in which it interacts and interrelates and imports from other countries and the Food and Drug Administration and other aspects of the responsibilities of the Federal Government overseeing these kinds of operations and activities, which are not being handled effectively. They are being handled very poorly.

I mean, one of the things that you said in response to a question was that a lot of other countries take much better care and caution in inspecting the quality of food that is imported into their countries, whereas the importers here of food into our country are not engaging in that effectively. They don't seem to be too concerned about it. Their major concern is what is the maximization of the profits and not the maximization of the quality of the materials that are being imported.

Go ahead.

Ms. HAUTER. Sir, I wanted to add one other point from another USDA report on foreign agriculture service, and they are talking about the status of importing poultry. And they say that the regulatory agency in China states that it is not economical to do this. "Rising international broiler prices and international transportation costs, combined with the unfavorable exchange rate, make re-exports uncompetitive. The issue of cooked poultry exports to the U.S. remain's China's top market access priority for agriculture."

Mr. HINCHEY. Could I ask—or has it run out? Have I run out?

Ms. DELAURO. Yes, it has. Unfortunately we didn't start the clock, Maurice, but you did go over.

Mr. HINCHEY. But the clock varies from time to time, I see.

Ms. DELAURO. No, the clock has been no guarantee. That is why I let you just let it go.

Mrs. Emerson.

Mrs. EMERSON. Madam Chair, can I yield a minute—no, a second of my time—no, a couple seconds of my time to Maurice?

I just want to answer your question about what companies import Chinese products. Well, here you have smoked oysters, Haddon House Food Products, Inc., in Medford, New Jersey. Here are some nice smoked oysters for you.

Oh, and here are Harris Teeter mandarin oranges. You missed this at the beginning, so I thought I should show you. Harris Teeter oranges, these are imported from China by Harris Teeter.

Mr. HINCHEY. I am not interested in it from the point of view of being able to purchase it myself, you know.

Mrs. EMERSON. Here is JFC International, Inc. This is dried seaweed. This is another Harris Teeter product. Oh, and then the best one. The best one are cooked noodles in who knows what kind of water.

Simply Asia, and this company is called Simply Asia Foods, Inc, Union City Boulevard, Union City, California. So it is a lot of little companies.

Mr. HINCHEY. I wonder who those little companies are connected to.

Mrs. EMERSON. Harris Teeter probably does it on its own and other generic brands of groceries.

Oh, here is yet another one. Excuse me. Oh, this is just Harris Teeter. But, anyway, I just wanted to point out that I think it is probably fairly prolific. None of those are chicken products, by the way. There is some frozen shrimp and squid and octopus in that bag, too, but it is defrosted. I am not going to get it out. People may get too hungry. It is lunchtime.

Mr. BROSCH. Just mention, Mrs. Emerson, that in the chicken import and export trade there are lots of small niche businesses that are involved in the import and export business. It is not dominated by the large companies. They are largely the producers and processors, and most of import export is by smaller niche companies.

Mrs. EMERSON. Yes, I was going to make that point.

Regardless, you may not want to eat that stuff. I don't, but that is beside the point. But just to answer your question, since the bag of goodies was sitting here next to me, I thought I couldn't resist.

Mr. HINCHEY. I am not sure that is an answer to the questions that I was asking, but I think it is an interesting set of circumstances where you have a lot of small companies that are engaged in this. One of the questions is, who are these small companies, who are they associated with, what corporations are they entangled with and in what way, and what are the actual import-export circumstances that are going on?

All of these things are very important. I thank you for bringing up the little packages, but there is an awful lot more information that has to come out here.

Mrs. EMERSON. I am not disagreeing, but I am going to ask my question now. I am going to ask my question now, because I probably will run into yellow time here.

My first question goes to you, Ms. Wallach, and I apologize for having been gone for 30 minutes, but I had something else I had to do.

Obviously, you take aim in your testimony at the equivalency requirements in trade agreements and also are critical of USDA's administration of this policy, and you recommend that we act to require that only food that meets our safety standards is eligible for sale in the United States. And I think that appears to me like a goal of requiring other nations to harmonize their regulations with ours.

I do want to note that HACCP, just for example, when they came into effect in 1996 they had already been required in Europe, in the European seafood industry. And when they, the Europeans, adopted those regulations, it was even difficult for them to determine what U.S. equivalency would be and what the competent U.S. entity would be, whether it is Food and Drug Administration or USDA with whom they should negotiate. So while we have a safe food supply, we can't claim to possess or quickly implement all the best food safety ideas, and a diversity of approaches probably isn't bad, because we really care about the results at the end of the day.

You do seem to raise important concerns regarding USDA's interpretation and implementation of equivalency policy. It is very hard to see how meat samples that are gathered by private company employees could be as reliable as those gathered by government employees or how procedures changed from those originally evaluated

can apparently be grandfathered in. Are these problems that could, even if you don't believe ideally, could they be addressed by tightening of administration policy, number one?

And I know, for example, that you mentioned—I was told that while I was gone that you mentioned to Mr. Latham that our phytosanitary agreements do not require China to choose inspection locations. So could that also be fixed administratively? And are you aware of any upcoming decisions we should watch for that may provide insight into the way USDA will interpret the equivalency standard?

Ms. WALLACH. I think the way forward is to do a rulemaking to establish a new FSIS policy for determining equivalence. I think that there are problems with the concept of equivalence. It has limits, as I lay out in my testimony, overall that cannot be overcome, even with the best policy.

But it is also the case that we can get a heck of a lot closer to safe by having the right equivalence policy, which is why it is important to do a new policy if we are going to do equivalence determination, again, knowing that there are limits to what under that system you can do.

One of the main benefit of pieces of policy space that exists is in the WTO sanitary and phytosanitary agreement there is no definition of equivalence. There is a requirement that in fact that the countries get to decide if the exporting country standards meet their standards, which is why you have this huge diversity of how it has been implemented by other countries. And USDA has been a little schizophrenic about this question, which is why we need new rulemaking.

In their report on the concept of equivalence, USDA, there is a FSIS report that says meat and poultry and egg products exported from another nation must meet all safety standards applied to foods produced in the United States. That is what they say is the definition of equivalence.

But in the actual regulation that established the current policy they say, the United States can no longer require countries wishing to export meat and poultry products to have inspection systems that are at least as safe as those of the U.S.

Those are direct contradictions, and I would say the new rule has to have the first version be the version.

Then the question becomes, if you look at the level of safety, the inspection system, the system of oversight, and the access to information in the system, are each of those systems delivering the level that is the U.S. level? And that is where we have had a major failure. Because we have had just clear—like, for instance, the U.S. standard requires continuous inspection, and we have held countries equivalent over and over and over, even though they don't have continuous inspection.

We require government inspectors, not company inspectors. We have allowed countries to stay equivalent. These are not like close, like hmm, is it the right pathogen test to do it this way or that way? These are just really obvious.

So some of the things we have to do in a new regulation as well as making clear that what we are really looking for is there may be other ways to really be equal to us, that you don't have to do

it exactly the same way but that you really have to get to our level, which is not the current system.

In addition, we need to do things like have the equivalence determinations expire so that actually they get redone and there is a new rulemaking to make sure. To have a system basically when there are audits which need to be more frequent and funded. That when an audit fails the equivalence determination is suspended, the right to import is pulled until it gets fixed. The country then can say, come back, make sure it is fixed. Once it is fixed, it can be reinstated.

Under the current system, audit after audit after audit finds the most horrific things; and not only is the equivalence not suspended but the right to actually export is not changed. Having the rule be that the U.S. inspectors decide which plants, once you have the system, then you still have the U.S. certifying particular plants, what the Japanese and EU are doing. Having more on-sight inspection, so it is not just an annual audit, please God, but on a regular basis you have inspectors going through the plants. Those are all ways you can certainly improve the current system.

And as well having all these rulemakings on the record so that each country when they change a rule you have a new notice and comment, which, by the way, is what NHTSA does. The NHTSA process and also the substance, which explicitly says they give priority, actually, their exception to equal to is higher than, so that they look for an upward harmonization. So if another country is doing it better, smarter, higher standards, then we can accept that. And, in fact, the way that their rulemaking is done it calls on us to think about harmonizing to the other country. So it is a list-up system, and it is all done on the record. So, procedurally, it is more inclusive.

Mrs. EMERSON. You told Jack that you would be a little bit more comfortable with Japan's equivalency. Do you feel the same way about the EU?

Ms. WALLACH. The reason why I hedged is because I don't know on paper what it requires. What I know is what the reports are of how it is being implemented in China.

I could review both of those systems and get back to you about what the actual system says. I just hadn't done that homework.

Mrs. EMERSON. If you don't mind.

Ms. WALLACH. I am happy to look it up.

And, Mr. Kingston, Honduras and Nicaragua are importing meat under their equivalence determination. The meat man has informed us.

Mr. KINGSTON. Any problems with it? Any illnesses?

Mr. CORBO. Not that we know of.

Mrs. EMERSON. I am at red.

Ms. DELAURO. I want to thank Mrs. Emerson.

I just wanted to say that the problems are worldwide. And, Mrs. Emerson, there was an FSIS inspection in 2003 of the Canadian system. The FSIS found it so bad they told the Secretary that public health was at risk. They recommended an enforcement review. The review was deferred by the Secretary, that FSIS work with the Canadians.

Mrs. EMERSON. Referred?

Ms. DELAURO. Deferred, I am sorry. So that FSIS went back in 2005 and they found largely the same problems.

I will get the information to you on the Canadian issue, because I think it is important. This is not a singling out a place because——

Ms. WALLACH. The two Inspector General reports I would refer to your attention also that goes to the whole system.

Mrs. EMERSON. Thank you.

Ms. DELAURO. Mr. Farr.

Mr. FARR. Thank you very much, Madam Chairman.

This is a beautiful can of worms you have opened up. Listening to this I felt like we were talking, debating the Nuclear Arms Inspection Treaty, my guys will inspect your guys. And it seems to me that this raises so many questions that are worthwhile raised, and I do think we probably need to revisit it all.

You have to keep in mind that all agriculture is grown somewhere or all poultry or cattle are raised somewhere. In most cases, that is in a county or in a State, not just in a country; and each of those regions have their own regulations.

I was thinking about something we don't grow in our country, so we don't have that inspection process. But when you think about labeling fair trade coffee, it is not really much of an enforceable label. It is supposedly coffee that is grown in ecologically sensitive ways. It is supposed to pay their—and coffee growers are small, little, independent farms, just from my experience of being a Peace Corps volunteer in Latin America and Colombia where they grow a lot of coffee. It is supposed to pay the wages and benefits. That is a label that we all accept in this country.

But we also have set up this kind of different process for food, because we put it in the Federal Government as a separate inspection for meat and poultry. We don't have a Federal inspection for everything else. This is the only specialized inspection we have.

And so, therefore, if you are going to get into it—and I have a lot of cattle operators now who want to grow and serve their own beef, just like they say their neighbors can grow grapes and process them and put them in a bottle and put the label on the bottle. It is very difficult to do that, to put it on meat, saying this is Jack Barion Ranch's grass-fed cattle. And they want to do that because of all these issues on animal safety. Yet to get it into an inspection process and slaughtered in a slaughterhouse and keep your label on it versus trying to get a meat inspector to come down and watch a small slaughter, it is just not happening.

So this is a whole market that I know Marcy is very interested in, in how do we develop this market on our own? So I think the difficulty in here is we get unintended consequences as we try to build the perfect sanitized system.

Fresh produce, in my area, the most fresh produce in the world, Salinas Valley, most of it lettuce, you don't have a kill step with lettuce. And what you have had is recalls on E. coli contamination, salmonella contamination. And guess what is happening? What we are seeing is that even with the best management practices in the world on how you grow this stuff safely you still have now the new sort of private sector coming in with their corporate risk managers saying to growers, you have to grow to our standards, have nothing

to do with science. And growers are having to kill every rodent, which is now hurting the wildlife population, particularly the raptors. And what they are finding is they are having to use more pesticides and herbicides because their integrated pest management systems are destroyed by these mandates from corporate, not from Federal. And yet if you are going to sell lettuce to McDonald's, it buys a lot of lettuce, you want to make sure that you meet their standards.

And I think when you get into other countries it gets more difficult. Because equivalency is supposed to be that you are as good as we are, and that is why we allow you to import stuff.

I have dealt with how we in California put inspectors in Hawaii. When you get on a plane in Hawaii, you have to go through an ag inspector. California pays for that, because we don't want those medflies coming back to California.

So we have done this stuff where you put our people in other countries. They put their own inspectors on the ground in Holland. And, therefore, they know they are not going to get contamination coming into Japan. We are not even getting in.

When you get into trying to do trade, what happens if a pest—like we have a glassy-winged sharpshooter. You cannot move that to any other State, can't move it outside the country, because we have banned anything coming in.

So this is really what it is, is a can of worms. How do you set these national standards, which I do think we ought to have, but still not put it away so that the small farmer—I think if you have these health standards that we are going to require for selling produce in a grocery store apply to the produce that is in the farmers market, you are going to kill farmers markets, because they are not going to be able to meet those standards.

You know, I don't think we have had many illnesses because people have bought food from farmers markets.

So I would really be interested. Ms. Wallach, you said that in your paper here—I noticed the sentence that WTO equivalency rule shows U.S. law and agency regulations and practices must change, as well as trade agreement constraints on food safety. It is not only a matter of the agency's doing better but changes to underlying policies.

How do we meet those standards so that indeed—you know, we can't just say—it is interesting. Why do we export so much poultry but not allow anybody to import? Because that is the trade deal. We are not going to allow our stuff into their country unless we take stuff from their country. That is just a fair deal.

Now, they ought to be traded on equivalent standards. That is for sure. And if you are a country that is struggling, how—the laws in Mexico on food inspection are great, but the infrastructure for that, trying to hire people with those kinds of degrees and pay them the salaries they pay them in their Federal workforce or in their state workforce isn't happening. And so there is stuff done under the table.

So I am really concerned about do we sort of have to develop a training course and equivalency standard for professional ethics and professional standards and have kind of the world meet that if we are going it to import from those countries? How do we get

there from here? It is one thing to say, let's just change these laws, but, as you pointed out, Ms. Wallach, these countries have some good laws; they just don't have the ability to enforce them. How do we close that missing gap?

Ms. WALLACH. Well, I think one of the best ways to try and not have the unintended consequences problems is—and there is three levels of change. There is the trade agreements, there is statutes, and the regulations.

On the regulatory level, which gets to coming up with a new system for what the equivalence policy should be for USDA, doing it as an on the record rulemaking at least provides an opportunity for all the potentially interested parties to get their two cents in. As we saw with the organic standard, frequently tens of thousands of people get their two cents in. So that is a way where, unintentionally, some standard could be set that somebody who is on the ground producing would get in a comment that would be important. So that is one of the procedural questions.

On the question of the difference in the infrastructure and the funding, that is part of what a new U.S. equivalence policy has to take into consideration. Right now, under the current policy, they do what is called a paper audit. And so there are some splendid systems. They are just not enforced. They are beautifully written.

The problem is there are only a few plant audits, for instance, even with Canada where things are enforced. But we did 4 out of 200 plants we looked at to see actually what was on paper, what was on going on in the plants. With China, you saw there were some 25 plus plants, considering there were actually 6 places that were looked at.

So having a system where we actually, in determining not just what is on paper but what is happening, take into account is there a capacity.

And, number three, having our inspectors certifying what plants means that if we are saying these three plants are the ones, then that is where the resources go.

Mr. FARR. Do they do that here? For example, when they come to buy, foreign countries come to our country, do they come in and inspect our plants and select which ones so that their country decides, EU or Japan?

Ms. WALLACH. It depends on the country. EU and Japan do go look at our plants.

Mr. FARR. And they see whether those plants meet their standards.

Ms. HAUTER. And Russia does.

Ms. WALLACH. I don't know about Russia. But EU and Japan, yes, they pick our plants.

There is no violation of any trade agreement obligation. It is our bad past policy that explicitly said we would no longer do that. It is in the rule. So that is just one very clear thing we should change.

Mrs. EMERSON. Will the gentleman yield?

You asked the question of how often they come to inspect our plants?

Ms. WALLACH. That I don't know. I don't know. I can try and find that out.

Mr. FARR. But what I am pointing out is there is also now another movement which is the private sector, this idea of we will have our own corporate inspections outside; we are not trusting government enough. And that is dangerous. Because then you are setting corporate standards that have no good science behind them, and you are going to ruin a lot of other—as I have seen in our area, you are essentially running in conflict with all of the best management practices you are taught about trying to grow things in an open environment.

Mrs. EMERSON. Sam, that is a little bit of a generalization. We don't know. Because there is liability that those companies, if they import bad stuff, so surely they have got to have some standards.

Mr. FARR. Sure. But when they are coming and telling the growers in California, which probably has the toughest standards in the Nation on everything—pesticides, herbicides, farm worker practices, OSHA standards, all of that—that you have got to go kill/poison all of the rodents—and one Federal inspector was so shocked when they arrived in the Salinas Valley, saying, oh, my God, birds fly over these crops; we will have to prevent that.

I mean, that is the kind of reaction that people are having now when they find contamination of E. coli and salmonella is because these products don't have a kill step. I am pointing out it is all kind of convoluted, but it gets very complicated when you get down to the grower level of how you are going to meet these national or Federal or international standards that aren't practical.

Ms. WALLACH. The regulatory process I think can be dealt with that way.

On the statutory level, in my testimony I recommend we go back to an equal to standard. I don't think we had to change the statute. But even if we don't, the agency can basically have a rule that requires that, as you put it, you are showing their stuff is up to our standards.

And then the third thing is the trade agreements. There are issues beyond equivalence where the trade agreement sanitary, phytosanitary, and technical barriers to trade chapters rules actually do have constraints, not just on imported food safety but products, toys, other products; and those constraints were put in place under this notion of basically facilitation of trade volume over everything else. And that is out of balance.

Mr. FARR. Do you have a paper on that?

Ms. WALLACH. I do have a paper on that.

And, moreover, you were a cosponsor last year of the trade act, the Trade Reform Accountability Development and Employment Act, that calls for renegotiation of the food safety and product standards language so that you basically have the balance. So we get the benefits of trade but that we don't sacrifice the necessary safety.

The basic principle of it is, if doesn't discriminate, i.e., as long as you trade the foreign and the domestic good the same, it is not a trade issue. And we shouldn't have trade agreements setting a subjective limit on safety. The question is discrimination, and then the question is done.

And so that is the same issue with equivalence. If we had everyone treated the same, we wouldn't really have a trade issue.

So that bill has been introduced again this year, and there are 106 cosponsors, so it may have the hope of a review of the actual trade agreements in the renegotiations.

Mr. FARR. Does that answer all these questions? I am not sure it does. We will talk about that later.

Ms. DELAURO. Marcy Kaptur.

Ms. KAPTUR. Thank you, Madam Chair, for a very, very interesting hearing. I had two other events I had to be at before this one, so I am sorry I couldn't be here at the beginning. But I have read your testimony, and we thank you for being here.

What runs through my mind is how, especially in the food arena, when something is said exactly the opposite actually occurs. So, for example, when we had the fight on labeling, and rather than labeling we get deceptions. So you will get a label that says, no cholesterol, real big letters. And then you look at the back, high in saturated fats. There it is, you know, 40 percent. How you get a 60 percent fat content in chicken pie, I can't figure out how you can get it so filled with saturated fat.

You think of the term NAFTA, North American Free Trade Agreement. It is anything but free. We have had over a trillion dollars of trade deficit racked up with both Mexico and Canada since its start, a trillion dollars. So many lost jobs, but we call it free. It isn't free. It is very, very expensive. That doesn't say anything about what has happened in Mexico or Canada.

We talked about the word equivalency. It is actually not equivalent.

So what you have to do when you get into the food arena is, whatever they say, just reverse it; and then you will begin to understand the truth. You will begin get to the truth.

I grew up in a store, our family store. And our father, who was a small businessman, bless his soul, called our store Supreme Market. We used to wrap up the meat; and he would put his label on there, Supreme Market, address, name, phone number, everything. We were so proud of everything that was made there.

And as I have watched what has happened over the period of time, I think what is missing in the food sector is true ethics accountability and the former American ethic, going back to the founding of the Republic, of great respect for the earth and its productive abilities. You can walk around these buildings and see women holding shafts of wheat, and as it became a more mechanized society the ethic was missing. Something has happened, and it is very serious.

And when I look at this food safety issue and the importation issue, what you generally get is people don't want labels. They don't want to know.

Those in charge of the food system today—and small grocers like our father were drummed out of business because of contracts that Maurice somewhat referenced—this is a true story—where dad used to go into Swift and Armor in those days, and I would go with him, and the man who was in the cooler would say you can't have those anymore for your store because it was prime meat because the supermarkets have bought the whole case. So you can only have the choice meat, not the prime meat.

I remember our father's face, probably one reason I am in Congress today, because I lived the inequity in our family. And thank God for the man in the case who said to our dad, hey, Kappy, it is okay. I will switch carcasses. They won't know anyway. Our dad knew what the best was.

But something has happened with the ethics of food, and it goes beyond any one regulation. It is the reason that as we talk about inspection somehow the mechanized system has made us forget our values. And I say that because of many of the interests represented in the audience today. We thank those who want to call us to a higher ethic.

And maybe it is a restoration of the original ethic of stewardship and a respect for the earth and respect for people who produce our food—and I don't want to get too religious, but in the denomination I am a member of the symbol of a table and breaking bread is very important. There is even a very serious religious element to all of this that somehow when we allow contaminated goods to flow to anyone's table—and the more poor you are the more likely it is that contamination will flow to you—something is really wrong inside the system. No matter how profitable it is, if the ethics are missing, we have changed as a country, and it is not good.

So my question really is to Mr. Brosch. It is my understanding that if a foreign food processor of meat in Mexico is sending goods here—we were told by USDA 11 companies, I guess, do that down there, 11 different plants—that we send our inspectors in there because there have been problems with Mexico and then those goods flow here. My question is, do you know who pays for the inspectors? Is there a fee on the importer to pay for those inspectors or do the taxpayers pay for that? I am very interested in that.

Mr. BROSCH. I think this is paid by the taxpayer. I don't believe this is a fee for service, but that is in the red meat area. There is no poultry coming from Mexico, and I am more familiar with the poultry situation.

Ms. KAPTUR. Okay. I am concerned about equity here and the way in which we handle this whole food movement back and forth.

In the area of invasive species, though that is not the subject of today's meeting, but when we get contamination in this country, there is no international—this goes to my question, my second question, which is, if you looked at the amount of money we as taxpayers are having to pay for the mistakes, environmental mistakes happening inside this country—take my district, 10 percent—we have more trees than any other area of Ohio. We are going to lose 10 percent of our tree cover, like that, from the emerald ash borer. And who is responsible? Nobody, nobody. So where does the bill get placed? On the taxpayer. I say that is wrong.

So my question really is, what is the international claims court or torts court? Where do you take the importer, where do you take the exporter to get—I want my money back. For every tree, for all the money I have had to appropriate, for all the city governments who have to hire people to cut down and replant these trees, where do I get justice in this system?

For the kids who got sick in Michigan eating those strawberries in those little yogurt things or Sundaes that they were eating up there when that came in from Mexico and was packaged in Los An-

geles, who went to court? Where is the court case? None. No ethics. No responsibility. No justice. What kind of a system is this?

So my question to you is, you are here today on trade agreements and equivalency standards. But how do we get ahold of the whole enchilada and control those who are doing this at our borders?

Jo Ann held up those products there. All right. So if something goes wrong—nothing ever went wrong in our dad's store; nobody ever got sick. But if they had, they knew exactly where they got it.

Now what is the system that we have today to assure that quality and that justice? Whether it is food or whether it might be invasive species, what is the mechanism internationally where we can get justice? Because it doesn't exist right now.

Ms. HAUTER. I don't think we have one.

Ms. KAPTUR. We don't have one. Madam Chair, we are left with this regulatory—this Swiss cheese regulatory mechanism that doesn't work and putting the burden on the taxpayer to pay for everything. It is a whacky, unjust system.

Ms. DELAURO. Ms. Hauter, do you want to respond?

Ms. HAUTER. I was going to respond generally.

I think it is beyond the scope of this panel today, but I think we really need to do a complete assessment of our food system, from the way that the Farm Bill impacts small farmers, the concentration that is present in this country, the way that small farmers really can't compete, even though we hear in their name that our agricultural policies are really all about helping family farmers. And I think that we need to promote the types of policies that are going to allow a more local food system. I know Congressman Farr mentioned someone in his district who is trying to slaughter on a very local basis.

We have recently released a report on this issue where we assess the USDA regulations, and it is very difficult for any small producer to compete, whether they are trying to produce meat, cheese, or vegetables. And so what we really need is a shake-up and to really look holistically at the system.

Now, I don't have an answer for how that is going to happen, but that is the only way that we are going to straighten out our food safety system.

Ms. KAPTUR. If you have proposals along those lines that you could share, we would be very interested in your ideas.

Ms. HAUTER. We would be happy to do so.

Ms. WALLACH. The only thing that I would add is that not only isn't there such a system, but, in fact, the existing enforceable international government system is the trade agreements, which set an explicit ceiling on many of those issues of consumer justice.

So not that I want to give the invasive species issue, get your blood boiling more, but in fact certain actions that the United States has taken to try and control various invasive species have been threatened with WTO attacks under the sanitary and phytosanitary agreement arguing that they are not the least trade-restrictive means. And particularly the Asian long-horned beetle, we were going to require a particular kind of fumigation and temperature treatment of the pallets that come in the wood of the shipping pallets coming from Asia. And we got a demarche, which is

the first step to a WTO challenge, from China on behalf of Hong Kong, threatening that that wasn't the least trade restrictive way to try and limit the invasive species infestation.

And, in fact, our own USDA or APHIS I think had done the sort of testing of what could you do to allow the trade to continue but not have the pallets causes a serious problem and decided that was not just the least straight, that was the only way. It had to be a certain temperature, and it had to be zapped by a certain chemical. So we never implemented that. It was a threat, that we took the threat seriously and didn't want the challenge. So——

Ms. DELAURO. Mr. Brosch, do you want comment?

Mr. BROSCH. Yeah, we can't do this here today.

There have been a lot of statements about what the sanitary and phytosanitary agreement says and doesn't say. I happen to be one of the two U.S. negotiators of this agreement, was involved in it for 6 years. I would just like to state for the record that I wouldn't agree with a lot of things that have been said about that. If we had a longer time and a different thing, we could have a debate on that. I know we don't have that time.

But I don't believe that we ever intended during the negotiation to put a ceiling on the level of safety that any country could choose; and, in fact, it says that explicitly in the agreement. It says that any country can choose its appropriate level of sanitary or phytosanitary protection. And that is the core of that agreement. So I would have to disagree with that. I don't think that is true.

With respect to people threatening to sue us on least restrictive means, you know, as I say as a lawyer to my friends all the time who are worried about lawsuits, you can always be sued. The question is whether somebody can beat you or not.

If that is the question, if in fact the facts are as represented there, I don't think the United States should be afraid if somebody is threatening to sue. If we do get sued, we can defend that; and we have defended cases. I have personally defended cases for the United States.

The last thing I would like to say is there have been a lot of things said about conspiracies or deals done within the Department to trade safety for food. And I was not at the Department in 2006 when this occurred, but I was at the Department between 1989 and 1999 and served under about five Secretaries of Agriculture and a number of under secretaries, served directly with them and was a negotiator in the Uruguay Round on agriculture and the SBS agreement and the NAFTA.

I can tell you, Ms. Chairman—I would say this under oath—I was never once in a meeting where anyone suggested that we should trade benefit for safety. I have never heard that during my time in the Government. I just want to say for the good people at USDA who do their job every day, I think that that is, at least in my experience, not a correct assessment of the way they go about their business.

Ms. WALLACH. I just want to address the ceiling/no floor issue, because it can be addressed on two different grounds.

First of all, the only kind of standard—I think you will agree with me—that can be challenged is the domestic standard that provides a higher level of protection than is deemed appropriate in the

agreement. There is no mechanism for challenging the lack of a protection. There is no floor. The only thing that can get challenged is a higher level of protection, not the failure to provide some kind of a food safety protection. So when we say that prioritizes trade facilitation over safety, when there is only a ceiling, i.e. Being challenged for too high, not too low, that is pretty much only a ceiling.

The second point is the provision you just read, was article sub 1 of the basic rights and obligations, but if you keep going through the other three rights and obligations you get to the crux of what I was talking about, the least trade restrictive rule, which is members shall ensure that any sanitary or phytosanitary measures apply only to the extent necessary to protect human, animal, plant or health are based on scientific principles and is not maintained without sufficient scientific evidence.

And then it goes on to continue to say, sanitary and phytosanitary measures which conform to international standards and recommendations shall be deemed to be necessary, but everything that doesn't conform, i.e., everything that is higher, is subject to challenge. And, again, there is no way to challenge things that are lower, so thus the ceiling versus the floor.

Ms. DELAURO. Mr. Kingston. What I will do is, Mr. Kingston, and I know Mrs. Emerson has one more question and do that, and then I have a few questions, and then we will try to move to winding down.

Mr. KINGSTON. Ms. Hauter, you get money from Public Citizen right?

Ms. HAUTER. No.

Mr. KINGSTON. You don't? I am looking at their Web page, and it lists usage of Public Citizen money, and it does list Food and Water Watch.

Ms. HAUTER. We were a spin-off from Public Citizen. We get no funding from Public Citizen.

Mr. KINGSTON. There is no relationship, but it is listed on the Web page.

Ms. HAUTER. No, no formal relationship. We have a collegial relationship. Our program grew, and we are getting outside of the main mission of Public Citizen, and so we started another group. It is a 501(c)(3), its own funders. We have no financial relationship.

Ms. WALLACH. If you are looking at our 990s, I believe in 2006 we had to pay them out the remaining grants when they got their own bank accounts. They used to be a division of Public Citizen, and they spun out as an independent organization, but we still are their former mother ship.

Mr. KINGSTON. I just want to bring that up. Because one of the previous questions was that somehow these small businesses are maybe puppets or front groups for the big, evil, large businesses. And I just want to say—I am looking at it.

And I want to also go on to say, since you asked, that I am disappointed. After telling you I voted with you on some trade agreement, your political donations, Al Franken for Senate, American Votes, American Civil Liberties Union, American Association of the University of Women, Common Cause, Democrats for the Future, Democrat Congressional Camp Committee, the Democrat National

Committee, Harry Reid for Senate, Hope Fund, League of Women Voters, Levin for Senate—I am looking for Kingston—Obama——

Ms. WALLACH. That doesn't happen to be this Lori Wallach, because I don't make enough to give those kind of contributions.

Mr. KINGSTON. It is not your Web site. It is Public Citizen's.

Ms. WALLACH. We don't have a PAC, so we don't give any contributions. Now I personally am too broke. Were I interested in giving those contributions—you will find I did support Donna Edwards.

Mr. KINGSTON. You are a group that was nonprofit, founded by Ralph Nader in 1971, correct?

Ms. WALLACH. Uh-huh.

Mr. KINGSTON. I am just going off your Web page. I am disappointed that you guys——

Ms. WALLACH. We don't have a PAC is what I am telling you. We are a (c)(3) and a (c)(4).

Mr. KINGSTON. Do you do things for these groups? I will show you this Web page.

Ms. WALLACH. Yeah, I would be interested in seeing that, as would our general counsel.

Ms. DELAURO. Jack.

Mr. KINGSTON. And the only reason why I am saying that is because there were questions about some—Mr. Brosch had listed in the back of his testimony their groups. And so, you know, if he has a prejudice or a bias we can say, well, it is obviously Monsanto or National Retail Federation or National Turkey Federation that he is pushing for.

But I am just trying to figure out if there is a relationship there or not, and you said there isn't. I am just saying the Web page says there is. I will take your word for it, because I respect it as accurate.

Now, let me ask you, Mr. Brosch, there have been some questions about our trust of Canada and our trust of the EU and our distrust of China. Why is that accurate or inaccurate? Should we trust China?

Mr. BROSCH. Well, I think that we trust Canada and the European Union because the process that we have put into place has gone forward and our scientists and our regulators have taken a look at those countries. There have been questions raised by the chairwoman about Canada and about——

Ms. DELAURO. Continue.

Mr. BROSCH [continuing]. About situations with Canada. We send the people back there. They work with those folks. We send people to Europe all the time. Mostly they send people here, the Europeans; and we work with those on a regular basis.

I think it is that process that essentially improves the product you get or don't get. You make decisions during that process whether you are going to allow that trade to continue, you are going to allow certain plants. As plants get delisted, you go take a look at them. That process goes forward.

We don't have that kind of experience with China. China has developed something of a reputation with respect to other products, not necessarily meat and poultry but milk and Melamine and other

products, and that has spilled over now, and people are painting with a broad brush.

As I said, the Europeans and Japanese, the people we are talking about and the people we trust or trust us, are importing poultry from those countries. So I think it is a matter of process, and it seems to me we set up a scientific process. We have regulators we hopefully can trust—

Mr. KINGSTON. Let me ask you, Ms. Wallach. You had said to Mr. Bishop earlier that we don't have the system that Japan has in place. You said you are not quite sure what Europe has in place, but you would agree that we could learn from what Europe is doing if they don't have a track record. Well, if they have a track record for good or bad, we can learn from that, correct?

Ms. WALLACH. I think that they, looking at the same circumstances in China, decide they needed their own on-site inspectors, special days to run their export lines, and a very high 50 to 70 percent border inspection to me indicates that they found problems and that was one way they thought they could deal with it to try and make it safe. I think we should learn from that experience.

By the way, I will send you Public Citizen's 990s. We don't take any corporate or government money. We have 100,000 members, and we get a little bit of foundation money for books.

Mr. KINGSTON. That is what your Web page says, and it actually says something very impressive: Your average donation is $28. That is good.

I am not disputing that. I am just saying that information came from the Web page, that it suggested there was a relationship, lists a relationship.

The only thing I want to point out is that Mr. Brosch has his members listed, and I think it is always good to know who is related to who.

Now, let me ask you this. Ms. Wallach had talked about an annual audit and the right to look back and close down and keep up with new technology. In your opinion, is your group supportive of those? That sounds reasonable to me, frankly. Would you guys be supportive of that?

Mr. BROSCH. An annual audit of the——

Mr. KINGSTON. Of a Chinese facility.

Mr. BROSCH. Oh, I believe that they do that now, Congressman.

Mr. KINGSTON. They do do that now?

Mr. BROSCH. FSIS regular——

Ms. DELAURO. Not all of—they don't look at all of the plants.

Mr. BROSCH. I don't know if they look at all of the plants, but they have an annual or nearly annual audit of the system of the country that we are dealing with.

Mr. KINGSTON. Ms. Wallace, do you know what risk-based inspection is?

Ms. WALLACH. Uh-huh.

Mr. KINGSTON. Do you support that?

Ms. WALLACH. I think there are elements of concern where the highest points of risk are, but I don't support the program that has been played with here, that has been tested here.

Mr. KINGSTON. Do you support the concept of it?

Ms. WALLACH. I think that you can emphasize what are the riskiest practices and places to look. For instance, yes, I support elements of it. The way FSIS has been doing reinspection at the border used to be based on what particular facilities and counties had the worst record. So you would know, boy, that plant has been having problems. I am going to do more of that. They went to a random sample system, which to me was crazy. So while the rest of the system was going to risk—yeah.

Mr. KINGSTON. Internationally, could a concept like that be helpful in a situation like this where you have stated you have a little more comfort level with Canada than you would with China? Would a risk-based inspection approach work?

Ms. WALLACH. I think that one of the things about redoing the regulations is taking into account the different levels of infrastructure and funding available in different countries. Because one of the big failings now is you have a paper audit that looks at what the laws are in the book, but then you have no idea if they are actually implemented. So I don't know if that would be risk or reality based.

But, for instance, in a country that has very limited funding or a culture of having a lack of government accountability or secrecy of reporting problems, et cetera, I would be much more interested in having, for such a country to get the right to import, to have lots of U.S. inspection and oversight on the ground, as compared to a country that is having—for Canada, I would rather focus on the E. coli standards and less about that particular issue.

Mr. KINGSTON. Also, one thing I wanted to mention—I know I am out of time and, Ms. Hauter, you want to say something.

You know, if I could get a local farmer to produce and sell it to the local school board, one of the barriers in keeping him from doing that are many of the regulations that Ralph Nader groups have supported. And it is very frustrating. Because I know I think from reading that you prefer locally grown food, and I think many of us do. But I know one of the huge problems in the local farmers selling to the local school board are regulations that have been thrust upon the market, really because of litigation and things. And I would love to work with a group like yours to say, okay, how do you get a local farmer to sell to a local school board and get around some of those regulations that are burdening him and prohibiting him from it. But I don't know if we can get there at this point, because there is so much litigation that our society is in love with right now.

Ms. WALLACH. Needs to be updated just like the international standards need to be updated.

Ms. HAUTER. Congressman, we would love to give you the report that we just published on small slaughter and what needs to be done in a regulatory framework to make local slaughter possible.

I also just want to say about risk-based inspection that the National Academy of Science just found that there is not the data available to show that risk-based inspection works, and we have a lot of concerns about the way that it would be implemented.

Mr. KINGSTON. You know, I haven't read that report but look forward to it. I can say this, having some knowledge of the food business since I used to sell product liability insurance and I have sold

to food processors, that there are certain processors that have violations just as there are restaurants that have more violations than others. And if you have an inspector that has 4 hours I would rather have him go to the frequent violator than somebody who has a really strong track record. And that is what risk-based inspection is.

But I am not pushing risk-based inspection right now. We have had some good hearings on that. I can't even believe he is still sitting here.

But my question really was, if you trust Canada and Europe, does an international risk-based inspection that would go after the Chinese shoring up their program work?

Mr. BROSCH. Mr. Kingston, about your local production, there is under FSIS rules a 20,000 bird exemption for small local production. So if someone is a producer of less than 20,000 birds a year, he can, he or she, whoever is running that business can do that and be outside the FSIS inspection system; and the rationale is that person is selling locally and all of their customers know where they are getting their product.

Ms. DELAURO. Mrs. Emerson. I think you had one question.

Mrs. EMERSON. I actually have one and a half.

Ms. DELAURO. Go for it.

Mrs. EMERSON. Just because, since we have got off the subject of Chinese chicken, sort of, I do have one question I want to ask of Ms. Wallach and then a general question that I would like each of you all to answer.

Back on phyto and phytosanitary, in your written testimony you mention the EU's ban on artificial growth hormones in meat and the millions that they have had to pay in WTO, because of the adverse WTO finding. I am just curious. In your opinion, was that a necessary food safety regulation or was it protectionism?

Ms. WALLACH. I think it is the right of the people who are going to eat the food to decide the standard. So the test for trade should be did they apply the same standard domestically as they sought to apply to imports. So at the point that they actually had successfully banned it, because that wasn't the case in the first couple of years, the same artificial growth hormones for their own producers, then their consumers have a right to expect the same for the product in the market that is coming from an imported source. So I believe that was legitimate when it became non-discriminatory, and they maintained their right to do that by paying the sanctions.

Mrs. EMERSON. Okay, I appreciate that.

Tomorrow, we have before us a new food safety bill; and we are going to vote for it under suspension of the rules in the House—pardon?

Ms. DELAURO. That is not clear.

Mrs. EMERSON. Oh, I thought that was what we were doing.

Let's forget that we might vote for it under suspension.

Can I just get your all's take? Have we done enough with regard to USDA and with regard to the FDA and will any of the things that we have discussed today be helped by that food safety bill?

Because I want to make sure that we are going to be in a position where some of the equivalency and the like, that we are actually addressing all of those things, if we are going to take it up.

Because I think we have to do something. Obviously, today's hearing would point that out. But I want to know what we are doing is on the right track.

Mr. BROSCH. I apologize. If I had known you would ask that question, I would have prepared for it.

Mrs. EMERSON. Well, I didn't know I was going to ask it. Since we went off Chinese chicken, I figured I might as well ask.

Mr. BROSCH. I am not really prepared to answer that question.

Ms. WALLACH. I am in the same boat.

Ms. HAUTER. We would have much preferred the legislation that Congresswoman DeLauro had introduced.

Mr. KINGSTON. Hear hear.

Mrs. EMERSON. We would agree with you. I was just wondering.

Ms. HAUTER. We have concerns about this legislation, although we are not generally opposing it. We are hoping that some of these concerns are worked out. The fees on small farmers, less—too much regulation on small producers. The bill does, however, increase vigilance on imports for FDA. It is just going to be very costly.

Mrs. EMERSON. We can find the money. We should make sure——

Ms. HAUTER. We would be happy to give you our written assessment of the bill.

Mrs. EMERSON. Well, if you can give it to us today.

Ms. HAUTER. We can.

Mrs. EMERSON. Thank you. Maybe when you get back to your office.

Ms. HAUTER. Okay.

Ms. DELAURO. Yes, I think the authorizers have got to come to the Appropriations Committee to deal with the funding to carry out what it is they have talked about carrying out.

I know Mr. Bishop doesn't have any more questions. I have three and a half, and then we truly will wrap up. You all have been wonderfully patient with us.

Under the system approved by FSIS, China will only be able to deal with processed chicken that originates largely in the United States or Canada. Let me just ask the three of you—and it is a quick question. How will we be able to tell if what is shipped back is exactly the same product that was sent to China, especially since we will not have U.S. inspectors in the Chinese plants? And how do we know whether the product is cooked to the appropriate temperature in order to assist with that process of safety?

Ms. HAUTER. We won't.

Ms. DELAURO. Ms. Wallach.

Ms. WALLACH. We won't.

Mr. BROSCH. It will be based upon a series of records and an audit of records, as I understand it. That is how that process works. So it is based upon a review of records, of in and out, shipments in, shipments out, and the time in which they do the processing, how they run the lines.

Ms. DELAURO. And to know that we have—not getting a domestic poultry product in return, because, as you know, domestic Chinese poultry is still prohibited to the United States because of high incidents of Avian flu.

Mr. BROSCH. The rule doesn't allow it. That is I think the basic legal restriction of the rule. It doesn't allow use of anything except poultry from approved——

Ms. DELAURO. And given the level of inspections we have on the ground there, that we can, both in terms of inspections and of cooking the product to the appropriate temperature, your view is that we will be able to address that.

Mr. BROSCH. I think that FSIS could address that. They are not here, again, but I think they are the people who will have to answer your question.

Ms. DELAURO. Okay.

Ms. WALLACH. As far as the temperature, we would have to rely on, under an equivalence determination, whatever system is going on in China that we are deeming to say is okay. And this would be a question, if you had more inspectors on the ground, if you would actually be able to stay on top of that.

As far as the prospect of chicken laundering, bringing in one source and recruiting another one, I think that would be something that would be very hard to avoid, even given the potential of tracking the paper. I think that is almost impossible to avoid. Which begs the question of if you have got a phytosanitary reason why you are very nervous about having a particular product, i.e., an animal illness, do you ever allow then a processed chicken stem from that place until the actual animal disease is controlled?

Ms. DELAURO. A recent CDC report found that poultry was the most commonly identified source of food poisoning in the United States. That was recounted in the newspapers in an article by Gardner Harris, I think, on June 12. I think it was in the New York Times. And I have spoken to food safety scientists at CDC and others about the key issues involved in assuring poultry products are safe, and the most important factor they cite is maintaining correct temperatures throughout.

This is a particular challenge for China. Let me quote from a USDA publication that was released this month. It is entitled Imports From China and Food Safety Issues. Refrigerated storage and transport equipment in China is relatively scarce. When temperature-controlled infrastructure is available, power outages, railroad delays, and delivering temperature standards may lead to spoilage.

Is such a system equivalent to ours? Are these reasonable risks for us to take with American consumers? Mr. Brosch?

Mr. BROSCH. Well, I think the first information you had, that poultry was the food most associated with food-borne illness may be a little bit distorted. My understanding that that data that is based on two outbreaks in two prisons, where they had a substantial number of incidents in those prisons, and that there is, in fact, further data on that study that sort of corrects that. So my recommendation is we will try to get you some information on that, but I think that that is not quite accurate.

Ms. DELAURO. The temperature issue, can you address that?

Mr. BROSCH. Yes, I think what we have got is a situation where, if China is approved and China is allowed to do this, what we will have is a limited number of plants near the ports who are going to be the ones who will source this. They are going to be the ones closest to receive the product coming in.

By the way, we don't anticipate there is going to be a lot of trade in this. The idea of bringing poultry all the way from the United States to Canada and then being able to process it and bring it back is going to be a very small amount of trade. Probably a specialized item like a Chinese specialized food item or something like that, but we don't anticipate that they are going to be near the borders. Those are going to be the plants that are already processing for Japan and for Europe. I don't think we are going to see plants that are far away from the borders or away from the main part of the industrial heartland of China providing chicken under this plan.

Ms. DELAURO. That is interesting. That is not something that we had heard about, bringing, you know, stuff from the ports and industrial.

So, in any case, let me just ask—well, go ahead, please. I didn't ask you, Ms. Wallach.

Ms. WALLACH. I was going to say if that is potentially the safest way to do it, then that should be part of the rule that would be the equivalence determination. This gets more to the idea of thinking about where the risks are and then having specific determinations for specific countries. And I say that as a person who knows trade and not the technical details. But having just heard that for the first time to translate it to what the equivalence policy would be, you then would want to make that the rule. Because, otherwise, the way things are now, China decides which plan.

Ms. DELAURO. That is right.

Ms. Hauter.

Ms. HAUTER. And this speaks to the problem of having a very decentralized regulatory system, where local authorities make a lot of decisions and where we are certifying that the whole country is safe, rather than the way that Europe does it, looking at different regions.

Ms. DELAURO. Yes. This was, again, an ERS report, July, 2009, Imports From China and Food Safety Issues. I talked about what was on one page now. This is page 17 of that report.

Most of the violations flagged by FDA and imports from China over the annualized periods were problems linked to the processing and handling of food products, rather than to farm production practices. Filth generally results from introducing dirt or foreign materials and unsanitary packing or processing of facilities.

Page 45, exported products often bring a higher price than those sold on the domestic Chinese market because of the higher costs of strict safety controls and the large differential between domestic and rural prices. Because the difference in prices is so wide, producers have strong incentives to sell inferior products for export produced at lower costs with fewer safety controls, which creates a challenge in policing supply chains to ensure that unsafe products are excluded.

The last comment I want to make from the report, which is at page 26, which refers to a publication called The China Price by Alexandra Harney; and the quote is, the difficulty of conducting reliable company audits in China is highlighted by Harney's description of, quote, shadow factories, sophisticated strategies to falsify records, and other means of evading audits by foreign customers.

I think those come out of a USDA ERS publication, which I believe gets at the heart of what today's issue is about, not only about China but the whole issue of equivalency and where we go for the future.

I wanted to address a beef issue, if I might. I don't know if anybody wants to comment on those comments. I think they speak for themselves.

Again, this is a China-U.S. poultry dispute. It is Jeffrey Baker, Congressional Research, July 16, 2009. It says here, and I quote, China is the only market completely closed to U.S. beef exports and represents one of the largest potential growth markets for U.S. beef, worth in excess of $100 billion.

Mr. Brosch, can you tell me why we haven't taken China to the WTO over this?

Mr. BROSCH. I don't know. I think that the closing of the beef market had to do with a couple of limited incidents of Mad Cow that were picked up in the northwest part of the United States. There has been a lot of back and forth with the Chinese on this, and—I don't know—maybe Ambassador Kirk in his statement recently that he plans to increase enforcement, maybe that is what he will be looking at.

Ms. DELAURO. But I am interested, because you represent a coalition of a whole group of people who have a significant interest in the beef market here. Why hasn't the U.S. brought suit or a complaint of the WTO if this is—and I have no reason to dispute CRS here.

Mr. BROSCH. No, I don't dispute that.

Of course, you can't bring a private right of action in the WTO. Our groups could not file a lawsuit at the WTO. It is a country-to-country agreement actions have to be brought by the U.S. government.

Ms. DELAURO. Well, that is what I am asking. I mean, this is not a group without sufficient clout, if you will.

Mr. BROSCH. Well, I can tell you, for example, we think that poultry has been unfairly excluded from South Africa for about 10 years; and I have personally been in to see, I think, every person in the world; and I still haven't been able to get the U.S. Trade Representative to take that case.

Ms. DELAURO. Do you think we should? Your view, do you think we should?

Mr. BROSCH. Well, actually, the one group I don't represent is the beef people. So I don't know what discussions they have had, but perhaps so. But it is a frustration a lot of times when you try to get those decisions made.

Ms. DELAURO. Okay. I have one more question, but I think Ms. Kaptur does. I will ask my question, and then it is the end, guys.

Ms. KAPTUR. Madam Chair, I don't know if anyone has asked this question or not, but I wanted to ask Mr. Brosch or the other witnesses, which food chain in the United States sells the most imported Chinese chicken, to your knowledge?

Mr. BROSCH. Nobody, because we don't have any imported Chinese chicken.

Ms. KAPTUR. We have none. Prior to the ban?

Mr. BROSCH. We never have had any. They banned it before there was any imports. So we don't have any Chinese chicken.

Ms. KAPTUR. So we have never had imports of Chinese chicken into our country.

Mr. BROSCH. Not to my knowledge.

Ms. KAPTUR. Even before the ban. All right.

And I wonder if any of our witnesses have any information about the incidence of the swine flu. In fact, I was at the University of Wisconsin recently and heard that there is a theory that flies in lagoon pits east of Mexico City related to a very large swine production facility may actually be the nexus of the carrier from the lagoon pit to children that live here there. Have you had any confirmation of this or could you provide anything to the record?

Ms. HAUTER. We have heard that theory; and we can provide you with what we have seen, mostly news articles.

Ms. KAPTUR. But I was at a meeting with very high-level researchers where they had traced everyone who had left the country and then anybody that got the swine flu around the globe, and then they traced it back to this particular area. I believe it was east of Mexico City.

I remember when we had the NAFTA fight, and we said that meat production would be moving south of the border. And people said, oh, that could never be done, because they don't have enough water and so forth. There is a million animal hog-producing platform down there, and the question is whether or not this can be linked. So I would appreciate any information that you have.

Ms. HAUTER. There are also other issues related to the illness. There are E. coli bacteria, not the 0157, that also cause illness; and ARS has written about this. They are present in imported meat products. And these are bacteria that aren't currently in the U.S.

And so this is another consideration. Because we don't test for these pathogens domestically, we can't test meat products of our trade partners, and this is something that needs to be addressed.

Ms. KAPTUR. You know, it is interesting, Madam Chair, the supermarket that I shop at on occasion back home, I noticed in the supermarket's case just in the last 6 months or so the meat that is now on there, if it is labeled, will have a label that says from U.S., Mexico, or Canada. So I assume under NAFTA one cannot identify the country but only the trade agreement. Could anyone comment on that?

Mr. BROSCH. Well, there is a complication with respect to NAFTA trade, because there are movements across—especially in the Texas area and on the Canadian border there is movement of small animals. For example, you may have a breeder operation in Canada where they will sell—they will be born, and then they will sell small animals across the border. Then the question is, is that an animal that is Canadian or American? And I think the rules say that it has to be completely born, raised, and fed, or something like that. So if you have got the movement of small breeding animals across the border, then you have a hard time identifying either as Canadian or American.

And then also there is a movement of breeder animals from the United States across the border into Mexico, and there is a big business in that. So it is a very difficult thing to do that with re-

spect to NAFTA countries because of that particular movement on the border.

Ms. KAPTUR. Very, very interesting. Thank you.

Mr. KINGSTON. I wanted to ask one more question at some point.

Ms. DELAURO. All right. Why don't you go ahead.

Mr. KINGSTON. I wanted to ask, are you guys familiar with we moved catfish from FDA to USDA? Does that concern you? Do you want to react?

Mr. CORBO. Tony Corbo from Food & Water Watch.

We were opposed at the time of moving it over because of the staffing shortage problems that FSIS had just dealing with meat, poultry. And I have been quoted as saying they had a tough enough time doing four-legged animals; they don't need fins as well.

But the issue now that it is over there, and you all have already appropriated, you know, money for the program to be set in motion, that I think we are going to have to go through the program and set up a system for domestic catfish inspections so that it could also be applied to the imports. And so we see this as an opportunity to really assess. Because we are importing an awful lot of seafood and we are importing a lot of catfish and a lot of it is showing up with illegal antibiotics, that FSIS may have an opportunity here to get control of the unsafe imports that are coming into this country.

Mr. KINGSTON. Well, let me ask you this. It was actually moved because of trade, not because of food safety; correct?

Ms. DELAURO. Yes.

Mr. CORBO. The Catfish Farmers of America, they were the ones who successfully got it moved over. And I agree with you. There were trade arguments used.

But in looking at the data from FDA in terms of what they have been able to intercept, they are not getting it all. You have products coming into this country from Vietnam and from China and from Thailand that do not meet our food safety standards. And so if we are——

Mr. KINGSTON. We will have the equivalency standard though, right?

Mr. CORBO. They will have to set up a system. FSIS will have to set up a system. And what is remarkable about this language in the farm bill is that not only will the processing facilities have to meet the inspection standards, but it also gives FSIS on-farm inspection capabilities and transportation inspection capabilities, which we don't have for meat and poultry now.

Ms. DELAURO. I would just add there, I was in conversation when we were doing the farm bill with catfish farmers. I told them I wasn't sure—actually, I was more than not sure; I didn't think it was such a good idea. But we did put in very tough language to try to deal with this, you know. What we did and one of the big issues with regard to trade was the percentage of the market that was being taken by foreign imports, and the foreign imports were coming in just laden with antibiotics.

I refer you to yesterday's, I don't know if it was The New York Times or the Washington Post, but I think it was The New York

Times that talked about salmon coming in from Chile, and the salmon from Chile is loaded with antibiotics.

Now, there, again, if we begin to change our standards and do what we want to do, you know, that can—I mean, again, the level of the agreement, I don't know what it is specifically with that—we then are in a weakened position to deal with trying to protect the public health of this country. But I think it has been laid out as to what has happened with regard to catfish.

Done.

Mr. KINGSTON. Yes.

Ms. DELAURO. I think it is important, and Ms. Kaptur is not here, but, again, processed foods are excluded from country of origin labeling requirements.

So I think we need to reiterate that fact.

Also, one of the points I wanted to make with regard to the science and a prior question here is and, again, this was science and from CDC and others, with U.S. chickens, and this is a quote, are fragile, easily contaminated with bacteria. It also says that every step increases risk. It is kill, clean, gut, getting it to the consumers. You need to do it as quickly as possible; and, in fact, it is crucial with regard to temperature. If the appropriate temperature—and keeping it that way.

It is hard for me to believe. I would be less than honest if I didn't express my view on this, that getting U.S.-Canadian chicken, getting it to China and maintaining a level of temperature, getting there, what happens there with the processing and defrosting and what happens there, who knows how it is being cooked. We are not even sure, two out of three are not sure, that the process—that we are getting back a U.S. or a Canadian chicken, coming back here.

This is science. This is not some coming out of the door, out of the closet saying, okay, I think today we will look at this process, Chinese chicken, and say that, you know, it can put us at risk in terms of health. So that is science, and it is risk-based.

Last question. This is, Ms. Hauter, you shared, I think, what is an interesting piece of information from ARS Research, that, and I quote, strains of food-borne pathogens not common to the United States are contaminating meat and poultry products that are imported.

Can you just discuss the research findings on that or get us the research findings in more detail and get us a summary of that research? Because, I suspect that has health implications. Do you know if FSIS is taking this research into consideration in its equivalence determinations? If not, should it?

I was interested in your statement that you have a document from FDA that says, and I quote, that half of the foods that have been associated with food-borne illness have been imported. And can you submit us a copy of that statement from the FDA for the record?

Ms. HAUTER. Yes, we are happy to submit that. We had to sue to get it, but we now have the information, and we will provide it.

Ms. DELAURO. Great.

Ms. HAUTER. We can also provide the other information. FSIS also had a public meeting on the issue of the other types of bacteria.

[The information follows:]

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Inspections/Assessments 03R233 FY 2007	Foodborne Biological Hazards - 03

3. PROGRAM TYPE: [ ] COMPLIANCE PROGRAM [ ] PROGRAM CIRCULAR [X] ASSIGNMENT

4. OBJECTIVES

Conduct inspections at foreign firms actually exporting food to the U.S., in order to learn more about the conditions in the manufacturing of foods from a number of countries. Identify generic problems with specific food industries in specific countries and, when warranted, will take regulatory actions to better control the entry of questionable product(s), and demonstrate, by FDA's presence, our commitment to food safety.

5. PROGRAM JUSTIFICATION

The number of illnesses and deaths related to food borne illness, due to the presence of microbial pathogens has reached an unacceptably high level in the U.S. To the best of our knowledge, approximately half of the foods that have been associated with food borne illness have been imported. The President and Congress have recognized this problem and proposed and funded a Food Safety Initiative to better define the extent of the problem, and to promote an effective approach to ameliorate it. An important aspect of this new initiative is to increase our knowledge of the conditions under which a variety of foods are manufactured in foreign countries.

6. FIELD OBLIGATIONS

ORA/DFI shall assist CFSAN by reviewing imported food entry and compliance data to assist in determining the countries and firms whose inspections would be of greatest value to the Agency.

ORA/DFI shall plan inspections of foreign firms recommended by CFSAN in so far as contacting the firms and foreign governments and working out the logistics of travel. ORA shall select investigators, whose training and experience best qualifies them to conduct inspections at specific foreign firms. ORA shall assure timely submissions of EIRs to CFSAN review and classification. The Investigator shall prepare and, after obtaining any CFSAN team member concurrence, submit the entire original EIR to the Imports Branch no later than 30 days following the trip. Submit individual EIRs as they are completed. Don't delay until all EIRs from a particular trip are completed; rather submit each EIR individually as they are completed due to workflow issues. Prioritize submission of EIRs based on classification (i.e., OAI and VAI before NAI).

In FY 07, 100 foreign inspections of food firms are planned. On a "for cause" basis as needed, additional inspections may be requested by CFSAN, such as those needed to follow-up on food borne outbreaks.

PAC REPORTING INSTRUCTIONS: All CFSAN foreign inspection time is planned under PAC 03R233. Report accomplishments against PAC 03R233, using the Foreign Inspection Operation Code 11.

7a. SELECTION OF ESTABLISHMENTS TO BE COVERED: [ ] BY DISTRICT OFFICE [ ] BY CENTER [X] BY BOTH

b. INSPECTION TYPE: [ ] COMPREHENSIVE [ ] ABBREVIATED [X] DIRECTED

c. PRODUCT(S)	d. INDUSTRY/PRODUCT CODE(S)
All foods, with emphasis on frozen, ready to eat foods, fresh produce, foods implicated in food-borne infection outbreaks, infant formulas, seafood, cheese, etc.	02-50, 54

e. EXAM TYPE: [X] CHEMICAL [X] MICROBIOLOGICAL [X] PHYSICAL [ ] ENGINEERING [X] MICROANALYTICAL [ ] OTHERS *(Specify)*

f. CHECK THE FOLLOWING ATTRIBUTES

Check appropriate domestic compliance program for details.

g. SPECIAL EQUIPMENT, METHODS, AND HANDLING

Resources for samples collected as part of infant formula or medical food foreign inspections are planned under those programs.

FORM FDA 2621 (7/99) PREVIOUS EDITION IS OBSOLETE **ORA WORKPLANNING SHEET** PAGE NO. 03-20

2007 ORA WORKPLAN OCTOBER 1, 2006

1. PROGRAM/ASSIGNMENT TITLE	2. PPS PROJECT NAME/NUMBER
Foreign Inspections/Assessments	Foodborne Biological Hazards - 03

3. PROGRAM/ASSIGNMENT CODE(S)	4. WORK ALLOCATION PLANNED BY	5. OPERATIONAL FTE POSITIONS
03R233	[X] ORA [ ] CENTER	4.2

REGION	6. DISTRICT/ SPECIALIZED LABORATORY	1 INSPECTIONS FOREIGN	2 INVESTIGATIONS (Hours)	9 FOREIGN ASSESSMENT TECHNICAL ASSISTANCE (HOURS) *						9 OTHER OPERATIONS (Hours)
	TOTAL FIELD	100		950						
	HEADQUARTERS									
NE	REGIONAL STAFF									
	NEW ENGLAND									
	NEW YORK									
	REGIONAL LAB									
	WEAC									
CE	REGIONAL STAFF									
	BALTIMORE									
	CHICAGO									
	CINCINNATI									
	DETROIT									
	MINNEAPOLIS									
	NEW JERSEY									
	PHILADELPHIA									
	FORENSIC CHEM CTR									
SE	REGIONAL STAFF									
	ATLANTA									
	FLORIDA									
	NEW ORLEANS									
	SAN JUAN									
	REGIONAL LAB									
SW	REGIONAL STAFF									
	DALLAS									
	DENVER									
	KANSAS CITY									
	SOUTHWEST IMPORT DISTRICT									
	REGIONAL LAB									
PA	REGIONAL STAFF									
	LOS ANGELES									
	SAN FRANCISCO									
	SEATTLE									
	PACIFIC REGIONAL LABORATORY-SW									
	PACIFIC REGIONAL LABORATORY-NW									
	HOURS PER OPERATION	30.0		*						
	TOTAL HOURS	3000		950						
	CONVERSION FACTOR	950		950						
	TOTAL OPERATIONAL FTEs	3.16		1.00						

9. REMARKS

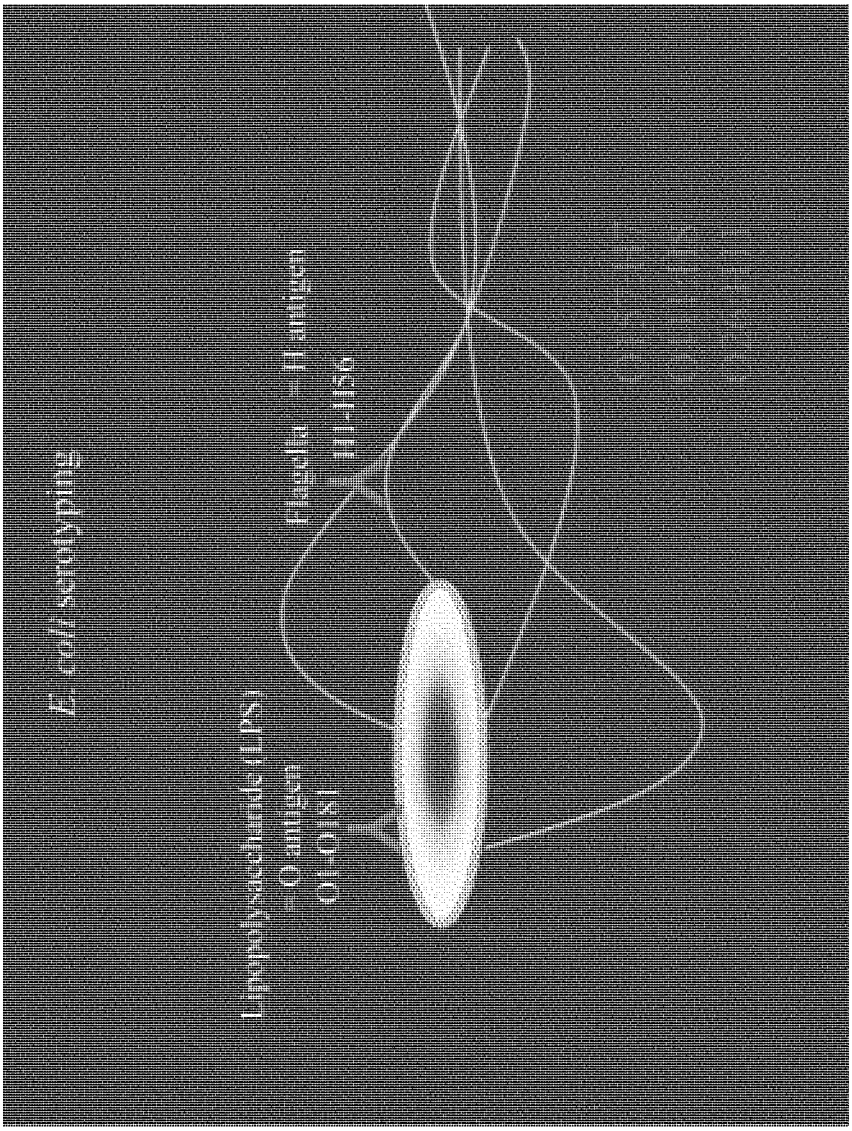
Foreign activities per DFI inspection distribution. * Technical Assistance can include but is not limited to training, presentations, speeches, site visits, outreach, workshops, seminars or meetings with partnership groups trade associations etc. Per CFSAN, report accomplishments under PAC 03R233.

Note: CFSAN may request additional foreign inspections as warranted by foodborne outbreaks and other "for cause" reasons.

Non-O157 Shiga Toxin-producing
E. coli: Status and Relevance to
Food Safety
The Food Safety Group
U.S. Meat Animal Research Center
USDA-ARS
Clay Center, Nebraska

Presentation Outline/Objectives
• Introduction
• Our perspective on non-O157 STEC
• Prevalence of non-O157 STEC
• Efficacy of the current interventions
• Summary and concluding remarks

Nomenclature


E. coli serotyping
Lipopolysaccharide (LPS)
= O antigen
O1-O181
Flagella = H antigen
H1-H56

Our Perspective

- Mode of Operation (for any pathogen)
  - What is the prevalence?
  - Are the current interventions effective?
  - What is the prevalence in the ground beef supply — should we be concerned?

Our Perspective

- Although non-O157 STEC is getting a lot of media attention recently, this is not a new issue for us: we have been working on this issue for years - collecting and publishing data, as well as testing many entities that will reduce non-O157 in meat products.
- There are many kinds of non-O157 STEC, but only a subset appears to be important for human disease.

Our Perspective

- STEC are a natural part of the animal microflora.
- The interventions that work to reduce STEC O157 on meat also work to reduce non-O157 STEC.
- Finding non-O157 STEC is not easy, but we have made progress in developing methods that work, and we are happy to share them.

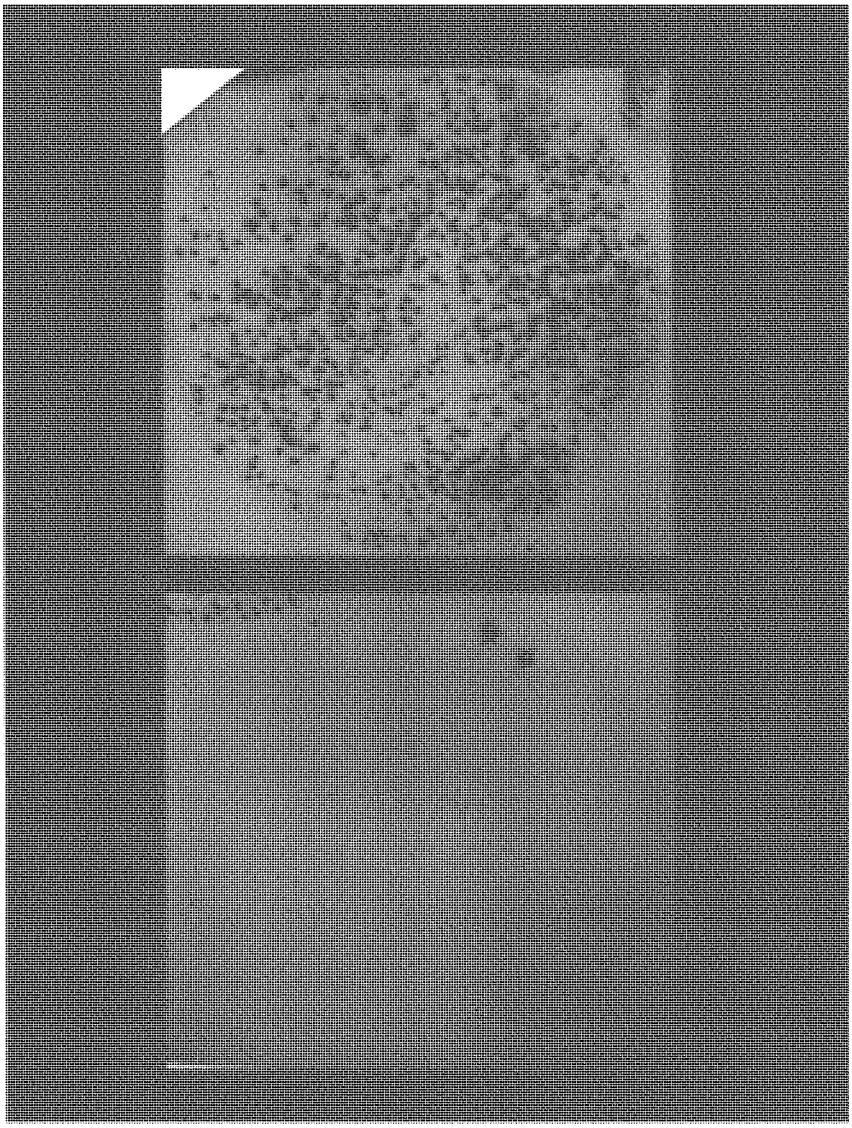
Methodology (until 2006)

- Prepare samples as with *E. coli* O157:H7
- Enrich as with *E. coli* O157:H7
- PCR a sample of the enrichment for Shiga toxin genes

Methodology (until 2006)

Colony Hybridization

- Grow colonies from sample enrichments on agar media
- Transfer colonies to nylon membranes
- Lyse cells and fix DNA to the membrane
- Hybridize with DNA probes for Shiga toxin genes
- Detect bound probe
- Identify target colonies



Methodology - Continued

- Pick colony and obtain pure culture for characterization
- Characterize for virulence factors
- Perform biochemical characterization to confirm that isolates are *E. coli*
  - *Shigella dysenteriae*, *Citrobacter freundii*, and *Enterobacter cloacae* have been found to produce Shiga toxins.
- Once confirmed, then serotype (O and H typing)

Washed Sheep Blood Agar
for isolation of non-O157 STEC

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ISSN 1433-1128
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NOTES

Rapid Detection and Isolation of Shiga-Like Toxin (Verocytotoxin)-Producing *Escherichia coli* by Direct Testing of Individual Enterohemolytic Colonies from Washed Sheep Blood Agar Plates in the VTEC-RPLA Assay

LOTHAR BEUTIN,* SONJA ZIMMERMANN, and KERSTIN GLEIER

Escherichia coli Reference Laboratory, Department of Microbiology, Robert Koch Institute, D-13353 Berlin, Germany

Received 6 May 1998; accepted for publication 9 July 1998; revised 5 August 1998

By combining the enterohemolysin test and the VTEC-RPLA test (specific for the detection of Shiga-like toxin 1 (SLT-I), SLT-II, and SLT-IIc), single colonies of SLT-producing *Escherichia coli* were found to constitute between 0.03 and 66.1% of the coliform flora in human stool cultures and were isolated and characterized within 72 to 96 h.

Some types of Shiga-like toxin (SLT)-producing *Escherichia coli* (STEC) are important human pathogens causing hemorrhagic colitis and hemolytic uremic syndrome (HUS). The detection of these pathogens from patients' stool samples can be complicated when STEC strains are present in low numbers and low if phenotypical traits for their identification are absent (4, 8). About 60% of STEC strains isolated from human children exhibit a typical enterohemolytic phenotype on washed sheep blood agar which can be employed as a diagnostic marker for their identification (1, 5). In order to establish a rapid identification and isolation system for STEC from human stool, we combined the enterohemolysin test as a microbiological screening system for STEC with the VTEC-RPLA test as a rapid detection system for SLT production.

The STEC strains and the *E. coli* hemolysin are described elsewhere (2, 3, 7). Washed sheep blood agar plates were prepared in our laboratory (11) and compared with commercially available enterohemolysin agar plates (9) for the detection of different *E. coli* hemolysins (3, 7). No differences between both types of plates for detection of different hemolytic phenotypes was found. All STEC strains were analyzed for Vero cell toxicity as described previously (3, 5); *stx1* and *stx2* genes were detected by DNA-DNA hybridization and by PCR (*stx1*, *stx2*, and *stx-negative*; PCR (2, 5); *eae* and *ehx* were distinguished as described previously (6).

For the isolation of fecal SLT-I, a stool aliquot of about was emulsified into a tube containing 5 ml of sterile triptic soy broth. The stool culture was incubated without shaking for 30 to 22 h at 37°C. The next day, the grown culture was serially diluted (tenfold in phosphate-buffered saline (PBS), pH 7.2). From each dilution (100 to 10^{-5}), 0.1 ml was spread with a glass rod on Endo agar (Merck, Darmstadt, Germany) and enterohemolysin agar. The plates were incubated for 20 to 22 h at 37°C. The enterohemolysin agar plates were inspected for hemolysis after 3 h of incubation (indicating only α-hemolysin) and after overnight incubation (indicating all types of hemolysins). The titer of coliform bacteria was calculated by counting.

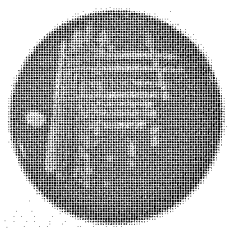

FIG. 1. Enterohemolysin agar plate inoculated with the stool sample of an adult patient. *E. coli* strains were isolated from the enterohemolysin plate, after overnight incubation.

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Letters in Applied Microbiology 2001, 32, 193–198

Mitomycin-supplemented washed blood agar for the isolation of Shiga toxin-producing *Escherichia coli* other than O157:H7

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Seikan Laboratories, Inc., 1460-8 Mitoda, Tokomachi, Katongun, Chiba 289-2047, [1]Saitama Prefectural Hanzen-Gun, Hanzen-machi, Hikigun, Saitama and [3]Nippon Institute of Biological Sciences, Oume, Tokyo, Japan

2001/18: received 17 January 2001, revised 19 February 2001 and accepted 6 June 2001

K. SUGIYAMA, K. INOUE AND R. SAKAZAKI 2001

Aims: Isolation and recognition of the prominent Shiga toxin (Stx)-producing strains of *Escherichia coli* (STEC) serovar O157:H7 can be confirmed easily by their late fermentation of sorbitol and lack of β-glucuronidase activity, but there has been no culture method of choice for detecting non-O157 STEC strains because of their biochemical diversity. Apart from Stx, many STEC strains produce enterohaemolysin (Ehly) regardless of their serovars.

Methods and Results: Although washed blood agar media, with or without the addition of antibiotics (vancomycin, cefixime, and cefsulodin) (WBA and WBVCCA), have been used to detect Ehly, a proportion of STEC strains consistently failed to produce haemolysin on these media. Washed blood agar medium was therefore studied further in order to increase the yield of strains producing Ehly.

Conclusions: It was found that the addition of 0.5 μg ml^{-1} of mitomycin C to the agar medium (WBMA) markedly increased the number of such strains. Thus, of 188 STEC strains comprising 95 O157 and 90 non-O157 STEC consisting of 54 serovars. Ninety-seven per cent of these strains produced haemolysin on WBMA, compared with only 76% and 83%, respectively, on WBA and WBVCCA.

Significance and Impact of the Study: The appearance of the Ehly zone of haemolysis that was easily distinguishable from that of α-haemolysin was enhanced by the incorporation of mitomycin C into washed-blood medium.

INTRODUCTION

Shiga toxin-producing *Escherichia coli* (STEC) is an important human pathogen causing haemorrhagic colitis and the haemolytic uraemic syndrome (HUS). The most important serovar implicated in these complaints is *E. coli* O157:H7, and selective media containing sorbitol as a chromogenic substrate for β-glucuronidase activity are used in the routine screening for this serovar or its mutantic variant. STEC serovars other than O157:H7 have also been implicated, both in sporadic cases and in outbreaks. However, no biochemical markers have been found to distinguish them from commensal *E. coli*. The only cultural method for the detection of non-O157 STEC strains was washed sheep blood agar containing Ca^{2+} ions (WBA) (Beutin *et al.* 1989). The method is based on the finding that STEC strains produce a characteristic zone of haemolysis on this agar. Unfortunately, a considerable proportion of non-O157 STEC strains failed to produce Ehly on this medium (Beutin *et al.* 1989, Bettelheim 1995).

Law *et al.* (1992) described the detection by ELISA of low numbers of STEC in mixed cultures grown in the presence of mitomycin C. We added mitomycin C to WBA (WBMA) in expectation of the same effect on Ehly production and found a marked increase in the number of Ehly positive strains. WBMA was also compared with an another agar based medium (WBVCCA) developed by Ichinohe *et al.* (1998), who added antibiotics to WBA to give more selectivity for STEC strains. In the present paper, the

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Complexity of the current non-O157 Assay

- 0 Hr: Sample arrives, is weighed and TSB is added for enrichment for 12 hrs at 42°C
- At 12th hr: A sample is removed for detection of virulence factors by PCR – takes 3-4 hrs
- At the 16th hr: If positive, a sample of the enrichment is plated onto sheep blood agar and allowed to grow at 37°C for 16-18 hrs
- At the 34th hr: Colonies are picked for virulence factor detection again – 3-4 hrs
- At the 38th hr: Streak onto MacConkey agar and incubate overnight
- At 50th hr: Pick a colony, make an agar stab and ship for serotyping – takes a week to two to get the results back

Best case: 62 continuous hrs; reality: 2 weeks

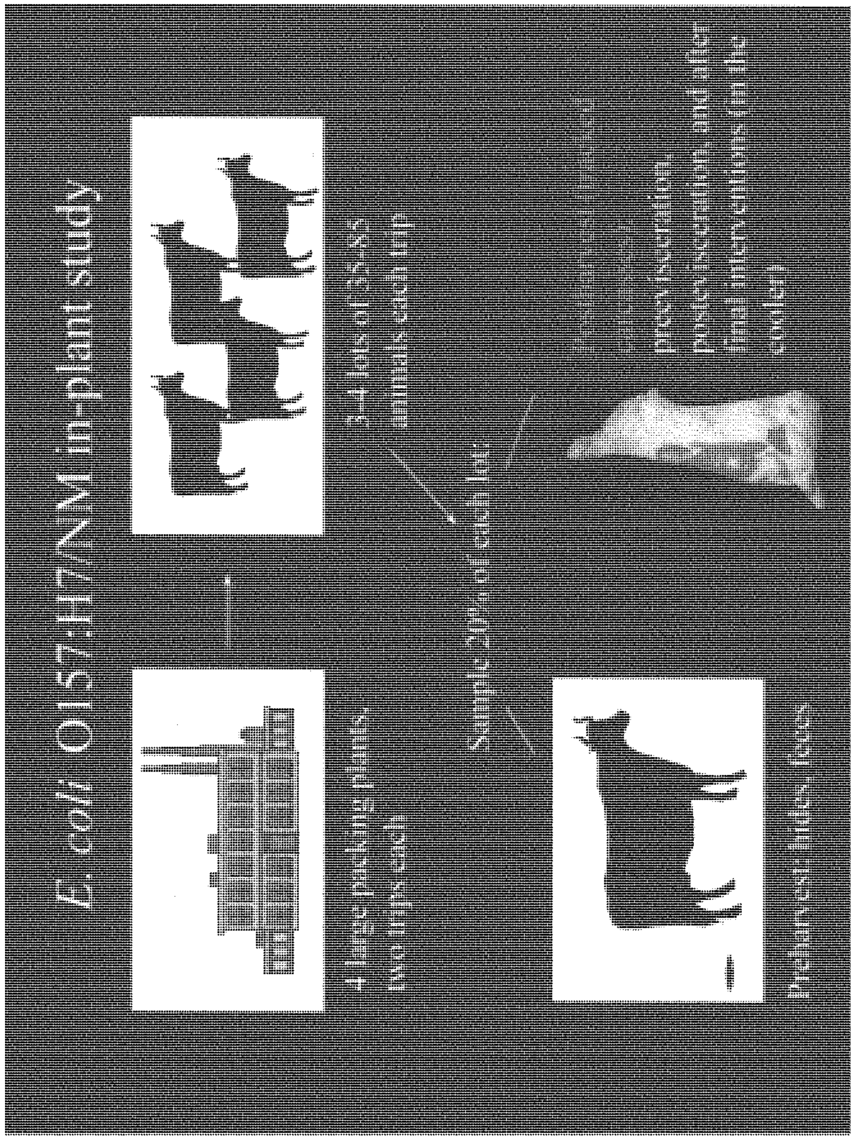
Top Non-O157 Serotypes (CDC)
O26 — 22% of non-O157 STEC
O111 — 16% of non-O157 STEC
O103 — 12% of non-O157 STEC
O121 — 9% of non-O157 STEC
O45 — 7% of non-O157 STEC
O145 — 5% of non-O157 STEC

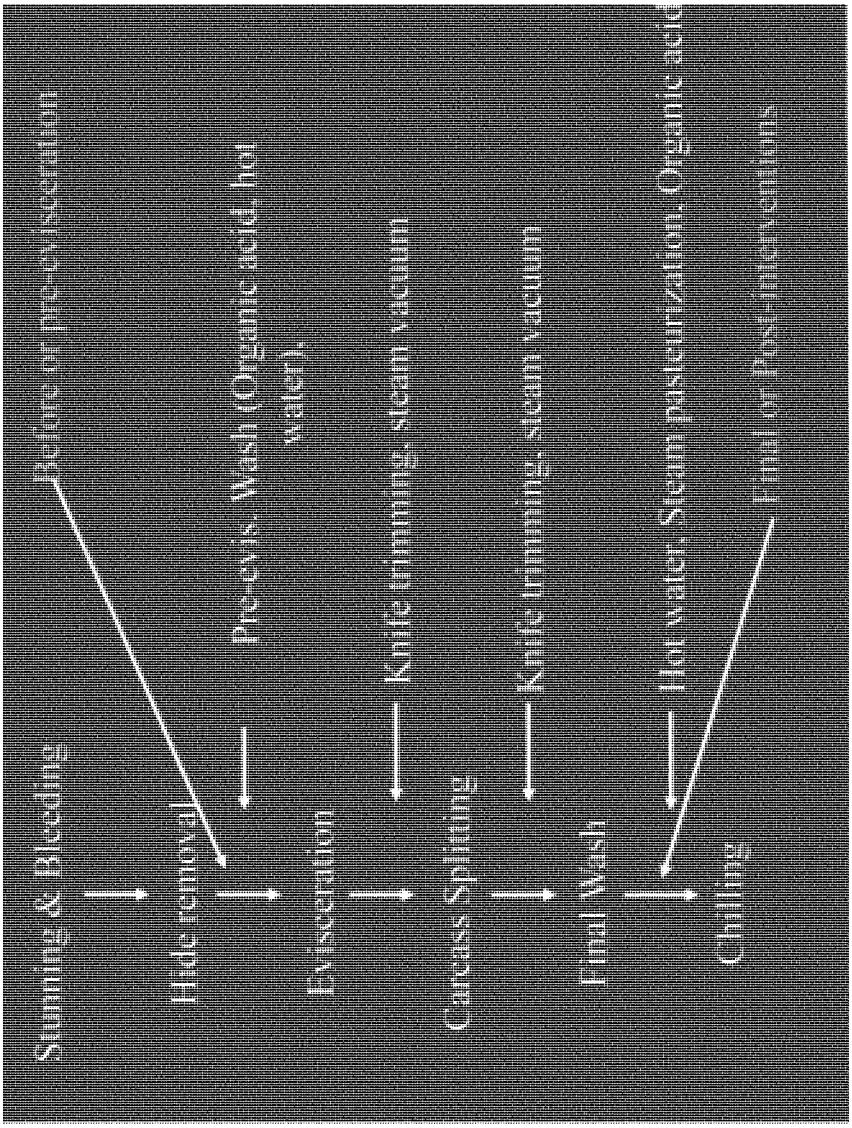
Prevalence of Non-O157 STEC

- Commercial fed cattle processing plants
- Commercial fed cattle processing plants as a function of the season of the year
- Commercial cow/bull processing plants
- Commercial lamb processing plants
- Imported raw ground beef material (trim)
- National ground beef supply

We are very appreciative of the U.S. meat industry for allowing us to use their facilities as our laboratory.

Commercial Fed Cattle Processing Plants


E. coli O157:H7/NM in-plant study
4 large packing plants,
two trips each
3-4 lots of 35-85
animals each trip
Sample 20% of each lot:
Preharvest: hides, feces
Postharvest (tracked
carcasses):
preevisceration,
postevisceration, and after
final interventions (in the
cooler)


Stunning & Bleeding
Hide removal
Evisceration
Careass Splitting
Final Wash
Chilling
Before or pre-evisceration
Pre-evis. Wash (Organic acid, hot water).
Knife trimming, steam vacuum
Knife trimming, steam vacuum
Hot water, Steam pasteurization, Organic acid
Final or Post-interventions

Results

	Pre-evisceration (No intervention)	Final (after all interventions)
E. coli O157	44.4% (144/324 carcasses)	1.8% (6/326 carcasses)
Non-O157 STEC	54% (180/334 carcasses)	8.3% (27/326 carcasses)

Serogroup Distribution of Non-O157 STEC Isolates

Serogroup	# of isolates	Before	Final
O142	54	46	8
O121	31	31	0
O5	22	19	3
O171	18	16	0
O113	15	12	3
O132	14	11	1
O8	13	11	2
O88	10	10	0
O6	9	8	1
O139	9	5	4
O172	9	7	2
OX3	9	3	6
O104	5	1	4
O117	5	5	0
O15	4	4	0
O165	4	4	0
O5	3	3	0
O55	3	3	0
O153	3	3	0
O168	3	0	3
O10	2	2	0
O45	2	2	0
O103	2	2	0
O109	2	1	3
O119	2	2	0
O145	2	2	0
OX28	2	2	0

None of the top 6 CDC serotypes were found on the carcasses after the full complement of all the interventions:

- Interventions are effective

Virulence Attributes

- *E. coli* can cause human disease when they possess *stx*1 or *stx*2.

- Individuals infected with strains producing Shiga toxin 2 are more likely to develop severe disease than those infected with strains carrying Shiga toxin 1.

- It is commonly thought that *E. coli* must contain *stx*1 or *stx*2 and *eae* (intimin) to have the highest chance of causing disease in humans – of course there are always exceptions.

STEC Virulence Factor Profiles

STEC virulence factors	# of Isolates	Before	Final
stx1	152	135	17
stx2	93	78	15
stx1, stx2	15	15	0
stx1, eae	2	2	0
stx1, hlyA	8	3	5
stx2, hlyA	19	17	2
stx1, stx2, hlyA	31	23	8
stx1, stx2, eae	1	1	0
stx1, eae, hlyA	8	6	2
stx2, eae, hlyA	20	20	0
stx1, stx2, eae, hlyA	12	10	2
Total	361	310	51

From 2/326 carcasses

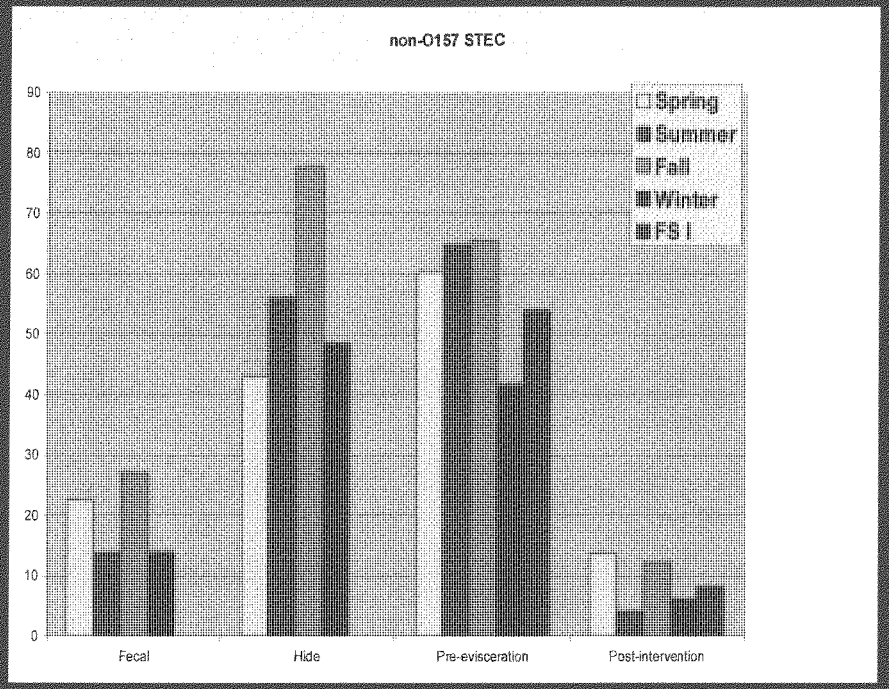
Before & After = Before and after interventions

Prevalence of Non-O157 STEC

- Commercial fed cattle processing plants
- Commercial fed cattle processing plants as a function of the season of the year
- Commercial cow/bull processing plants
- Commercial lamb processing plants
- Imported raw, ground beef products (trim)
- National ground beef supply

Study Design

- Season effect
- *E. coli* O157, *Salmonella*, non-O157 STEC
- 3 plants
- 2 visits/plant/season
- 100 samples/site/plant/season
- Feces, hide, pre-evisceration, and post-intervention samples came from the same animal/carcass


non-O157 STEC
90
80
70
60
50
40
30
20
10
0
Spring
Summer
Fall
Winter
FS I
Fecal
Hide
Pre-evisceration
Post-intervention

STEC Virulence Factor Profiles

Virulence factors	Fecal	Hide	Before	After
stx1	66	678	308	64
stx2	187	223	657	85
stx1, stx2	51	99	96	12
stx1, *hly A*	49	71	46	12
stx2, *hly A*	93	152	311	30
stx1, stx2, *hly A*	39	55	135	0
stx1, eae	1	1	1	0
stx2, eae	3	3	1	0
stx1, stx2, eae	0	0	1	0
stx1, eae, *hly A*	13	34	62	19
stx2, eae, *hly A*	17	31	39	11
stx1, stx2, eae, *hly A*	0	10	8	0
Total	518	1284	1537	239

From 22/1232 carcasses

Enumeration of STEC on Post-Intervention Carcasses
(as determined by PCR for *stx*)

		Cells per 100 cm²	
Season	# Samples	MPN Index	95% C.I.
spring	66	< 3.0	0.0-9.5
spring	1	3.6	0.2-18.1
spring	1	7.4	1.3-20.3
spring	1	38.2	17.7-82.6
summer	32	< 3.0	0.0-9.5
fall	63	< 3.0	0.0-9.5
fall	2	3	0.2-9.6
fall	3	3.6	0.2-18.1
winter	31	< 3.0	0.0-9.5

Prevalence of Non-O157 STEC

- Commercial fed cattle processing plants
- Commercial fed cattle processing plants as a function of the season of the year.
- Commercial cow/bull processing plants
- Commercial lamb processing plants
- Imported raw ground beef material (trim)
- National ground beef supply

Study Design

- 3 plants
- Samples collected in spring/summer
- 3 days of sample collection
- 96 samples/site
- Pelt/fleece, Pre-evisceration, and Post-intervention
- APC, *E. coli* O157:H7, *Salmonella*, and non-O157 STEC

Prevalence of Non-O157:H7 STEC at Different Sites in Lamb Processing Plants (*stx* PCR)

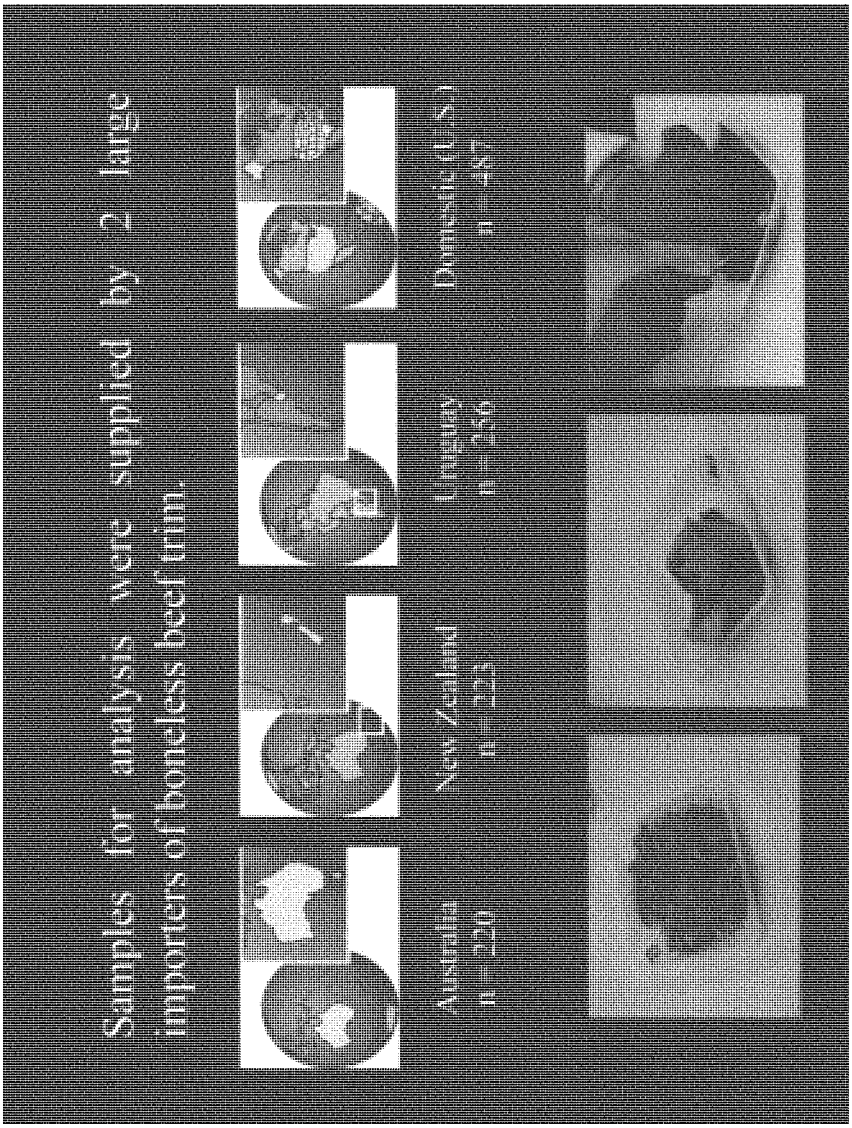
		# Positive (%)		
	N	Pelt	Before	Final
Stx PCR	846	729 (86.2)	665 (78.6)	690 (81.6)
Isolate	846	-	-	488 (57.7)

STEC Virulence Factor Profiles

STEC virulence factors	# of isolates	% of isolates
stx1	91	18.6
stx2	9	1.8
stx1, stx2	224	46.0
stx1, hlyA	19	3.9
stx2, hlyA	1	0.2
stx1, stx2, hlyA	142	29.1
stx1, eae	0	0.0
stx2, eae	0	0.0
stx1, stx2, eae	0	0.0
stx1, eae, hlyA	2	0.4
stx2, eae, hlyA	0	0.0
stx1, stx2, eae, hlyA	0	0.0
Total	488	100.0

Non-O157:H7 STEC Found on Post-Intervention Lamb Carcasses
None are on the CDC top 6 list

STEC Prevalence in
Imported and Domestic
Boneless Beef Trim
Used for Ground Beef


Samples for analysis were supplied by 2 large importers of boneless beef trim.
Australia
n = 220
New Zealand
n = 223
Uruguay
n = 256
Domestic (U.S.)
n = 487

STEC

Frequency of STEC isolation
in boneless beef trim by country of origin

	AUS	NZ	URU	DOM
n	220	223	256	487
Isolate positive samples	9	4	40	28
STEC isolated	10	4	52	32

Serotypes of STEC isolated by country

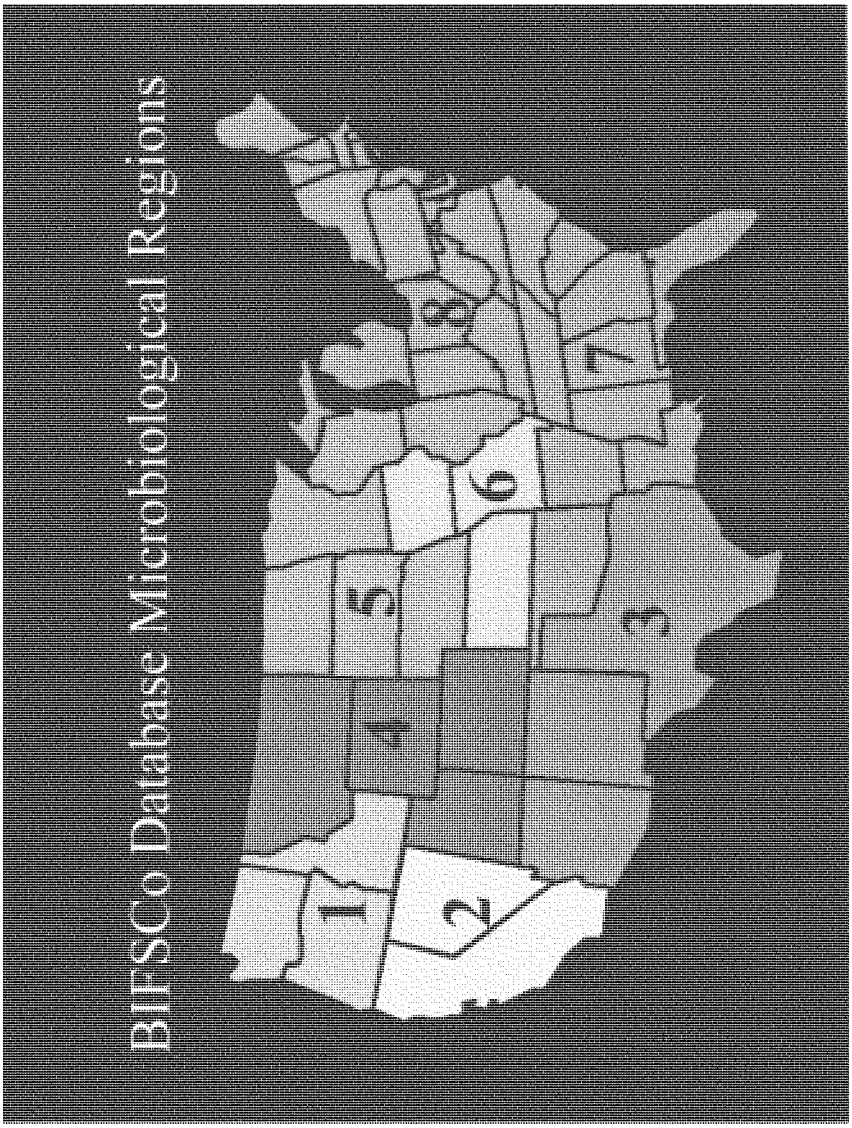
AUS	NZ	URU		DOM	
O5:H11	O26:H8	O5:H25	O116:H28	O5:H26	O117:H4
O7:H35	**O26:H11**	O6:H26	O156:H11	**O8:H19***	O132:H4
O111:H36*	O84:H9	O6:H34	**O165:H19***	**O20:H19**	O133:H38
O113:H21	**O163:H19**	O8:H19	O163:H26	O53:H18	O142:H34
O117:H7		**O8:H19***	**O168:H-**	O73:H4	O156:H25
O171:H-		O113:H21*	O174:H11	O75:H18	**O165:H-**
O181:H-		**O50:H19***	O174:H28*	**O79:H7**	O171:H2
O91:H2		O98:H14	O174:H36	O81:H4	O173:H11
		O51:H18	O81:H2	O85:H28	O174:H36
		O74:H35*	**O81:H11***	O91:H10	O185:H11
		O92:H8	O81:H18	O98:H32	O81:H2
		O85:H18	O81:H27*	O111:H4	O81:H2
		O91:H8*	O81:H28	O113:H21	O81:H32
		O85:H17	O81:H29	O116:H21	O81:H31
		O98:H38*	O81:H46*		**O8:H-**
		O113:H21	O81:H31		
		O111:H6	O81:H32		

Underlined serotypes have been associated with human illness.

Bolded serotypes have been associated with Hemolytic Uremic Syndrome (HUS).

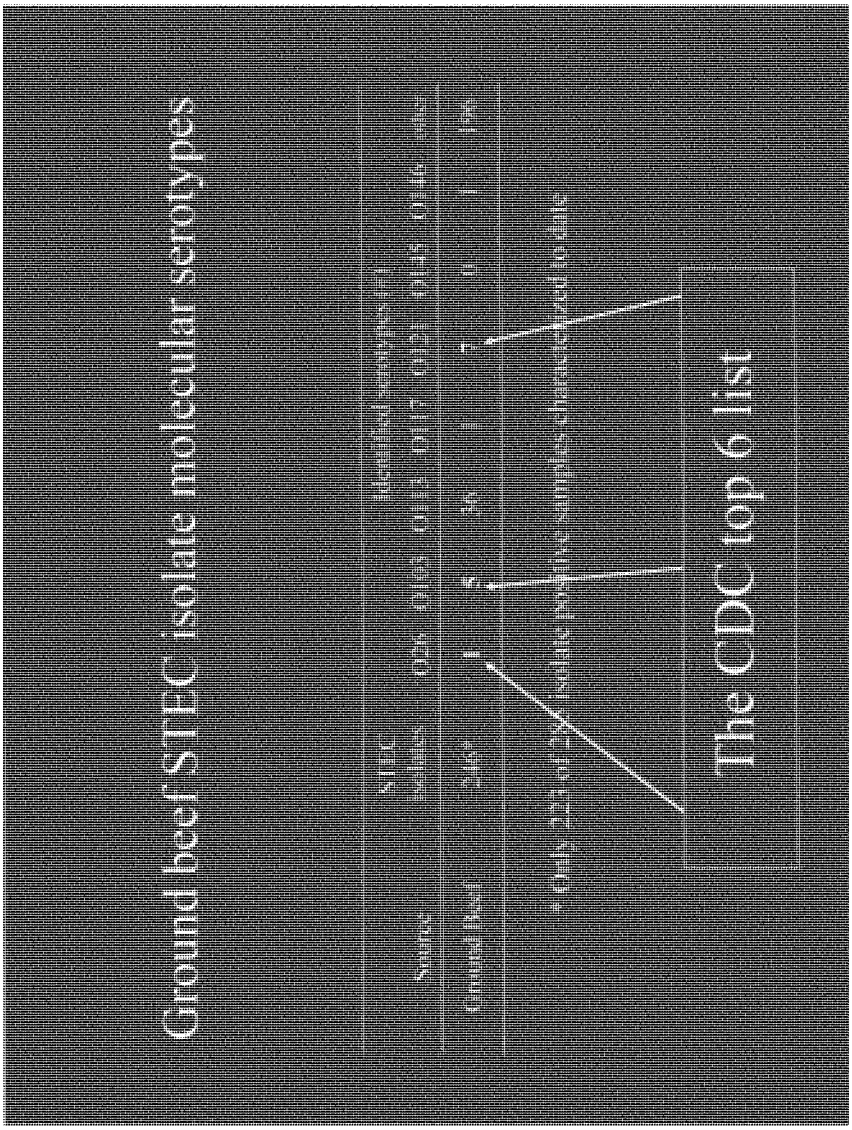
What is the Prevalence in the Ground Beef Supply?

A national survey of the prevalence
of non-O157 Shiga toxin-producing
E. coli in ground beef


BIFSCo Database Microbiological Regions
1
2
3
4
5
6
7
8

Ground beef non-O157 STEC screening and isolation results

Total samples screened	3668	of 4136 in study
positive for stx1 and/or stx2 by PCR	962	
samples with 1 or more STEC isolated	285/962	
samples with STEC isolate in top 6 non-O157 O-serogroups	13/223	



Virulence gene distribution of the 13 STEC isolates from Ground Beef in top 6 CDC O-Groups

STEC virulence factors	# of Isolates
stx1	4
stx2	1
stx1, stx2	0
stx1, hlyA	0
stx2, hlyA	4
stx1, stx2, hlyA	0
stx1, eae, hlyA	4
stx2, eae, hlyA	0
stx1, stx2, eae, hlyA	0
Total	13

Summary
• % of ys positive 26.2%
• % the top 6 CDC 5.8%
• % the top 6 CDC most likely to cause disease 1.8% (n=11)

Summary and Conclusions

- STEC are a natural part of the animal microflora.
- Some Non-O157 STEC can cause severe disease in humans.
- Non-O157 STEC is found at high frequency in pre-harvest samples (feces and hides).
- Non-O157 STEC is probably just as prevalent, maybe more, than O157 STEC in pre-harvest samples.
- Interventions used at the processing plants affect STECs similarly.

Summary and Conclusions

- A very small proportion of the non-O157 STECs (11.3, 7.3, 0.40, and 2.0%) have the combination of virulence factors that provide the maximum likelihood of causing disease.
- In 10,159 samples (carcass, trim and ground beef), we have detected the top 6 CDC serotypes only from 15 samples; a fraction of these have the ability to cause disease.
- To the best of our knowledge, there has never been a meat-borne non-O157 STEC outbreak in the United States.

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Ms. DELAURO. Great. Let me just say a thank you to all of my colleagues, those who are here who hung in to the bitter end, and to the ranking member, who I know cares deeply about these issues, and Mr. Bishop as well, and those who had to go to other meetings today.

I want to thank each of our panelists. Thank you for your knowledge and intellect and your candor and the suggestions about how we move to the future.

I think we laid out some information, but, ultimately, it is about how we move to proceed for the future, which we all have an interest in. And I would love to be able to, you know, after this meeting, collect ideas of how we might try to deal with the issue of the Chinese chicken in the short term and also how we deal with equivalence and how this can lead us to equivalence in the long term.

So I thank you all very, very much.

Mr. KINGSTON. And I also wanted to say, you know, those Chinese products I am cooking them in my office, and I wanted to invite Tony and Dr. Raymond to co-host a little brunch with me, and we will have some good eating.

Ms. DELAURO. I hope you are not alone, Jack. Thank you very much.

This hearing is completed. Thank you.

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