GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

November 4, 2005

The Honorable James M. Jeffords
Ranking Minority Member
Committee on Environment and Public Works
United States Senate

The Honorable Frank R. Lautenberg
United States Senate

The Honorable Patrick Leahy
United States Senate

Subject: *Chemical Regulation: Approaches in the United States, Canada, and the European Union.*

Chemicals are used to produce items widely used throughout society, including consumer products such as cleansers, paints, plastics, and fuels, as well as industrial solvents and additives. While chemicals play an important role in everyday life, some may be harmful to human health and the environment. Some chemicals, such as lead and mercury, are highly toxic at certain doses and need to be regulated because of health and safety concerns. In 1976, the Congress passed the Toxic Substances Control Act (TSCA) in part to authorize the Environmental Protection Agency (EPA) to regulate chemicals that pose an unreasonable risk to human health or the environment.[1] TSCA addresses chemicals that are manufactured, imported, processed, distributed in commerce, used, or disposed of in the United States and authorizes EPA to assess chemicals before they enter commerce (new chemicals) and review those already in commerce (existing chemicals). TSCA excludes certain chemical substances, including among other things pesticides that are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); and food; food additives; drugs; cosmetics or devices that are regulated under the Federal Food, Drug and Cosmetic Act (FFDCA).

For existing chemicals, TSCA authorizes, but does not specifically require, EPA to review the risks of chemicals included in TSCA's inventory of existing chemicals.

[1]Pub. L. No. 94-469, 40 Stat. 2003 (1976) (codified at 15 U.S.C. §§ 2601-2692).

Using its authority under TSCA, EPA has required testing for less than 200 of the over 62,000 chemicals that were already in commerce when EPA began reviewing chemicals in 1979. Since then, upon receiving notice of commencement that the company has begun manufacturing a chemical, EPA has added another 20,000 chemicals to its inventory after reviewing them under its new chemical review program. If EPA finds that a reasonable basis exists to conclude that a chemical presents or will present an unreasonable risk to human health or the environment, TSCA generally requires EPA to impose regulatory requirements. When doing so, EPA must apply the least burdensome regulatory requirement to adequately protect against a chemical's risk.[2] EPA can promulgate a rule that bans or restricts the chemical's production, processing, distribution in commerce, disposal or use, or that requires warning labels be placed on the chemical. Canada and the European Union also maintain inventories of existing chemicals.

TSCA generally requires chemical companies to notify EPA at least 90 days before beginning production, manufacture, or import of a new chemical—or before manufacturing or processing a chemical for a use that EPA has determined by rule is a significant new use—by submitting a premanufacture notice.[3] Such notices are to provide information on the chemical's identity, production process, anticipated production volume, intended uses, potential exposure and release levels, disposal, and byproducts. A premanufacture notice is required for all levels of production or import. In addition, companies are required to provide EPA any test data that they possess or control related to the chemical's effect on health or the environment and a description of any other data concerning the chemical's environmental or health effects known to or reasonably ascertainable by the companies. EPA has these 90 days to review the chemical information in the premanufacture notice and identify the chemical's potential risks. On the basis of this review, EPA makes a decision to (1) take no action; (2) after making certain findings under TSCA, require controls on the use, manufacture, processing, distribution in commerce, or disposal of the chemical pending development of test data; or (3) ban or otherwise regulate the chemical pending the receipt and evaluation of test studies performed by the chemical's manufacturer. As of June 2005, EPA's reviews resulted in some action being taken to reduce the risks of over 3,500 of the 32,000 new chemicals that companies had submitted for review.[4]

Under Canadian Environmental Protection Act (CEPA) regulations, companies must submit certain information and test data to the government when production or importation volumes reach certain levels. Under CEPA, the Ministers of Health and the Environment must assess the information provided on a new chemical to

---

[2]15 U.S.C. § 2605. Unlike Canadian and European Union legislation, which subject chemical companies to notification requirements only after manufacturing has begun, and production or marketing of the chemical reaches a certain level, TSCA requires a premanufacture notice.

[3]15 U.S.C. § 2604.

[4]These chemicals reviewed do not include EPA's review of the chemicals manufactured by companies that EPA exempted from the premanufacture notice requirements: 717 Test Marketing Exemption Applications; 7,888 Low Volume Exemptions; 35 Low Release/Low Exposure Exemptions; and 2,530 Polymer Exemptions. EPA may exempt a chemical company from the premanufacture notice requirement, upon application from the company showing to EPA's satisfaction that the chemical will not present any unreasonable risk of injury to human health or the environment.

determine whether it is toxic or capable of becoming toxic. Canada defines new chemicals as those that are not on Canada's Domestic Substances List—a list of all known chemicals that (1) were in commercial use in Canada between January 1, 1984, and December 31, 1986; (2) were manufactured in or imported into Canada by any person in a quantity of 100 kilograms or more in any calendar year during that period; or that (3) have subsequently been fully assessed under CEPA. According to Canadian officials, a new chemical is generally added to the existing chemicals inventory only after a certain level of production or importation has been reached and specified testing for that level has been performed without conditions being placed on the chemical's manufacture or importation.

The European Union's current chemical control legislation[5] generally requires chemical companies to notify a member state regulatory agency once the marketing level of a new chemical reaches 10 kilograms.[6] The European Union maintains a new chemicals inventory—separate from the one for existing chemicals—and the chemicals in this inventory are subject to additional testing by the chemical company and review by the authorities when the annual amount marketed reaches certain levels.[7] Furthermore, the European Union is currently considering revising its chemical control legislation through proposed legislation known as Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) that would largely eliminate the distinction between new and existing chemicals and would require chemical companies to submit certain basic information on chemicals produced over certain volumes.[8]

In this context, you asked that we provide comparative information on the following chemical control laws: TSCA, CEPA, the current European Union legislation, and REACH as proposed. Specifically, you asked that we provide information on the

---

[5]The current European Union chemical legislation consists of four major pieces of legislation with adaptations to technical progress over the years: Council Directive 67/548/EEC: "Classification, Packaging and Labeling of Dangerous Substances," Council Directive 76/769/EEC: "Marketing and Restrictions," Council Regulation 793/93: "Existing Substances Evaluation," and Council Directive 88/379/EEC, as replaced by 99/45/EC: "Preparations" as well as a number of other directives. In general, a European Union directive is a binding collective decision made by the member states, acting through their national Government Ministers in the Council of the European Union and the Parliament.

[6]According to a European Union official, the competent authority acts on behalf of all member states and informs these agencies of the notification. Normally, the applicant must wait 60 days for a reaction to this notification before marketing a chemical. The amount of test data required, increases with the volume marketed.

[7]New chemicals are identified as those not listed on the European Inventory of Existing Commercial Chemical Substances (EINECS), a list of approximately 100,000 chemicals deemed to be on the European Community market on September 18, 1981.

[8]The European Union is currently considering a proposal known as REACH. COM 2003 0644 (03), Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} Proposal for a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation, and restriction of chemicals. A European Union representative estimates that the earliest possible adoption of REACH is the end of 2006 with the first registrations arriving in 2010.

approaches of (1) controlling chemical risks, (2) reviewing existing chemicals used in commerce, (3) assessing new chemicals, and (4) handling confidential business information. The laws and regulations discussed in this letter are sometimes augmented by various other mechanisms for controlling chemicals. For example, in the United States, this includes programs implemented under other environmental laws such as the Clean Air Act; the Clean Water Act; the Federal Food, Drug, and Cosmetic Act; and the Federal Insecticide, Fungicide, and Rodenticide Act, as well as programs in which the chemical industry voluntarily participates. Details on some of these other chemical control mechanisms are discussed in our June 2005 report on options that exist to control harmful chemicals.[9] For purposes of this report, we have focused on TSCA, CEPA, and current and proposed European Union chemical control legislation. It is important to note that the manner in which new and existing chemicals are defined under these pieces of legislation varies and, as EPA notes in its comments, may make for some imperfect comparisons. To the extent possible, we have attempted to highlight such differences when comparing various legislative provisions.

To respond to your request, we reviewed EPA's policies and guidelines on the chemical review and control programs for new and existing chemicals. We also obtained information from and discussed chemical laws with chemical control agency representatives of Canada and the European Union. These efforts were augmented by interviews with EPA officials. We performed our work between July 2005 and October 2005 in accordance with generally accepted government auditing standards.

In summary, TSCA authorizes EPA to take a number of control actions with regard to new chemicals or uses of chemicals that EPA has determined by rule are significant new uses. To control existing chemicals under TSCA, EPA must present substantial evidence that a reasonable basis exists to conclude that the chemical presents or will present an unreasonable risk to human health or the environment. The United States Court of Appeals for the Fifth Circuit has stated that EPA must consider the costs of any proposed action in evaluating what risks are unreasonable.[10] EPA must also apply the least burdensome regulatory requirement. In contrast, under Canadian and European Union legislation the costs of various controls are to be considered in deciding the particular control action to be taken, but these costs are not factors in determining whether to control a chemical.

Under TSCA, EPA is not required to systematically prioritize existing chemicals for purposes of determining their risks, although EPA relies upon mechanisms such as voluntary testing programs and advice from federal advisory groups to help ensure that it gives priority to the chemicals posing the greatest risks. Both CEPA and the proposed REACH legislation contain requirements for systematically prioritizing and reviewing existing chemicals.

---

[9]GAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458 (Washington, D.C.: June 13, 2005).

[10]*Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

For new chemicals, TSCA requires that chemical companies submit for EPA's review any data already in their possession on the chemicals' health and ecological effects, potential exposures and on their physical chemical properties, with the premanufacture notice (PMN) generally required before chemical companies may manufacture the chemicals.[11] Chemical companies generally do not have such data at the time they submit the PMN for the chemicals and are not required to develop the data unless EPA promulgates a test rule. Under REACH, chemical companies would be required to develop and submit data on the physical properties and health and ecological effects of new chemicals with the initial notification and, subsequently before the chemicals reach certain levels of production.

Regarding the protection of confidential business information that is provided to the regulatory agencies, TSCA, CEPA, and the European Union current and proposed legislation have provisions for protecting such information from inappropriate disclosures, although the specifics of the protection varies. One of the objectives of the proposed REACH legislation is to make information on chemicals more widely available to the public.

Approaches to Controlling Chemical Risks

TSCA authorizes EPA to take a number of control actions with regard to new chemicals.[12] If EPA determines that there is insufficient information available to permit a reasoned evaluation of the health and environmental effects of a chemical and that (1) in absence of such information, the chemical may present an unreasonable risk of injury to health or the environment or (2) it is or will be produced in substantial quantities and (a) it either enters or may reasonably be anticipated to enter the environment in substantial quantities or (b) there is or may be significant or substantial human exposure to the chemical, then EPA can issue a proposed order or seek a court injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of the chemical. In addition, if EPA finds that there is a reasonable basis to conclude that a new chemical may pose an unreasonable risk before it can protect against such risks by otherwise regulating the chemical under TSCA, EPA can (1) issue a proposed rule, effective immediately, to require the chemical to be marked with adequate warnings or instructions, to restrict its use, or to ban or limit the production of the chemical or (2) seek a court injunction or issue a proposed order to prohibit the manufacture, processing, or distribution of the chemical.

In addition, under TSCA, EPA generally must apply regulatory requirements—banning or restricting the chemical's production, processing, distribution in commerce, disposal or use, or requiring a warning label—to chemicals for which EPA finds a reasonable basis exists to conclude that the chemical presents or will present an unreasonable risk to human health or the environment. EPA must choose the

[11]Premanufacture notices are also generally required for new uses of an existing chemical if EPA promulgates a rule determining that the use of the chemical constitutes a significant new use.

[12]EPA could also take these actions for a use of a chemical that EPA has determined by rule is a significant new use.

least burdensome requirement that will adequately protect against the risk. As we noted in our earlier report,[13] this presents a high evidentiary burden for EPA in regulating chemicals. When reviewing EPA's asbestos rule, the United States Court of Appeals for the Fifth Circuit stated that in evaluating what risks are unreasonable EPA must consider the costs of any proposed actions. Moreover, the court noted that TSCA's requirement that EPA impose the least burdensome regulation reinforces the view that EPA must balance the costs of its regulations against their benefits. EPA must also consider and publish a statement regarding the effects of the chemical on health and the environment and the magnitude of human and environmental exposure; the benefits of the chemical for various uses and the availability of substitutes for those uses; and the reasonably ascertainable consequences of the rule, after consideration of the effect on the national economy, small businesses, technological innovation, the environment, and public health. If another law would sufficiently eliminate or reduce the risk of injury to health or the environment, then EPA may not promulgate a TSCA rule unless it finds that it is in the public interest to do so, considering all relevant aspects of the risk, a comparison of the estimated costs of compliance under TSCA and the other law, and the relative efficiency of actions under TSCA and the other law to protect against risk of injury.

Under CEPA, regulators are authorized to control chemicals that are (1) determined to be toxic on the basis of a screening assessment and (2) where the Ministers of Health and the Environment have made certain determinations.[14] A chemical may not be regulated under CEPA to the extent that it is regulated by or under another act that, in the opinion of the Governor in Council, provides sufficient protection to the environment and human health. In general, the costs and benefits of control actions are not factors in determining the risk posed by a chemical nor are they determinative of whether any control action should be taken. Rather, they may be factors in deciding what control action to take. Moreover, Canadian regulators are not required to choose the "least burdensome" regulatory requirements.

Under current chemical control legislation in the European Union, member states take the lead on assessing the risks of chemicals. For existing chemicals, once a health and environmental risk assessment is completed, the lead member state makes a draft risk assessment, including risk reduction measures, which is submitted to a committee established by the existing chemicals regulation that has representatives of all member states and the Commission. The committee decides if more information is needed and what types of risk reduction measures are needed. Between 1993 and October 2003 only 140 high volume existing chemicals had been singled out for risk assessment and a limited number have completed the process. According to the European Commission, decisions on further testing of substances

[13]GAO-05-458.

[14]The Ministers must be satisfied that (a) the chemical may have a long-term harmful effect on the environment and is (i) persistent and bioaccumulative in accordance with the regulations, and (ii) inherently toxic to human beings or non-human organisms, as determined by laboratory or other studies, and (b) the presence of the chemical in the environment results primarily from human activity. A substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity; (b) constitute or may constitute a danger to the environment on which life depends; or (c) constitute or may constitute a danger in Canada to human life or health.

can only be taken via a lengthy committee procedure and can only be requested from industry after authorities have proven that a substance may present a serious risk.

The proposed REACH legislation would generally require chemical companies to register all chemicals produced or imported in quantities over 1,000 kilograms (2,204.6 pounds) per manufacturer or importer per year. For certain uses of registered chemicals of very high concern, chemical companies are required to seek authorization for those uses. These chemicals of very high concern are those that are carcinogenic, mutagenic, or toxic for reproduction; persistent, bioaccumulative and toxic or very persistent and very bioaccumulative; and those that cause serious and irreversible effects to humans or the environment, such as endocrine disrupters. Companies using such chemicals or placing them on the market would need to apply for an authorization for each use of the chemical, and an authorization would be granted if the risk to human health or the environment from the use of the substance is adequately controlled. Even if the risks cannot be adequately controlled, a time-limited authorization could also be granted if it was shown that the socioeconomic benefits outweigh the risks and if there were no suitable alternative substances or technologies. In this case, it is recommended that the applicant submit a plan to develop alternative substances or technologies. Downstream users could use a substance for an authorized use provided that they obtained the substance from a company to which an authorization has been granted and that they meet the conditions of that authorization. Such downstream users also would be required to notify the chemical control agency that they are using an authorized substance.

Approaches to Reviewing Existing Chemicals

TSCA, CEPA, and the current European Union chemical control legislation generally do not require chemical companies to develop test data for existing chemicals, unless the regulatory agencies first make certain findings and take regulatory action. Unlike CEPA, which provides for the systematic categorization and review of existing chemicals, TSCA does not require EPA to prioritize and review existing chemicals.

For existing chemicals, REACH would require chemical companies subject to registration requirements that import or manufacture above a certain quantity to provide test data to regulatory authorities on the chemical's physical properties, and ecological and health effects. Both the current European Union legislation and REACH provide for (1) the regulatory agencies' prioritization of existing chemicals for assessment and (2) chemical companies' notification to regulatory agencies of new uses of existing chemicals (under current legislation if manufactured or imported at a level of 10,000 kilograms (22,046 pounds) or more per year) so that regulators may assess the potential risk of the new use of the chemical.

Existing chemicals are defined differently under each country's chemical control legislation. In the United States, existing chemicals are defined as those chemicals on the TSCA Inventory.[15] In Canada, existing chemicals are those chemicals on the Domestic Substances List, including chemicals that—between January 1, 1984, and December 31, 1986—were in commercial use in Canada, used for commercial

[15]This includes the initial TSCA Inventory as well as those new chemicals which commenced manufacturing and thus were added to the Inventory.

manufacturing practices, or manufactured or imported into Canada in a quantity of 100 kilograms or more in any calendar year. The list is regularly amended to include additional substances that have been notified and assessed under the new substances provisions of CEPA. Current European Union legislation defines existing chemicals as those listed on the European Inventory of Existing Commercial Chemical Substances (EINECS)—those chemicals deemed to be in the community market on September 18, 1981. The proposed REACH would largely eliminate the distinction between existing and new chemicals. Table 1 provides additional information on the treatment of existing chemicals in the United States, Canada, and the European Union.

Table 1: Regulation of Existing Chemicals in the United States, Canada, European Union

	United States Toxic Substances Control Act (TSCA)	Canadian Environmental Protection Act (CEPA)	European Union Current Chemical Legislation	European Union Proposed Regulation: Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
Are chemical companies generally required to develop basic data on the physical chemical properties of existing chemicals?[a]	**No** • Unless EPA promulgates a test rule to require the development of such data chemical companies are not required to develop physical chemical property data on chemicals.[b]	**No** • However, to assess whether a chemical is toxic or capable of becoming toxic, or to assess whether to control a chemical, the Ministers of Health and the Environment may publish a notice requiring the submission of existing information, including information on the composition of the chemical. If the Ministers have reason to suspect, or it has been determined under CEPA, that the chemical is toxic or capable of becoming toxic, then they may send the company a notice requiring testing.	**No** • Chemical companies that produce or import more than 1,000,000 kilograms (2,204,623 pounds) of a chemical in a year must submit physical chemical data. Companies must make all reasonable efforts to obtain existing data, but they are not bound to carry out further tests on animals in order to submit such data.[c]	**Yes** • Chemical companies subject to the registration requirements that manufacture or import 1,000 kilograms (2,204.6 pounds) or more of a chemical must provide physical chemical data and develop such data if necessary.

Are chemical companies generally required to develop basic health and ecological effects data for existing chemicals?[d]	**No** • Unless EPA promulgates a test rule, chemical companies are not required to develop and submit toxicity information to EPA.[e]	**No** • However, to assess whether a chemical is toxic or capable of becoming toxic, or to assess whether to control a chemical, the Ministers of Health and the Environment may publish a notice requiring the submission of existing information, including information on the composition of the chemical. If the Ministers have reason to suspect, or it has been determined under CEPA, that the chemical is toxic or capable of becoming toxic, then they may send the company a notice requiring testing.	**No** • While chemical companies that produce more than 1,000,000 kilograms (2,204,623 pounds) of a chemical must make all reasonable efforts to obtain existing toxicological and health effects data, they are not bound to conduct tests on animals in order to submit such data.	**Yes** • Chemical companies that manufacture or import 10,000 kilograms (22,046 pounds) or more of a chemical subject to registration requirements must provide basic data, and develop such data if necessary, on toxicity and mutagenicity.
Is there a requirement to systematically prioritize and assess existing chemicals?	**No** • TSCA does not require EPA to systematically prioritize and assess existing chemicals, and EPA estimates it has assessed about 200 of the 60,000 chemicals in the initial TSCA Inventory not reviewed through the new chemical review program. TSCA established an Interagency Testing Committee (ITC) to recommend, on behalf of member Federal Agencies, chemicals that EPA should give priority consideration to in promulgating test rules. EPA must either initiate rulemaking or publish its reasons for not doing so.	**Yes** • CEPA requires the systematic categorization and screening assessment of all existing chemicals.[f]	**No** • However, the European Commission, in consultation with the member states must regularly draw up lists of priority chemicals requiring immediate attention because of their potential effects on human health or the environment. For chemicals on the list, manufacturers and importers must submit all relevant available information but do not have to develop this information.	**Yes** • REACH would require the proposed European Chemicals Agency to develop criteria for prioritizing all registered chemicals for further review based on a risk-based approach. Criteria for evaluation would include consideration of hazard data, exposure data and production volume and whether the registrant submits a plan for animal testing.[g]

Are chemical companies generally required to notify regulators of significant changes in the uses of existing chemicals?	**No** • Companies are not required to notify EPA of changes in the uses of existing chemicals unless EPA promulgates a significant new use rule. In 2006, chemical companies will begin reporting use information under revised inventory update rules promulgated by EPA.[h]	**No** • Chemical companies generally are not required to notify regulatory agencies of new uses unless the chemical is specified on the Domestic Substances List as a chemical for which notification of a significant new activity is required.	**Yes** • Chemical companies manufacturing or importing more than 10,000 kilograms (22,046 pounds) of a chemical per year must submit new uses of the chemical that substantially change the type, form, magnitude, or duration of exposure to the chemical.	**Yes** • Chemical companies must immediately inform the proposed European Chemicals Agency in writing of new uses of chemicals for which the company may be reasonably aware of and, according to an EU official, may be required to update the registration file.
Can regulators require pollution prevention plans for toxic chemicals?	**No** • TSCA does not authorize EPA to require chemical companies to prepare pollution prevention plans for chemicals.[i]	**Yes** • The Minister of Environment shall issue environmental quality objectives that specify goals or purposes for pollution prevention or environmental control, including goals or purposes stated in quantitative or qualitative terms for carrying out CEPA's mandate related to preserving the quality of the environment. The agency may also issue a notice requiring companies to prepare and implement pollution prevention plans for chemicals on Canada's List of Toxic Substances.	**No** • Chemical legislation does not authorize the European Union environmental agency to require chemical companies to prepare pollution prevention plans for the chemicals they manufacture or import.[j]	**No** • The REACH legislation would not authorize the European Union environmental agency to require chemical companies to prepare pollution prevention plans for the chemicals they manufacture or import.[j]

Source: GAO analysis of selected legislation.

[a]For existing chemicals, we are defining basic physical chemical properties as including properties identified on the Organization for Economic Co-operation and Development's (OECD) Screening Information Data Set (SIDS), such as melting point, boiling point, relative density, vapor pressure, partition co-efficient: n-Octanol/Water, and water solubility. The octanol-water partition coefficient is the ratio of the concentration of a chemical in octanol and in water at equilibrium and at a specified temperature. This test is used in many environmental studies to help determine the fate of chemicals in the environment.

[b]EPA in cooperation with industry, environmental groups, and other interested parties launched the High Production Volume Challenge Program to voluntarily gather information and ensure that a minimum set of basic data on approximately 2,800 high-production volume chemicals—those produced at 1 million pounds or more per year—would be available to EPA. Chemical companies were invited to voluntarily sponsor these chemicals and submit data summaries of existing information along with a test plan that proposes a strategy to fill data gaps for either an individual chemical or for a category of chemicals. EPA intends to use these data to prioritize these chemicals for additional review and testing.

[c]Council Regulation (EEC) No 793/93 requires chemical companies to update this information if they obtain new data on physico-chemical properties, toxicological, or ecotoxicological effects where it is likely to be relevant to the evaluation of the risk posed by the chemical.

[d]The OECD SIDS is the minimum amount of data required for making an initial hazard assessment of High Production Volume chemicals agreed upon by OECD.

[e]However, if the company obtains information that reasonably supports the conclusion that the chemical presents a substantial risk to human health or the environment, TSCA requires that the company immediately notify EPA about this information.

[f]The Ministers of Health and Environment are to categorize chemicals on the Domestic Substances List to identify those that (1) may present to individuals in Canada the greatest potential for exposure or (2) are persistent or bioaccumulative in accordance with the regulations and inherently toxic to human beings or to nonhuman organisms. Once categorization has been completed, the Ministers shall conduct screening assessments for such chemicals to determine whether they are toxic or capable of becoming toxic.

[g]According to a European Union official—under REACH—as originally proposed all registrations of chemicals including a plan for animal testing, will be evaluated. Furthermore, for other registered substances, member states could use these criteria to include chemicals they believe present a risk to health or the environment in a plan for evaluation. The European Parliament Committee on the Environment, Public Health and Food Safety recently proposed an amendment to REACH, yet to be confirmed by the European Parliament in plenary session, that instead proposes giving the European Chemicals Agency the task of compiling the list and giving the agency a greater role in the decision making procedure for chemical evaluation.

[h]In 2003, EPA amended its TSCA Inventory Update Rule (IUR), which is primarily used to gather certain information on chemicals produced at more than a basic threshold volume in the year reported. Among other things, EPA raised the basic production volume reporting threshold from 10,000 to 25,000 pounds; required chemical companies producing or importing chemicals at a site at or above this threshold to report the number of workers reasonably likely to be exposed to the chemical at each site; and added a reporting threshold of 300,000 pounds per site at or above which chemical companies must report readily obtainable exposure-related use and processing information.

[i]According to EPA, the United States has considerable experience utilizing tools and incentives to facilitate the entry into market safer chemicals or use of safer processes as demonstrated with the Green Chemistry and Design for the Environment Programs and the utilization by industry of the P2 Framework tools prior to submitting new chemicals for consideration. In addition, section 6602 (b) of the Pollution Prevention Act of 1990 states that it is the policy of the United States that “pollution should be prevented or reduced at the source whenever feasible." The act required EPA to establish an office to carry out the functions of the EPA Administrator under the act, including the development and implementation of a strategy to promote source reduction. The act also requires many owners and operators of manufacturing facilities to report annually on source reduction and recycling activities.

[j]According to a European Union official, while a pollution prevention plan is not required under European Union chemical legislation, it is obligatory under the Integrated Pollution Prevention and Control Directive.

Approaches to Reviewing New Chemicals

The United States, Canadian, and European Union regulatory authorities review the risks of new chemicals, although they do so at different times. For example, TSCA requires chemical companies to notify EPA before beginning manufacture of new chemicals, while CEPA and both current European Union legislation and the proposed REACH require chemical companies to notify regulatory authorities only

after the new chemical has reached certain levels of manufacture or importation. In addition, depending on production volumes, Canada and the European Union require chemical companies to develop and submit data to the government on the physical chemical properties, as well as basic toxicological and health effects data, for new chemicals along with their notifications or registrations. In contrast, TSCA only requires chemical companies to submit data already in their possession on the physical properties and on the chemicals' health and ecological effects and exposures. Companies generally do not have such data at the time new chemicals are submitted for EPA's review, and TSCA does not require them to develop test data unless EPA promulgates a test rule. In the absence of test data obtained from chemical companies, the burden of developing data to assess the risks of new chemicals primarily falls on EPA, which uses scientific models to predict a new chemical's properties and toxicity based on comparisons with other chemicals of similar molecular structures that have previously been tested.[16] EPA also takes into account the information that chemical companies provide on the anticipated potential uses and estimated exposures of the new chemicals.

Canadian chemical control laws and those in effect and proposed in the European Union require, to varying degrees, that chemical companies develop and submit for review test data on the physical chemical properties and toxicological characteristics and health effects of exposures to new chemicals. The testing required depends on the importation or production volume of the chemical.

New chemicals are defined differently under each country's chemical control legislation. In the United States, new chemicals are defined as those not on the TSCA Inventory. In Canada, new chemicals are those not on Canada's Domestic Substances List. [17] Current European Union legislation defines new chemicals as those not listed on EINECS. The proposed REACH would largely eliminate the distinction between existing and new chemicals. Table 2 provides information on the treatment of new chemicals in the United States, Canada, and the European Union.

[16]For additional information on EPA's use of models, see our report GAO-05-458.

[17]New chemicals that are accepted as being in commercial use internationally are listed on the Non-Domestic Substances List—which is based on the TSCA Inventory—and are subject to lesser requirements. Unless otherwise noted below, we are referring to new chemicals that are not on the Non-Domestic Substances List.

Table 2: Regulation of New Chemicals in the United States, Canada, European Union

	United States Toxic Substances Control Act (TSCA)	Canadian Environmental Protection Act (CEPA)	European Union Current Chemical Legislation	European Union Proposed Regulation: Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH)
Are chemical companies generally required to develop basic data on the physical chemical properties of new chemicals?[a]	**No** • Chemical companies are not required to test new chemicals before they are submitted to EPA for review unless EPA promulgates a test rule.[b]	**Yes** • Under the New Substances Notification Regulations chemical companies are required to provide certain basic physical chemical data for new chemicals produced or imported above 1,000 kilograms (2,204.6 pounds) in a calendar year.[c]	**Yes** • Chemical companies that are subject to the notification requirements must submit certain basic physical chemical data. The extent of information and testing required varies, based on production or importation volume.	**Yes** • Chemical companies subject to the registration requirements that manufacture or import 1,000 kilograms (2,204.6 pounds) or more must provide certain basic physical chemical data.
Are chemical companies generally required to develop basic health and ecological effects data for new chemicals?[d]	**No** • Chemical companies are not required to develop basic toxicological and health effects data for new chemicals before they are submitted to EPA for review unless EPA promulgates a test rule.[e]	**Yes** • Under the New Substances Notification Regulations, chemical companies must provide basic data on toxicity and health effects data for chemicals produced or imported above 1,000 kilograms (2,204.6 pounds) in a calendar year.[f]	**Yes** • Chemical companies that are subject to the notification requirements must submit certain basic toxicological data. The extent of information and testing required varies, based on production or importation volume.	**Yes** • Chemical companies subject to the registration requirements that produce 10,000 kilograms (22,046 pounds) or more of a chemical must develop and provide basic data on toxicity and mutagenicity.

Is there a requirement for the annual disclosure of production quantities of chemicals?	**No** • Chemical companies must provide EPA a reasonable estimate of the total production volume of a new chemical with the premanufacture notice. After EPA's review of the new chemical and chemical companies have notified EPA that production of the chemical has begun, EPA places the chemical on the TSCA Inventory and the chemical is subject to existing chemical regulations, including the Inventory Update Rule.	**No** • However, under the New Substances Notification Regulations, chemical companies manufacturing or importing more than 1,000 kilograms (2,204.6 pounds) in any calendar year of a chemical that is not on Canada's Non-Domestic Substances List (NDSL) must provide an estimate of the quantity to be manufactured or imported annually.[f]	**No** • However, chemical companies that are subject to the notification requirements must submit a technical dossier, which includes an estimate of overall production and/or import volume per year. Chemical companies must notify regulators of changes in the annual or total quantities placed on the European Union Community Market, but are not otherwise required to annually disclose production quantities.	**No** • However, chemical companies subject to the registration requirement must include information on the overall manufacture or import of a chemical in metric tons per year in a technical dossier with their registration. Chemical companies must immediately report any significant changes in the annual or total quantities manufactured or imported, but are not otherwise required to annually disclose production quantities.

Source: GAO analysis of selected legislation.

[a]Such data could include any of the information required in the Screening Information Data Set (SIDS), which is the minimum amount of data required for making an initial hazard assessment of High Production Volume Chemicals agreed upon by the Organization for Economic Co-operation and Development (OECD). CEPA, Current European Union legislation and the proposed REACH legislation all require at least six physical chemical properties identified in the SIDS, including melting point, boiling point, relative density, vapor pressure, partition co-efficient: n-Octanol/Water, and water solubility—CEPA only requires this be reported in the water solubility is 10^{-6} g/L or greater—for new chemicals produced over certain volumes. The remaining two properties dissociation constant and oxidation reduction potential are required by some legislation, but not all. Oxidation-reduction potential is not required under CEPA, and current European Union legislation and REACH do not require dissociation constant.

[b]Testing is not required for new chemicals unless the EPA promulgates a test rule, but companies must submit (1) any test data in the possession or control of the company related to the chemicals effect on health or the environment and (2) a description of any other data concerning the environmental and health affects that is known or reasonably ascertainable by the company. Companies must also inform EPA if they obtain information, which reasonably supports the conclusion that a chemical presents a substantial risk of injury to health or the environment.

[c]For chemicals listed on the Non-Domestic Substances List (NDSL), the threshold is 10,000 kilograms (22,046 pounds) in a calendar year.

[d]SIDS is the minimum amount of data required for making an initial hazard assessment of High Production Volume Chemicals agreed upon by OECD. CEPA, current European Union legislation and proposed REACH all require at least three toxicological properties, including acute toxicity, repeated dose toxicity, and genetic toxicity for new chemicals produced over certain volumes. Current European Union legislation and proposed REACH also require reproductive toxicity once reporting thresholds have been met.

[e]Testing is not required for new chemicals unless the EPA promulgates a test rule, but companies must submit (1) any test data in the possession or control of the company related to the chemicals effect on health or the environment and (2) a description of any other data concerning the environmental and health affects that is known or reasonably ascertainable by the company. Companies must also inform EPA if they obtain information that reasonably supports the conclusion that a chemical presents a substantial risk of injury to health or the environment.

[f]For chemicals listed on the NDSL, the threshold is 10,000 kilograms (22,046 pounds) in a calendar year.

Approaches to Confidential Business Information

TSCA, CEPA, current European Union legislation, and REACH all provide for chemical companies to claim certain information as confidential, but they vary in their treatment of such information. For example, TSCA does not allow EPA to share confidential business information with foreign governments in efforts toward developing and harmonizing methods for assessing chemical hazards. CEPA, however, provides for the sharing of confidential information with foreign governments under agreements or arrangements where the foreign government keeps the information confidential. REACH contains similar provisions, also allowing for disclosure to international organizations under agreements where they protect confidential information.

EPA's ability to make publicly available the information that it collects under TSCA is limited. EPA is required under the act to protect trade secrets and privileged or confidential commercial or financial information against unauthorized disclosures, and this information generally cannot be shared with others, such as state health and environmental officials and foreign governments.[18] Other federal agencies and federal contractors can obtain access to this confidential business information in order to carry out their responsibilities. TSCA does not treat health and safety data as confidential and EPA can also disclose other information that it determines is necessary to disclose in order to protect health or the environment from an unreasonable risk.

In Canada, information that companies request to be treated as confidential is not to be disclosed, except in certain circumstances. The Canadian Minister of the Environment may disclose certain information upon giving 24 hours notice to the company, if (1) the disclosure is in the interest of public health, public safety or the protection of the environment and (2) the public interest in the disclosure (a) outweighs in importance any material financial loss or prejudice to the competitive position of the person who provided the information or on whose behalf it was provided and (b) any damage to the privacy, reputation, or human dignity of any individual that may result from disclosure.

European Union legislation also allows chemical companies to make confidentiality claims. In the European Union, a company may indicate that information is commercially sensitive and that disclosure may be harmful to the company industrially and commercially and, therefore, that the company wishes to keep the information secret from all persons other than the competent authorities and the European Commission. Secrecy, however, does not apply to the trade name of the substance, certain physicochemical data concerning the substance, possible ways of rendering the substance harmless, the interpretation of the toxicological and ecotoxicological tests and the name of the body responsible for the tests, and certain recommended methods and precautions and emergency measures. The authority receiving the information is to decide on its own responsibility what information is covered by commercial and industrial secrecy. The chemical company can go to court and appeal the authority's decision.

[18]15 U.S.C. § 2613.

Under REACH, as originally proposed, one of the objectives of the new system for the management of industrial chemicals would be to make information on chemicals more widely available. According to a European Union official, the proposed legislation has precise provisions on the issue of disclosure of information. Certain information will always be regarded as available to the public, where other information is always confidential, even if a producer does not make the claim. For the remaining information categories, chemical companies may claim confidentiality. Whenever a request for access to documents held by the proposed European Chemicals Agency is made, the agency would be required to inform the registrant of the chemical or other party concerned of the request. That party would have 30 days to submit a declaration identifying information that it wishes to remain confidential because the information is considered commercially sensitive and disclosing it might harm the party commercially. The agency would consider the information and decide whether to accept the declaration. The party could appeal this decision. The following information would be among the types of information that would not be treated as confidential: the trade name(s) of the substance; physicochemical data on the substance and on pathways and environmental fate; the result of each toxicological and ecotoxicological study; if essential to classification and labeling, the degree of purity of the substance and the identity of impurities and/or additives that are known to be dangerous; guidance on safe use; and information contained in the safety data sheet (except for the name of the company or other information accepted as confidential in REACH). Recent amendments to REACH proposed by the European Parliament Committee on the Environment, Public Health, and Food Safety, still to be confirmed by the European Parliament in plenary session, would reintroduce provisions of current European Union legislation requiring industry to justify confidentiality. The European Chemicals Agency would only have to inform parties other than the registrant of a request where appropriate.

The following information would be treated as confidential, even if the company did not claim it as confidential: details of the full composition of a preparation, the precise use, function, or application of a substance or preparation, the precise tonnage of the substance or preparation manufactured or placed on the market, and links between a manufacturer or importer and its downstream users. However, in exceptional cases where there are immediate risks to human health, safety, or the environment, REACH would authorize the proposed European Chemicals Agency to disclose this information.

Scope and Methodology

This report describes the approaches the United States, Canada and the European Union have taken in regulating chemicals in commerce. In addressing these issues, we obtained information on EPA's implementation of TSCA and the chemical control programs of Canada and the European Union. To understand other chemical control regulation, we collected documentation and interviewed individuals knowledgeable about (1) the Toxic Substances Control Act and (2) foreign chemical control laws or proposed legislation: (a) the Canadian Environmental Protection Act, 1999 and (b) the European Union's chemical control legislation and proposed Registration, Evaluation, Authorisation and Restriction of Chemicals. The European Union and

Canada were chosen because they have recently taken action to revise their chemical legislation. In 1999, Canada revised its chemical control law and in 2003, the European Union proposed a new regulation. The European Union and Canada were also selected because they have characteristics that are similar to those of the United States: Canada and the European Union member countries are industrialized nations and have extensive experience with the review and control of chemical substances. In addition, Canada and the European Union produce a considerable amount of chemicals. Furthermore, EPA officials and chemical industry representatives recommended these countries for comparison with TSCA. Our descriptions of Canadian and European Union legislation are based on our review of the laws, technical literature, government documents describing their chemical control programs, and follow-up discussions with government officials. Given the time frames available to complete our work, we relied primarily upon work previously performed for our report issued in June 2005, as supplemented by additional interviews and document review.

Our review was performed between July 2005 and October 2005 in accordance with generally accepted government auditing standards.

Agency Comments and Our Evaluation

EPA provided comments on the information included in a draft of our report on November 1, 2005. EPA said that our report (1) attempts to compare functions that are fundamentally different due to varying definitions of "new" and "existing" chemicals under TSCA, CEPA, and the European Union legislation; (2) does not reflect the range of regulatory options that exist for existing and new chemicals, focusing almost exclusively on sections 4 and 6 of TSCA; (3) should offer the same level of information across the four regulatory approaches of TSCA, CEPA, EU current legislation, and proposed REACH; and (4) should address enforcement activities.

We agree that it is important to note the differing definitions of "new" and "existing" chemicals under TSCA, CEPA, and the European Union legislation in comparing these laws. Where possible, we have attempted to highlight the impact of such differences when comparing various legislative provisions. We added additional language to the beginning of the report to draw attention to this point. Despite the different definitions of new and existing chemicals, we believe that it is possible to draw some useful comparisons between the legislative provisions and chemical control functions under those provisions.

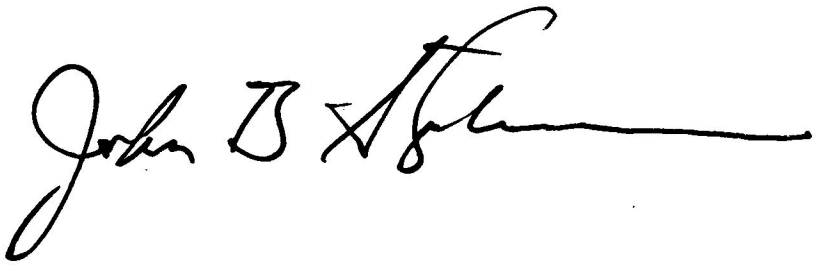
Likewise, we agree with EPA's comment that our draft report would benefit from a more complete discussion of regulatory tools available under TSCA. In response to EPA's comments, we have added a discussion of section 5(e) and section 5(f) of TSCA to the final report. We have also added references to EPA's utilization of modeling tools and to our June 2005 report that more fully discusses actions that EPA has taken under TSCA. Moreover, as we stated in our draft report and as this final report states, the laws and regulations discussed in this letter are sometimes augmented by various other mechanisms for controlling chemicals, such as programs under other environmental laws and voluntary programs. Again, we refer readers to our June 2005 report for more information.

With regard to EPA's comments regarding additional points that the report should address, we agree that such additional information could be useful, but given time constraints we were not able to add this information into this report. Given the short period available to complete our work, we agreed with the requesters of our report to primarily rely upon the work we had previously performed regarding TSCA and the other countries, as supplemented by appropriate and necessary follow-up work. We have generally attempted, given the information available to us, to present a similar amount of detail for the United States, Canadian, and European Union legislation. In some cases, the amount of detail presented in this report varies because some laws contain more detail than others. With regard to EPA's suggestion that the report would benefit from a discussion of enforcement activities, we did not perform the work that would enable us to address enforcement activities in this report. Such activities, however, are an important part of our ongoing work in the area of chemical regulation in the United States, Canada, and the European Union.

EPA's comments are reproduced in the enclosure.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the congressional committees with jurisdiction over EPA and its activities; the Administrator, EPA; and the Director, Office of Management and Budget. We also will make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you have any questions about this report, please contact me at (202) 512-3841 or stephensonj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Ed Kratzer, Assistant Director; David Bennett; John Delicath; Aaron Kaminsky; and Amy Webbink made key contributions to this report.



John B. Stephenson
Director, Natural Resources
and Environment

Enclosure

Comments from the Environmental Protection Agency

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 1 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. John Stephenson
Director
Natural Resources and Environment
Government Accountability Office
Washington, DC 20548

Dear Mr. Stephenson:

Thank you for the opportunity to review and comment on the proposed draft Government Accountability Office (GAO) report entitled *"Chemical Regulation: Approaches in the United States, Canada, and the European Union"* (GAO-06-217R). The Report provides comparative information on the United States (U.S.) Toxic Substances Control Act (TSCA), the Canadian Environmental Protection Act (CEPA), the European Union's (EU) current and proposed chemical control legislation in relation to the approaches of (1) controlling chemical risks, (2) reviewing existing chemicals used in commerce, (3) assessing new chemicals not yet in commerce, and (4) handling confidential business information.

Chemicals are an integral part of modern society which provide benefits and may present risks. TSCA recognizes that the benefits of chemicals to society and their risks must be taken into account in considering whether and what regulatory controls are appropriate in a given circumstance. EPA is proud of the progress we have made in protecting human health and the environment. To date, TSCA authority has provided the Agency the ability to review more than 40,000 new chemicals prior to introduction into the marketplace and we have restricted or otherwise regulated over 1,600 of these chemicals while a similar number have been withdrawn by the manufacturer, often in the face of EPA action. TSCA provides a wide array of tools available to protect against risks and facilitate the assessment of risks. These tools, [discussed in your June 2005 Report on the Agency's chemical regulation efforts (GAO 05-458)] include, among an array of other regulatory and non-regulatory approaches, TSCA section 5(e) which allows EPA to regulate based on risk or exposure concerns "pending the development of information" that is needed to assess the chemical's risks, and TSCA section 5(a)(2) significant new use rules that require persons to notify EPA in advance of manufacture, import, or processing for a designated new use so that EPA can assess and regulate the use if appropriate before it begins. The Agency utilizes a variety of tools including modeling such as the Structural Activity Relationship (SAR), voluntary and innovative

Internet Address (URL) • http://www.epa.gov
Recycled/Recyclable • Printed with Vegetable Oil Based Inks on 100% Postconsumer, Process Chlorine Free Recycled Paper

approaches, and information gathering and dissemination to ensure that we have the ability to make informed decisions prior to chemical production at any level and to facilitate the entry into the market of safer chemicals and substitutes.

The Agency also works to target chemical data development, information collection and risk management on chemicals already in commerce, including aggressively obtaining data on a key set of chemicals on the TSCA Inventory. EPA's "numerous control actions" noted in your June 2005 detailed report on the Agency's chemical regulation efforts (GAO 05-458) speak to the range of approaches applied by the Agency in the chemical review program.

In this reply to GAO's request for comment, EPA has focused its comments on information as it relates to descriptions of the U.S. authorities and certain critical distinctions among the various authorities compared. While EPA appreciates the observations and comparisons, there are a few comments for your consideration. Technical comments are provided in the enclosed attachment.

The Report attempts to compare functions that are fundamentally different due to variations in definitions applied to "new" versus "existing" chemicals under each government's chemical control legislation. In the U.S., a key concept is "commerce" or "commercial purposes." Under TSCA, a "new chemical substance" means any chemical substance that is not included in the chemical substance list compiled and published under TSCA section 8(b), i.e., it not on the TSCA Inventory and generally has not been manufactured or processed for commercial purposes in the United States since three years before the passage of TSCA. Conversely, an "existing chemical" is generally one that is on the TSCA Inventory and is or has been (since the establishment of the Inventory) in commerce. As both Canada and the EU approaches are somewhat different as to what delineates a "new" versus "existing" chemical, the comparisons are often awkward and in some cases not appropriate. The definitions are fundamental to understanding the approaches and establish key differences not accounted for in the Report and more specifically in the two comparison tables. While the footnotes attempt to correct the problem, the questions in the table which are the focus of the points under consideration are often not aligned with the U.S. definitions and, therefore, approaches. For example, in the new chemicals table, the third question asks about an annual requirement for the disclosure of production quantities of new chemicals. Given the U.S. definition of new chemicals (generally not in commerce), the answer is an automatic no without regard to the fact that these substances would be considered an "existing" chemical if in production. One approach to deal with this is to use language such as "new chemicals or, in the case of the U.S., former new chemicals." This point should be explained the first time it appears.

The Report does not reflect the range of regulatory options for new and existing chemicals, instead focusing on the most restrictive of the TSCA options, setting-up an awkward and inappropriate comparison with the other governments' authorities. With regard to TSCA authority, the Report focuses almost exclusively on sections 4 and 6, which suggests that they are the only mechanisms available to facilitate the development

of data and reduction of risks in the statute. As reflected in your earlier detailed report GAO 05-458, this is clearly not the case and therefore sets the stage for an inaccurate comparison with the other governments' authorities. In addition, it should be noted, the framework of options in the U.S. for controlling chemical risks identified under the authorities of TSCA is larger than this one statute. This point is also generally true for Canadian and EU systems.

The Report does not offer the same level of information across the four regulatory approaches of TSCA, CEPA, EU current chemical legislation and proposed REACH. A more complete description of the parameters at play in CEPA and the EU current and proposed authorities would offer a more balanced observation. For example, on page 7, the first paragraph describes the EU assessment process. In the last sentence there is reference to a determination if more information is needed and risk reduction measure decisions. While with the U.S. description there is more specific detailed information on "findings" that trigger these actions, there is no discussion with regards to the findings or factors that are considered within the EU before regulating a chemical. It seems appropriate that the CEPA and EU legislative authorities be given similar treatment as the U.S. authority so that more fully-informed comparisons can be made.

In addition, the Report does not address enforcement, an important component of any chemical regulation scheme. The U.S. has specific enforcement authorities to support chemical review and control regulations. The Report would benefit from a discussion of the various enforcement capabilities across the various schemes of U.S., Canada and the EU compared in the document.

Thank you for this opportunity to review and comment on the report GAO-06-217R, *"Chemical Regulation: Approaches in the United States, Canada, and the European Union."* We look forward to continuing to work with the General Accountability Office and Congress on our efforts to ensure chemical safety and protection of human health and the environment.

Sincerely,

Wendy C. Hamnett for

Charles M. Auer
Director
Office of Pollution Prevention
and Toxics

Attachment

(360615)

GAO's Mission

The Government Accountability Office, the audit, evaluation and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday, GAO posts newly released reports, testimony, and correspondence on its Web site. To have GAO e-mail you a list of newly posted products every afternoon, go to www.gao.gov and select "Subscribe to Updates."

Order by Mail or Phone

The first copy of each printed report is free. Additional copies are $2 each. A check or money order should be made out to the Superintendent of Documents. GAO also accepts VISA and Mastercard. Orders for 100 or more copies mailed to a single address are discounted 25 percent. Orders should be sent to:

U.S. Government Accountability Office
441 G Street NW, Room LM
Washington, D.C. 20548

To order by Phone: Voice: (202) 512-6000
TDD: (202) 512-2537
Fax: (202) 512-6061

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm
E-mail: fraudnet@gao.gov
Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Gloria Jarmon, Managing Director, JarmonG@gao.gov (202) 512-4400
U.S. Government Accountability Office, 441 G Street NW, Room 7125
Washington, D.C. 20548

Public Affairs

Paul Anderson, Managing Director, AndersonP1@gao.gov (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, D.C. 20548