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SAFE CHEMICALS ACT OF 2011

DECEMBER 27, 2012.—Ordered to be printed

Mrs. BOXER, from the Committee on Environment and Public Works, submitted the following

R E P O R T

together with

MINORITY VIEWS

[To accompany S. 847]

[Including cost estimate of the Congressional Budget Office]

The Committee on Environment and Public Works, to which was referred the bill (S. 847) to amend the Toxic Substances Control Act to ensure that risks from chemicals are adequately understood and managed, and for other purposes, having considered the same, reports favorably thereon with amendments and recommends that the bill, as amended, do pass.

PURPOSES OF THE LEGISLATION

To amend the Toxic Substances Control Act (42 U.S.C. 2601 et seq.) to enhance protections for public health and to better safeguard environmental quality by ensuring that risks from toxic chemicals are adequately understood and managed, and for other purposes.

GENERAL STATEMENT AND BACKGROUND

Summary

The Safe Chemicals Act (S. 847) would give the Environmental Protection Agency (EPA) several new tools to address chemical substances and mixtures in commerce, including:

- Requiring manufacturers to develop and submit safety data for each chemical they produce, while avoiding duplicative or unnecessary testing;
- Prioritizing chemicals based on risk, so that the EPA can focus its resources on evaluating those chemicals that are most likely to cause harm while also working through the backlog of untested existing chemicals;
- Placing the burden of proof on chemical manufacturers to demonstrate the safety of their chemicals;
- Restricting uses of chemicals that cannot be proven safe;
- Establishing a public database to catalog the information submitted by chemical manufacturers and contained in the EPA's safety determinations;
- Promoting innovation in research and the development of safer chemical alternatives; and
- Encouraging new, safe chemicals onto the market using an expedited review process.

Need for the Safe Chemicals Act of 2011

President Ford signed TSCA into law in 1976, and since then Congress has added three chemical-specific titles on asbestos, indoor radon, and lead. TSCA regulates the manufacture, importation, and processing of chemicals. TSCA does not regulate some types of chemical substances, such as pesticides, tobacco, and nuclear materials.

TSCA gives EPA authority to compile an inventory of existing chemical substances, known as the TSCA Chemical Substance Inventory (Inventory). The data was submitted from 1975–1978 and the first list was published in 1979 (approximately 55,000 chemicals were in commerce). Currently, the Inventory lists more than 84,000 chemical substances. The listing is based solely on whether substances were or are available for sale and use in the U.S. The list grows as new chemicals enter the marketplace.

The EPA's ability to use TSCA has been impacted by a 1991 court decision that requires the Agency to prove that each individual use of a chemical presents an unreasonable risk and EPA's proposed action is the least burdensome option to address such risks before EPA can restrict each such use. *Corrosion Proof Fittings* v. *EPA,* 947 F.2d 1201 (1991).

The Government Accountability Office (GAO) has conducted a number of investigations on the EPA's risk assessments and toxic substances policies in the last few years. Such GAO investigations have included: "Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective" (1994); "Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program" (2005); "Chemical Regulation: Approaches in the United States, Canada, and the European Union" (2005); "Chemical Regulation: Comparison of U.S. and Recently Enacted European Union Approaches to Protect Against the Risks of Toxic Chemicals" (2007); and "Chemical Assessments, Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System" (2008).

In January 2009, GAO placed EPA's chemical management program on its list of "high risk" programs. GAO, High Risk Series:

An Update (2009). The GAO determined that the program is a major management challenge for EPA using the following description:

Transforming EPA's processes for assessing and controlling toxic chemicals. EPA has failed to develop sufficient chemical assessment information to limit public exposure to many chemicals that may pose substantial health risks. In January 2009, GAO added a new issue—the need to transform EPA's process for assessing and controlling toxic chemicals—to its list of high-risk areas warranting increased attention by Congress and the executive branch.

Principles of TSCA Reform

There are a series of principles on reforming the Toxic Substances Control Act (TSCA), from the EPA, various States, and a national chemical industry association.

EPA principles of TSCA reform

On September 29, 2009, EPA Administrator Lisa Jackson released principles for chemical management legislation to help inform Congressional efforts to reauthorize and strengthen TSCA's effectiveness. The Agency's principles state:

The U.S. Environmental Protection Agency (EPA) is committed to working with the Congress, members of the public, the environmental community, and the chemical industry to reauthorize the Toxic Substances Control Act (TSCA). The Administration believes it is important to work together to quickly modernize and strengthen the tools available in TSCA to increase confidence that chemicals used in commerce, which are vital to our Nation's economy, are safe and do not endanger the public health and welfare of consumers, workers, and especially sensitive sub-populations such as children, or the environment.

The following Essential Principles for Reform of Chemicals Management Legislation (Principles) are provided to help inform efforts under way in this Congress to reauthorize and significantly strengthen the effectiveness of TSCA. These Principles present Administration goals for updated legislation that will give EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals.

Principle No. 1: Chemicals should be reviewed against safety standards that are based on sound science and reflect risk-based criteria protective of human health and the environment

EPA should have clear authority to establish safety standards that are based on scientific risk assessments. Sound science should be the basis for the assessment of chemical risks, while recognizing the need to assess and manage risk in the face of uncertainty.

Principle No. 2: Manufacturers should provide EPA with the necessary information to conclude that new and existing chemicals are safe and do not endanger public health or the environment

Manufacturers should be required to provide sufficient hazard, exposure, and use data for a chemical to support a determination

by the Agency that the chemical meets the safety standard. Exposure and hazard assessments from manufacturers should be required to include a thorough review of the chemical's risks to sensitive subpopulations.

Where manufacturers do not submit sufficient information, EPA should have the necessary authority and tools, such as data call in, to quickly and efficiently require testing or obtain other information from manufacturers that is relevant to determining the safety of chemicals. EPA should also be provided the necessary authority to efficiently follow up on chemicals which have been previously assessed (e.g., requiring additional data or testing, or taking action to reduce risk) if there is a change which may affect safety, such as increased production volume, new uses or new information on potential hazards or exposures. EPA's authority to require submission of use and exposure information should extend to downstream processors and users of chemicals.

Principle No. 3: Risk management decisions should take into account sensitive subpopulations, cost, availability of substitutes and other relevant considerations

EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account a range of considerations, including children's health, economic costs, social benefits, and equity concerns.

Principle No. 4: Manufacturers and EPA should assess and act on priority chemicals, both existing and new, in a timely manner

EPA should have authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations. Clear, enforceable and practicable deadlines applicable to the Agency and industry should be set for completion of chemical reviews, in particular those that might impact sensitive sub-populations.

Principle No. 5: Green chemistry should be encouraged and provisions assuring transparency and public access to information should be strengthened

The design of safer and more sustainable chemicals, processes, and products should be encouraged and supported through research, education, recognition, and other means. The goal of these efforts should be to increase the design, manufacture, and use of lower risk, more energy efficient and sustainable chemical products and processes.

TSCA reform should include stricter requirements for a manufacturer's claim of Confidential Business Information (CBI). Manufacturers should be required to substantiate their claims of confidentiality. Data relevant to health and safety should not be claimed or otherwise treated as CBI. EPA should be able to negotiate with other governments (local, state, and foreign) on appropriate sharing of CBI with the necessary protections, when necessary to protect public health and safety.

Principle No. 6: EPA should be given a sustained source of funding for implementation

Implementation of the law should be adequately and consistently funded, in order to meet the goal of assuring the safety of chemicals, and to maintain public confidence that EPA is meeting that goal. To that end, manufacturers of chemicals should support the costs of Agency implementation, including the review of information provided by manufacturers.

Senator Inhofe's principles of TSCA reform

Senator Inhofe has also stated his fundamental principle for reforming TSCA. These principles are:

- Use data and methods based on the best available science and risk-based assessment.
- Include cost/benefit considerations for the private-sector and consumers.
- Protect proprietary business information, as well as information that should be protected for security reasons.
- Prioritize reviews for existing chemicals.
- Does not include any provision that encourages litigation or citizen suits.
- Does not include any provision that compels product substitution.

Selected State Principles of TSCA Reform

Several states have also demonstrated an interest in reforming TSCA. The States of California, New Hampshire, Connecticut, New Jersey, Illinois, New York, Maine, Oregon, Maryland, Vermont, Massachusetts, Washington, and Michigan issued a set of principles on the reform of TSCA. These principles state:

Require Chemical Data Reporting. Chemical and product manufacturers should be required to develop and provide chemical health and safety information, as well as exposure and use data, including the presence of toxic chemicals in products and the associated chemical hazards and risks, to regulators, businesses, and the public.

Demonstrate Chemicals and Products Are Safe. Manufacturers should provide the necessary information to regulators to conclude that new and existing chemicals and products in commerce are safe and do not endanger the public or the environment. The public has a right to expect that the products they use are safe.

Prioritize Chemicals of Concern. Government should identify and prioritize chemicals of concern in order to regulate the most problematic chemicals in commerce, and have the authority to take timely action to protect people and the environment. Sufficient resources should be made available to support these actions.

Protect the Most Vulnerable. Chemical regulation should be designed to protect the most vulnerable, including pregnant women and children.

Promote Safer Chemicals and Products. Based on green chemistry principles, manufacturers should be required to assess and identify safer alternatives to problematic chemicals of concern. Government should establish protocols for evaluating potential alternatives to chemicals of concern.

Address Emerging Contaminants. Emerging chemicals of concern, including nanoscale materials, need to be assessed for public and environmental safety before they go into widespread commerce and use.

Strengthen Federal Law & Preserve States' Rights. States acknowledge the need for a strong federal chemical regulation system, while expressly preserving the authority of state and localities to implement measures to manage chemicals of concern.

Fund State Programs. Effective state-federal governance should enhance the role of states in TSCA implementation, promote data and information sharing, and provide sustained funding for state programs. The states are in a unique position to provide innovative, cost-effective solutions for chemicals of concern prioritization, interstate data sharing, and safer chemical alternatives assessments.

Industry Association's Principles on TSCA Reform

The American Chemistry Council has also issued "10 Principles for Modernizing TSCA." These principles state:

The American Chemistry Council and its members support Congress' effort to modernize our nation's chemical management system. Such a system should place protecting the public health as its highest priority, and should include strict government oversight. It should also preserve America's role as the world's leading innovator and employer in the creation of safe and environmentally sound technologies and products of the business of chemistry.

The current chemical management law, the Toxic Substances Control Act (TSCA), is more than 30 years old. It should be modernized to keep pace with advances in science and technology. Moreover, the law must provide the Environmental Protection Agency with the resources and the authority to do its job effectively.

We have previously offered general concepts on which to base a modern chemical management system. This document expands upon those concepts and begins to provide more detail, which we hope will be useful to policy makers. We will continue to refine the details of our principles for modernizing TSCA and are committed to working with all stakeholders toward enactment of effective legislation.

1. Chemicals should be safe for their intended use.

- Ensuring chemical safety is a shared responsibility of industry and EPA.
- Industry should have the responsibility for providing sufficient information for EPA to make timely decisions about safety.
- EPA should have the responsibility for making safe use determinations for high priority chemicals, focusing on their most significant uses and exposures.
- Safe use determinations should integrate hazard, use, and exposure information, and incorporate appropriate safety factors.
- Consideration of the benefits of chemicals being evaluated, the cost of methods to control their risks, and the benefits and costs of alternatives should be part of EPA's risk management decision making, but should not be part of its safe use determinations.
- Other agencies, such as FDA and CPSC, should continue to make safety decisions for products within their own jurisdictions.

2. EPA should systematically prioritize chemicals for purposes of safe use determinations.

• Government and industry resources should be focused on chemicals of highest concern.

• The priorities should reflect considerations such as the volume of a chemical in commerce; its uses, including whether it is formulated in products for children; its detection in biomonitoring programs; its persistent or bioaccumulative properties; and the adequacy of available information.

3. EPA should act expeditiously and efficiently in making safe use determinations.

• Since a chemical may have a variety of uses, resulting in different exposure potentials, EPA should consider the various uses and focus on those resulting in the most significant exposures.

4. EPA should complete safe use determinations within set timeframes.

• Companies that manufacture, import, process, distribute, or use chemicals should be required to provide EPA with relevant information to the extent necessary for EPA to make safe use determinations.

• Companies throughout the chain of commerce should be responsible for providing necessary hazard, use, and exposure information.

• EPA should be authorized to require companies, as appropriate, to generate relevant new data and information to the extent reasonably necessary to make safe use determinations without having to prove risk as a prerequisite or engaging in protracted rulemaking.

• Testing of chemicals should progress to more complex and expensive tests through a tiered approach as needed to identify hazards and exposures of specific concern.

• To minimize animal testing, existing data should be considered prior to new testing, and validated alternatives to animal testing should be used wherever feasible.

• Existing data and information should be leveraged in EPA's safe use determinations, including data and information from other mandatory and voluntary programs such as REACH and the U.S. High Production Volume challenge.

5. Potential risks faced by children should be an important factor in safe use determinations.

• Safe use determinations should consider the effects of a chemical on children and their exposure to the chemical.

• Safe use determinations should consider whether an extra margin of safety is needed to protect children.

6. EPA should be empowered to impose a range of controls to ensure that chemicals are safe for their intended use.

• The controls could range from actions such as labeling, handling instructions, exposure limits and engineering controls to use restrictions and product bans.

• The controls should be appropriate for managing the risk, taking into account alternatives, benefits, costs, and uncertainty.

7. Companies and EPA should work together to enhance public access to chemical health and safety information.

• EPA should make chemical hazard, use, and exposure information available to the public in electronic databases.

• Other governments should have access to confidential information submitted under TSCA, subject to appropriate and reliable protections.

• Companies claiming confidentiality in information submittals should have to justify those claims on a periodic basis.

• Reasonable protections for confidential as well as proprietary information should be provided.

8. EPA should rely on scientifically valid data and information, regardless of its source, including data and information reflecting modern advances in science and technology.

• EPA should establish transparent and scientifically sound criteria for evaluating all of the information on which it makes decisions to ensure that it is valid, using a framework that addresses the strengths and limitations of the study design, the reliability of the test methods, and the quality of the data.

• EPA should encourage use of good laboratory practices, peer review, standardized protocols, and other methods to ensure scientific quality.

9. EPA should have the staff, resources, and regulatory tools it needs to ensure the safety of chemicals.

• EPA's budget for TSCA activities should be commensurate with its chemical management responsibilities.

10. A modernized TSCA should encourage technological innovation and a globally competitive industry in the United States.

• A new chemical management system should preserve and enhance the jobs and innovative products and technologies contributed by the business of American chemistry.

• Implementation of TSCA should encourage product and technology innovation by providing industry certainty about the use of chemicals.

Public health, environmental, and labor's principles for reforming TSCA

A coalition of public health, environmental, labor and business representatives also issued "A Platform for Reform of the Toxic Substances Control Act." This platform states:

A reformed Toxic Substances Control Act (TSCA) would serve as the backbone of a sound and comprehensive chemicals policy that protects public health and the environment, while restoring the luster of safety to U.S. goods in the world market. Any effective reform of TSCA should:

• Immediately Initiate Action on the Worst Chemicals: Persistent, bioaccumulative toxicants (PBTs) are uniquely hazardous. Any such chemical to which people could be exposed should be phased out of commerce. Exposure to other toxic chemicals, such as formaldehyde, that have already been extensively studied, should be reduced to the maximum extent feasible.

• Require Basic Information for All Chemicals: Manufacturers should be required to provide basic information on the health hazards associated with their chemicals, how they are used, and the ways that the public or workers could be exposed.

• Protect the Most Vulnerable: Chemicals should be assessed against a health standard that explicitly requires protection of the most vulnerable subpopulations. That population is likely to usu-

ally be children, but it could also be workers, pregnant women, or another vulnerable population.

• Use the Best Science and Methods: The National Academy of Sciences' recommendations for reforming risk assessment at the Environmental Protection Agency (EPA) should be adopted. Regulators should expand development and use of information gleaned from "biomonitoring," the science of detecting human chemical contamination, to inform and impel efforts to reduce these exposures.

• Hold Industry Responsible for Demonstrating Chemical Safety: Unlike pharmaceuticals, chemicals are currently presumed safe until proven harmful. The burden of proving harm falls entirely on EPA. Instead, chemical manufacturers should be responsible for demonstrating the safety of their products.

• Ensure Environmental Justice: Effective reform should contribute substantially to reducing the disproportionate burden of toxic chemical exposure placed on people of color, low income people and indigenous communities.

• Enhance Government Coordination: The EPA should work effectively with other agencies, such as FDA, that have jurisdiction over some chemical exposures. The ability of the states to enact tougher chemical policies should be maintained and state/federal cooperation on chemical safety encouraged.

• Promote Safer Alternatives: There should be national support for basic and applied research into green chemistry and engineering, and policy should favor chemicals and products that are shown to be benign over those with potential health hazards.

• Ensure the Right to Know: The public, workers, and the marketplace should have full access to information about the health and environmental hazards of chemicals and the way in which government safety decisions are made.

In light of this and other information, the Committee moved to consider Senator Lautenberg's bill, S. 847, in order to advance the efforts to increase protections for public health and environmental quality, strengthen the public's right-to-know about chemical substances and mixtures, and promote the use of safe chemicals in commerce.

Senator Lautenberg's Amendment to S. 847

At the Committee's business meeting in July, 2012, Senator Lautenberg offered an amendment to his introduced bill that modified the underlying text while maintaining the essential elements of the introduced bill. The amendment sought to better focus resources on evaluating priority chemicals by directing EPA to evaluate chemicals in stages, screen chemicals to limit the number that require a full safety standard determination, and prioritize chemicals in need of safety standard determinations. The amendment directed EPA to rely on existing information first and require additional testing only to the extent necessary to demonstrate safety. The amendment also modified the bill's protections for confidential business information (CBI) and provisions to encourage innovation in the development of chemicals. Specifically, EPA was directed to provide varying levels of CBI protection depending on the information's category, and companies were provided with options to quickly bring new chemicals into commerce through a process that is similar to existing TSCA requirements.

SECTION-BY-SECTION ANALYSIS

Section 1. Short title

Section 1 provides that the short title of the bill is the "Safe Chemicals Act of 2011".

Sec. 2. Purposes

Section 2 defines the purpose for which the bill was created.

Sec. 3. Findings, policy and goal

Section 3 contains the findings that support enactment of the bill; the policies that guide application of the bill, and the goals that the bill seeks to achieve.

Sec. 4. Definitions

Section 4 contains the definitions of the bill.

Sec. 5. Minimum information sets and testing of chemical substances

Section 5 describes the processes used to ensure that required information is submitted under the Act.

Subsection (a) describes the minimum sets of information that manufacturers and others would have to submit to EPA for chemicals. The section requires a tiered approach to requiring such information, along with the requirements for information quality and reliability and alternative testing methods.

Subsection (b) describes the broad testing authority provided to the Administrator.

Subsection (c) describes specific requirements for test rules and orders, including factors that EPA must consider when requiring testing and methodologies and protocols for such tests.

Subsection (d) describes the exemptions from testing rules and order and various methods of reimbursement.

Subsection (e) describes the requirement for notice related to testing rules and orders.

Subsection (f) describes the process for agencies working to share information concerning chemical substances.

Subsection (g) describes the certification requirements that apply to a testing rule or order.

Sec. 6. New chemical substances and new uses of chemical substances

Subsection (a) contains definitions that apply to this section.

Subsection (b) contains the requirements for the manufacture or process of new chemical substances.

Subsection (c) contains the requirements for new uses of existing chemical substances.

Subsection (d) describes the notice requirements that apply to new chemical substances.

Subsection (e) describes requirements that apply to chemical substances that exhibit special substance characteristics.

Subsection (f) describes the requirements for data and other factors that apply to the manufacturing or processing of certain chemical substances.

Subsection (g) describes the notice requirements for certain chemical substances.

Subsection (h) describes the procedures and requirements for EPA determinations that certain chemical substances or uses may be exempt from certain requirements based on a scientific consensus of intrinsic safety.

Subsection (i) describes the certification requirements that apply under this section or a rule or order issued promulgated or issued under this section.

Sec. 7. Batching, categorization, prioritization, safety standard determination, and risk management.

Section 7 amends sections 6 and 202 of TSCA to include new text.

Section 7(a) amends section 6 of TSCA as follows:

Subsection (a) of section 6 of TSCA, as amended, describes the requirements of the batching process that the Administrator shall use for reviewing chemical substances.

Subsection (b) of section 6 of TSCA, as amended, describes the categorization and prioritization process that the Administrator shall implement for chemical substances.

Subsection (c) of section 6 of TSCA, as amended, describes the legal effect of the Administrator's determinations under this section.

Subsection (d) of section 6 of TSCA, as amended, describes the responsibilities and requirements for the process of making safety standards determinations for chemical substances.

Subsection (e) of section 6 of TSCA, as amended, describes the process for taking expedited action to address chemical substances of very high concern.

Subsection (f) of section 6 of TSCA, as amended, describes the requirements that apply to the Administrator issuing a risk management order under subsections (d) and (e).

Subsection (g) of section 6 of TSCA, as amended, describes the requirements that apply to the Administrator issuing a quality control order.

Subsection (h) of section 6 of TSCA, as amended, describes the exemptions that apply to certain restrictions contained in various provisions of TSCA.

Subsection (i) of section 6 of TSCA, as amended, describes special requirements that apply to mercury.

Subsection (j) of section 6 of TSCA, as amended, describes special requirements that apply to asbestos.

Subsection (k) of section 6 of TSCA, as amended, describes the certification requirements that apply to submissions made under this section.

Subsection (l) of section 6 of TSCA, as amended, describes the effective date of any regulation or order under this section.

Section 7(b) amends section 202(3) of TSCA by amending the definition of asbestos.

Sec. 8. Imminent hazards

Section 8 amends section 7 of TSCA to include new text.

Subsection (a) describes the scope of the Administrator's authority to commence civil actions and undertake other measures to address imminent hazards under this law.

Subsection (b) describes the scope of relief authorized under this law.

Sec. 9. Reporting and retention of information

Section 9 amends section 8 of TSCA to include new text.

Subsection (a) of section 8 of TSCA, as amended, contains the definitions that apply to this section.

Subsection (b) of section 8 of TSCA, as amended, describes the applicable scope and criteria that apply to identifying chemical substances.

Subsection (c) of section 8 of TSCA, as amended, describes the periodic reporting requirements for manufacturers and processors of certain chemical substances and provides the Administrator with rulemaking authority to implement such provisions.

Subsection (d) of section 8 of TSCA, as amended, describes the requirements that apply to support the declarations and reports required under this section.

Subsection (e) of section 8 of TSCA, as amended, describes the Administrator's authority to issue rules for the provision of information to assist the Administrator in the administration of the law.

Subsection (f) of section 8 of TSCA, as amended, describes the requirements for updating information under this section.

Subsection (g) of section 8 of TSCA, as amended, describes the Administrator's authority to issue rules or order requiring the maintenance of records of chemical substances and to report on chemical substances.

Subsection (h) of section 8 of TSCA, as amended, describes the requirements for the Administrator to maintain an inventory of chemical substances.

Subsection (i) of section 8 of TSCA, as amended, describes the public's access to information under this law.

Subsection (j) of section 8 of TSCA, as amended, describes the requirements and Administrator's authority related to the retention and submission of records concerning significant adverse reactions.

Subsection (k) of section 8 of TSCA, as amended, describes the requirements concerning submission of and request for information in the possession of other federal agencies.

Subsection (l) of section 8 of TSCA, as amended, describes the requirements to provide the Administrator with notice of information concerning the presence of a substantial risk of injury to health or the environment from a chemical substance.

Subsection (m) of section 8 of TSCA, as amended, describes the certification requirements that apply to information submitted under this section.

Subsection (n) of section 8 of TSCA, as amended, describes scope of the Administrator's authority to implement and enforce reporting requirements under this section.

Sec. 10. Relationship to other Federal laws

Section 10 amends section 9 of TSCA.

Subsection (1) describes the scope of the Administrator's authority to notify and request that another federal agency act to address risks related to a failure to meet the safety standard under this title, as well as the Administrator's authority to act in lieu of another agency's failure to act following a request for action by the Administrator.

Sec. 11. Inspections and subpoenas

Section 11 amends section 11 of TSCA.

Subsection (a) describes the locations and samples that the Administrator can access and the methods that the Administrator can use to conduct inspections under this law.

Subsection (b) describes the scope the Administrator's authority to conduct inspections under this law.

Subsection (c) describes the Administrator's information gathering authorities under this law.

Subsection (d) describes the Administrator's authorities to issue warrants under this law.

Sec. 12. Exports

Section 12 amends section 12 of TSCA to ensure this section is consistent with the policies and provisions of TSCA, as amended by this Act.

Sec. 13. Entry into Customs Territory of the United States

Section 13 amends section 13 of TSCA to ensure this section is consistent with the policies and provisions of TSCA, as amended by this Act, and shifting federal responsibilities since TSCA was enacted.

Sec. 14. Disclosure of data

Section 14 replaces section 14 of TSCA.

Subsection (a) describes the legal scope of the data disclosure requirements under this law.

Subsection (b) describes the categories of confidential business information under this law.

Subsection (c) describes the designations and treatment of confidential business information under this law.

Subsection (d) describes the civil penalties for wrongful disclosure or wrongful requests for protection under this law.

Subsection (e) describes Congress' access to information under this law.

Subsection (f) describes the special rules that apply to information concerning risks to workers under this law.

Sec. 15. Prohibited acts

Section 15 amends section 15 of TSCA to make technical and conforming changes to TSCA and to expand the types of wrongful acts that are prohibited by this Act.

Sec. 16. Penalties

Section 16 amends section 16 of TSCA to make technical and conforming changes to TSCA and to enhance the penalties for certain violations of this law.

Sec. 17. Specific enforcement and seizure

Section 17 amends section 17 of TSCA to make technical and conforming changes to TSCA and to enhance the Administrator's authority to compel compliance with this law.

Sec. 18. Preemption

Section 18 clarifies the legal effect of this Act on other State and local laws.

Sec. 19. Judicial review

Section 19 amends section 19 of TSCA to make technical and conforming changes to TSCA and to enhance the scope of judicial review for certain violations of this law.

Sec. 20. Citizens' civil actions

Section 20 amends section 20 of TSCA to make technical and conforming changes to TSCA and to enhance the authority of citizen attorneys generals to assist in the enforcement of the provisions of this law.

Sec. 21. Citizens' petitions

Section 21 amends section 21 of TSCA to make technical and conforming changes to TSCA and to enhance the ability of citizens to petition for action that is consistent with the provisions of the law.

Sec. 22. Employment effects

Section 22 amends section 24 of TSCA to make technical and conforming changes to TSCA and to modify the scope of the amended text.

Sec. 23. Administration of the Toxic Substances Control Act

Section 23 amends section 26 of TSCA to facilitate the Administrator's expeditious implementation of this law.

Sec. 24. State programs

Section 24 amends section 28 of TSCA to enhance the Administrator's coordination with states relating to data sharing and management of chemical substances.

Sec. 25. Authorization or appropriations

This section authorizes appropriations as are necessary to carry out this Act.

Sec. 26. Additional requirements

Section 26 amends TSCA to create a new section 29, which authorizes the Children's Environmental Health Research Program.

Subsection (a) of the new section 29 describes the timeline for creation and consultation requirements of the program, and authorizes the Administrator to enter into contracts or to make grants under the program.

Subsection (b) describes the requirements for an Interagency Science Advisory Board on Children's Health Research.

Subsection (c) requires the creation of biomonitoring requirements related to prenatal and infant exposure to chemicals.

Sec. 30. Reduction in animal-based testing

Section 30 amends TSCA to create a new section 30 that is designed to minimize the use of animal-based testing of chemical substances or mixtures.

Subsection (a) requires the Administrator to take actions to facilitate and fund studies that minimize the use of animals.

Subsection (b) requires the Administrator to create an Interagency Science Advisory Board on Alternative Testing Methods.

Subsection (c) describes the actions needed to implement the alternative testing methods program.

Subsection (d) establishes the criteria for adapting or waiving the animal testing requirements.

Sec. 31. Safer alternatives and green chemistry and engineering

Section 31 creates a new section 31 of TSCA that authorizes a green chemistry and engineering program.

Subsection (a) requires the Administrator to establish the green chemistry and engineering program.

Subsection (b) requires the Administrator to establish a Green Chemistry Research Network.

Subsection (c) requires the Administrator to make grants to promote the green chemistry and engineering program.

Subsection (d) requires the Administrator to establish a Green Chemistry Workforce Education and Training Program.

Sec. 32. Cooperation with international efforts

Section 32 creates a new section 32 of TSCA that authorizes the Administrator to cooperate in international efforts to develop a common protocol or database of chemical substances and to develop safer alternatives to chemical substances.

Sec. 33. Reliable information and advice

Section 33 creates a new section 33 of TSCA that requires the Administrator take certain actions to ensure data reliability.

Sec. 34. Hot spots

Section 34 creates a new section 34 of TSCA that requires the Administrator to identify localities that are disproportionately exposed to chemical substances or mixtures.

Subsection (a) contains the definitions that apply to this section.

Subsection (b) requires that the Administrator promulgate regulations to establish criteria to define disproportionate exposure and identify localities disproportionately exposed.

Subsection (c) requires that the Administrator identify localities that are disproportionately exposed, described the data that may be used and requirements for public participation.

Subsection (d) requires that the Administrator publish a locality list.

Subsection (e) describes the legal scope of this section.

Subsection (f) requires that the Administrator publish and update action plans to carry out this section.

Subsection (g) requires an annual report to Congress on progress in carrying out this section.

Sec. 35. Application of this act to Federal agencies

Section 35 creates a new section 35 of TSCA that applies the Act to all federal agencies.

Subsection (a) requires federal agencies to comply with substantive and procedural requirements of this Act.

Subsection (b) describes the substantive and procedural requirements that apply to all federal agencies.

Subsection (c) waives the sovereign immunity of the United States with respect to those applicable substantive and procedural requirements.

Subsection (d) makes clear that federal agents, employees, or officers acting within the scope of their employment cannot be held personally liable for civil penalties under the Act.

Subsection (e) makes clear that federal agents, employees, or officers are subject to criminal sanctions under the Act.

Subsection (f) describes criteria for the President to grant exemptions under the Act.

Subsection (g) authorizes the Administrator to take administrative enforcement action against Federal agencies for noncompliance with the Act.

Sec. 36. Implementation of Stockholm Convention, the LRTAP POPS Protocol, and the Rotterdam Convention

Section 36 creates a new section 36 of TSCA that provides implementation language that will facilitate ratification of the Stockholm Convention and related global treaties on persistent organic pollutants (POPs), to allow the United States to reassert global leadership on POPs and strengthen the Unites States' role in international negotiations on additional chemical substances of concern.

Subsection (a) contains the definitions that apply to this section.

Subsection (b) describes the procedures for the United States' implementation of the international agreements on POPs.

Subsection (c) provides that the requirements of this section will be enforced in the same manner as rules and orders under section 6 of TSCA.

Subsection (d) provides conforming amendments.

LEGISLATIVE HISTORY

Senator Lautenberg introduced S. 847 on April 14, 2011, with Senators Boxer, Franken, Klobuchar and Schumer as original cosponsors. The bill was received, read twice and referred to the Committee on Environment and Public Works. On July 25, 2012, the Committee on Environment and Public Works met to consider the bill. The bill was ordered reported favorably with amendment by a vote of 10 ayes and 8 nays.

HEARINGS

In the 112th Congress, on February 3, 2011, the Subcommittee on Superfund, Toxics and Environmental Health hearing entitled, "Assessing the Effectiveness of U.S. Chemical Safety Laws."

On November 17, 2011, the Full Committee on Environment and Public Works and the Subcommittee on Superfund, Toxics and Environmental Health held a joint hearing entitled, "Legislative Hearing on the Safe Chemicals Act."

On July 24, 2012, the Full Committee on Environment and Public Works and the Subcommittee on Superfund, Toxics, and Environmental Health held a joint hearing entitled, "Oversight of EPA Authorities and Actions to Control Exposures to Toxic Chemicals."

ROLLCALL VOTES

The Committee on Environment and Public Works met to consider S. 847 on July 25, 2012. The bill, as amended, was ordered reported favorably by a vote of 10 yeas to 8 nays.

REGULATORY IMPACT STATEMENT

In compliance with section 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee makes evaluation of the regulatory impact of the reported bill. The Committee finds that it is impracticable to determine the exact regulatory impact because of the necessary future agency rules and activities to implement the Act.

MANDATES ASSESSMENT

In compliance with the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), the Committee finds that this legislation would impose intergovernmental mandates or private sector mandates as those terms are defined in the Unfunded Mandates Reform Act (UMRA). The Congressional Budget Office concurs, finding S. 847 contains intergovernmental or private-sector mandates as defined in the UMRA.

OCTOBER 1, 2012.

Hon. BARBARA BOXER,
Chairman, Committee on Environment and Public Works,
U.S. Senate, Washington, DC.

DEAR MADAM CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 847, the Safe Chemicals Act of 2011.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Susanne Mehlman.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

S. 847—Safe Chemicals Act of 2011

Summary: S. 847 would modify the Toxic Substances Control Act (TSCA), the law that regulates the manufacture, importation, and processing of chemicals, with the aim of shifting the burden from the Environmental Protection Agency (EPA) to chemical manufacturers to prove that substances are safe before they enter the marketplace. This new responsibility for chemical manufacturers would be accomplished primarily by increasing the amount of information about chemical toxicity and usage that they would be required to submit to EPA. Enacting this legislation also would require EPA to undertake other activities that would encourage and support the development of safer alternatives to existing hazardous chemical substances.

CBO estimates that implementing this legislation would cost $128 million over the next five years, assuming appropriation of the necessary amounts, as EPA would incur additional administrative costs to meet the new requirements imposed by S. 847.

Enacting S. 847 could affect direct spending and revenues because the bill would increase some existing civil and criminal penalties for violations of TSCA, establish some new civil and criminal penalties for violations related to that act, and authorize EPA to charge fees to chemical manufacturers. Therefore, pay-as-you-go procedures apply to S. 847. CBO estimates that any changes in revenues and direct spending would not be significant.

S. 847 would impose intergovernmental and private-sector mandates, as defined in the Unfunded Mandates Reform Act (UMRA), by regulating the manufacture, processing, use, and disposal of chemicals. Because the mandates on intergovernmental entities would depend on the scope of future regulations, CBO cannot determine whether the aggregate cost of the mandates would exceed the annual threshold established in UMRA ($73 million in 2012, adjusted annually for inflation). Because a large number of chemicals could be affected by the new requirements, CBO estimates that the aggregate cost of the private-sector mandates would probably exceed the annual threshold ($146 million in 2012, adjusted annually for inflation.)

CBO has not reviewed provisions in section 26 of S. 847 that would implement international agreements for mandates. Section 4 of UMRA excludes from the application of that act any legislative provisions that are necessary for the ratification or implementation of international treaty obligations. CBO has determined that those provisions fall within that exclusion.

Major Provisions: The bill's major provisions would:

- Require EPA, as part of the chemical approval process, to establish requirements for what data firms must submit so that EPA can assess risk;
- Require EPA to prioritize all chemicals already in use so that their safety and the methods used to manage their risks can be evaluated;
- Require EPA to establish a health-based standard for chemical use and require that chemical manufacturers produce scientific data demonstrating adherence to that standard;
- Authorize EPA, in some cases, to issue administrative orders instead of rules, exempt certain EPA decisions from judicial review, and increase public access to EPA's decisions and information about chemicals;
- Allow EPA to implement three international agreements pertaining to organic pollutants and hazardous chemicals; and
- Require EPA to establish a program to create market incentives for the development of safer alternatives to chemicals, establish a children's environmental health research program, and conduct a study to determine the presence of certain chemicals in pregnant women and infants.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 847 is shown in the following table. The costs of this legislation fall within budget function 300 (natural resources and environment).

	By fiscal year, in millions of dollars—					
	2013	2014	2015	2016	2017	2013–2017
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Estimated Authorization Level	30	30	30	30	30	150
Estimated Outlays	12	26	30	30	30	128

Note: Implementing S. 847 also could increase revenue collections and related direct spending from fines and penalties, but CBO estimates that any collections over the 2013–2022 period would not be significant.

Basis of estimate: For this estimate, CBO assumes that S. 847 will be enacted near the end of 2012 and that the necessary amounts will be appropriated each year.

Spending subject to appropriation

While some EPA activities currently performed under TSCA would be replaced by new requirements under S. 847, CBO estimates that implementing this legislation would increase EPA's workload for regulating chemical safety by about 30 percent each year. That estimate is based on historical information about how other large regulatory programs have been implemented by EPA (such as acid rain) and on other information provided by the agency. According to EPA, the agency currently requires, on average, an appropriation of about $105 million annually to implement and enforce TSCA. That funding supports about 360 employees and includes about $5 million for grants to states to enforce TSCA. Subject to appropriation of the necessary amounts, CBO estimates that EPA would require about $30 million annually over the next five years to cover the costs of additional personnel, contractors, and other administrative activities associated with meeting the new requirements of this legislation.

Over the next two years, CBO expects that EPA would focus primarily on producing guidance documents and cost-benefit analyses and performing other administrative tasks related to the rulemaking process for new chemicals and substances already in use. EPA also would establish internal processes and information technology systems necessary to prioritize the analysis of tens of thousands of chemicals and to implement other related programs in subsequent years. According to the agency, such activities are routinely carried out by contractors; as a result, the majority of the estimated $30 million annual funding needed over this period would cover contractor costs. By 2015, as more implementation and enforcement of the new provisions of TSCA would begin, CBO estimates that EPA would shift funding to cover additional personnel.

Direct spending and revenues

Enacting S. 847 also could affect direct spending and revenues because this bill would increase some existing civil and criminal penalties as well as establish some new fines. Criminal penalties are recorded as revenues, then deposited in the Crime Victims Fund, and later spent; civil penalties are recorded as revenues. CBO estimates that any increase in criminal or civil penalties under the bill would not be significant.

Implementing this legislation also would authorize EPA to charge fees to chemical manufacturers who are required to submit data under the bill. The legislation indicates that such fees could be used to defray the cost of administering the changes proposed

by this bill. Any additional fees collected under this provision would be recorded as an increase in revenues in the budget. However, because those fees could not be charged until sufficient amounts have been appropriated to EPA for the TSCA regulatory program, no additional revenues can be attributed directly to enacting S. 847.

Pay-As-You-Go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. CBO estimates that any increase in revenues and direct spending resulting from changes in criminal or civil penalties would not be significant over the 2013–2022 period.

Intergovernmental and private-sector impact: The bill would authorize EPA to develop new regulations for the use and disposal of chemicals and the inspection of facilities where chemicals are stored. Such regulations would constitute intergovernmental mandates, as defined in UMRA. The bill would impose an additional intergovernmental mandate by preempting state regulations that conflict with federal requirements. Because the scope of future regulations is unclear and the number of intergovernmental entities potentially affected by the requirements is unknown, CBO cannot determine whether the aggregate cost of the intergovernmental mandates would exceed the annual threshold established in UMRA ($73 million in 2012, adjusted annually for inflation).

The bill would impose private-sector mandates on manufacturers and processors of chemicals by requiring them to submit additional data and comply with safety standards. Both new and existing chemicals currently sold in the United States would be subject to the mandates in the bill. According to information from industry experts, manufacturers and processors of chemicals could incur costs of $1 million or more per chemical to demonstrate compliance with safety standards. In addition to the requirements on manufacturers and processors, any regulations governing the use and disposal of chemicals and the inspection of facilities also would impose mandates on private entities. Because a large number of entities would likely be affected by the new requirements, CBO estimates that the aggregate cost of the private-sector mandates would probably exceed the annual threshold established in UMRA ($146 million in 2012, adjusted annually for inflation.)

CBO has not reviewed legislative provisions in section 26 that would implement international agreements for mandates. Section 4 of UMRA excludes from the application of that act any legislative provisions that are necessary for the ratification or implementation of international treaty obligations. CBO has determined that those provisions fall within that exclusion.

Estimate prepared by: Federal Spending: Susanne Mehlman; Impact on State, Local, and Tribal Governments: Melissa Merrell; Impact on the Private Sector: Amy Petz.

Estimate approved by: Theresa Gullo, Deputy Assistant Director for Budget Analysis.

MINORITY VIEWS

BACKGROUND

S. 847, the Safe Chemicals Act (SCA), finishes its fourth congress without bipartisan or industry support. Although the bill's author notes the importance of having a strong chemical regulatory framework at the federal level, the legislation, both as originally introduced and as amended in committee, represents an unworkable program that would likely be crippling to manufacturing in the United States. Despite efforts from the minority to both contribute in a constructive manner as well as to bring the regulated community to the table the intransigent nature of the authors and the majority on this issue continue to bog down reform. Accordingly, the minority finds it difficult to ascertain if the legislation is intended as anything more than a fundraising tool for the environmental left.

The minority finds ample reason for reforming industrial chemical regulation currently managed under the Toxic Substances Control Act (TSCA). Ongoing challenges with the U.S. Environmental Protection Agency's (EPA) chemical risk assessment programs and the lack of sound science at the agency necessitate reform. Most notably, the National Academy of Sciences' review of formaldehyde (issued in April 2011) expressed continued frustration with the quality, methodology and transparency of the conclusions EPA had achieved, and were "recurring". Current reforms being undertaken by the agency are insufficient and strengthening of data quality and transparency laws are appropriate.

EXAMPLES OF PROBLEMS WITH THE SCA

1. *Safety Standard Can Not Be Applied:* The safety standard called for in the SCA cannot practically be applied to the diverse array of chemicals regulated under TSCA. It imposes a standard that in essence mandates a showing that the chemical, in all applications, causes no harm, which may be impossible to demonstrate. This could adversely impact the ability of American companies to manufacture everything from automobile components to advanced medical equipment.

2. *Aggregate Exposure Assessments Only Worsens the Safety Standard Problem:* The requirement, under the SCA, to demonstrate that no harm will result from aggregate exposure to the chemical necessitates an analysis of every human and environmental exposure to a specific chemical from all sources—even natural sources. Many chemicals have thousands of uses, making this requirement technically and practically impossible to meet. This is an example of overregulation—a provision that neither the regulated entities nor the regulator can possibly fulfill.

3. *The SCA Would Significantly Stifle Domestic Research and Development of New Chemicals:* The SCA seeks to fix a system that is not broken by discarding the successful new chemicals review program that exists today in TSCA in favor of a new, highly inflexible and overly burdensome structure. This review and approval process would undoubtedly stifle US research and development of innovative chemicals and applications. Furthermore, the lack of predictability in the proposed new and untested process, stemming from undefined data generation requirements to extended EPA review times, only compounds this problem, particularly for chemical uses that undergo constant improvement.

4. *The SCA Fails to Balance Calls for Greater Transparency with Sensitive Business Information Needs:* The SCA provides EPA with the authority to needlessly abandon long-standing law and practice governing the protection of sensitive confidential business information. There are no qualifications or criteria as to how this authority should be applied—a glaring omission that might be expected to lead to arbitrary decision-making. The lack of transparency and predictability built into the authority is legitimate cause for concern. The threat to the protection of legitimate trade secrets and commercially sensitive information is further worsened by the SCA provisions that mandate disclosure of commercially sensitive information solely because of presence of certain hazard characteristics in a substance. No consideration is given as to how the substance is used, or what the actual exposure to the substance is: basically, the actual risk, if any, posed by use of the substance is irrelevant. The information protection provisions in the SCA create a strong disincentive to any business to perform research and development of new and innovative products in the United States.

5. *Data and Information Gathering Authority Is Needlessly Overbroad:* Any provision that would give EPA authority to require the generation of new, relevant data should be based on the proposition that this "missing" data is necessary for the evaluative process. Legitimate need for information should be the driver. The SCA, however takes an entirely different approach by mandating that EPA establish "minimum information sets" as EPA "determines appropriate" and requiring that these shall include "sufficient information" for EPA to conduct an assessment of the chemical. The SCA sets no limits on the authority of EPA. Conducting testing or gathering information solely for the sake of generating and compiling information is burdensome and wasteful, both for businesses that must devote enormous resources to comply and on government that must then accept and handle volumes of information it did not need.

6. *The SCA Not Only Fails to Address One of the Major Criticisms of TSCA, It Worsens the Problem:* The perceived lack of a strong, central federal chemical management system has been offered as a reason why states and municipalities have felt compelled to enact chemical management legislation. This burdensome patchwork of at times inconsistent regulations, would be eliminated, the argument goes, if there was a strong and effective TSCA. Having one chemical regulatory system administered at the federal level and eliminating the need for a state and local regulations would make compliance more practical, provide uniform protection, and

promote a stronger economy by reducing unnecessary burdens on businesses and state and local governments. Yet, even after imposing hosts of new and burdensome requirements, the SCA fails to limit the continued growth of state and local regulation, thereby increasing the significant burden on American industry.

Thanks to our abundant fossil fuel supplies, made available through our advances in hydraulic fracturing and directional drilling technologies, the chemical manufacturing sector is seeing resurgence in investment and jobs in the United States. Despite four years of dismal economic growth, the domestic fossil fuel and chemical manufacturing sector has been a bright spot. Accordingly, it remains imperative that we do not stifle the economic and job potential of these industries with a regulatory framework that is unworkable, but rather focus on enhancing consumer protections and improving the law through reasonable bipartisan reform that would strengthen consumer confidence while protecting our economy and jobs.

JIM INHOFE.
DAVID VITTER.

CHANGES IN EXISTING LAW

In compliance with section 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by the bill as reported are shown as follows: Existing law proposed to be omitted is enclosed in [black brackets], new matter is printed in *italic*, existing law in which no change is proposed is shown in roman:

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TOXIC SUBSTANCES CONTROL ACT

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TOXIC SUBSTANCES CONTROL ACT [1]

[As Amended Through P.L. 110–414, Enacted October 14, 2008]

TITLE I—CONTROL OF TOXIC SUBSTANCES

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

This Act may be cited as the "Toxic Substances Control Act".

TABLE OF CONTENTS

TITLE I—CONTROL OF TOXIC SUBSTANCES

Sec. 1. Short title and table of contents.
Sec. 2. [Findings, policy and intent] *Findings, policy, and goal.*
Sec. 3. Definitions.
Sec. 4. [Testing of chemical substances and mixtures] *Minimum data set and testing of chemical substances.*
Sec. 5. Manufacturing and processing notices.
Sec. 6. [Regulation of hazardous chemical substances and mixtures] *Prioritization, safety standard determination, and risk management.*
Sec. 28. State programs.
Sec. 29. Children's Environmental Health Research Program.
Sec. 30. Reduction of animal-based testing.
Sec. 31. Safer alternatives and green chemistry and engineering.
Sec. 32. Cooperation with international efforts.
Sec. 33. Reliable information and advice.
Sec. 34. Hot spots.
Sec. 35. Application of this Act to Federal agencies.
Sec. 36. Implementation of Stockholm Convention, the LRTAP Pops Protocol, and the Rotterdam Convention.
Sec. 37. Annual report.
Sec. 38. Authorization of appropriations.
Sec. [29. Authorization for appropriations.
Sec. [30. Annual report.

[1] The Toxic Substances Control Act (15 U.S.C. 2601–2692) consists of Public Law 94–469 (Oct. 11, 1976; 90 Stat. 2003) and the amendments made by subsequent enactments.

Sec. [31. Effective date.]

* * * * * * *

SEC. 2. FINDINGS, POLICY, AND [INTENT] goal**.**

[(a) FINDINGS.—The Congress finds that—

[(1) human beings and the environment are being exposed each year to a large number of chemical substances and mixtures.

[(2) among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment; and

[(3) the effective regulation of interstate commerce in such chemical substances and mixtures also necessitates the regulation of intrastate commerce in such chemical substances and mixtures.

[(b) POLICY.—It is the policy of the United States that—

[(1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;

[(2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and

[(3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

[(c) INTENT OF CONGRESS.—It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this Act.]

(a) FINDINGS.—Congress finds that—

(1) each year human beings and the environment are exposed to a large number of chemical substances;

(2) the chemical industry, an important part of the United States economy, provides valuable products that are used in diverse manufacturing industries and other commercial, institutional, and consumer applications;

(3) more than 3 decades after the enactment of this Act, people and the environment in the United States are still exposed to thousands of chemicals whose safety has not been adequately reviewed and may harm health and the environment;

(4) the incidence of some diseases and disorders linked to chemical substance exposures is on the rise;

(5) biomonitoring of chemical substances in humans reveals that people in the United States carry hundreds of hazardous chemicals in their bodies;

(6) the concentrations of certain chemical substances that persist and accumulate are increasing in the environment and in human bodies and are found across the world, including in the remote Arctic in which Native Americans face increasing contamination of traditional foods;

(7) differences in metabolism and physiology at certain stages of development can make infants and children more vulnerable than adults to the effects of chemical exposure, especially exposure that occurs in utero, during infancy, and during other critical periods of development;

(8) manufacturers and processors of chemicals should supply sufficient health and environmental information before distributing products in commerce;

(9) the Administrator must have and exercise the authority to develop sufficient information to assess chemical safety, and to act effectively when the Administrator obtains information that indicates there are risks of harmful exposure to chemical substances;

(10) there is significant global trade in the chemical sector and many of the companies that conduct business in the United States must also comply with chemical safety regulatory programs in other countries, and the data that is generated to comply with those other regulatory programs may be useful in understanding hazards and exposures of chemical substances presented in the United States; and

(11) a revised policy on the safety of chemical substances will assist in renewing the manufacturing sector of the United States, create new and safer jobs, spur innovations in green chemistry, restore confidence domestically and internationally in the safety of products of the United States, and ensure that products of the United States remain competitive in the global market.

(b) POLICY.—It is the policy of the United States—

(1) to protect the health of children, workers, consumers, and the public, and to protect the environment from harmful exposures to chemical substances;

(2) to promote the use of safer alternatives and other actions that reduce the use of and exposure to hazardous chemical substances and reward innovation toward safer chemicals, processes, and products;

(3) to require that chemicals in commerce meet a risk-based safety standard that protects vulnerable and affected populations and the environment;

(4) to require companies to provide sufficient health and environmental information for the chemical substances that the companies manufacture, process, or import as a condition of allowing those companies to distribute chemical substances in commerce;

(5) to improve the quality of information on chemical safety and use;

(6) to guarantee the right of the public and workers to know about the hazards and uses of chemical substances that the public and workers may be exposed to by maximizing public access to information on chemical safety and use; and

(7) to strengthen cooperation between and among the Federal Government and State, municipal, tribal, and foreign governments.

(c) GOAL.—It is the goal of the United States to address the harmful exposure of vulnerable or affected populations to chemical substances caused by the distribution of chemical substances in commerce by—

(1) reviewing all chemical substances for safety and identifying the highest priority chemical substances for expedited review;

(2) determining whether chemical substances in commerce meet the safety standard under this title;

(3) applying appropriate restrictions to the use of a chemical substance, where warranted; and

(4) encouraging the replacement of harmful chemicals and processes with safer alternatives.

SEC. 3. DEFINITIONS.

As used in this Act:

(1) The[1] term "Administrator" means the Administrator of the Environmental Protection Agency.

(2) AGGREGATE EXPOSURE.—

(A) IN GENERAL.—Subject to subparagraph (B), the term 'aggregate exposure' means exposure from all sources of a chemical substance, including exposure from—

(i) the manufacture, processing, distribution, use, and disposal of that chemical substance; and

(ii) all other sources of that chemical substance, including—

(I) contamination of food, air, water, soil, and house dust from current or prior uses or activity;

(II) accidental releases;

(III) permitted sources of pollution;

(IV) nonpoint sources of pollution;

(V) documented background levels from natural and anthropogenic sources; and

(VI) a mixture or article containing that chemical substance.

(B) INCLUSIONS.—The term 'aggregate exposure' includes exposure from a chemical substance that is not considered to be a chemical substance under this Act solely because of the use of that substance as, or in, a food, food additive, cosmetic, or device (as those terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)).

(3) BIOACCUMULATIVE.—

(A) IN GENERAL.—The term 'bioaccumulative' means, with respect to a chemical substance or mixture, that the

[1] In Public Law 94–469, which enacted this section, the word "the" was lower case. "The" has been shown capitalized to reflect the probable intent of Congress.

chemical substance or mixture, as determined by the Administrator, can significantly accumulate in biota, as indicated through monitoring data, or is highly likely to accumulate in biota, as indicated by other evidence.

(B) UPDATE.—To reflect the best available science, the Administrator may, by rule, revise the definition of the term 'bioaccumulative' in such a way that reflects the state of the science and provides for equal or greater protection of human health and the environment.

(4) CHEMICAL IDENTITY.—The term 'chemical identity' includes—

(A) each common and trade name of a chemical substance;

(B) the name of a chemical substance appearing in International Union of Pure and Applied Chemistry nomenclature and the most current Collective Index format;

(C) each Chemical Abstracts Service registration number of a chemical substance; and

(D) the molecular structure of a chemical substance.

[(2)**]***(5)***[**(2)(A) Except as provided in subparagraph (B)**]**

(5) CHEMICAL SUBSTANCE.—

(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), the term "chemical substance" means any organic or inorganic substance of a particular molecular identity, including—

(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and

(ii) any element or uncombined radical.

[(B) Such term**]**

(B) EXCLUSIONS.—The term 'chemical substance' does not include—

(i) any mixture,

(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide,

(iii) tobacco or any tobacco product,

(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act),

(v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code), and

(vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

The term "food" as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e)

and 4(f) of the Poultry Products Inspection Act), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act).

(C) INCLUSIONS.—Notwithstanding molecular identity, the Administrator may determine that a variant of a chemical substance is a new chemical substance under section 5(a)(6).

[(3)**]***(6)* The term "commerce" means trade, traffic, transportation, or other commerce (A) between a place in a State and any place outside of such State, or (B) which affects trade, traffic, transportation, or commerce described in clause (A).

(7) CUMULATIVE EXPOSURE.*—The term 'cumulative exposure' means the sum of aggregate exposure to each of the chemical substances that are known or suspected to contribute appreciably to the risk of the same or a similar adverse effect.*

[(4) The terms "distribute in commerce" and "distribution in commerce" when used to describe an action taken with respect to a chemical substance or mixture or article containing a substance or mixture mean to sell, or the sale of, the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.**]**

(8) DISTRIBUTE IN COMMERCE.—The terms 'distribute in commerce' and 'distribution in commerce', when used to describe an action taken with respect to a chemical substance (or mixture or article containing that chemical substance), mean—

(A) to sell, or the sale of, the substance, mixture, or article in commerce;

(B) to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article;

(C) to hold, or the holding of, the substance, mixture, or article after its introduction into commerce; or

(D) to export or offer for export the substance, mixture, or article.

(9) END CONSUMER.—The term 'end consumer' means an individual or other entity that purchases and uses or consumes a chemical substance (or mixture or article containing that chemical substance).

[(5)**]***(10)* The term "environment" includes water,*ambient and indoor* air, and land and the interrelationship which exists among and between water, air, and land and all living things.

(11) FEDERAL AGENCY.—The term 'Federal agency' means any department, agency, or other instrumentality of the Federal Government, any independent agency or establishment of the Federal Government including any Government corporation, and the Government Printing Office.

[(6)**]***(12)* The term "health and safety study" means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational expo-

sure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act.

[(7)]*(13)* The term "manufacture" means to import into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedules of the United States), produce, or manufacture.

[(8)]*(14)* The term "mixture" means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.

[(9)]*(15)* The term "new chemical substance" means any chemical substance [which is not included in the chemical substance list compiled and published under section 8(b)] *for which the manufacturer or processor of the chemical substance has not submitted a declaration under section 8(a).*

(16) PERSISTENT.—

(A) IN GENERAL.—The term 'persistent' means, with respect to a chemical substance or mixture, that the chemical substance or mixture, as determined by the Administrator, significantly persists in 1 or more environmental media, as indicated by monitoring data or other evidence.

(B) UPDATE.—To reflect the best available science, the Administrator may, by rule, revise the definition of the term 'persistent' in such a way that reflects the state of the science and provides for equal or greater protection of human health and the environment.

(17) PERSON.—

(A) IN GENERAL.—The term 'person' means an individual, trust, firm, joint stock company, corporation (including a Government corporation), partnership, association, State, municipality, commission, political subdivision of a State, or any interstate body.

(B) INCLUSIONS.—The term 'person' includes each Federal agency and any officer, agent, or employee of a Federal agency.

[(10)]*(18)* The term "process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce—

(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or

(B) as part of an article containing the chemical substance or mixture.

[(11)]*(19)* The term "processor" means any person who processes a chemical substance or mixture.

(20) SPECIAL SUBSTANCE CHARACTERISTIC.—

(A) IN GENERAL.—The term 'special substance characteristic' means a physical, chemical, or biological characteristic, other than molecular identity, that the Administrator determines, by order or rule, may significantly affect the risks posed by substances exhibiting that characteristic.

(B) CONSIDERATIONS.—In determining the existence of special substance characteristics, the Administrator may consider—

(i) size or size distribution;

(ii) shape and surface structure;

(iii) reactivity; and

(iv) any other properties that may significantly affect the risks posed.

[(12) The term "standards for the development of test data" means a prescription of—

[(A) the—

[(i) health and environmental effects, and

[(ii) information relating to toxicity, persistence, and other characteristics which affect health and the environment,

for which test data for a chemical substance or mixture are to be developed and any analysis that is to be performed on such data, and

[(B) to the extent necessary to assure that data respecting such effects and characteristics are reliable and adequate—

[(i) the manner in which such data are to be developed,

[(ii) the specification of any test protocol or methodology to be employed in the development of such data, and

[(iii) such other requirements as are necessary to provide such assurance.]

[(13)]*(21)* The term "State" means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

(22) TOXIC.—The term 'toxic', with respect to a chemical substance or mixture, means that the chemical substance or mixture has a toxicological property—

(A) meeting the criteria for Category 1 or Category 2 for any of the toxicity endpoints established by the Globally Harmonized System for the Classification and Labeling of Hazardous Substances;

(B) that causes an adverse effect that has been demonstrated in humans or other exposed organisms; or

(C) for which the weight of evidence (such as demonstration of an adverse effect described in subparagraph (B), laboratory studies, or data for a chemical from the same chemical class that exhibits that adverse effect) demonstrates the potential for an adverse effect in humans or other exposed organisms.

(23) TOXICOLOGICAL PROPERTY.—The term 'toxicological property' means actual or potential toxicity or other adverse effects of a chemical substance or mixture, including actual or potential effects of exposure to a chemical substance or mixture on—

(A) mortality;

(B) morbidity, including carcinogenesis;

(C) reproduction;

(D) growth and development;

(E) the immune system;

(F) the endocrine system;

(G) the brain or nervous system;

(H) other organ systems; or

(I) any other biological functions in humans or nonhuman organisms.

[(14)]*(24)* The term "United States", when used in the geographic sense, means all of the States.

(25) VULNERABLE HUMAN POPULATION.—The term 'vulnerable human population' means a human population that is subject to disproportionate exposure to, or the potential for disproportionate adverse effect from exposure to, a chemical substance or mixture, including—

(A) infants, children, and adolescents;

(B) pregnant women;

(C) elderly;

(D) individuals with preexisting medical conditions;

(E) workers that work with chemical substances and mixtures; and

(F) members of any other appropriate population identified by the Administrator.

* * * * * * *

[SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

[(a) TESTING REQUIREMENTS.—If the Administrator finds that—

[(1)(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

[(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

[(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

[(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

[(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

[(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; and

[(2) in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture;

the Administrator shall by rule require that testing be conducted on such substance or mixture to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

[(b)(1) TESTING REQUIREMENT RULE.—A rule under subsection (a) shall include—

[(A) identification of the chemical substance or mixture for which testing is required under the rule,

[(B) standards for the development of test data for such substance or mixture, and

[(C) with respect to chemical substances which are not new chemical substances and to mixtures, a specification of the period (which period may not be of unreasonable duration) within which the persons required to conduct the testing shall submit to the Administrator data developed in accordance with the standards referred to in subparagraph (B).

[In determining the standards and period to be included, pursuant to subparagraphs (B) and (C), in a rule under subsection (a), the Administrator's considerations shall include the relative costs of the various test protocols and methodologies which may be required under the rule and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule. Any such rule may require the submission to the Administrator of preliminary data during the period prescribed under subparagraph (C).

[(2)(A) The health and environmental effects for which standards for the development of test data may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment. The characteristics of chemical substances and mixtures for which such standards may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristic which may present such a risk. The methodologies that may be prescribed in such standards include epidemiologic studies, serial or hierarchical tests, in vitro tests, and whole animal tests, except that before prescribing epidemiologic studies of employees, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health.

[(B) From time to time, but not less than once each 12 months, the Administrator shall review the adequacy of the standards for development of data prescribed in rules under subsection (a) and

shall, if necessary, institute proceedings to make appropriate revisions of such standards.

[(3)(A) A rule under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph (B) to conduct tests and submit data to the Administrator on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such data on behalf of the persons making the designation.

[(B) The following persons shall be required to conduct tests and submit data on a chemical substance or mixture subject to a rule under subsection (a):

[(i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the manufacture of such substance or mixture.

[(ii) Each person who processes or intends to process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the processing of such substance or mixture.

[(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the distribution in commerce, use, or disposal of such substance or mixture.

[(4) Any rule under subsection (a) requiring the testing of and submission of data for a particular chemical substance or mixture shall expire at the end of the reimbursement period (as defined in subsection (c)(3)(B)) which is applicable to test data for such substance or mixture unless the Administrator repeals the rule before such date; and a rule under subsection (a) requiring the testing of and submission of data for a category of chemical substances or mixtures shall expire with respect to a chemical substance or mixture included in the category at the end of the reimbursement period (as so defined) which is applicable to test data for such substance or mixture unless the Administrator before such date repeals the application of the rule to such substance or mixture or repeals the rule.

[(5) Rules issued under subsection (a) (and any substantive amendment thereto or repeal thereof) shall be promulgated pursuant to section 553 of title 5, United States Code, except that (A) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submission; (B) a transcript shall be made of any oral presentation; and (C) the Administrator shall make and publish with the rule the findings described in paragraph (1)(A) or (1)(B) of subsection (a) and, in the case of a rule respecting a mixture, the finding described in paragraph (2) of such subsection.

[(c) EXEMPTION.—(1) Any person required by a rule under subsection (a) to conduct tests and submit data on a chemical substance or mixture may apply to the Administrator (in such form and manner as the Administrator shall prescribe) for an exemption from such requirement.

[(2) If, upon receipt of an application under paragraph (1), the Administrator determines that—

[(A) the chemical substance or mixture with respect to which such application was submitted is equivalent to a chemical substance or mixture for which data has been submitted to the Administrator in accordance with a rule under subsection (a) or for which data is being developed pursuant to such a rule, and

[(B) submission of data by the applicant on such substance or mixture would be duplicative of data which has been submitted to the Administrator in accordance with such rule or which is being developed pursuant to such rule,

the Administrator shall exempt, in accordance with paragraph (3) or (4), the applicant from conducting tests and submitting data on such substance or mixture under the rule with respect to which such application was submitted.

[(3)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the existence of previously submitted test data and if such exemption is granted during the reimbursement period for such test data (as prescribed by subparagraph (B)), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

[(i) to the person who previously submitted such test data, for a portion of the costs incurred by such person in complying with the requirement to submit such data, and

[(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

[In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

[(B) For purposes of subparagraph (A), the reimbursement period for any test data for a chemical substance or mixture is a period—

[(i) beginning on the date such data is submitted in accordance with a rule promulgated under subsection (a), and

[(ii) ending—

[(I) five years after the date referred to in clause (i), or

[(II) at the expiration of a period which begins on the date referred to in clause (i) and which is equal to the pe-

riod which the Administrator determines was necessary to develop such data,

whichever is later.

[(4)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the fact that test data is being developed by one or more persons pursuant to a rule promulgated under subsection (a), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

[(i) to each such person who is developing such test data, for a portion of the costs incurred by each such person in complying with such rule, and

[(ii) to any other person who has been required under this subparagraph to contribute with respect to the costs of complying with such rule, for a portion of the amount such person was required to contribute.

[In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider the factors described in the second sentence of paragraph (3)(A). An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

[(B) If any exemption is granted under paragraph (2) on the basis of the fact that one or more persons are developing test data pursuant to a rule promulgated under subsection (a) and if after such exemption is granted the Administrator determines that no such person has complied with such rule, the Administrator shall (i) after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption, and (ii) notify in writing such person of the requirements of the rule with respect to which such exemption was granted.

[(d) NOTICE.—Upon the receipt of any test data pursuant to a rule under subsection (a), the Administrator shall publish a notice of the receipt of such data in the Federal Register within 15 days of its receipt. Subject to section 14, each such notice shall (1) identify the chemical substance or mixture for which data have been received; (2) list the uses or intended uses of such substance or mixture and the information required by the applicable standards for the development of test data; and (3) describe the nature of the test data developed. Except as otherwise provided in section 14, such data shall be made available by the Administrator for examination by any person.

[(e) PRIORITY LIST.—(1)(A) There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of a rule under subsection (a). In making such a recommendation with respect to

any chemical substance or mixture, the committee shall consider all relevant factors, including—

[(i) the quantities in which the substance or mixture is or will be manufactured,

[(ii) the quantities in which the substance or mixture enters or will enter the environment,

(iii) the number of individuals who are or will be exposed to the substance or mixture in their places of employment and the duration of such exposure,

[(iv) the extent to which human beings are or will be exposed to the substance or mixture,

[(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to present an unreasonable risk of injury to health or the environment,

[(vi) the existence of data concerning the effects of the substance or mixture on health or the environment,

[(vii) the extent to which testing of the substance or mixture may result in the development of data upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted, and

[(viii) the reasonably foreseeable availability of facilities and personnel for performing testing on the substance or mixture.

[The recommendations of the committee shall be in the form of a list of chemical substances and mixtures which shall be set forth, either by individual substance or mixture or by groups of substances or mixtures, in the order in which the committee determines the Administrator should take action under subsection (a) with respect to the substances and mixtures. In establishing such list, the committee shall give priority attention to those chemical substances and mixtures which are known to cause or contribute to or which are suspected of causing or contributing to cancer, gene mutations, or birth defects. The committee shall designate chemical substances and mixtures on the list with respect to which the committee determines the Administrator should, within 12 months of the date on which such substances and mixtures are first designated, initiate a proceeding under subsection (a). The total number of chemical substances and mixtures on the list which are designated under the preceding sentence may not, at any time, exceed 50.

[(B) As soon as practicable but not later than nine months after the effective date of this Act, the committee shall publish in the Federal Register and transmit to the Administrator the list and designations required by subparagraph (A) together with the reasons for the committee's inclusion of each chemical substance or mixture on the list. At least every six months after the date of the transmission to the Administrator of the list pursuant to the preceeding [1] sentence, the committee shall make such revisions in the list as it determines to be necessary and shall transmit them to the Administrator together with the committee's reasons for the revisions. Upon receipt of any such revision, the Administrator shall publish in the Federal Register the list with such revision,

[1] So in law. Probably should be "preceding".

the reasons for such revision, and the designations made under subparagraph (A). The Administrator shall provide reasonable opportunity to any interested person to file with the Administrator written comments on the committee's list, any revision of such list by the committee, and designations made by the committee, and shall make such comments available to the public. Within the 12-month period beginning on the date of the first inclusion on the list of a chemical substance or mixture designated by the committee under subparagraph (A) the Administrator shall with respect to such chemical substance or mixture either initiate a rulemaking proceeding under subsection (a) or if such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not initiating such a proceeding.

[(2)(A) The committee established by paragraph (1)(A) shall consist of eight members as follows:

[(i) One member appointed by the Administrator from the Environmental Protection Agency.

[(ii) One member appointed by the Secretary of Labor from officers or employees of the Department of Labor engaged in the Secretary's activities under the Occupational Safety and Health Act of 1970.

[(iii) One member appointed by the Chairman of the Council on Environmental Quality from the Council or its officers or employees.

[(iv) One member appointed by the Director of the National Institute for Occupational Safety and Health from officers or employees of the Institute.

[(v) One member appointed by the Director of the National Institute of Environmental Health Sciences from officers or employees of the Institute.

[(vi) One member appointed by the Director of the National Cancer Institute from officers or employees of the Institute.

[(vii) One member appointed by the Director of the National Science Foundation from officers or employees of the Foundation.

[(viii) One member appointed by the Secretary of Commerce from officers or employees of the Department of Commerce.

[(B)(i) An appointed member may designate an individual to serve on the committee on the member's behalf. Such a designation may be made only with the approval of the applicable appointing authority and only if the individual is from the entity from which the member was appointed.

[(ii) No individual may serve as a member of the committee for more than four years in the aggregate. If any member of the committee leaves the entity from which the member was appointed, such member may not continue as a member of the committee, and the member's position shall be considered to be vacant. A vacancy in the committee shall be filled in the same manner in which the original appointment was made.

[(iii) Initial appointments to the committee shall be made not later than the 60th day after the effective date of this Act. Not later than the 90th day after such date the members of the committee shall hold a meeting for the selection of a chairperson from among their number.

[(C)(i) No member of the committee, or designee of such member, shall accept employment or compensation from any person subject to any requirement of this Act or of any rule promulgated or order issued thereunder, for a period of at least 12 months after termination of service on the committee.

[(ii) No person, while serving as a member of the committee, or designee of such member, may own any stocks or bonds, or have any pecuniary interest, of substantial value in any person engaged in the manufacture, processing, or distribution in commerce of any chemical substance or mixture subject to any requirement of this Act or of any rule promulgated or order issued thereunder.

[(iii) The Administrator, acting through attorneys of the Environmental Protection Agency, or the Attorney General may bring an action in the appropriate district court of the United States to restrain any violation of this subparagraph.

[(D) The Administrator shall provide the committee such administrative support services as may be necessary to enable the committee to carry out its function under this subsection.

[(f) REQUIRED ACTIONS.—Upon the receipt of—

[(1) any test data required to be submitted under this Act, or

[(2) any other information available to the Administrator, which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects, the Administrator shall, within the 180-day period beginning on the date of the receipt of such data or information, initiate appropriate action under section 5, 6, or 7 to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding that such risk is not unreasonable. For good cause shown the Administrator may extend such period for an additional period of not more than 90 days. The Administrator shall publish in the Federal Register notice of any such extension and the reasons therefor. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review under chapter 7 of title 5, United States Code. This subsection shall not take effect until two years after the effective date of this Act.

[(g) PETITION FOR STANDARDS FOR THE DEVELOPMENT OF TEST DATA.—A person intending to manufacture or process a chemical substance for which notice is required under section 5(a) and who is not required under a rule under subsection (a) to conduct tests and submit data on such substance may petition the Administrator to prescribe standards for the development of test data for such substance. The Administrator shall by order either grant or deny any such petition within 60 days of its receipt. If the petition is granted, the Administrator shall prescribe such standards for such substance within 75 days of the date the petition is granted. If the petition is denied, the Administrator shall publish, subject to section 14, in the Federal Register the reasons for such denial.]

SEC. 4. MINIMUM INFORMATION SETS AND TESTING OF CHEMICAL SUBSTANCES.

(a) MINIMUM INFORMATION SETS.—

(1) RULE.—

(A) IN GENERAL.—Subject to subparagraphs (B) and (C), and not later than 1 year after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall establish, by rule, such minimum information sets as the Administrator determines to be appropriate to evaluate chemical substances under sections 5 and 6.

(B) GENERAL REQUIREMENTS.—The rule promulgated pursuant to subparagraph (A) shall—

(i) provide for varied or tiered information to be provided for different chemical substances;

(ii) identify the particular minimum information set that applies to a chemical substance;

(iii) require each minimum information set to include sufficient information for the Administrator to conduct a screening-level risk assessment of the chemical substance, including information on the characteristics, toxicological properties, environmental and biological fate and behavior, exposure, and use of a chemical substance;

(iv) specify information quality and reliability requirements applicable to the information submitted in the minimum information sets; and

(v) accommodate the use of alternative testing methods and testing strategies to generate information quickly, at low cost, and with reduced use of animal-based testing, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening, to the extent such methods and strategies would yield information of equivalent quality and reliability.

(C) SPECIFIC REQUIREMENTS.—The rule promulgated pursuant to subparagraph (A) shall establish minimum information sets sufficient for the Administrator to administer this Act, including to carry out—

(i) categorization of new chemical substances under section 5(b)(2), including the identification of information—

(I) sufficiently robust to generally support the categorization of a new chemical substance as a substance of very low concern under section 5(b)(2)(D)(iii)(II); and

(II) in the absence of which the Administrator shall designate a new chemical substance to be a substance with insufficient information under section 5(b)(2)(D)(iv);

(ii) categorization of existing chemical substances under section 6(b)(3), including the identification of information—

(I) sufficiently robust to generally support the categorization of an existing chemical substance as a substance of very low concern under section 6(b)(3)(B)(ii); and

(II) in the absence of which the Administrator shall designate an existing chemical substance to be a substance with insufficient information under section 6(b)(3)(B)(iv);

(iii) assignment of chemical substances to priority classes under section 6(b)(4);

(iv) safety standard determinations—

(I) for new uses of existing chemical substances under section 5(b)(2); and

(II) for chemical substances under section 6(d); and

(v) safety standard redeterminations under section 6(d)(5)(E).

(2) SUBMISSION OF MINIMUM INFORMATION SET.—Each manufacturer and processor of a chemical substance shall submit the minimum information set for the chemical substance to the Administrator—

(A) for new chemical substances, concurrent with the notice required under section (5)(b)(1)(A); and

(B) for existing chemical substances, as specified in section 6 or otherwise specified by the Administrator in the rule promulgated pursuant to paragraph (1)(A).

(3) PROHIBITION.—In addition to any other authorities available under this Act, the Administrator may, by order, take any action authorized under section 6(f) if a manufacturer or processor is in violation of paragraph (2).

(b) TESTING.—

(1) GENERAL SUBMISSIONS.—

(A) IN GENERAL.—The Administrator may, by rule or order, require testing with respect to any chemical substance, and the submission of test results by a specified date, as appropriate for making any determination or carrying out any provision of this Act. Such testing may be required—

(i) to provide information in addition to the information specified in any applicable minimum information set under subsection (a); and

(ii) of persons to whom the Administrator decides not to apply a requirement to submit a minimum information set under subsection (a).

(B) EFFECT ON OTHER AUTHORITY.—Nothing in this paragraph limits the authority of the Administrator under paragraph (2).

(2) SAMPLE SUBMISSIONS.—

(A) IN GENERAL.—The Administrator may, by rule or order, require the submission of a sample of any chemical substance in such manner as the Administrator determines enables the Administrator to conduct any tests necessary for making any determination or carrying out any provision of this Act.

(B) EFFECT ON OTHER AUTHORITY.—Nothing in this paragraph limits the authority of the Administrator under paragraph (1).

(3) PROHIBITION.—In addition to any other authorities available under this Act, the Administrator may, by order, take any action authorized under section 6(f) if a manufacturer or processor is in violation of a rule or order under paragraph (1).

(4) EXEMPTION.—If a manufacturer or processor ceases all manufacture or processing of a chemical substance pursuant to its submission of a declaration of cessation of manufacture or processing under section 8(b)(4) for the chemical substance, the manufacturer or processor shall be exempted from the requirements of this subsection.

(c) TEST RULES OR ORDERS.—

(1) IN GENERAL.—A rule or order issued under subsection (b) shall include—

(A) identification of the chemical substance for which testing is required under the rule or order;

(B) standards for the development of test information for that substance; and

(C) a specification of the period (which may not be of unreasonable duration) within which the persons required to conduct the testing shall submit to the Administrator information developed in accordance with the standards referred to in subparagraph (B).

(2) CONSIDERATIONS.—

(A) IN GENERAL.—In determining the standards and period to be required under subparagraphs (B) and (C) of paragraph (1), the Administrator shall consider—

(i) the relative costs of the various test protocols and methodologies that may be required under the rule or order; and

(ii) the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule.

(B) PRELIMINARY INFORMATION.—Any rule or order issued by the Administrator under this subsection may require a manufacturer or processor to submit preliminary information during the period described in paragraph (1)(C).

(3) TYPES OF HEALTH AND ENVIRONMENTAL INFORMATION.—

(A) IN GENERAL.—The Administrator may prescribe standards for the development of test information under this subsection for health and environmental information, including—

(i) information pertaining to carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, or cumulative, synergistic, or any other effect that may be considered in a safety standard determination;

(ii) information pertaining to exposure to the chemical substance, including information regarding the presence of the chemical substance in human blood, fluids, or tissue; and

(iii) information pertaining to—

(I) bioaccumulation;

(II) persistence;

(III) acute toxicity;

(IV) subacute toxicity;

(V) chronic toxicity; and

(VI) any other characteristic that may present an adverse effect.

(B) METHODOLOGIES.—

(i) IN GENERAL.—The Administrator may prescribe methodologies in standards for the development of test information, including—

(I) epidemiologic studies;

(II) biomonitoring or environmental monitoring studies;

(III) serial or hierarchical tests;

(IV) in vitro tests;

(V) whole animal tests, consistent with section 30; and

(VI) any other methodology deemed appropriate by the Administrator.

(ii) REQUIREMENT.—Prior to prescribing epidemiologic studies of employees, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health.

(C) REVIEW.—Periodically, but not less frequently than once every 3 years, the Administrator shall—

(i) review the adequacy of the standards for development of information prescribed under subparagraph (A); and

(ii) if necessary, institute proceedings to make appropriate revisions of those standards.

(4) PERSONS REQUIRED TO CONDUCT TESTS AND SUBMIT INFORMATION.—

(A) IN GENERAL.—Except as provided in subparagraph (B), a rule or order under subsection (b) respecting a chemical substance shall specify the persons required to conduct tests and submit information to the Administrator on the substance.

(B) EXCEPTION.—The Administrator may permit 2 or more of the persons described in subparagraph (A) to designate 1 of the persons or a qualified third party to conduct the tests and submit the information on behalf of the persons making the designation.

(C) LIABILITY.—All persons described in subparagraphs (A) and (B) shall remain liable for compliance with any requirements subject to the designation.

(5) EXPIRATION OF RULES AND ORDERS.—

(A) IN GENERAL.—Any rule or order under subsection (b) that requires the testing and submission of information for a particular chemical substance shall expire at the end of the applicable reimbursement period (as defined in subsection (d)(3)) unless, prior to that date, the Administrator withdraws the rule or order.

(B) CATEGORY OF CHEMICAL SUBSTANCES.—A rule or order under subsection (b) that requires the testing and submission of information for a category of chemical substances shall expire with respect to a chemical substance in-

cluded in the category at the end of the applicable reimbursement period (as defined in subsection (d)(3)) unless, prior to that date, the Administrator withdraws the rule or order with respect to the substance entirely.

(d) EXEMPTIONS.—

(1) IN GENERAL.—Any person required by a rule or order under subsections (a) or (b) to conduct tests and submit information for a chemical substance may apply to the Administrator (in such form and manner as the Administrator determines necessary) for an exemption from the requirement.

(2) ACTION BY ADMINISTRATOR.—In accordance with paragraph (3) or (4), the Administrator shall exempt an applicant under paragraph (1), if, on receipt of the application, the Administrator determines that—

(A) the chemical substance for which the application was submitted is equivalent to a chemical substance for which—

(i) information has been submitted to the Administrator in accordance with a rule or order under subsection (a) or (b); or

(ii) information is being developed in accordance with the rule or order; and

(B) submission of information by the applicant for the substance would be duplicative of information that—

(i) has been submitted to the Administrator in accordance with the rule or order under subsection (a) or (b); or

(ii) is being developed in accordance with the rule or order.

(3) REIMBURSEMENT DUE TO EXEMPTION.—

(A) DEFINITION OF REIMBURSEMENT PERIOD.—In this paragraph, the term 'reimbursement period', with respect to any test information for a chemical substance, means a period that—

(i) begins on the date on which the test information is submitted in accordance with a rule or order issued under subsection (a) or (b); and

(ii) ends on the later of—

(I) 5 years after the date referred to in clause (i); and

(II) the date which, as determined by the Administrator, provides the applicant with a time period which is sufficient to develop the test information.

(B) REIMBURSEMENT FOR PREVIOUSLY SUBMITTED TEST INFORMATION.—

(i) IN GENERAL.—Except as provided in clause (ii), for an exemption under paragraph (2)(B)(i), if the exemption is granted during the reimbursement period for the test information, the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined by the Administrator) to—

(I) the person who previously submitted the test information, for a portion of the costs incurred by

the person in complying with the information submission requirement; and

(II) any other person who has been required under this subsection to contribute with respect to the costs, for a portion of the amount the person was required to contribute.

(ii) EXCEPTION.—Clause (i) shall not apply if there is agreement on the amount and method of reimbursement between an exempted person described in clause (i) and the persons described in subclauses (I) and (II) of that clause.

(iii) CONSIDERATIONS.—In promulgating rules for the determination of fair and equitable reimbursement to the persons described in subclauses (I) and (II) of clause (i) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including—

(I) the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed; and

(II) the share of the market for the substance of the person required to provide reimbursement in relation to the share of the market of the persons to be reimbursed.

(C) REIMBURSEMENT DUE TO EXEMPTION FOR TEST INFORMATION BEING DEVELOPED IN ACCORDANCE WITH RULE OR ORDER.—

(i) IN GENERAL.—Except as provided in clause (ii), for an exemption under paragraph (2)(B)(ii), the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined by the Administrator) to—

(I) each person who is developing the test information, for the portion of the costs incurred by each person in complying with the rule or order; and

(II) any other person who has been required under this subsection to contribute with respect to the costs of complying with the rule or order, for a portion of the amount the person was required to contribute.

(ii) EXCEPTION.—Clause (i) shall not apply if there is agreement on the amount and method of reimbursement between an exempted person described in clause (i) and the persons described in subclauses (I) and (II) of that clause.

(iii) CONSIDERATIONS.—In promulgating rules for the determination of fair and equitable reimbursement to the persons described in subclauses (I) and (II) of clause (i) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Com-

mission, consider the factors described in subparagraph (B)(iii).

(iv) LACK OF COMPLIANCE.—If any exemption is granted under paragraph (2) on the basis that 1 or more persons are developing test information pursuant to a rule or order promulgated or issued under subsection (a) or (b), and after the exemption is granted, the Administrator determines that no person has complied with the rule or order, the Administrator shall—

(I) after providing written notice and an opportunity for a hearing to the person who holds the exemption, by order, terminate the exemption; and

(II) notify in writing the person of the requirements of the rule or order with respect to which the exemption was granted.

(e) NOTICE.—

(1) IN GENERAL.—Not later than 15 days after the date of receipt of any test information pursuant to a rule or order under subsection (a) or (b), the Administrator shall publish in the Federal Register a notice of the receipt of the test information.

(2) REQUIREMENTS.—Subject to section 14, each notice shall—

(A) identify the chemical substance for which information has been received;

(B) list—

(i) the commercial and consumer uses or intended commercial and consumer uses of the substance known to the Administrator; and

(ii) the information required by the applicable standards for the development of test information; and

(C) describe the nature of the test information developed.

(3) AVAILABILITY.—Subject to section 14, the Administrator shall make the test information described in this subsection available on a publicly accessible Internet site.

(f) REQUESTS FROM OTHER AGENCIES FOR ADDITIONAL INFORMATION OR TESTING.—

(1) IN GENERAL.—The head of a Federal agency may request the Administrator to seek the information on behalf of that agency if the head of that Federal agency determines that—

(A) information relating to a chemical substance, including information derived from new testing or monitoring, would assist that Federal agency in carrying out the duties or exercising the authority of that agency; but

(B) the requested information is not available to that agency.

(2) DUTY OF ADMINISTRATOR.—Not later than 60 days after the date of receipt of a request under paragraph (1), the Administrator shall—

(A) subject to section 14, make the information available to the requesting agency or institution;

(B) issue a request under section 8(k) to require—

(i) the submission of existing pertinent information to the Administrator; and

(ii) a copy of any such submission to be furnished to the requesting agency or institution;

(C) issue a rule or order under subsection (b)—

(i) to develop the information; and

(ii) to require the developed information to be furnished to the requesting agency or institution; or

(D) publish in the Federal Register the reason for which none of the actions described in this paragraph were taken.

(g) CERTIFICATION.—Each person who submits information under this section or under a rule or an order promulgated or issued by the Administrator under this section shall accompany the information with a certification signed by a responsible official that each statement contained in the submission—

(1) is accurate and reliable; and

(2) includes all material facts known to, in the possession or control of, or reasonably ascertainable by, the person.

[SEC. 5. MANUFACTURING AND PROCESSING NOTICES.

[(a) IN GENERAL.—(1) Except as provided in subsection (h), no person may—

[(A) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 8(b), or

[(B) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use,

unless such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of subsection (b).

[(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including—

[(A) the projected volume of manufacturing and processing of a chemical substance,

[(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

[(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

[(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

[(b) SUBMISSION OF TEST DATA.—(1)(A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit test data for such substance pursuant to a rule promulgated under section 4 before the submission of such notice, such person shall submit to the Administrator such data in accordance with such rule at the time notice is submitted in accordance with subsection (a)(1).

[(B) If—

[(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and

[(ii) such person has been granted an exemption under section 4(c) from the requirements of a rule promulgated under section 4 before the submission of such notice,

such person may not, before the expiration of the 90-day period which begins on the date of the submission in accordance with such rule of the test data the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(B).

[(2)(A) If a person—

[(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and

[(ii) is not required by a rule promulgated under section 4 before the submission of such notice to submit test data for such substance, such person shall submit to the Administrator data prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

[(B) Data submitted pursuant to subparagraph (A) shall be data which the person submitting the data believes show that—

[(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

[(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(B), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

[(3) Data submitted under paragraph (1) or (2) shall be made available, subject to section 14, for examination by interested persons.

[(4)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.

[(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including—

[(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

[(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

[(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those

uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.

[(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5, United States Code, except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, (ii) a transcript shall be kept of any oral presentation, and (iii) the Administrator shall make and publish with the rule the finding described in subparagraph (A).

[(c) EXTENSION OF NOTICE PERIOD.—The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b) before which the manufacturing or processing of a chemical substance subject to such subsection may begin. Subject to section 14, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

[(d) CONTENT OF NOTICE; PUBLICATIONS IN THE FEDERAL REGISTER.—(1) The notice required by subsection (a) shall include—

[(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 8(a)(2), and

[(B) in such form and manner as the Administrator may prescribe, any test data in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and

[(C) a description of any other data concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable. Such a notice shall be made available, subject to section 14, for examination by interested persons.

[(2) Subject to section 14, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) or of data under subsection (b), the Administrator shall publish in the Federal Register a notice which—

[(A) identifies the chemical substance for which notice or data has been received;

[(B) lists the uses or intended uses of such substance; and

[(C) in the case of the receipt of data under subsection (b), describes the nature of the tests performed on such substance and any data which was developed pursuant to subsection (b) or a rule under section 4.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

[(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c) has not expired, and (B) each chemical substance for which such notification period has expired since the last publication in the Federal Register of such list.

[(e) REGULATION PENDING DEVELOPMENT OF INFORMATION.—(1)(A) If the Administrator determines that—

[(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and

[(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or

[(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,the Administrator may issue a proposed order, to take effect on the expiration of the notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c), to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities.

[(B) A proposed order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c), and (ii) unless the Administrator has, on or before the issuance of the proposed order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

[(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the date such manufacturer or processor received the notice required by subparagraph (B)(ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect.

[(2)(A)(i) Except as provided in clause (ii), if with respect to a chemical substance with respect to which notice is required by subsection (a), the Administrator makes the determination described in paragraph (1)(A) and if—

[(I) the Administrator does not issue a proposed order under paragraph (1) respecting such substance, or

[(II) the Administrator issues such an order respecting such substance but such order does not take effect because objections were filed under paragraph (1)(C) with respect to it,the Administrator, through attorneys of the Environmental Protec-

tion Agency, shall apply to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer or processor, as the case may be, of such substance is found, resides, or transacts business for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance (or to prohibit or limit any combination of such activities).

[(ii) If the Administrator issues a proposed order under paragraph (1)(A) respecting a chemical substance but such order does not take effect because objections have been filed under paragraph (1)(C) with respect to it, the Administrator is not required to apply for an injunction under clause (i) respecting such substance if the Administrator determines, on the basis of such objections, that the determinations under paragraph (1)(A) may not be made.

[(B) A district court of the United States which receives an application under subparagraph (A)(i) for an injunction respecting a chemical substance shall issue such injunction if the court finds that—

[(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and

[(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or

[(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance.

[(C) Pending the completion of a proceeding for the issuance of an injunction under subparagraph (B) respecting a chemical substance, the court may, upon application of the Administrator made through attorneys of the Environmental Protection Agency, issue a temporary restraining order or a preliminary injunction to prohibit the manufacture, processing, distribution in commerce, use, or disposal of such a substance (or any combination of such activities) if the court finds that the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance may expire before such proceeding can be completed.

[(D) After the submission to the Administrator of test data sufficient to evaluate the health and environmental effects of a chemical substance subject to an injunction issued under subparagraph (B) and the evaluation of such data by the Administrator, the district court of the United States which issued such injunction shall, upon petition, dissolve the injunction unless the Administrator has initiated a proceeding for the issuance of a rule under section 6(a) respecting the substance. If such a proceeding has been initiated, such court shall continue the injunction in effect until the effective date of the rule promulgated in such proceeding or, if such pro-

ceeding is terminated without the promulgation of a rule, upon the termination of the proceeding, whichever occurs first.

[(f) PROTECTION AGAINST UNREASONABLE RISKS.—(1) If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance with respect to which notice is required by subsection (a), or that any combination of such activities, presents or will present an unreasonable risk of injury to health or environment before a rule promulgated under section 6 can protect against such risk, the Administrator shall, before the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

[(2) The Administrator may issue a proposed rule under section 6(a) to apply to a chemical substance with respect to which a finding was made under paragraph (1)—

[(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

[(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 6(a), or

[(C) any combination of the requirements referred to in subparagraph (B). Such a proposed rule shall be effective upon its publication in the Federal Register. Section 6(d)(2)(B) shall apply with respect to such rule.

[(3)(A) The Administrator may—

[(i) issue a proposed order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1), or

[(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance. A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance.

[(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 6 can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing or distribution in commerce of such substance or to prohibit any combination of such activities.

[(C) The provisions of subparagraphs (B) and (C) of subsection (e)(1) shall apply with respect to an order issued under clause (i)

of subparagraph (A); and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B).

[(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C), the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment.

[(g) STATEMENT OF REASONS FOR NOT TAKING ACTION.—If the Administrator has not initiated any action under this section or section 6 or 7 to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, with respect to which notification or data is required by subsection (a)(1)(B) or (b), before the expiration of the notification period applicable to the manufacturing or processing of such substance, the Administrator shall publish a statement of the Administrator's reasons for not initiating such action. Such a statement shall be published in the Federal Register before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

[(h) EXEMPTIONS.—(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) to permit such person to manufacture or process a chemical substance for test marketing purposes—

[(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, and

[(B) under such restrictions as the Administrator considers appropriate.

[(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit data for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that—

[(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which data has been submitted to the Administrator as required by subsection (b)(2), and

[(ii) submission of data by the applicant on such substance would be duplicative of data which has been submitted to the Administrator in accordance with such subsection, the Administrator shall exempt the applicant from the requirement to submit such data on such substance. No exemption which is granted under this subparagraph with respect to the submission of data for a chemical substance may take effect before the beginning of the reimbursement period applicable to such data.

[(B) If the Administrator exempts any person, under subparagraph (A), from submitting data required under subsection (b)(2)

for a chemical substance because of the existence of previously submitted data and if such exemption is granted during the reimbursement period for such data, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

[(i) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b)(2) to submit such data, and

[(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

[(C) For purposes of this paragraph, the reimbursement period for any previously submitted data for a chemical substance is a period—

[(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such data to the Administrator, and

[(ii) ending—

[(I) five years after the date referred to in clause (i), or

[(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data, whichever is later.

[(3) The requirements of subsections (a) and (b) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

[(A) scientific experimentation or analysis, or

[(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product, if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

[(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment. A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (3) of section 6(c).

[(5) The Administrator may, upon application, make the requirements of subsections (a) and (b) inapplicable with respect to the manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

[(6) Immediately upon receipt of an application under paragraph (1) or (5) the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

[(i) DEFINITION.—For purposes of this section, the terms "manufacture" and "process" mean manufacturing or processing for commercial purposes.]

SEC. 5. NEW CHEMICAL SUBSTANCES AND NEW USES OF CHEMICAL SUBSTANCES.

(a) DEFINITIONS.—In this section:

(1) MANUFACTURE AND PROCESS.—The terms 'manufacture' and 'process' mean manufacture or process, respectively, for commercial purposes.

(2) TEST MARKETING.—The term 'test marketing' does not include any provision of a chemical substance or mixture, or an article containing a chemical substance or mixture, to an end consumer of the chemical substance, mixture, or article.

(b) NEW CHEMICAL SUBSTANCES.—

(1) NOTICES.—Except as provided in subsection (h), no person may manufacture a new chemical substance, or process the chemical substance for a use that is proposed to meet the criteria described in section 6(h)(2)(B), unless—

(A) the person submits to the Administrator a notice, in accordance with subsection (g)(1)(A), of the intention of the person to manufacture or process the substance;

(B) the person complies with subsection (f); and

(C) the Administrator finds that—

(i) the new chemical substance is likely to meet the safety standard under section 6(d), which shall be limited to substances assigned by the Administrator to 1 of the categories described in paragraph (2)(D)(iii); or

(ii) the person has established by clear and convincing evidence that 1 or more uses of the new chem-

ical substance meet the criteria described in section 6(h)(2)(B), in which case—

(I) the Administrator may by order allow the person to manufacture or process the substance only for such use or uses in accordance with subparagraph (A) of section 6(h)(2);

(II) the procedures and requirements specified in subparagraphs (A), (C), (D), and (E) of section 6(h)(2) shall apply; and

(III) the Administrator shall not, upon receipt of a notice of commencement for the chemical substance under subsection (d), add the chemical substance to the active inventory established under section 8(h)(1).

(2) CATEGORIZATION OF NEW CHEMICAL SUBSTANCES.—

(A) RULE.—Not later than 1 year after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall promulgate a rule that—

(i) designates the categories in accordance with subparagraph (D) and specifies the process and criteria the Administrator will use to categorize new chemical substances; and

(ii) describes criteria and factors the Administrator will use to assess weight of evidence and the quality and reliability of information used to inform categorization decisions.

(B) INFORMATION SOURCES.—In categorizing a new chemical substance, the Administrator shall consider information on the substance available to the Administrator at the time the categorization decision is to be made, including information—

(i) received by the Administrator from the manufacturer or processor of the substance in accordance with subsection (f);

(ii) submitted to a governmental body in another jurisdiction, to the extent that the information is accessible to the Administrator;

(iii) derived through application of validated structure-activity relationship or other models developed by the Administrator to estimate the environmental and human health effects, environmental and biological fate and behavior, and exposure potential of chemical substances;

(iv) inferred based on the degree of similarity of the structure or properties of the new chemical substance to those of 1 or more other chemical substances for which reliable information exists that is relevant to predicting the potential environmental or human health effects, environmental or biological fate and behavior, or exposure potential of the new chemical substance; and

(v) any additional information the Administrator determines is needed to categorize the substance, including information identified as needed based on the anal-

ysis by the Administrator of estimated or inferred information described in clauses (iii) and (iv).

(C) TIMING.—Not later than 90 days after the date of receipt of a notice under paragraph (1)(A), the Administrator shall assign the new chemical substance for which the notice was submitted to 1 of the categories described in subparagraph (D).

(D) CATEGORIES.—

(i) IN GENERAL.—The rule promulgated pursuant to subparagraph (A) shall incorporate, establish criteria for, and further specify as needed, the categories described in this subparagraph, to 1 of which each new chemical substance for which a notice is submitted pursuant to paragraph (1) shall be assigned.

(ii) SUBSTANCES OF VERY HIGH CONCERN.—

(I) IN GENERAL.—The Administrator shall designate as a substance of very high concern any new chemical substance that—

(aa) is toxic, persists in the environment, and is bioaccumulative; or

(bb) is highly hazardous.

(II) REQUIREMENTS.—

(aa) IN GENERAL.—The Administrator shall allow the submitter of a notice under paragraph (1)(A) for a new chemical substance assigned to the category described in this clause to manufacture or process the new chemical substance only in accordance with paragraph (1)(C)(ii).

(bb) PROHIBITION.—No other person may manufacture or process the chemical substance unless the person has submitted a notice pursuant to paragraph (1) and the requirements of paragraph (1)(C)(ii) have been met with respect to that notice.

(iii) SUBSTANCES LIKELY TO MEET THE SAFETY STANDARD.—

(I) IN GENERAL.—

(aa) The Administrator shall designate as a substance likely to meet the safety standard any new chemical substance that the Administrator determines, based on available information, would likely meet the safety standard under section 6(d)—

(AA) for uses and under conditions specified by the submitter of the notice for the new chemical substance pursuant to paragraph (1); or

(BB) for uses and under additional conditions that could be specified by the Administrator in making a safety standard determination for the substance.

(bb) The Administrator shall assign to the category described in item (aa) any new chem-

ical substance that meets the criteria specified in subclause (II) or (III).

(II) SUBSTANCES OF VERY LOW CONCERN.—

(aa) IN GENERAL.—Within the category described in subclause (I), the Administrator shall designate as a substance of very low concern any new chemical substance that, based on robust information, the Administrator determines possesses intrinsic low-hazard properties so that no further action by the Administrator is warranted unless and until the Administrator receives new information that warrants a different categorization of the chemical substance.

(bb) BASIS OF DESIGNATION.—In identifying new chemical substances to be placed in the category described in this subclause, the Administrator shall base the designation of a new chemical substance as a substance of very low concern on the applicable minimum information set required under section 4, unless the Administrator determines that such designation of a particular new chemical substance—

(AA) can be made to a high degree of confidence based on less information; or

(BB) requires information in addition to the full minimum information set to address conflicting or ambiguous findings, in which case the Administrator may require the development and submission of the additional information.

(III) SUBSTANCES TO UNDERGO SAFETY STANDARD DETERMINATIONS.—Within the category described in subclause (I), the Administrator shall designate as a substance to undergo a safety standard determination any new chemical substance that the Administrator determines, based on a screening of available use, hazard, and exposure information, has information available for the chemical substance that is sufficiently robust to determine that the chemical substance does not meet the criteria for the categories described in subclause (II) or clause (ii) or (iv).

(IV) REQUIREMENT.—For a new chemical substance designated as likely to meet the safety standard pursuant to subclause (II) or (III), the Administrator shall, upon submission of a notice of commencement described in subsection (d)—

(aa) add the chemical substance to the active inventory described in section 8(h)(1); and

(bb) for a chemical substance designated to undergo a safety standard determination, at the discretion of the Administrator accounting for timing of the submission and workload

considerations, add the chemical substance to the current batch or hold the substance until the next batch of substances to be prioritized in accordance with section 6(b)(4).

(V) MANUFACTURING AND PROCESSING.—Pending the completion of a safety standard determination under section 6(d), a chemical substance designated as a substance likely to meet the safety standard may be manufactured or processed for uses and under conditions specified by the Administrator in determining that the chemical substance is likely to meet the safety standard—

(aa) by the submitter of the notice for the chemical substance submitted pursuant to paragraph (1)(A), upon submission of a notice for the chemical substance pursuant to subsection (d);

(bb) by other manufacturers of the chemical substance, once the chemical substance has been placed on the active inventory described in section 8(h)(1), upon submission of a declaration for the chemical substance pursuant to section 8(b)(1)(B); or

(cc) by processors of the substance, upon compliance with the requirements of section 8(e).

(iv) SUBSTANCES WITH INSUFFICIENT INFORMATION.—

(I) IN GENERAL.—The Administrator shall designate as a substance with insufficient information any new chemical substance for which the Administrator concludes, after gathering and screening available use, hazard, and exposure information, that needed information for the chemical substance is not available, is insufficient, or is not of sufficient quality and reliability to allow for an informed categorization decision.

(II) REQUIRED SUBMISSION.—For substances designated under this clause, the Administrator shall require submission of the applicable minimum information set specified under section 4 as needed to inform categorization decisionmaking for new chemical substances.

(III) RECATEGORIZATION.—Following submission of the applicable minimum information set for the chemical substance pursuant to subclause (II), the Administrator shall recategorize the chemical substance using the categories and process described in this paragraph.

(IV) PROHIBITION.—Notwithstanding paragraph (1)(C)(ii), no person may manufacture or process a chemical substance designated under this clause until and unless the information described in subclause (II) has been submitted and the Administrator has recategorized the substance, at which

time the provisions applicable to the category to which the substance has been assigned shall apply.

(v) SUBSTANCES UNLIKELY TO MEET THE SAFETY STANDARD.—

(I) IN GENERAL.—The Administrator shall designate as a substance unlikely to meet the safety standard any new chemical substance that the Administrator determines, based on available information, would be unlikely to meet the safety standard under section 6(d)—

(aa) for uses and under conditions specified by the submitter of the notice for the chemical substance pursuant to paragraph (1); or

(bb) for other uses or under additional conditions that the Administrator may evaluate in making a safety standard determination for the chemical substance.

(II) PROHIBITION.—Except as provided under clause (ii), no person may manufacture or process a chemical substance designated under this clause.

(c) NEW USES OF EXISTING CHEMICAL SUBSTANCES.—

(1) NEW USES OF EXISTING CHEMICAL SUBSTANCES PRIOR TO SAFETY STANDARD DETERMINATION.—

(A) IN GENERAL.—Except as provided in subparagraph (B), with respect to an existing chemical substance for which the Administrator has not made a safety standard determination under section 6(d), no person may manufacture or process the chemical substance—

(i) for a use that was not ongoing on the date of enactment of the Safe Chemicals Act of 2011; or

(ii) at a volume that is significantly increased from the volume as of the date of enactment of the Safe Chemicals Act of 2011.

(B) EXCEPTION.—A person may manufacture or process a chemical substance in a manner prohibited by subparagraph (A) if—

(i) the person submits to the Administrator the notice specified in subsection (g)(1)(B);

(ii) the person complies with subsection (f); and

(iii) such manufacturing or processing is consistent with subsection (b)(2)(D)(iii)(V).

(C) GUIDANCE.—Not later than 90 days after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall issue guidance for the purpose of identifying what constitute new uses and significantly increased production volumes under this paragraph.

(2) NEW USES OF EXISTING CHEMICAL SUBSTANCES THAT MEET THE SAFETY STANDARD.—

(A) IN GENERAL.—For an existing chemical substance for which the Administrator has determined under section 6(d) that the manufacturers and processors of the chemical substance have established that the substance meets the applicable safety standard, no person may manufacture, process, distribute in commerce, use, or dispose of the chemical sub-

stance, or a mixture or article containing the chemical substance for uses, at production volumes, or in manners other than those the Administrator specified in the safety standard determination, unless—

(i) the person submits to the Administrator a notice in accordance with subsection (g)(1)(C) of the intention of the person to manufacture, process, distribute in commerce, use, or dispose of the chemical substance, or a mixture or article containing the chemical substance, for the new use or at a new production volume, or in such other manner that is inconsistent with a specified condition or term in the safety standard determination made by the Administrator for that substance; and

(ii) the Administrator determines that the person submitting the notice has established that the chemical substance will continue to meet the safety standard if the allowed uses, production volumes, or other specified conditions or terms for that substance, are revised to encompass the new use, new production volume, or other manner of manufacturing, processing, distribution in commerce, use, or disposal.

(B) AMENDMENT TO SAFETY STANDARD DETERMINATION.—If the conditions described in clauses (i) and (ii) of subparagraph (A) are satisfied, the Administrator shall, by order, amend the safety standard determination for the chemical substance to include the new use, production volume, or other manner of manufacturing or processing among the allowed uses, production volumes, or manners of manufacturing, processing, distribution in commerce, use, or disposal of the chemical substance.

(C) SAFETY STANDARD DETERMINATION.—

(i) IN GENERAL.—Except as provided in clauses (ii) and (iii), not later than 180 days after the date of receipt of a notice pursuant to subparagraph (A)(i), the Administrator shall determine whether the person submitting the notice has established that the chemical substance will continue to meet the safety standard under section 6(d).

(ii) EXTENSION.—The Administrator may extend the determination deadline under clause (i) by 1 or more additional periods not to exceed 1 year in the aggregate, in such manner as the Administrator determines necessary.

(iii) FAILURE TO MAKE A TIMELY DETERMINATION.—The failure of the Administrator to make a timely determination in accordance with this paragraph shall not be sufficient to satisfy subparagraph (A)(ii).

(d) NOTICE OF COMMENCEMENT.—

(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer or processor commences manufacturing or processing of a new chemical substance, the manufacturer or processor shall submit to the Administrator a notice of commencement of manufacture or processing.

(2) REQUIREMENTS.—The notice of commencement shall—

(A) be considered equivalent to the declaration required under subparagraph (A) or (C) of section 8(b)(2); and

(B) include the information described in section 8(b)(5).

(3) WITHDRAWAL.—A person who has submitted a notice for a chemical substance under subsection (b) or (c), and has not commenced with manufacture or processing of the substance, may withdraw the notice.

(e) CHEMICAL SUBSTANCES EXHIBITING SPECIAL SUBSTANCE CHARACTERISTICS.—

(1) DETERMINATION.—The Administrator shall determine by order or rule that a variant of a chemical substance exhibiting 1 or more special substance characteristics—

(A) is a use that is separate from any use of the chemical substance that does not exhibit the special substance characteristics; or

(B) is a distinct chemical substance.

(2) REQUIREMENTS FOR VARIANTS THAT ARE SEPARATE USES.—In the case of a chemical substance that the Administrator determines to be a separate use based on the special substance characteristics of the chemical substance, the manufacturer or processor shall satisfy such further conditions as the Administrator establishes, by order or rule.

(3) REQUIREMENTS FOR VARIANTS THAT ARE DISTINCT CHEMICAL SUBSTANCES.—In the case of a chemical substance that the Administrator determines to be a distinct chemical substance based on the special substance characteristics of the chemical substance, and that is not listed on the active inventory established under section 8(h)(1), the manufacturer or processor shall comply with the requirements of subsection (b).

(f) SUBMISSION OF DATA.—

(1) IN GENERAL.—A person shall submit to the Administrator data in accordance with the rule or order at the time that notice is submitted under subsection (b) or (c) if the person is required to submit to the Administrator—

(A) under subsection (b) or (c), a notice prior to beginning the manufacture or processing of a chemical substance; and

(B) under section 4(b), test data for the chemical substance prior to the submission of the notice.

(2) AVAILABILITY.—Subject to section 14, the Administrator shall make any test data submitted under paragraph (1) available on a publicly accessible Internet site.

(3) TIMING.—Except as provided under subsection (b)(2)(D)(iv), the Administrator may require a person subject to an information requirement for a chemical substance under this subsection or section 4 to submit the information—

(A) prior to and as a condition of the Administrator assigning the substance to a category;

(B) as a condition of commencement of manufacture or processing; or

(C) as a condition of exceeding a specified manufacturing volume or expanding use of the substance.

(g) CONTENT AND AVAILABILITY OF NOTICE.—

(1) CONTENT.—

(A) NEW CHEMICAL SUBSTANCES.—A notice under subsection (b)(1) shall include—

(i) the chemical identity and any special substance characteristics of the chemical substance;

(ii) the identity and primary business location of the manufacturer;

(iii) the information described in section 8(h)(5)(B)(ii);

(iv) the minimum information set described in section 4(a), where applicable; and

(v) a statement that—

(I) the new chemical substance is likely to meet the safety standard under section 6(d); or

(II) the 1 or more uses proposed for the new chemical substance meet the criteria described in section 6(h)(2)(B).

(B) NEW USES OF EXISTING CHEMICAL SUBSTANCES PRIOR TO SAFETY STANDARD DETERMINATION.—A notice under subsection (c)(1) shall include all updates to the declaration described in section 8(b)(2) and information described in section 8(h)(5)(B)(ii) that is relevant to the new use, new production volume, or other new manner of manufacturing or processing.

(C) NEW USES OF EXISTING CHEMICAL SUBSTANCES THAT MEET THE SAFETY STANDARD.—A notice under subsection (c)(2) shall include—

(i) all updates to the declaration described in section 8(b)(2);

(ii) information described in section 8(h)(5)(B)(ii) that is relevant to the new use, new production volume, or other new manner of manufacturing or processing;

(iii) all updates to the minimum information set described in section 4(a) relevant to the new use, new production volume, or other new manner of manufacturing or processing; and

(iv) a statement that the chemical substance will continue to meet the safety standard if the allowed uses, production volumes, or other specified conditions or terms for that chemical substance are revised to encompass the new use, production volume, or other manner of manufacturing or processing.

(2) AVAILABILITY.—Subject to section 14, the Administrator shall make the notices under paragraph (1) available on a publicly accessible Internet site.

(3) PUBLIC INFORMATION.—Subject to section 14, not later than 5 days (excluding Saturdays, Sundays, and legal holidays) after the date of the receipt of a notice under subsection (b), (c), or (d), or of data under subsection (f), the Administrator shall make available on a publicly accessible Internet site a notice that—

(A) identifies the chemical substance for which notice or information has been received;

(B) lists the uses or intended uses of the chemical substance;

(C) for substances for which a notice is submitted under subsection (b)(1), is promptly updated to specify the category to which the Administrator has assigned the substance pursuant to subsection (b)(2) once the assignment has been made;

(D) in the case of the receipt of data under subsection (f), describes—

(i) the nature of the tests performed with respect to the chemical substance; and

(ii) any data that were received under subsection (f) or a rule or order under section 4; and

(E) references the availability of the minimum information set, where applicable.

(4) LIST OF NOTICES.—At the beginning of each month, the Administrator shall make available on a publicly accessible Internet site a list of each chemical substance for which a notice has been received under subsection (b), (c), or (d).

(h) EXEMPTIONS.—

(1) INTRINSICALLY SAFE SUBSTANCES.—

(A) EXEMPTION.—

(i) IN GENERAL.—If the Administrator determines that scientific consensus exists that the intrinsic properties of a new chemical substance are such that the chemical substance does not and would not pose any risk of injury to human health or the environment under any intended or reasonably anticipated levels of production, patterns of use, or exposures arising at any stage across the lifecycle of the chemical substance, the Administrator may, by order, exempt the chemical substance, or particular uses of such substances, from 1 or more of the requirements of this section.

(ii) BASIS OF DETERMINATION.—A determination under clause (i)—

(I) shall be based on consideration of the intrinsic properties of the chemical substance; and

(II) shall not be based on findings or assumptions of low human or environmental exposure to such substances.

(B) NOTICE OF DETERMINATION AND EXEMPTION.—Not later than 30 days after providing an exemption pursuant to subparagraph (A), the Administrator shall publish in the Federal Register a notice that—

(i) subject to section 14, provides the specific identity of the chemical substance or category;

(ii) if a particular use of the chemical substance is exempted under subparagraph (A), describes the particular use of the chemical substance that the Administrator has exempted; and

(iii) explains and documents the basis for the determination and exemption of the Administrator.

(C) RECONSIDERATION OF EXEMPTION.—

(i) IN GENERAL.—The Administrator may reconsider and revoke or modify any exemption provided under

subparagraph (A) at any time if the Administrator determines that—

(I) the conditions specified in subparagraph (A) are no longer met; or

(II) such action is necessary to protect human health or the environment or is otherwise in the public interest.

(ii) PUBLICATION.—In the event of a revocation or modification under clause (i), the Administrator shall publish a notice of the grounds for the revocation.

(D) PRIOR REGULATORY EXEMPTIONS.—

(i) REVIEW.—

(I) IN GENERAL.—Not later than 180 days after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall review exemptions that were granted pursuant to subsection (h)(4) of this section as in effect on the day before that date of enactment.

(II) EFFECT OF EXEMPTION.—An exemption described in subclause (I) shall continue to be in effect until the date on which the Administrator determines, by order, that—

(aa) the exemption is not appropriate under this section, at which time the exemption shall cease to be in effect; or

(bb) the exemption is appropriate under this section, at which time the Administrator may issue an order to modify or continue in effect the exemption pursuant to subparagraph (A).

(ii) POLYMERIC CHEMICAL SUBSTANCES.—Notwithstanding subparagraph (A) and any previously issued exemption applicable to polymeric chemical substances—

(I) subsection (d) shall apply to new polymeric chemical substances eligible for the previously issued exemption—

(aa) during the period prior to a determination by the Administrator pursuant to clause (i) applicable to such substances; and

(bb) after a determination by the Administrator pursuant to clause (i)(II)(bb) that continuation of the prior exemption is appropriate for some or all such substances, for such substances to which the continuation applies; and

(II) all of this section shall apply to new polymeric chemical substances eligible for the previously issued exemption after a determination by the Administrator pursuant to clause (i)(II)(aa) that continuation of the prior exemption is not appropriate for some or all such substances, for such substances to which the determination applies.

(E) NO LIMITATION ON AUTHORITY.—Nothing in this paragraph limits or otherwise affects the authority of the Administrator under any other provision of this Act.

(2) TEST MARKETING PURPOSES.—Subject to paragraph (6), the Administrator may, upon application, exempt any person from any requirement of subsection (b), (c), or (f) to permit the person to manufacture or process a chemical substance for test marketing purposes—

(A) upon a showing by the person, in a manner that the Administrator determines, that the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance (including any combination of those activities) will not endanger human health or the environment; and

(B) under such restrictions as the Administrator considers appropriate.

(3) EQUIVALENT CHEMICAL SUBSTANCES.—

(A) IN GENERAL.—The Administrator shall, upon application, fully or partially exempt any person from the requirement to submit any data under subsection (b) or (f) if, on receipt of an application, the Administrator determines that—

(i) the chemical substance for which the application was submitted is equivalent to a chemical substance for which data has been submitted to the Administrator as required by this Act; and

(ii) submission of data by the applicant on the chemical substance would be duplicative of data which has been submitted to the Administrator in accordance with this Act.

(B) EFFECTIVE DATE.—No exemption under this paragraph may take effect before the beginning of the reimbursement period applicable to the data.

(C) FAIR AND EQUITABLE REIMBURSEMENT.—

(i) DEFINITION OF REIMBURSEMENT PERIOD.—In this subparagraph, the term 'reimbursement period', with respect to any previously submitted data for a chemical substance, means a period—

(I) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of the chemical substance by the person who submitted the data to the Administrator; and

(II) ending on the later of—

(aa) the date that is 5 years after the date referred to in subclause (I); or

(bb) the expiration of the period, which begins on the date referred to in subclause (I) and is equal to the period that the Administrator determines to be necessary to develop the data.

(ii) REIMBURSEMENT.—Except as provided in clause (iii), if the Administrator exempts any person, under subparagraph (A), and the exemption is granted during the reimbursement period for that data, the Administrator shall order the person granted the exemption to

provide fair and equitable reimbursement (in an amount determined by the Administrator)—

(I) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by the person in complying with the requirement under this title to submit the data; and

(II) to any other person who has been required under this subparagraph to contribute with respect to the costs, for a portion of the amount the person was required to contribute.

(iii) EXCEPTION.—Clause (ii) shall not apply if the person exempted under that clause and the persons described in subclauses (I) and (II) of that clause agree on the amount and method of reimbursement.

(iv) CONSIDERATIONS.—In promulgating rules for the determination of fair and equitable reimbursement to the persons described in subclauses (I) and (II) of clause (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including—

(I) the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed; and

(II) the share of the market for the chemical substance of the person required to provide reimbursement to the share of the market of the persons to be reimbursed.

(4) SMALL QUANTITIES SOLELY FOR EXPERIMENTATION, RESEARCH, AND ANALYSIS.—

(A) IN GENERAL.—If the conditions described in subparagraph (B) are met, subsections (b), (c), and (f) shall not apply with respect to the manufacturing or processing of any chemical substance that is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(i) scientific experimentation or analysis; or

(ii) chemical research on, or analysis of the chemical substance or another chemical substance, including such research or analysis for the development of a product.

(B) CONDITIONS.—All persons engaged in the experimentation, research, or analysis for a manufacturer or processor shall be notified (in such form and manner as the Administrator may prescribe) of any risk to human health that the manufacturer, processor, or the Administrator has reason to believe may be associated with that chemical substance.

(5) TEMPORARY EXISTENCE.—Subject to paragraph (6), the Administrator may, upon application, exempt from subsections (b), (c), and (f) the manufacturing or processing of any chemical substance—

(A) that exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance; and

(B) to which there is no, and will not be, human or environmental exposure.

(6) PUBLICATION.—

(A) IN GENERAL.—As soon as practicable after the date of receipt of an application under paragraph (2) or (5), the Administrator shall publish in the Federal Register notice of the receipt of the application.

(B) REQUIREMENTS.—The Administrator shall—

(i) give interested persons an opportunity to comment upon any application described in subparagraph (A);

(ii) not later than 45 days after the date of receipt of an application, approve or deny the application; and

(iii) publish in the Federal Register notice of the approval or denial of the application.

(i) CERTIFICATION.—Each submission required under this section or under a rule or an order promulgated or issued by the Administrator under this section shall be accompanied by a certification signed by a responsible official of the manufacturer or processor that each statement contained in the submission—

(1) is accurate and reliable; and

(2) includes all material facts required by the applicable provision of this section or rule or order under this section.

[SEC. 6. REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES.

[(a) SCOPE OF REGULATION.—If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents, or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements:

[(1) A requirement (A) prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

[(2) A requirement—

[(A) prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

[(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

[(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with

or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.

[(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

[(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

[(6)(A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.

[(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

[(7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such risk of injury, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Any requirement (or combination of requirements) imposed under this subsection may be limited in application to specified geographic areas.

[(b) QUALITY CONTROL.—If the Administrator has a reasonable basis to conclude that a particular manufacturer or processor is manufacturing or processing a chemical substance or mixture in a manner which unintentionally causes the chemical substance or mixture to present or which will cause it to present an unreasonable risk of injury to health or the environment—

[(1) the Administrator may by order require such manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of such chemical substance or mixture; and

[(2) if the Administrator determines—

[(A) that such quality control procedures are inadequate to prevent the chemical substance or mixture from presenting such risk of injury, the Administrator may order the manufacturer or processor to revise such quality control procedures to the extent necessary to remedy such inadequacy; or

[(B) that the use of such quality control procedures has resulted in the distribution in commerce of chemical substances or mixtures which present an unreasonable risk of injury to health or the environment, the Administrator may order the manufacturer or processor to (i) give notice of such risk to processors or distributors in commerce of any such substance or mixture, or to both, and, to the extent reasonably ascertainable, to any other person in possession of or exposed to any such substance, (ii) to give public notice of such risk, and (iii) to provide such replacement or repurchase of any such substance or mixture as is necessary to adequately protect health or the environment.

[A determination under subparagraph (A) or (B) of paragraph (2) shall be made on the record after opportunity for hearing in accordance with section 554 of title 5, United States Code. Any manufacturer or processor subject to a requirement to replace or repurchase a chemical substance or mixture may elect either to replace or repurchase the substance or mixture and shall take either such action in the manner prescribed by the Administrator.

[(c) PROMULGATION OF SUBSECTION (a) RULES.—(1) In promulgating any rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement with respect to—

[(A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture,

[(B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,

[(C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and

[(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

[If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule under subsection (a) to protect against such risk of injury unless the Administrator finds, in the Administrator's discretion, that it is in the public interest to protect against such risk under this Act. In making such a finding the Administrator shall consider (i) all relevant aspects of the risk, as determined by the Administrator in the Administrator's discretion, (ii) a comparison of the estimated costs of complying with actions taken under this Act and under such law (or laws), and (iii) the relative efficiency of actions under this Act and under such law (or laws) to protect against such risk of injury.

[(2) When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5, United States Code (without regard to any reference in such section to sections 556 and 557 of such title), and shall also (A) pub-

lish a notice of proposed rulemaking stating with particularity the reason for the proposed rule; (B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available; (C) provide an opportunity for an informal hearing in accordance with paragraph (3); (D) promulgate, if appropriate, a final rule based on the matter in the rulemaking record (as defined in section 19(a)), and (E) make and publish with the rule the finding described in subsection (a).

[(3) Informal hearings required by paragraph (2)(C) shall be conducted by the Administrator in accordance with the following requirements:

[(A) Subject to subparagraph (B), an interested person is entitled—

[(i) to present such person's position orally or by documentary submissions (or both), and

[(ii) if the Administrator determines that there are disputed issues of material fact it is necessary to resolve, to present such rebuttal submissions and to conduct (or have conducted under subparagraph (B)(ii)) such cross-examination of persons as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to such issues.

[(B) The Administrator may prescribe such rules and make such rulings concerning procedures in such hearings to avoid unnecessary costs or delay. Such rules or rulings may include (i) the imposition of reasonable time limits on each interested person's oral presentations, and (ii) requirements that any cross-examination to which a person may be entitled under subparagraph (A) be conducted by the Administrator on behalf of that person in such manner as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to disputed issues of material fact.

[(C)(i) Except as provided in clause (ii), if a group of persons each of whom under subparagraphs (A) and (B) would be entitled to conduct (or have conducted) cross-examination and who are determined by the Administrator to have the same or similar interests in the proceeding cannot agree upon a single representative of such interests for purposes of cross-examination, the Administrator may make rules and rulings (I) limiting the representation of such interest for such purposes, and (II) governing the manner in which such cross-examination shall be limited.

[(ii) When any person who is a member of a group with respect to which the Administrator has made a determination under clause (i) is unable to agree upon group representation with the other members of the group, then such person shall not be denied under the authority of clause (i) the opportunity to conduct (or have conducted) cross-examination as to issues affecting the person's particular interests if (I) the person satisfies the Administrator that the person has made a reasonable and good faith effort to reach agreement upon group representation with the other members of the group and (II) the Administrator determines that there are substantial and relevant

issues which are not adequately presented by the group representative.

[(D) A verbatim transcript shall be taken of any oral presentation made, and cross-examination conducted in any informal hearing under this subsection. Such transcript shall be available to the public.

[(4)(A) The Administrator may, pursuant to rules prescribed by the Administrator, provide compensation for reasonable attorneys' fees, expert witness fees, and other costs of participating in a rulemaking proceeding for the promulgation of a rule under subsection (a) to any person—

[(i) who represents an interest which would substantially contribute to a fair determination of the issues to be resolved in the proceeding, and

[(ii) if—

[(I) the economic interest of such person is small in comparison to the costs of effective participation in the proceeding by such person, or

[(II) such person demonstrates to the satisfaction of the Administrator that such person does not have sufficient resources adequately to participate in the proceeding without compensation under this subparagraph.

[In determining for purposes of clause (i) if an interest will substantially contribute to a fair determination of the issues to be resolved in a proceeding, the Administrator shall take into account the number and complexity of such issues and the extent to which representation of such interest will contribute to widespread public participation in the proceeding and representation of a fair balance of interests for the resolution of such issues.

[(B) In determining whether compensation should be provided to a person under subparagraph (A) and the amount of such compensation, the Administrator shall take into account the financial burden which will be incurred by such person in participating in the rulemaking proceeding. The Administrator shall take such action as may be necessary to ensure that the aggregate amount of compensation paid under this paragraph in any fiscal year to all persons who, in rulemaking proceedings in which they receive compensation, are persons who either—

[(i) would be regulated by the proposed rule, or

[(ii) represent persons who would be so regulated,

may not exceed 25 per centum of the aggregate amount paid as compensation under this paragraph to all persons in such fiscal year.

[(5) Paragraphs (1), (2), (3), and (4) of this subsection apply to the promulgation of a rule repealing, or making a substantive amendment to, a rule promulgated under subsection (a).

[(d) EFFECTIVE DATE.—(1) The Administrator shall specify in any rule under subsection (a) the date on which it shall take effect, which date shall be as soon as feasible.

[(2)(A) The Administrator may declare a proposed rule under subsection (a) to be effective upon its publication in the Federal Register and until the effective date of final action taken, in accordance with subparagraph (B), respecting such rule if—

[(i) the Administrator determines that—

[(I) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before such effective date; and

[(II) making such proposed rule so effective is necessary to protect the public interest; and

[(ii) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under clause (i)(I), a court has in an action under section 7 granted relief with respect to such risk associated with such substance or mixture. [Such a proposed rule which is made so effective shall not, for purposes of judicial review, be considered final agency action.

[(B) If the Administrator makes a proposed rule effective upon its publication in the Federal Register, the Administrator shall, as expeditiously as possible, give interested persons prompt notice of such action, provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), for a hearing on such rule, and either promulgate such rule (as proposed or with modifications) or revoke it; and if such a hearing is requested, the Administrator shall commence the hearing within five days from the date such request is made unless the Administrator and the person making the request agree upon a later date for the hearing to begin, and after the hearing is concluded the Administrator shall, within ten days of the conclusion of the hearing, either promulgate such rule (as proposed or with modifications) or revoke it.]

SEC. 6. BATCHING, CATEGORIZATION, PRIORITIZATION, SAFETY STANDARD DETERMINATION, AND RISK MANAGEMENT.

(a) BATCHING.—

(1) IN GENERAL.—To ensure that an efficient and orderly process and pace is established for the determination of safety of chemical substances in commerce and the application of risk management measures as needed, the Administrator shall establish a system for assigning chemical substances into batches in accordance with this subsection.

(2) REQUIREMENTS.—

(A) TIMING.—Not later than 270 days after the date of enactment of the Safe Chemicals Act of 2011, and not less frequently than once every 5 years thereafter until all chemical substances listed on the active portion of the inventory established under section 8(h)(1) have been assigned to a batch, the Administrator shall assign chemical substances on the active portion of the inventory to batches of chemical substances under this subsection.

(B) NUMBER.—Each batch established under this subsection shall include a number of chemical substances approximately equal to the number of chemical substances for which reports are submitted to the Administrator under the chemical data reporting rule as of the date of enactment of the Safe Chemicals Act of 2011.

(C) PUBLICATION.—The Administrator shall publish, subject to section 14, the list of chemical substances assigned

to each batch promptly on designation of the chemical substances to the batch.

(3) INITIAL BATCH.—

(A) IN GENERAL.—Subject to subparagraph (B), the initial batch of chemical substances designated under paragraph (2)(A) shall include the chemical substances for which reports are submitted to the Administrator under the chemical data reporting rule as of the date of enactment of the Safe Chemicals Act of 2011.

(B) INCLUSIONS AND EXCLUSIONS.—Notwithstanding subparagraph (A), the Administrator may—

(i) include in the initial batch chemical substances that—

(I) are manufactured at volumes below the threshold used under the chemical data reporting rule to designate chemical substances subject to basic reporting under that rule; but

(II) are used or released into the environment in a manner that the Administrator determines warrants early evaluation; and

(ii) exclude from the initial batch chemical substances that—

(I) are reported to the Administrator under the chemical data reporting rule; but

(II) are used or released into the environment in a manner that the Administrator determines does not warrant early evaluation.

(4) SUBSEQUENT BATCHES.—The Administrator shall assign chemical substances to subsequent batches in a manner that the Administrator determines reflects the extent to which the chemical substances warrant earlier or later evaluation.

(b) CATEGORIZATION AND PRIORITIZATION.—

(1) REGULATIONS.—Not later than 1 year after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall promulgate regulations that—

(A) establish the categories and specify the process and criteria the Administrator will use to categorize chemical substances, which shall be consistent with paragraph (3)(B), beginning with those chemical substances assigned to the initial batch described in subsection (a)(3);

(B) designate the process and criteria the Administrator will use to prioritize chemical substances that are placed in the category of chemical substances to undergo safety standard determinations, which shall be consistent with the priorities described in paragraph (4);

(C) describe how the categorization and prioritization process and criteria relate to, and take into account, the categorization and prioritization decisions made in other jurisdictions, including States and foreign governments; and

(D) describe criteria and factors the Administrator will use to weigh evidence and assess the quality and reliability of information used to inform categorization and prioritization decisions.

(2) INFORMATION SOURCES.—

(A) IN GENERAL.—In making categorization and prioritization decisions, the Administrator shall take into consideration information regarding chemical substances that is available to the Administrator at the time the decisions are made, including information that is—

(i) received by the Administrator from manufacturers or processors pursuant to requirements under section 8(b) and (c);

(ii) included in any minimum information set required under section 4;

(iii) submitted to the Administrator that is relevant to the categorization or prioritization of the chemical substance; and

(iv) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible to the Administrator.

(B) INFORMATION FROM MANUFACTURERS AND PROCESSORS.—

(i) IN GENERAL.—Subject to clause (ii), on designation by the Administrator under paragraph (3)(B)(iii) of a chemical substance safety standard determination, any manufacturer or processor of a designated chemical substance and any trade association or voluntary consortium that represents a manufacturer or processor of a designated chemical substance may provide to the Administrator information that—

(I) relates to the chemical substances manufactured or processed by the applicable manufacturer or processor;

(II) is in the possession of, or known to, the manufacturer, processor, trade association, or consortium; and

(III) is not already available to the Administrator.

(ii) REQUIREMENT.—If a manufacturer, processor, trade association, or consortium elects to provide information to the Administrator under clause (i), the manufacturer, processor, trade association, or consortium shall provide all relevant information in the possession of, or known to, the manufacturer, processor, trade association, or consortium for each chemical substance designated by the Administrator that is manufactured or processed by the applicable manufacturer or processor.

(iii) METHOD OF SUBMISSION.—Information described in this subparagraph may be submitted to the Administrator by—

(I) a manufacturer or processor—

(aa) on an individual basis; or

(bb) through a trade association or voluntary consortium; and

(II) a trade association or voluntary consortium that has developed relevant information on behalf

of the manufacturers or processors of designated chemical substances represented by the trade association or voluntary consortium.

(3) CATEGORIZATION OF CHEMICAL SUBSTANCES.—

(A) TIMING.—

(i) INITIAL BATCH.—Not later than 180 days after the date of promulgation of regulations pursuant to paragraph (1), the Administrator shall publish, subject to section 14, the category assignments for the initial batch of chemical substances identified under subsection (a)(3), using the categories described in subparagraph (B).

(ii) SUBSEQUENT BATCHES.—Not later than 180 days after the date on which the Administrator designates each subsequent batch of chemical substances under subsection (a)(2)(A), the Administrator shall publish the category assignments for the chemical substances in the batch.

(B) CATEGORIES.—The regulation promulgated pursuant to paragraph (1) shall incorporate, establish criteria for, and further specify as needed, the following categories into which chemical substances in each batch shall be placed:

(i) SUBSTANCES OF VERY HIGH CONCERN.—

(I) IN GENERAL.—The Administrator shall designate as substances of very high concern those chemical substances—

(aa) for which there is evidence of widespread exposure and that—

(AA) are toxic, persist in the environment, and are bioaccumulative; or

(BB) are highly hazardous;

(bb) that are subject to regulation under section 6 or 7 of this Act (as in effect on the day before the date of enactment of the Safe Chemicals Act of 2011); or

(cc) that are subject to a voluntary phaseout, administered by the Administrator, that has been completed or is underway at the time the category designation is made.

(II) INFORMATION SET.—A minimum information set, as specified under section 4, need not be submitted or otherwise available for a chemical substance to be designated a substance of very high concern under this clause.

(ii) SUBSTANCES OF VERY LOW CONCERN.—

(I) IN GENERAL.—The Administrator shall designate as substances of very low concern those chemical substances that, based on robust information, the Administrator determines possess intrinsic low-hazard properties such that no further action by the Administrator is warranted, unless the Administrator receives new information that warrants a different categorization of the chemical substance.

(II) FACTORS FOR CONSIDERATION.—In designating chemical substances to be placed in the very low concern category under this clause, the Administrator shall—

(aa) take into consideration whether chemical substances in commerce have received, as of the date of enactment of the Safe Chemicals Act of 2011, exemptions under section 5 of this Act (as in effect on the day before the date of enactment of the Safe Chemicals Act of 2011) based on anticipated low intrinsic hazard; and

(bb) in general, base the designation on a minimum information set as required under section 4, unless the Administrator determines that such designation of a particular chemical substance—

(AA) can be made to a high degree of confidence based on less information; or

(BB) requires information in addition to the full minimum information set to address conflicting or ambiguous findings, in which case the Administrator may require the development and submission of the additional information.

(iii) SUBSTANCES TO UNDERGO SAFETY STANDARD DETERMINATIONS.—The Administrator shall designate as substances to undergo safety standard determinations those chemical substances that the Administrator determines—

(I) based on a screening of available use, hazard, and exposure information, do not meet the criteria for the categories described in clauses (i) and (ii); and

(II) are the subject of available information that is sufficiently robust to inform prioritization decisions to be made for the chemical substances under paragraph (4).

(iv) SUBSTANCES WITH INSUFFICIENT INFORMATION.—

(I) IN GENERAL.—The Administrator shall designate as substances with insufficient information those chemical substances for which the Administrator determines, after gathering and screening available use, hazard, and exposure information, that information is not available, is insufficient, or is not of sufficient quality and reliability to allow for an informed categorization decision.

(II) MINIMUM INFORMATION SET.—

(aa) IN GENERAL.—For chemical substances designated under this clause, the Administrator shall require submission of the applicable minimum information set specified under section 4 as needed to inform categorization decisionmaking.

(bb) TIMING.—The minimum information set shall be submitted to the Administrator—

(AA) not later than 5 years after the date of enactment of the Safe Chemicals Act of 2011 for the initial batch of chemical substances identified under subsection (a)(3); and

(BB) not later than 5 years after the assignment of a chemical substance to the category under this clause for subsequent batches.

(III) RECATEGORIZATION.—

(aa) IN GENERAL.—After submission of the minimum information set for a chemical substance pursuant to subclause (I), the Administrator shall recategorize the chemical substance using the categories and process described in this paragraph.

(bb) DISCRETION OF ADMINISTRATOR.—The Administrator, taking into account the timing of the submission and workload considerations, may—

(AA) add a chemical substance to a current batch; or

(BB) hold the chemical substance until the next batch of chemical substances for recategorization.

(4) PRIORITIZATION OF CHEMICAL SUBSTANCES.—

(A) TIMING.—

(i) INITIAL BATCH.—Not later than 270 days after the date of promulgation of regulations pursuant to paragraph (1), the Administrator shall publish, subject to section 14, the priority class assignments, using the priority classes described in subparagraph (B), for the chemical substances in the initial batch of chemical substances identified under subsection (a)(3) that the Administrator has assigned to the category of chemical substances to undergo safety standard determinations.

(ii) SUBSEQUENT BATCHES.—Not later than 270 days after the date on which the Administrator designates each subsequent batch of chemical substances under subsection (a)(2)(A), the Administrator shall publish the priority class assignments for the chemical substances in the batch that the Administrator has assigned to the category of chemical substances to undergo safety standard determinations.

(B) CRITERIA.—The criteria used by the Administrator to assign chemical substances to priority classes shall take into account—

(i) potential impacts of the chemical substance on human health and the environment;

(ii) the hazard potential of the chemical substance, including classifications and designations of hazard characteristics by other authoritative entities;

(iii) the potential for exposure to the chemical substance; and

(iv) measurements of exposure for a given pathway of exposure, if available and reliable, in preference to less direct indicators of, or surrogates for, exposure potential for the same pathway.

(C) PRIORITY CLASSES.—The regulations promulgated pursuant to paragraph (1) shall establish the following priority classes and criteria, and further specify the process the Administrator will use to assign to the priority classes the chemical substances in each batch that the Administrator has assigned to the category of chemical substances to undergo safety standard determinations:

(i) PRIORITY CLASS 1.—

(I) IN GENERAL.—In each batch, the Administrator shall designate as Priority Class 1 those chemical substances that the Administrator determines warrant safety standard determinations in the near term.

(II) INITIAL ASSIGNMENT.—The Administrator shall in each batch initially designate as Priority Class 1 chemical substances that possess relatively greater hazard potential and for which there is evidence of more significant or widespread exposure.

(III) REASSIGNMENT.—As safety standard determinations for the chemical substance are completed, the Administrator may designate as Priority Class 1 any chemical substance initially assigned to a lower priority class, including chemical substances—

(aa) posing significant hazard concerns but of less or unknown exposure concern;

(bb) posing significant exposure concern but of less or unknown hazard concern; or

(cc) posing less hazard and exposure concerns.

(IV) FACTORS FOR CONSIDERATION.—In determining the number of chemical substances to be placed in Priority Class 1, the Administrator shall seek to balance considerations relating to—

(aa) the number of chemical substances for which safety standard determinations need to be conducted;

(bb) the resources available to the Administrator for conducting safety standard determinations; and

(cc) the deadlines for completion of safety standard determinations specified in subsection (d)(4).

(ii) PRIORITY CLASS 2.—

(I) IN GENERAL.—The Administrator shall designate as Priority Class 2 those chemical substances that the Administrator determines are of lower priority than Priority Class 1 substances

with respect to the timing for conducting safety standard determinations.

(II) MINIMUM INFORMATION SET.—

(aa) IN GENERAL.—For chemical substances designated under this clause, the Administrator shall require submission of the applicable minimum information set specified under section 4 as needed to inform prioritization decisionmaking.

(bb) TIMING.—The minimum information set shall be submitted to the Administrator—

(AA) not later than 5 years after the date of enactment of the Safe Chemicals Act of 2011 for chemical substances in the initial batch identified under subsection (a)(3) that are assigned to Priority Class 2; and

(BB) not later than 5 years after the assignment of a chemical substance to Priority Class 2 under this clause for subsequent batches.

(III) REPRIORITIZATION.—After submission of the minimum information set for a chemical substance under subclause (II), the Administrator shall, if warranted, recategorize or otherwise reprioritize the chemical substance using the priority classes and process described in this paragraph, together with other chemical substances in the batch undergoing prioritization at the time of the submission.

(IV) REPRIORITIZATION TO PRIORITY CLASS 1.—As safety standard determinations are completed on Priority Class 1 chemical substances pursuant to subsection (d), the Administrator shall reprioritize Priority Class 2 substances as Priority Class 1 at a pace consistent with—

(aa) the resources available to the Administrator for conducting safety standard determinations; and

(bb) the deadlines for completion of safety standard determinations specified in subsection (d)(4).

(iii) PRIORITY CLASS 3.—

(I) IN GENERAL.—The Administrator shall designate as Priority Class 3 those chemical substances that the Administrator determines may be set aside for further assessment until such time as—

(aa) safety standard determinations are completed on all Priority Class 1 and 2 substances; or

(bb) new information arises that warrants reprioritization of such a substance to a higher priority class.

(II) MINIMUM INFORMATION SET.—

(aa) IN GENERAL.—For a chemical substance designated under this clause, the Administrator shall not require submission of the applicable minimum information set specified under section 4 until such time as the chemical substance is reassigned to Priority Class 1 or 2.

(bb) SUBMISSION.—On reassignment of a chemical substance to Priority Class 1 or 2 under item (aa), the minimum information set shall be submitted to the Administrator not later than 5 years after the date of the reassignment.

(III) REPRIORITIZATION.—After submission of the minimum information set for a chemical substance pursuant to subclause (II), the Administrator shall reprioritize the chemical substance using the priority classes and process described in this paragraph, together with chemical substances in the batch undergoing prioritization at the time of the submission.

(IV) REPRIORITIZATION TO PRIORITY CLASSES 1 AND 2.—In conjunction with the reprioritization by the Administrator of Priority Class 2 substances as Priority Class 1, the Administrator shall reprioritize Priority Class 3 substances as Priority Class 1 or 2, at a pace consistent with—

(aa) the resources available to the Administrator for conducting safety standard determinations; and

(bb) the deadlines for completion of safety standard determinations specified in subsection (d)(4).

(c) TREATMENT AS FINAL AGENCY ACTION; NO JUDICIAL REVIEW; NONDISCRETIONARY DUTY.—

(1) IN GENERAL.—The designation by the Administrator of batches of chemical substances pursuant to subsection (a), the assignment of chemical substances to categories pursuant to subsection (b)(3), and the assignment of chemical substances to priority classes pursuant to subsection (b)(4), including any determination of the Administrator to include a specific chemical substance in, or exclude a specific chemical substance from, a designated batch, category, or priority class under this section, shall not be—

(A) considered to be a final agency action for the purpose of subchapter II of chapter 5, and chapter 7, of title 5, United States Code (commonly known as 'the Administrative Procedure Act'); or

(B) subject to judicial review.

(2) FAILURE TO ACT.—A failure by the Administrator to designate or publish a list of chemical substances assigned to a batch, category, or priority class in accordance with this subsection shall be—

(A) considered to be a failure to perform a nondiscretionary duty; and

(B) subject to judicial review.

(d) SAFETY STANDARD DETERMINATIONS FOR CHEMICAL SUBSTANCES.—

(1) IN GENERAL.—

(A) APPLICATION.—This paragraph applies to any determination or redetermination regarding whether a chemical substance meets the safety standards of this Act.

(B) RESPONSIBILITIES.—

(i) IN GENERAL.—For purposes of this Act, each manufacturer and processor of a chemical substance shall at all times bear the burden of proof in any legal proceeding relating to a decision of the Administrator regarding whether the chemical substance meets the safety standard.

(ii) DUTIES.—For purposes of this Act—

(I) it shall be the duty of the manufacturer or processor of a chemical substance to provide sufficient information for the Administrator to determine whether the chemical substance meets the safety standard; and

(II) it shall be the duty of the Administrator to determine whether a chemical substance meets the safety standard.

(2) ASSESSMENT OF RISK.—

(A) ASSESSMENT.—

(i) IN GENERAL.—A chemical substance that undergoes a safety standard determination under this section may be manufactured, processed, or distributed in commerce only if the Administrator determines that the chemical substance—

(I) meets the safety standard, taking into account any existing conditions or controls already in effect; or

(II) can meet the safety standard for all or some uses through the imposition of additional conditions.

(ii) REQUIREMENT.—Any assessment of risk used to support a determination that a chemical substance meets the safety standard under clause (i) shall be conducted by employees of the Environmental Protection Agency who are competent to conduct such assessments.

(B) SAFETY STANDARD.—

(i) IN GENERAL.—The Administrator shall base a determination of whether a safety standard for a chemical substance has been met under subparagraph (A) solely on considerations of human health and the environment, including the health of vulnerable populations.

(ii) CONSIDERATIONS.—In making a safety standard determination under this subsection, for each chemical substance, the Administrator shall—

(I) to the extent practicable, review and incorporate any available scientific information relating to the effect of cumulative exposure relevant to that chemical substance on human health and the environment; and

(II) find that a chemical substance meets the safety standard only if the Administrator finds that there is a reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance.

(C) FINANCIAL INTERESTS.—No person conducting an assessment described in subparagraph (A), or a peer review of such an assessment, may have a direct or indirect financial interest in the outcome of the assessment.

(D) METHODOLOGY.—

(i) IN GENERAL.—Subject to clause (ii), the Administrator shall use the best available science when conducting an assessment described in subparagraph (A).

(ii) CONSIDERATIONS.—For the purpose of determining the current best available science the Administrator shall base the determination on the recommendations of the National Academy of Sciences in the report entitled 'Science and Decisions'.

(iii) REVIEW.—Not later than 5 years after the date of enactment of the Safe Chemicals Act of 2011, and not less frequently than once every 5 years thereafter, the Administrator shall review the methodology under this paragraph and may revise the methodology to reflect new scientific developments or understandings.

(E) SCOPE.—An assessment described in subparagraph (A) shall address health or environmental impacts including potential or demonstrated cancer and noncancer endpoints.

(F) TRANSPARENCY.—In carrying out this subsection, the Administrator shall ensure that the approaches and resulting assessments are communicated in a manner that is transparent and understandable to—

(i) the public; and

(ii) risk managers.

(G) MANUFACTURE OR PROCESSING FOR EXPORT.—In the case of a chemical substance that is manufactured or processed in whole or in part for export, in determining whether the chemical substance meets the safety standard under subparagraph (A)(i), the Administrator shall take into account any risk—

(i) that the chemical substance may pose in the United States, including risks involving long-range transport of the chemical substance in the environment; or

(ii) involving the import of articles and mixtures containing the chemical substance.

(H) RISK ASSESSMENT NOT REQUIRED.—The Administrator shall not be required to conduct a risk assessment to

determine that a manufacturer or processor has not met the burden of proof under paragraph (1)(B).

(I) NO JUDICIAL REVIEW.—A determination by the Administrator that a manufacturer or processor has not established that the chemical substance meets the applicable safety standard under this subsection shall not be subject to judicial review.

(3) INFORMATION FOR SAFETY STANDARD DETERMINATIONS.—

(A) IN GENERAL.—In making a safety standard determination with respect to a chemical substance, the Administrator—

(i) shall take into consideration information regarding the chemical substance that is already available to the Administrator at the time the determination is to be made, including information—

(I) received by the Administrator from manufacturers or processors under this section or section 8;

(II) contained in any minimum information sets previously required under section 4;

(III) voluntarily submitted by manufacturers and processors in accordance with subsection (b)(2)(B);

(IV) submitted by any other party to the Administrator that is relevant to the conduct of a safety standard determination of the chemical substance; or

(V) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible to the Administrator;

(ii) shall require information needed to complete the applicable minimum information set for the chemical substance required under section 4(a);

(iii) may require, by regulation or order pursuant to section 4(b) or 8(e), manufacturers or processors of the chemical substance to develop and submit any additional information the Administrator determines is needed to conduct the safety standard determination of the chemical substance; and

(iv) shall take into consideration, but not rely on, assessments of safety or analyses of the effectiveness of existing control measures—

(I) submitted to the Administrator by any party; or

(II) conducted by a governmental entity in another jurisdiction.

(4) TIMING OF SAFETY STANDARD DETERMINATIONS.—

(A) PRIORITY CLASS 1.—

(i) IN GENERAL.—Beginning with chemical substances initially designated as Priority Class 1 under subsection (b)(4)(C)(i), the Administrator shall conduct safety standard determinations of all chemical substances assigned to the category of substances to under-

go safety standard determinations pursuant to subsection (b)(3)(B)(iii).

(ii) INITIAL BATCH.—Not later than 5 years after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall complete and publish safety standard determinations for all chemical substances designated as Priority Class 1 substances in the initial batch of chemical substances identified under subsection (a)(3).

(iii) SUBSEQUENT BATCHES.—Not later than 5 years after the date on which the Administrator designates chemical substances as Priority Class 1 in each subsequent batch of chemical substances under subsection (a)(2)(A), the Administrator shall complete and publish safety standard determinations for those Priority Class 1 substances in the batch.

(B) PRIORITY CLASSES 2 AND 3.—

(i) IN GENERAL.—Each chemical substance initially designated as Priority Class 2 or 3 shall become subject to reprioritization and safety standard determinations in accordance with subsection (b)(4).

(ii) REPRIORITIZATION.—Not later than 5 years after the date on which the Administrator designates a Priority Class 2 or 3 substance to be Priority Class 1, the Administrator shall complete and publish the safety standard determination on the chemical substance.

(C) NOTICE OF OVERDUE DETERMINATION.—If the Administrator fails to act by an applicable deadline under subparagraph (A) or (B), each manufacturer and processor of a chemical substance for which the Administrator has failed to act shall provide to the Administrator, the public, employees and recognized bargaining agents of any employees who are represented by bargaining agents of the manufacturer or processor, and each known customer who has purchased the chemical substance within a reasonable timeframe, as determined by the Administrator by regulation or order, a written notice that a determination by the Administrator of the safety of the chemical substance is pending.

(D) FAILURE OF MANUFACTURER OR PROCESSOR TO MEET DUTIES.—If a manufacturer or processor fails to meet any duty under this paragraph for a chemical substance, the Administrator, by order, may take any action authorized under subsection (f).

(5) OUTCOME OF SAFETY STANDARD DETERMINATIONS.—

(A) DETERMINATION.—

(i) IN GENERAL.—In making a safety standard determination for a chemical substance, the Administrator, by order, shall determine or redetermine, as appropriate, whether the manufacturers and processors of the chemical substance have established that the chemical substance meets the safety standard.

(ii) CONCURRENT PUBLICATION.—The Administrator—

(I) shall seek to publish safety standard determination and risk management decisions concurrently, to the maximum extent practicable; but

(II) shall not unduly delay the issuance of any safety standard determination if more information or analysis is required to make a determination regarding risk management.

(iii) OTHER REQUIREMENTS.—The Administrator—

(I) may publish safety standard determinations for chemical substances individually or in groups; but

(II) shall publish completed determinations—

(aa) not less frequently than annually; and

(bb) at a pace sufficient to demonstrate steady progress toward completing all such safety standard determinations within the required timeframe.

(iv) PUBLIC NOTICE AND COMMENT.—The Administrator shall provide reasonable public notice and opportunity for comment on all published safety standard determinations through any reasonable means of publication and solicitation of comments, including electronic means.

(B) POSITIVE SAFETY STANDARD DETERMINATION WITHOUT NEW CONDITIONS.—If the Administrator determines that a chemical substance meets the safety standard for all current uses and under conditions currently used, the Administrator shall specify in the order—

(i) the allowed uses of the chemical substance, which shall be limited to the uses evaluated in the determination; and

(ii) conditions on the specified uses that are currently used and are to be followed to ensure the safety standard is met, including conditions relating to the manufacture, processing, use, distribution in commerce, or disposal of a chemical substance or mixture or article containing the chemical substance.

(C) POSITIVE SAFETY STANDARD DETERMINATION WITH NEW CONDITIONS.—If the Administrator determines that a chemical substance can only meet the safety standard for a subset of all current uses or only under conditions beyond those currently used, the Administrator shall specify in the order—

(i) the allowed uses of the chemical substance, which shall be limited to the uses evaluated in the determination that the Administrator determines meet the safety standard; and

(ii) all current and all newly required conditions on the specified uses needed to ensure the safety standard is met, including conditions relating to the manufacture, processing, use, distribution in commerce, or disposal of a chemical substance or mixture or article containing the chemical substance, and any conditions described in subsection (f).

(D) EFFECTIVE DATE FOR POSITIVE SAFETY STANDARD DETERMINATION.—

(i) WITHOUT NEW CONDITIONS.—Effective beginning on the date that is 90 days after the date of a determination by the Administrator under subparagraph (B), no person shall manufacture, process, or distribute in commerce the chemical substance subject to the determination, or any mixture or article containing the chemical substance, for any use or under any condition other than those specified in the determination order.

(ii) WITH NEW CONDITIONS.—Effective beginning on the date that is 18 months after the date of a determination by the Administrator under subparagraph (C), except as provided in clause (iii), no person shall manufacture, process, or distribute in commerce the chemical substance subject to the determination, or any mixture or article containing the chemical substance, for any use or under any condition other than those specified in the determination order.

(iii) EXCEPTIONAL CIRCUMSTANCE.—The Administrator may grant a manufacturer or processor of a chemical substance a 1-time extension of the deadline for complying with a restriction under clause (ii), for a period of not longer than 5 years after the date of the determination by the Administrator under subparagraph (C), if the manufacturer or processor demonstrates—

(I) a compelling technological need to continue a restricted activity beyond the applicable 18-month time period; or

(II) that a factor wholly beyond the control of the manufacturer or processor prevents compliance with the restriction within that 18-month time period.

(E) REDETERMINATION.—

(i) IN GENERAL.—The Administrator shall initiate a redetermination of whether a chemical substance meets the safety standard if new information or significant changes in manufacture, processing, use, or distribution in commerce of the chemical substance, or mixtures or articles containing the chemical substance, raise a credible question as to whether the chemical substance continues to meet the safety standard.

(ii) NEW METHODOLOGIES.—The Administrator may initiate a redetermination of whether a chemical substance meets the safety standard if significant changes have occurred in the methodologies used in the initial safety standard determination such that a redetermination using the newer methodologies would provide a significantly improved determination of the safety of the chemical substance.

(iii) NEW INFORMATION.—For a chemical substance for which a safety standard determination has been completed, the Administrator shall assess, on an ongo-

ing basis, new information, including that obtained from reporting under section 8, to decide whether such information raises a credible question as to whether a chemical substance continues to meet the safety standard

(iv) PETITION FOR REDETERMINATION.—

(I) IN GENERAL.—Any person may petition the Administrator for a redetermination of whether a chemical substance continues to meet the safety standard.

(II) BASIS.—A person shall include in a petition under this clause a description of the basis for requesting the redetermination.

(III) ACTION BY ADMINISTRATOR.—On receipt of a petition under this clause, the Administrator shall—

(aa) not later than 30 days after the date of receipt, publish in the Federal Register a notice of receipt of the petition that specifies the chemical identity of the chemical substance to which the petition pertains;

(bb) make the petition available on request;

(cc) provide a reasonable opportunity for public review and comment on the petition and give due consideration to any comments received;

(dd) decide whether to make the requested redetermination; and

(ee) not later than 180 days after the date of receipt, publish in the Federal Register the decision and the basis for the decision.

(v) DEADLINE FOR COMPLETION.—Each redetermination carried out under this subparagraph shall be completed by not later than 3 years after the date of the decision to make the redetermination.

(F) NEGATIVE SAFETY STANDARD DETERMINATION.—

(i) RESTRICTION.—Except as provided in clause (ii) and subsection (h), effective beginning on the date that is 18 months after the date on which the Administrator makes a determination under this subsection that a chemical substance fails to meet the safety standard, regardless of whether additional restrictions on use or risk management conditions are imposed, no person shall manufacture, process, or distribute in commerce that chemical substance or any mixture or article containing the chemical substance.

(ii) EXCEPTIONAL CIRCUMSTANCE.—The Administrator may grant a manufacturer or processor of a chemical substance a 1-time extension of the deadline for complying with the restriction under clause (i), for a period of not longer than 5 years after the date of the determination by the Administrator under this subparagraph, if the manufacturer or processor demonstrates—

(I) a compelling technological need to continue a restricted activity beyond the applicable 18-month time period; or

(II) that a factor wholly beyond the control of the manufacturer or processor prevents compliance with the restriction within that 18-month time period.

(e) EXPEDITED ACTION FOR SUBSTANCES OF VERY HIGH CONCERN.—

(1) USE AND EXPOSURE ASSESSMENT.—

(A) IN GENERAL.—Not later than 180 days after the date on which a chemical substance is assigned to the category of substances of very high concern under subsection (b)(3)(B)(i), the Administrator may require, by order pursuant to section 8(g), the submission by manufacturers or processors of the chemical substance of any additional information the Administrator determines to be necessary to conduct an expedited assessment of the known uses of, and exposures to, the chemical substance.

(B) PUBLICATION.—Not later than 1 year after the date on which a chemical substance is assigned to the category of substances of very high concern under subsection (b)(3)(B)(i), the Administrator shall complete and publish an identification and assessment of the known uses of, and exposures to, the chemical substance.

(2) EXPOSURE REDUCTION.—

(A) USE RESTRICTIONS AND OTHER CONDITIONS.—As soon as practicable, but not later than 18 months, after the date on which a chemical substance is assigned to the category of substances of very high concern under subsection (b)(3)(B)(i), the Administrator shall impose, by order, use restrictions and other conditions, including the conditions specified in subsection (f), on the manufacturing, processing, use, distribution in commerce, and disposal of the chemical substance that the Administrator determines to be necessary to achieve the maximum practicable reduction in human or environmental exposure to the chemical substance.

(B) TIMING.—Except as provided in subparagraph (C) and subsection (h), effective beginning on the date that is 18 months after the date of issuance by the Administrator of the order described in subparagraph (A), no person shall manufacture, process, or distribute in commerce the chemical substance subject to the determination, or any mixture or article containing the chemical substance, for any use or under any condition other than those specified in the order issued under subparagraph (A).

(C) EXCEPTIONAL CIRCUMSTANCE.—The Administrator may grant a manufacturer or processor of a chemical substance a 1-time extension of the deadline for complying with the restriction under subparagraph (B), for a period of not longer than 5 years after the date of the determination by the Administrator under this paragraph, if the manufacturer or processor demonstrates—

(i) a compelling technological need to continue a restricted activity beyond the applicable 18-month time period; or

(ii) that a factor wholly beyond the control of the manufacturer or processor prevents compliance with the restriction within that 18-month time period.

(3) RESIDUAL RISK ASSESSMENT.—Not later than 1 year after the deadline specified in paragraph (2)(B), or of an alternative deadline provided under paragraph (2)(C), the Administrator shall—

(A) determine whether the chemical substance meets the safety standard for the chemical substance, taking into account the residual risk posed by continued exposure to the chemical substance; and

(B) impose any additional restrictions on use or other conditions under subsection (f) that the Administrator determines to be necessary to ensure that the chemical substance meets the safety standard.

(f) RISK MANAGEMENT.—In issuing an order under subsection (d) or (e), the Administrator may impose conditions on the manufacture, processing, use, distribution in commerce, or disposal of a chemical substance, or mixture or article containing a chemical substance, including a requirement—

(1) limiting the quantity of the chemical substance (or mixture or article containing that chemical substance) that may be manufactured, processed, or distributed in commerce;

(2)(A) prohibiting the manufacturing, processing, or distribution in commerce of the chemical substance (or mixture or article containing that chemical substance) for a particular use in a concentration in excess of a level specified by the Administrator; or

(B) limiting the quantity of the chemical substance (or mixture or article containing that chemical substance) that may be manufactured, processed, or distributed in commerce for—

(i) a particular use; or

(ii) a particular use in a concentration in excess of a level specified by the Administrator;

(3) that the chemical substance (or mixture, or article containing that chemical substance) be marked with, or accompanied by, clear and adequate warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of such activities, with the form and content of the warnings and instructions prescribed by the Administrator;

(4) that manufacturers and processors of the chemical substance (or mixture or article containing that chemical substance)—

(A) make and retain records of the processes used to manufacture or process the chemical substance (or mixture or article containing that chemical substance); and

(B) monitor or conduct tests that are reasonable and necessary to ensure compliance with this Act;

(5) prohibiting or otherwise regulating any manner or method of commercial use of the chemical substance (or mixture or article containing that chemical substance);

(6) prohibiting or otherwise regulating any manner or method of disposal of the chemical substance, mixture, or article, by—

(A) the manufacturer or processor of the chemical substance (or mixture or article containing that chemical substance); or

(B) any other person that uses or disposes of the chemical substance (or mixture or article containing that chemical substance) for commercial purposes;

(7) that the manufacturers and processors of the chemical substance, mixture, or article develop a risk reduction management plan, under subsection (h) or (e) of this section, to achieve a risk reduction specified by the Administrator; or

(8) that the Administrator otherwise determines is appropriate.

(g) QUALITY CONTROL ORDERS.—

(1) IN GENERAL.—If the Administrator has a reasonable basis to conclude that a particular manufacturer or processor is manufacturing or processing a chemical substance in a manner that may present a substantial endangerment to health or the environment, the Administrator may require, by order, that the manufacturer or processor submit to the Administrator a description of the quality control procedures followed in the manufacturing or processing of the chemical substance or mixture.

(2) ORDERS.—

(A) IN GENERAL.—If the Administrator determines that quality control procedures described in paragraph (1) are inadequate to prevent a chemical substance from presenting a risk of injury to human health or the environment, the Administrator may order the manufacturer or processor to revise the quality control procedures to the extent necessary to remedy the inadequacy.

(B) SUBSTANTIAL ENDANGERMENT.—If the Administrator determines that quality control procedures described in paragraph (1) have resulted in the distribution in commerce of a chemical substance that may present a substantial endangerment to human health or the environment, the Administrator may order the manufacturer or processor—

(i) to give notice of the endangerment to—

(I) processors or distributors (or both) in commerce of the chemical substance or mixture; and

(II) to the extent reasonably ascertainable, any other person in possession of or exposed to the chemical substance or mixture;

(ii) to give public notice of the endangerment; and

(iii) to provide for the replacement or repurchase, as prescribed by the Administrator, of the chemical substance as the Administrator determines to be necessary to adequately protect human health or the environment.

(h) EXEMPTIONS TO RESTRICTIONS.—

(1) APPLICATION.—This subsection applies to the restrictions established under section 5(b)(1)(C)(ii)(I), subsection (d)(5), and subsection (e).

(2) EXEMPTIONS.—

(A) IN GENERAL.—

(i) REQUEST.—A person who manufacturers, processes, distributes in commerce, uses, or disposes of a chemical substance, or a mixture or article containing a chemical substance may request an exemption from any restriction referred to in paragraph (1) to which they are subject for a specified use of the chemical substance.

(ii) ORDER.—The Administrator may grant, by order, an exemption from any restriction referred to in paragraph (1) for a period of not longer than 5 years if the person has established by clear and convincing evidence that the uses to be exempted meet the exemption criteria described in subparagraph (B).

(B) CRITERIA.—The Administrator may grant an exemption for the use of a chemical substance under subparagraph (A)(ii) if—

(i) the exemption is in the paramount interest of national security;

(ii) the lack of availability of the chemical substance would cause significant disruption in the national economy; or

(iii) the use for which the exemption is sought is a critical or essential use for which—

(I) no feasible safer alternative for the specified use of the chemical substance is available; or

(II) the specified use of the chemical substance, as compared to all available alternatives, provides a substantial net benefit to human health, the environment, or public safety.

(C) PUBLIC NOTICE.—If the Administrator grants an exemption for a chemical substance under this paragraph—

(i) the manufacturer or processor of the chemical substance shall provide a notice of the exemption to each known purchaser of—

(I) the chemical substance; and

(II) a mixture or article containing the chemical substance; and

(ii) the Administrator shall provide the public with a notice of the exemption.

(D) RENEWAL.—The Administrator may renew, by order, an exemption under this paragraph for 1 or more additional 5-year periods if the Administrator concludes, after providing public notice and an opportunity for comment, that the use of the chemical substance continues to meet the criteria described in subparagraph (B).

(E) CONDITIONS.—

(i) IN GENERAL.—The Administrator may impose, by order, any condition on an exemption issued under this paragraph that the Administrator determines to be necessary to ensure the protection of human health and the environment on the use of a chemical substance exempted under this paragraph.

(ii) COMPLIANCE.—Effective immediately after the Administrator establishes conditions on an exempted use under clause (i), the manufacturing, processing, or distribution in commerce of the chemical substance, or any mixture or article containing the chemical substance, shall be prohibited except to the extent that the conditions are satisfied.

(3) RESALE OF USED ARTICLES.—

(A) IN GENERAL.—The restrictions referred to in paragraph (1) shall not apply to the resale of an article subject to a restriction under subsection (b) if the article has previously been used by an end consumer.

(B) COMPLIANCE.—The Administrator may utilize the authorities contained in section 7 to address potential threats to public health and the environment from such articles.

(4) EXTENSIONS OF EFFECTIVE DATES FOR RETAIL SALE OF ARTICLES TO END CONSUMERS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), in the case of the retail sale to an end consumer of a chemical substance (or mixture or article containing that chemical substance) that is subject to a restriction described in paragraph (1), the Administrator may extend, by order, the effective date of the restriction by a period of not longer than 3 years, if the Administrator determines that the extension—

(i) is necessary and appropriate to allow for depletion of the existing retail inventory; and

(ii) will not present a substantial endangerment to human health or the environment.

(B) EXCEPTION.—An extension under subparagraph (A) shall not apply to any retailer that the Administrator determines has failed to comply with an order requesting information issued by the Administrator pursuant to section 8;

[(e)]*(i)* POLYCHLORINATED BIPHENYLS.—(1) Within six months after the effective date of this Act the Administrator shall promulgate rules to—

(A) prescribe methods for the disposal of polychlorinated biphenyls, and

(B) require polychlorinated biphenyls to be marked with clear and adequate warnings, and instructions with respect to their processing, distribution in commerce, use, or disposal or with respect to any combination of such activities.

Requirements prescribed by rules under this paragraph shall be consistent with the requirements of paragraphs (2) and (3).

(2)(A) Except as provided under subparagraph (B), effective one year after the effective date of this Act no person may manufacture, process, or distribute in commerce or use any polychlorinated biphenyl in any manner other than in a totally enclosed manner.

(B) The Administrator may by rule authorize the manufacture, processing, distribution in commerce or use (or any combination of such activities) of any polychlorinated biphenyl in a manner other than in a totally enclosed manner if the Administrator finds that such manufacture, processing, distribution in commerce, or use (or

combination of such activities) will not present an unreasonable risk of injury to health or the environment.

(C) For the purposes of this paragraph, the term "totally enclosed manner" means any manner which will ensure that any exposure of human beings or the environment by the polychlorinated biphenyl will be insignificant as determined by the Administrator by rule.

(3)(A) Except as provided in subparagraphs (B), (C), and (D)—

(i) no person may manufacture any polychlorinated biphenyl after two years after the effective date of this Act, and

(ii) no person may process or distribute in commerce any polychlorinated biphenyl after two and one-half years after such date.

(B) Any person may petition the Administrator for an exemption from the requirements of subparagraph (A), and the Administrator may grant by rule such an exemption if the Administrator finds that—

(i) an unreasonable risk of injury to health or environment would not result, and

(ii) good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl.

An exemption granted under this subparagraph shall be subject to such terms and conditions as the Administrator may prescribe and shall be in effect for such period (but not more than 1 year from the date it is granted, except as provided in subparagraph (D)) as the Administrator may prescribe.

(C) Subparagraph (A) shall not apply to the distribution in commerce of any polychlorinated biphenyl if such polychlorinated biphenyl was sold for purposes other than resale before two and one-half years after the date of enactment of this Act.

(D) [1] The Administrator may extend an exemption granted pursuant to subparagraph (B) that has not yet expired for a period not to exceed 60 days for the purpose of authorizing the Secretary of Defense and the Secretaries of the military departments to provide for the transportation into the customs territory of the United States of polychlorinated biphenyls generated by or under the control of the Department of Defense for purposes of their disposal, treatment, or storage in the customs territory of the United States if those polychlorinated biphenyls are already in transit from their storage locations but the Administrator determines, in the sole discretion of the Administrator, they would not otherwise arrive in the customs territory of the United States within the period of the original exemption. The Administrator shall promptly publish notice of such extension in the Federal Register.

(4) Any rule under paragraph (1), (2)(B), or (3)(B) shall be promulgated in accordance with paragraphs (2), (3), and (4) of subsection (c).

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[1] Section 317(a) of Public Law 109–364 (120 Stat. 2142) amends paragraph (3) of section 6(e). Subsection (b) of section 317 of such Public Law provides as follows:

(b) SUNSET DATE.—The amendments made by subsection (a) shall cease to have effect on September 30, 2012. The termination of the authority to grant exemptions pursuant to such amendments shall not effect the validity of any exemption granted prior to such date.

(5) This subsection does not limit the authority of the Administrator, under any other provision of this Act or any other Federal law, to take action respecting any polychlorinated biphenyl.

[(f) MERCURY.—

[(1) PROHIBITION ON SALE, DISTRIBUTION, OR TRANSFER OF ELEMENTAL MERCURY BY FEDERAL AGENCIES.—Except as provided in paragraph (2), effective beginning on the date of enactment of this subsection, no Federal agency shall convey, sell, or distribute to any other Federal agency, any State or local government agency, or any private individual or entity any elemental mercury under the control or jurisdiction of the Federal agency.

[(2) EXCEPTIONS.—Paragraph (1) shall not apply to—

[(A) a transfer between Federal agencies of elemental mercury for the sole purpose of facilitating storage of mercury to carry out this Act; or

[(B) a conveyance, sale, distribution, or transfer of coal.

[(3) LEASES OF FEDERAL COAL.—Nothing in this subsection prohibits the leasing of coal.]

[SEC. 7. IMMINENT HAZARDS.

[(a) ACTIONS AUTHORIZED AND REQUIRED.—(1) The Administrator may commence a civil action in an appropriate district court of the United States—

[(A) for seizure of an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture,

[(B) for relief (as authorized by subsection (b)) against any person who manufactures, processes, distributes in commerce, or uses, or disposes of, an imminent hazardous chemical substance or mixture or any article containing such a substance or mixture, or

[(C) for both such seizure and relief.

[A civil action may be commenced under this paragraph notwithstanding the existence of a rule under section 4, 5, 6, or title IV or an order under section 5 or title IV, and notwithstanding the pendency of any administrative or judicial proceeding under any provision of this Act.

[(2) If the Administrator has not made a rule under section 6(a) immediately effective (as authorized by subsection 6(d)(2)(A)(i)) with respect to an imminently hazardous chemical substance or mixture, the Administrator shall commence in a district court of the United States with respect to such substance or mixture or article containing such substance or mixture a civil action described in subparagraph (A), (B), or (C) of paragraph (1).

[(b) RELIEF AUTHORIZED.—(1) The district court of the United States in which an action under subsection (a) is brought shall have jurisdiction to grant such temporary or permanent relief as may be necessary to protect health or the environment from the unreasonable risk associated with the chemical substance, mixture, or article involved in such action.

[(2) In the case of an action under subsection (a) brought against a person who manufactures, processes, or distributes in commerce a chemical substance or mixture or an article containing a chemical substance or mixture, the relief authorized by paragraph (1) may

include the issuance of a mandatory order requiring (A) in the case of purchasers of such substance, mixture, or article known to the defendant, notification to such purchasers of the risk associated with it; (B) public notice of such risk; (C) recall; (D) the replacement or repurchase of such substance, mixture, or article; or (E) any combination of the actions described in the preceding clauses.

[(3) In the case of an action under subsection (a) against a chemical substance, mixture, or article, such substance, mixture, or article may be proceeded against by process of libel for its seizure and condemnation. Proceedings in such an action shall conform as nearly as possible to proceedings in rem in admiralty.

[(c) VENUE AND CONSOLIDATION.—(1)(A) An action under subsection (a) against a person who manufactures, processes, or distributes a chemical substance or mixture or an article containing a chemical substance or mixture may be brought in the United States District Court for the District of Columbia or for any judicial district in which any of the defendants is found, resides, or transacts business; and process in such an action may be served on a defendant in any other district in which such defendant resides or may be found. An action under subsection (a) against a chemical substance, mixture, or article may be brought in any United States district court within the jurisdiction of which the substance, mixture, or article is found.

[(B) In determining the judicial district in which an action may be brought under subsection (a) in instances in which such action may be brought in more than one judicial district, the Administrator shall take into account the convenience of the parties.

[(C) Subpoenas [1] requiring attendance of witnesses in an action brought under subsection (a) may be served in any judicial district.

[(2) Whenever proceedings under subsection (a) involving identical chemical substances, mixtures, or articles are pending in courts in two or more judicial districts, they shall be consolidated for trial by order of any such court upon application reasonably made by any party in interest, upon notice to all parties in interest.

[(d) ACTION UNDER SECTION 6.—Where appropriate, concurrently with the filing of an action under subsection (a) or as soon thereafter as may be practicable, the Administrator shall initiate a proceeding for the promulgation of a rule under section 6(a).

[(e) REPRESENTATION.—Notwithstanding any other provision of law, in any action under subsection (a), the Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator in such an action.

[(f) DEFINITION.—For the purposes of subsection (a), the term "imminently hazardous chemical substance or mixture" means a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture, or that any combination of such activities, is

[1] In Public Law 94–469, the word "subpoenas" is spelled "subpeonas". The spelling is corrected in this print to reflect the probable intent of Congress.

likely to result in such injury to health or the environment before a final rule under section 6 can protect against such risk.]

SEC. 7. IMMINENT HAZARDS.

(a) ACTIONS AUTHORIZED AND REQUIRED.—

(1) IN GENERAL.—The Administrator may commence a civil action in an appropriate district court of the United States for—

(A) seizure of a chemical substance or mixture, or any article containing a chemical substance or mixture, that may present an imminent and substantial endangerment to health or the environment;

(B) relief authorized under subsection (b) against any person that—

(i) manufactures, processes, distributes in commerce, uses, or disposes of a chemical substance or mixture, or any article containing a chemical substance or mixture, if the manufacture, processing, distribution in commerce, use, or disposal may present an imminent and substantial endangerment to health or the environment; or

(ii) contributes to an activity described in clause (i); or

(C) both seizure and relief described in subparagraphs (A) and (B), respectively.

(2) OTHER ACTIONS.—

(A) IN GENERAL.—The Administrator may issue such orders as are necessary to protect health or the environment from any manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any article containing such a substance or mixture, that may present an imminent and substantial endangerment to health or the environment, as determined by the Administrator.

(B) REQUIREMENT.—An order under subparagraph (A) may include such requirements imposed on the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or article containing the chemical substance or mixture, as the Administrator determines are necessary to protect health or the environment, including—

(i) the requirements described in section 6(c); and

(ii) the relief authorized under subsection (b).

(3) RELATIONSHIP TO EXISTING RULES, ORDERS, AND PROCEEDINGS.—A civil action may be commenced under paragraph (1), or other action may be taken under paragraph (2), notwithstanding—

(A) the existence of a rule or order under this Act; and

(B) the pendency of any administrative or judicial proceeding under this Act.

(b) RELIEF AUTHORIZED.—

(1) IN GENERAL.—The district court of the United States in which a civil action under subsection (a)(1) is brought shall have jurisdiction to grant such temporary or permanent relief

as are necessary to protect health or the environment from the risk associated with the activity involved in the civil action.

(2) TYPES OF RELIEF.—In the case of a civil action under subsection (a)(1) brought against a person that manufactures, processes, distributes in commerce, uses, or disposes of a chemical substance or mixture or an article containing a chemical substance or mixture, the relief authorized by paragraph (1) may include—

(A) the issuance of a mandatory order imposing any of the requirements described in section 6(c); and

(B) in the case of purchasers of the substance, mixture, or article known to the defendant—

(i) notification to the purchasers of the risk associated with the substance, mixture, or article;

(ii) public notice of the risk;

(iii) recall;

(iv) the replacement or repurchase of the substance, mixture, or article; or

(v) any combination of the actions described in section 6(c) or in clauses (i) through (iv) of this subparagraph; or

(C) such other relief as is necessary to protect health or the environment from the risk associated with the activity involved in the civil action.

(3) SEIZURE AND CONDEMNATION.—

(A) IN GENERAL.—A civil action under subsection (a)(1) against a chemical substance, mixture, or article may be proceeded against by process of libel for seizure and condemnation of the chemical substance, mixture, or article.

(B) PROCEEDINGS.—Proceedings in a civil action described in subparagraph (A) shall conform, to the maximum extent practicable, to proceedings in rem in admiralty.

(c) VENUE AND CONSOLIDATION.—

(1) VENUE.—

(A) IN GENERAL.—A civil action under subsection (a)(1) against a person that manufactures, processes, or distributes a chemical substance or mixture or an article containing a chemical substance or mixture may be brought in the United States District Court for the District of Columbia, or in any judicial district in which any of the defendants is found, resides, or transacts business.

(B) PROCESS.—Process in an action described in subparagraph (A) may be served on a defendant in any other district in which the defendant resides or may be found.

(C) CHEMICAL SUBSTANCES, MIXTURES, OR ARTICLES.—A civil action under subsection (a)(1) against a chemical substance, mixture, or article may be brought in any United States district court within the jurisdiction of which the chemical substance, mixture, or article is found.

(D) MULTIPLE JUDICIAL DISTRICTS.—In determining the judicial district in which a civil action may be brought under subsection (a)(1) in instances in which the action may be brought in more than 1 judicial district, the Ad-

ministrator shall take into account the convenience of the parties.

(E) SUBPOENAS.—Subpoenas requiring attendance of witnesses in a civil action brought under subsection (a)(1) may be served in any judicial district.

(2) CONSOLIDATION.—If proceedings under subsection (a)(1) involving identical chemical substances, mixtures, or articles are pending in courts in 2 or more judicial districts, the proceedings shall be consolidated for trial by order of any such court on application reasonably made by any party in interest, on notice to all parties in interest.

[SEC. 8. REPORTING AND RETENTION OF INFORMATION.

[(a) REPORTS.—(1) The Administrator shall promulgate rules under which—

(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require, and

[(B) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process—

[(i) a mixture, or

[(ii) a chemical substance in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product,

[shall maintain records and submit to the Administrator reports but only to the extent the Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of this Act.

[The Administrator may not require in a rule promulgated under this paragraph the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that the maintenance of such records or the submission of such reports, or both, is necessary for the effective enforcement of this Act. For purposes of the compilation of the list of chemical substances required under subsection (b), the Administrator shall promulgate rules pursuant to this subsection not later than 180 days after the effective date of this Act.

[(2) The Administrator may require under paragraph (1) maintenance of records and reporting with respect to the following insofar as known to the person making the report or insofar as reasonably ascertainable:

[(A) The common or trade name, the chemical identity, and molecular structure of each chemical substance or mixture for which such a report is required.

[(B) The categories or proposed categories of use of each such substance or mixture.

[(C) The total amount of each substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.

[(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.

[(E) All existing data concerning the environmental and health effects of such substance or mixture.

(F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.

[(G) In the initial report under paragraph (1) on such substance or mixture, the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method.

[To the extent feasible, the Administrator shall not require under paragraph (1), any reporting which is unnecessary or duplicative.

[(3)(A)(i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as the Administrator may require for publication of the first list of chemical substances required by subsection (b).

[(ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture—

[(I) subject to a rule proposed or promulgated under section 4, 5(b)(4), or 6, or an order in effect under section 5(e), or

[(II) with respect to which relief has been granted pursuant to a civil action brought under section 5 or 7,

to maintain such records on such substance or mixture, and to submit to the Administrator such reports on such substance or mixture, as the Administrator may reasonably require. A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2).

[(B) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of this paragraph and paragraph (1).

[(b) INVENTORY.—(1) The Administrator shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States. Such list shall at least include each chemical substance which any person reports, under section 5 or subsection (a) of this section, is manufactured or processed in the United States. Such list may not include any chemical substance which was not manufactured or processed in the United States within three years before the effective date of the rules promulgated pursuant to the last sentence of subsection (a)(1). In the case of a chemical substance for which a notice is submitted in accordance with section 5, such chemical substance shall be included in such list as of the earliest date (as determined by the Adminis-

trator) on which such substance was manufactured or processed in the United States. The Administrator shall first publish such a list not later than 315 days after the effective date of this Act. The Administrator shall not include in such list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product.

[(2) To the extent consistent with the purposes of this Act, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

[(c) RECORDS.—Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture. Records of such adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. Any other record of such adverse reactions shall be retained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record. Records required to be maintained under this subsection shall include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of any duly designated representative of the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

[(d) HEALTH AND SAFETY STUDIES.—The Administrator shall promulgate rules under which the Administrator shall require any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator—

[(1) lists of health and safety studies (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person, or (C) reasonably ascertainable by such person, except that the Administrator may exclude certain types or categories of studies from the requirements of this subsection if the Administrator finds that submission of lists of such studies are unnecessary to carry out the purposes of this Act; and

[(2) copies of any study contained on a list submitted pursuant to paragraph (1) or otherwise known by such person.

[(e) NOTICE TO ADMINISTRATOR OF SUBSTANTIAL RISKS.—Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture

presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

[(f) DEFINITIONS.—For purposes of this section, the terms "manufacture" and "process" mean manufacture or process for commercial purposes.]

SEC. 8. REPORTING AND RETENTION OF INFORMATION.

(a) DEFINITIONS.—In this section:

(1) KNOWN TO, OR REASONABLY ASCERTAINABLE BY.—The term "known to, or reasonably ascertainable by" has the meaning given the term in section 704.3 of title 40, Code of Federal Regulations (or successor regulations).

(2) MANUFACTURE AND PROCESS.—The terms "manufacture" and "process" mean manufacture and process, respectively, for commercial purposes.

(b) DECLARATIONS OF CHEMICAL SUBSTANCES IN COMMERCE.—

(1) SCOPE AND CRITERIA.—

(A) SCOPE.—The declarations described in this subsection shall apply only to chemical substances in commerce as of the date of enactment of the Safe Chemicals Act of 2011.

(B) CRITERIA.—The following criteria shall apply in identifying chemical substances to which the declarations described in this subsection apply:

(i) CURRENT COMMERCIAL INTEREST.—A chemical substance in which a manufacturer or processor has a current commercial interest shall include only chemical substances that the manufacturer or processor—

(I) is currently manufacturing or processing; or

(II) has manufactured or processed in the recent past and expects to manufacture or process again in the near future.

(ii) POTENTIAL COMMERCIAL INTEREST.—A chemical substance in which a manufacturer or processor has a potential commercial interest shall include only a chemical substance that may serve as a reasonable substitute for a chemical substance in which the manufacturer or processor has declared a current commercial interest.

(C) GUIDANCE.—Not later than 90 days after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall issue guidance further describing the criteria described in subparagraph (B) and specifying the supporting information manufacturers and processors are to include in declarations they submit pursuant to paragraph (2) or (3) for chemical substances in which they have a current or potential commercial interest.

(2) DECLARATION OF CURRENT COMMERCIAL INTEREST IN A CHEMICAL SUBSTANCE.—

(A) IN GENERAL.—Notwithstanding any other provision of law, not later than 180 days after the date of enactment of the Safe Chemicals Act of 2011, each manufacturer of a chemical substance in which the manufacturer has a cur-

rent commercial interest shall submit to the Administrator a declaration of the interest for the chemical substance.

(B) EXCLUSIONS OR EXEMPTIONS.—Declarations are required for all chemical substances in which a manufacturer has a current commercial interest, notwithstanding any exclusions or exemptions from other notification or reporting requirements provided in any other provision of this Act.

(C) PROCESSORS.—A processor of a chemical substance in which the processor has a current commercial interest that meets the criteria described in paragraph (1)(B)(i) may voluntarily submit to the Administrator a declaration for the chemical substance. Such a declaration shall be submitted not later than 1 year after the date of enactment of the Safe Chemicals Act of 2011.

(3) DECLARATION OF POTENTIAL COMMERCIAL INTEREST IN A CHEMICAL SUBSTANCE.—

(A) A manufacturer or processor may voluntarily submit to the Administrator, not later than 180 days after the date of enactment of the Safe Chemicals Act of 2011, a declaration for a chemical substance in which the manufacturer or processor—

(i) does not have a current commercial interest; but

(ii) has a potential commercial interest that meets the criteria described in paragraph (1)(B)(ii).

(B) If a manufacturer or processor commences the manufacture or processing of a chemical substance for which it submitted a declaration under this paragraph, the manufacturer or processor shall comply with the requirements of subsection (h)(5)(B).

(4) DECLARATION OF CESSATION OF MANUFACTURING OR PROCESSING.—A former or current manufacturer or processor of a chemical substance in which the manufacturer or processor no longer has a commercial interest may voluntarily submit to the Administrator, not later than 180 days after the date of enactment of the Safe Chemicals Act of 2011, a declaration that the manufacturer or processor has ceased, or will cease not later than 180 days after the date on which the declaration is submitted, all production, importation, processing, and export of the chemical substance.

(5) CONTENTS.—A declaration submitted under this subsection shall include for each chemical substance—

(A) the chemical identity and any special substance characteristics of the chemical substance;

(B) the identity and primary business location of the manufacturer or processor; and

(C) information supporting the declarant's basis for meeting the applicable criteria under paragraph (1)(B).

(6) REVIEW BY ADMINISTRATOR.—

(A) IN GENERAL.—The Administrator shall—

(i) review each declaration received under this subsection to determine whether the declaration conforms to the criteria and requirements of this subsection; and

(ii)(I) for a chemical substance for which 1 or more conforming declarations are submitted under para-

graph (2), add the chemical substance to the list of active chemical substances in the inventory established under subsection (h)(1);

(II) for a chemical substance for which the only conforming declarations submitted for the substance are submitted under paragraph (3), add the chemical substance to the list of inactive chemical substances in the inventory established under subsection (h)(5); and

(III) for a chemical substance for which the only conforming declarations submitted for the substance are submitted under paragraph (4), or for which no declaration has been submitted, remove the chemical substance from the inventories established under subsection (h).

(B) REVISIONS.—The Administrator shall allow a manufacturer or processor, as applicable, to promptly revise and resubmit any declaration submitted to the Administrator under this subsection if the Administrator determines that any omission or error in the original declaration was not intentional.

(c) PERIODIC REPORTING BY MANUFACTURERS.—

(1) IN GENERAL.—The Administrator shall—

(A) maintain the periodic reporting program of the agency applicable to manufacturers of chemical substances set forth in part 711 of title 40, Code of Federal Regulations (as in effect on the date of enactment of the Safe Chemicals Act of 2011), unless such reporting requirements are superseded pursuant to subparagraph (B); or

(B) establish a new periodic reporting program consistent with this subsection.

(2) RULEMAKING.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall specify, by rule—

(i) the chemical substances for which periodic reporting is required; and

(ii) the information a chemical manufacturer is required to submit to the Administrator for the chemical substances included under the periodic reporting program.

(B) EXEMPTIONS.—The rule promulgated under subparagraph (A) may exempt certain manufacturers, including small manufacturers, from—

(i) a requirement to participate in the periodic reporting program, if the Administrator determines that the participation of those manufacturers would not assist in the administration of this Act; or

(ii) specific reporting requirements, if the Administrator determines that the value of a particular reporting requirement, for the administration of this Act, would not be commensurate with the burden of the requirement on submitters.

(C) CONTENTS.—The rule promulgated under subparagraph (A) shall, at a minimum, require each manufacturer

of a chemical substance included in the periodic reporting program to submit to the Administrator—

(i) the chemical identity and any special substance characteristics of the chemical substance, the identity and primary business location of the manufacturer, and any updates to the supporting information submitted by the manufacturer in any declaration for an included chemical substance submitted under subsection (b);

(ii) a list of health and safety studies conducted or initiated by or for, known to, or reasonably ascertainable by, the manufacturer with respect to each included chemical substance;

(iii) a copy of each study described in clause (ii) in the possession or control of the manufacturer that has not previously been submitted to the Administrator; and

(iv) all other information specified by the Administrator in the rules promulgated under this subsection that is known to, in the possession or control of, or reasonably ascertainable by, the manufacturer or processor that has not previously been submitted to the Administrator regarding—

(I) the physical, chemical, and toxicological properties of the chemical substance;

(II) the manufacturer's annual production volume of the chemical substance;

(III) the uses of, and exposure and fate information relating to the manufacturer's production or import of the chemical substance; and

(IV) the name and location of each facility to which the manufacturer sends the chemical substance after manufacture for subsequent processing, distribution, or use.

(d) RECORDS TO SUPPORT DECLARATIONS AND PERIODIC REPORTS.—

(1) IN GENERAL.—Each manufacturer and processor of a chemical substance that is distributed in commerce shall—

(A) maintain records of the information submitted to the Administrator under subsections (b) and (c), as well as supporting information; and

(B) submit those records or that information to the Administrator upon request by the Administrator.

(2) BURDEN OF PROOF.—Each manufacturer and processor that submits to the Administrator a declaration under subsection (b) or a notice under subsection (h)(5)(B) shall at all times bear the burden of proving that the manufacturer or processor—

(A) has a current or potential commercial interest in the applicable chemical substance; or

(B) has ceased the production, importation, processing, and export of, the applicable chemical substance.

(e) SUBSTANCE IDENTIFICATION AND INFORMATION FOR CHEMICAL PROCESSORS.—

(1) RULEMAKING.—

(A) IN GENERAL.—Not later than 1 year after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall specify, by rule, the information that chemical processors are required to submit for chemical substances under this subsection as will assist the Administrator in the administration of this Act.

(B) EXEMPTIONS.—The rule promulgated under this paragraph may exempt certain processors, including small processors, from—

(i) a requirement to participate in the periodic reporting program, if the Administrator determines that the participation of those processors would not assist in the administration of this Act; or

(ii) specific reporting requirements, if the Administrator determines that the value of a particular reporting requirement, for the administration of this Act, would not be commensurate with the burden of the requirement on submitters.

(2) INFORMATION REQUIREMENTS.—The rule promulgated under paragraph (1) shall—

(A) specify the information that processors are required to submit for chemical substances that are—

(i) processed for use in 1 or more consumer or commercial product categories, as determined by the Administrator; and

(ii) intentionally added to 1 or more products during processing and not incidental to the end uses of the products;

(B) require each processor of a chemical substance identified under subparagraph (A) to submit the information specified in clauses (i) through (iii) of subparagraph (C) for the chemical substance, and to submit the information specified in clauses (iv) through (viii) of subparagraph (C)—

(i) separately for each applicable consumer and commercial product category; and

(ii) in aggregate form, taking into account the use by the processor of the chemical substance in all product categories;

(C) require each processor of a chemical substance identified under subparagraph (A) to identify in the submission of the processor—

(i) the corporate name and primary business location of the processor;

(ii) the chemical identity and any special substance characteristics of the chemical substance;

(iii) the applicable consumer or commercial product category or categories for which the processor processes the chemical substance;

(iv) the annual volume of the chemical substance processed by the submitter;

(v) any products intended for use by children aged 14 years or younger for use in which the processor processes the chemical substance;

(vi) the concentration range within which the maximum concentration of the substance used in each consumer and commercial product category falls;

(vii) the range within which the total number of commercial workers reasonably likely to be exposed to the chemical substance at the processing site falls; and

(viii) any other information regarding processing activities or product descriptors relating to the processor's processing of the chemical substance identified by the Administrator as necessary to understand the potential exposure from processed chemical substances or products in which the chemical substances are used; and

(D) require each processor to periodically report the information described in subparagraphs (B) and (C) for the chemical substances described in subparagraph (A).

(3) RECORDS.—The rules promulgated under paragraph (1) shall require processors of chemical substances to which those rules apply—

(A) to maintain records of the information described in paragraph (2); and

(B) to submit those records to the Administrator upon request by the Administrator.

(f) UPDATING OF INFORMATION.—

(1) IN GENERAL.—Each manufacturer or processor of a chemical substance that submits information to the Administrator under subsection (c) or (e) shall update the information—

(A) at a minimum every 4 years; and

(B) at any time that—

(i) the manufacturer or processor obtains knowledge of, comes into possession of, or generates significant new information regarding the production, processing, use, distribution, hazard, or exposure potential of the chemical substance; or

(ii) there is a significant change in the production, distribution in commerce, or use of the chemical substance by or known to the manufacturer or processor.

(2) GUIDANCE.—Not later than 1 year after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall issue guidance on what constitutes significant new information regarding or significant changes in the production, distribution in commerce, or use of a chemical substance.

(g) REPORTS.—

(1) REQUIREMENT.—

(A) IN GENERAL.—Except as provided in paragraph (2), the Administrator may by rule or order require any person who manufactures, processes, distributes in commerce, uses, or disposes of a chemical substance, or a mixture or article containing the chemical substance to maintain records of and report by a specified date any existing information concerning the substance that, in the judgment of the Administrator, would assist the Administrator in—

(i) making a safety standard determination with respect to a chemical substance;

(ii) determining testing or information needs for a chemical substance;

(iii) assigning a chemical substance to a batch, category, or priority class pursuant to section 6;

(iv) evaluating, developing, and implementing risk management conditions for a chemical substance;

(v) assessing hazards, exposures, or risks related to the manufacture, use, distribution, processing, or disposal of a chemical substance;

(vi) determining compliance with any provision of this Act; or

(vii) any other aspect of administering this Act.

(B) CHARACTERISTICS.—The Administrator may by rule or order require that any report or information submitted pursuant to this Act include chemical identity and special substance characteristics, as appropriate to the chemical substance that is the subject of the report or information.

(C) REQUIRED INFORMATION.—The Administrator shall by rule or order specify or modify the information that is required to be submitted with a particular report or information submission to establish the chemical identity and special substance characteristics of the subject chemical substance (or mixture or article containing that chemical substance) for the purposes of the report or information submission.

(2) EXEMPTIONS.—

(A) SMALL QUANTITIES FOR RESEARCH OR ANALYSIS.—In the case of the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research (including any such research or analysis for the development of a product), the Administrator may promulgate a rule or order under paragraph (1) only to the extent that the Administrator determines that the maintenance of records, submission of reports, or both, is necessary for the effective enforcement of this Act.

(B) SMALL BUSINESS.—The rules promulgated under this subsection may exempt certain small businesses from the rules promulgated under this subsection, if the Administrator determines that the participation of those small businesses would not assist in the administration of this Act.

(h) INVENTORIES.—

(1) ACTIVE INVENTORY.—The Administrator shall compile, keep current, and, subject to section 14, publish a list of each chemical substance that is manufactured or processed in the United States.

(2) CONTENTS.—

(A) IN GENERAL.—The list shall consist of those chemical substances for which—

(i) a notice is submitted under section 5(d), consistent with the requirements of section 5(b); or

(ii) a valid declaration is submitted under paragraph (2) of subsection (b).

(B) EXCLUSIONS.—The list shall not include—

(i) any chemical substance for which the only declarations submitted are submitted under paragraph (3) or (4) of subsection (b), or for which no declaration has been submitted; or

(ii) any chemical substance for which an exemption has been granted under section 5(b)(1)(C)(ii) or section 6(h)(2).

(3) TIMING.—

(A) IN GENERAL.—Except as provided in paragraph (2)(B), for a chemical substance for which a notice is submitted under section 5(d), the chemical substance shall be included in the list established under paragraph (1) as of the earliest date (as determined by the Administrator) on which the substance was manufactured or processed in the United States.

(B) PUBLICATION.—The Administrator shall first publish a list under paragraph (1) not later than 1 year after the date of enactment of the Safe Chemicals Act of 2011.

(4) SMALL QUANTITIES FOR RESEARCH OR ANALYSIS.—The Administrator shall not include in the list established under paragraph (1) any chemical substance that is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, the substance or another substance, including research or analysis for the development of a product.

(5) INACTIVE INVENTORY.—

(A) IN GENERAL.—The Administrator shall compile, keep current, and, subject to section 14, publish an inactive list on which the Administrator shall include each chemical substance for which the only declarations submitted for the substance are submitted under subsection (b)(3).

(B) REQUIREMENTS.—If a manufacturer or processor commences the manufacture or processing of a chemical substance on the inactive list, the manufacturer or processor shall—

(i) not less than 30 days before recommencing the manufacture or processing of the chemical substance, notify the Administrator; and

(ii) provide with the notification under clause (i)—

(I) the chemical identity and any special substance characteristics of the chemical substance;

(II) the identity and primary business location of the manufacturer;

(III) a list of health and safety studies conducted or initiated by or for, known to, or reasonably ascertainable by, the manufacturer or processor with respect to the chemical substance;

(IV) upon request of the Administrator, a copy of each study described in subclause (III) in the pos-

session or control of the manufacturer that has not previously been submitted to the Administrator;

(V) the projected annual manufacturing or processing volume for the chemical substance for each of the subsequent 3 years;

(VI) the name and location of each facility to which the chemical substance is expected to be sent, after manufacture or processing, for subsequent processing, distribution in commerce, or use; and

(VII) all other existing information known to, in the possession or control of, or reasonably ascertainable by the manufacturer or processor that has not previously been submitted to the Administrator regarding—

(aa) the toxicological properties of the chemical substance; and

(bb) the uses of, and exposure and fate information relating to, the chemical substance.

(C) ADMINISTRATOR ACTIONS.—For any chemical substance for which the Administrator receives a valid notification under subparagraph (B), the Administrator shall promptly—

(i) move the chemical substance to the active inventory established under paragraph (1); and

(ii) add the chemical substance to the current batch of chemical substances identified pursuant to section 6(a), and categorize the chemical substance with other chemical substances in the batch, pursuant to section 6(b).

(D) ADMINISTRATION.—Disclosure of any information provided in the notice described in subparagraph (B) shall be subject to section 14.

(6) CHEMICALS NOT LISTED ON OR REMOVED FROM THE INVENTORIES.—If a manufacturer or processor seeks to commence the manufacture or processing of a chemical substance that is not listed on the inventories established under paragraph (1) or (5), or that has been removed from the inventories pursuant to subsection (b)(6)(A)(ii)(III), the manufacturer or processor shall comply with section 5.

(i) PUBLIC ACCESS TO SIGNIFICANT INFORMATION.—

(1) ELECTRONIC DATABASE.—Not later than 1 year after the date of enactment of the Safe Chemicals Act of 2011, the Administrator, through collaboration as appropriate, shall establish—

(A) an electronic, Internet-accessible database for the storing and sharing of information relating to the toxicity and use of, and exposure to, chemical substances; and

(B) procedures for use in maintaining and updating the database.

(2) PUBLIC ACCESS.—Not later than 18 months after the date of enactment of the Safe Chemicals Act of 2011 or for decisions made or information submitted after that 18-month period, not later than 90 days after the date on which a decision is made

by the Administrator or information submitted under this title is received by the Administrator, the Administrator shall, subject to section 14, make available to the public via the Internet-accessible database described in paragraph (1) a description of all significant—

(A) decisions made by the Administrator under this title; and

(B) information submitted pursuant to this title.

(j) RECORDS OF SIGNIFICANT ADVERSE REACTIONS.—

(1) IN GENERAL.—Any person that manufactures, processes, or distributes in commerce any chemical substance shall maintain, and on request submit to the Administrator, records of significant adverse reactions to human health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture.

(2) DURATION.—

(A) IN GENERAL.—Records of the adverse reactions to the health of employees shall be retained for a period of 30 years after the date on which the reactions were first reported to or known by the person maintaining the records.

(B) OTHER RECORDS.—Any record of other adverse reactions shall be retained for a period of 5 years after the date on which information contained in the record was first reported to or known by the person maintaining the record.

(3) CONTENTS.—Records required to be maintained under this subsection shall include—

(A) records of consumer allegations of personal injury or harm to health;

(B) reports of occupational disease or injury; and

(C) reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source.

(k) INFORMATION IN THE POSSESSION OF OTHER FEDERAL AGENCIES.—

(1) SYNOPSES.—

(A) IN GENERAL.—Notwithstanding any other provision of law, from time to time, each Federal agency and Federal institution shall submit to the Administrator a synopsis of the data and records in the possession or control of the agency or institution, respectively, that may be useful to the Administrator in carrying out this Act.

(B) FORMAT AND CONTENT.—Not later than 1 year after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall prescribe, by order, the format, content, and level of detail of the synopses.

(C) INITIAL SUBMISSION.—Not later than 18 months after the date of enactment of the Safe Chemicals Act of 2011, each Federal agency and Federal institution shall make the initial submission of a synopsis of the agency and institution, respectively, to the Administrator.

(D) UPDATES.—At least once every 3 years, each Federal agency and Federal institution shall—

(i) update the synopsis of the agency and institution, respectively; and

(ii) submit the updated synopsis to the Administrator.

(2) REQUESTS BY THE ADMINISTRATOR.—Notwithstanding any other provision of law, on the request of the Administrator, any information in the possession or control of an agency or institution relating to a hazard of, use of, exposure to, or risk of, a chemical substance (or mixture or article containing that chemical substance) shall be submitted to the Administrator.

(l) NOTICE TO ADMINISTRATOR OF SUBSTANTIAL RISKS.—Any person that manufactures, processes, or distributes in commerce a chemical substance and that obtains information that reasonably supports the conclusion that the substance presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of the information unless the person has actual knowledge that the Administrator has been adequately informed of the information.

(m) CERTIFICATION.—Each submission required pursuant to this section or pursuant to a rule or an order promulgated or issued by the Administrator under this section, other than a submission under subsection (k), shall be accompanied by a certification signed by a responsible official of the manufacturer, processor, distributor, user, or disposer of a chemical substance that each statement contained in the submission—

(1) is accurate and reliable; and

(2) includes all material facts required by the applicable provision of this section or rule or order under this section.

(n) ADMINISTRATION.—

(1) IN GENERAL.—Nothing in this section limits the authority of the Administrator to require reporting under any other provision of this Act by any person who manufactures, processes, distributes in commerce, uses, or disposes of a chemical substance, or a mixture or article containing a chemical substance.

(2) VIOLATIONS.—In addition to all other authorities available for the enforcement of this Act, the Administrator may, by order, take any action authorized under section 6(f) if a person who manufactures, processes, distributes in commerce, uses, or disposes of a chemical substance, or a mixture or article containing a chemical substance violates any provision of this section.

(1) REPORT.—

(A) IN GENERAL.—If the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, or that any combination of those activities, does not meet a safety standard under this title or requires conditions or restrictions in order to the meet the safety standard, and the Administrator determines that action may be taken under a Federal law not administered by the Administrator to address the uses of, or exposure to, the chemical substance, the Administrator shall submit to the agency that administers the Federal law a report that—

(i) describes with specification the activity or combination of activities that prevent the chemical substance from meeting the safety standard or restrictions

or conditions required to meet the safety standard under this title;

(ii) requests that the agency—

(I) determine whether the 1 or more actions may be taken under Federal law administered by the agency;

(II) if the agency determines under clause (i) that the 1 or more actions may be taken, initiate and provide a timetable for the 1 or more actions; and

(III) respond to the Administrator with respect to the matters described in the report; and

(iii) includes a detailed statement of the information on which the report is based.

(B) PUBLICATION.—A report of the Administrator submitted under subparagraph (A) shall be promptly published in the Federal Register.

(C) ACTION BY RECIPIENT AGENCY.—Not later than 90 days after the date of receipt of a report from the Administrator under subparagraph (A), or by such earlier date as the Administrator may specify in such a report, an agency that receives the report shall—

(i) make all determinations requested by the Administrator in the report;

(ii) take all action necessary to ensure that a chemical substance meets the safety standard under this title, if appropriate;

(iii) include with the response of the agency a detailed statement of the findings and conclusions of the agency; and

(iv) publish that statement in the Federal Register.

(2) INITIATION OF ACTION.—If the Administrator submits a report under paragraph (1) with respect to a chemical substance to an agency, and the agency that receives the report initiates, within the period specified in the request under paragraph (1), a civil action under Federal law administered by the agency to ensure that a chemical substance meets the safety standard under this title, or requires restrictions or conditions to meet that safety standard, the Administrator may not take action under this Act with respect to the civil action (other than any action taken pursuant to section 7).

SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.

(a) LAWS NOT ADMINISTERED BY THE ADMINISTRATOR.—[(1) If the Administrator has reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—

[(A)(i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and

[(ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and

[(B) to respond to the Administrator with respect to the matters described in subparagraph (A).

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested response within such time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made. The response of an agency shall be accompanied by a detailed statement of the findings and conclusions of the agency and shall be published in the Federal Register.

[(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either—

[(A) issues an order declaring that the activity or combination of activities specified in the description of the risk described in the report does not present the risk described in the report, or

[(B) initiates, within 90 days of the publication in the Federal Register of the response of the agency under paragraph (1), action under the law (or laws) administered by such agency to protect against such risk associated with such activity or combination of activities, the Administrator may not take any action under section 6 or 7 with respect to such risk.]

(3) NO ACTION.—The Administrator may, by order, initiate action or a combination of actions under this Act to ensure compliance with the safety standard for a chemical substance under this title if—

(A) the Administrator submits a report under paragraph (1) with respect to a chemical substance; and

(B) the agency to which the report was submitted—

(i) determines that action cannot be taken under the authorities of the agency;

(ii) does not initiate action, if appropriate, within the period specified in the request under paragraph (1);

(iii) does not complete the action within the timeframe provided by the agency; or

(iv) fails to respond.

[(3)] [(4) If the Administrator has initiated action under section 6 or 7]

(4) CONSULTATION.—If the Administrator has initiated action under this Act with respect to a risk associated with a chemical substance or mixture which was the subject of a report made to an agency under paragraph (1), such agency shall before taking action under the law (or laws) administered by it to protect against such risk consult with the Administrator for the

purpose of avoiding duplication of Federal action [against such risk].

(b) LAWS ADMINISTERED BY THE ADMINISTRATOR.—The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

(c) OCCUPATIONAL SAFETY AND HEALTH.—In exercising any authority under this Act, [the Administrator shall not] *Administrator (1) shall not*, for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health[.]*; and*

(2) shall ensure that any actions to address workplace exposures that the Administrator takes or requires to be taken by manufacturers or processors of a chemical substance are consistent with the industrial hygiene hierarchy of controls

(d) COORDINATION.—In administering this Act, the Administrator shall consult and coordinate with the Secretary of Health, Education, and Welfare and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act [while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes]. The Administrator shall[, in the report required by section 30,] report annually to the Congress on actions taken to coordinate with such other Federal departments, agencies, or instrumentalities, and on actions taken to coordinate the authority under this Act with the authority granted under other Acts referred to in subsection (b).

[SEC. 11. INSPECTIONS AND SUBPOENAS.

[(a) IN GENERAL.—For purposes of administering this Act, the Administrator, and any duly designated representative of the Administrator, may inspect any establishment, facility, or other premises in which chemical substances, mixtures, or products subject to title IV are manufactured, processed, stored, or held before or after their distribution in commerce and any conveyance being used to transport chemical substances, mixtures, such products, or such articles in connection with distribution in commerce. Such an inspection may only be made upon the presentation of appropriate credentials and of a written notice to the owner, operator, or agent in charge of the premises or conveyance to be inspected. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and com-

pleted with reasonable promptness and shall be conducted at reasonable times, within reasonable limits, and in a reasonable manner.

[(b) SCOPE.—(1) Except as provided in paragraph (2), an inspection conducted under subsection (a) shall extend to all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of this Act applicable to the chemical substances, mixtures, or products subject to title IV within such premises or conveyance have been complied with.

[(2) No inspection under subsection (a) shall extend to—

[(A) financial data,

[(B) sales data (other than shipment data),

[(C) pricing data,

[(D) personnel data, or

[(E) research data (other than data required by this Act or under a rule promulgated thereunder),

unless, the nature and extent of such data are described with reasonable specificity in the written notice required by subsection (a) for such inspection.

[(c) SUBPOENAS.—In carrying out this Act, the Administrator may by subpoena require the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, and other information that the Administrator deems necessary. Witnesses shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. In the event of contumacy, failure, or refusal of any person to obey any such subpoena, any district court of the United States in which venue is proper shall have jurisdiction to order any such person to comply with such subpoena. Any failure to obey such an order of the court is punishable by the court as a contempt thereof.]

SEC. 11. INSPECTIONS AND SUBPOENAS.

(a) INSPECTIONS.—

(1) IN GENERAL.—For purposes of administering this Act, the Administrator, and any duly designated representative of the Administrator, may inspect—

(A) any establishment, facility, or other premises in which chemical substances, mixtures, or articles subject to this Act are manufactured, processed, stored, or held before or after distribution in commerce;

(B) any conveyance being used to transport such chemical substances, mixtures, or articles in connection with distribution in commerce; and

(C) any place at which records relating to the chemical substances, mixtures, or articles, or otherwise relating to compliance with this Act, are held.

(2) METHOD.—Each inspection under paragraph (1) shall be—

(A) commenced and completed with reasonable promptness; and

(B) conducted at reasonable times, within reasonable limits, and in a reasonable manner.

(3) SAMPLES.—The Administrator, and any duly designated representative of the Administrator, may inspect and obtain samples of any—

(A) chemical substance, mixture, or article; and

(B) container or labeling of a chemical substance, mixture, or article.

(b) SCOPE.—An inspection conducted under subsection (a) shall extend to all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) regarding whether the owner or operator of the premises, conveyance, or records has complied with provisions of this Act applicable to the chemical substances, mixtures, articles, or records.

(c) INFORMATION GATHERING.—

(1) IN GENERAL.—In carrying out this Act, the Administrator may require the attendance and testimony of witnesses and the production of such reports, papers, documents, items, answers to questions, and other information, including the development of analyses and other information, as the Administrator determines to be necessary.

(2) PAYMENT OF WITNESSES.—A witness described in paragraph (1) shall be paid the same fees and mileage that are paid witnesses in the courts of the United States.

(d) WARRANTS.—For purposes of enforcing this Act, upon a showing to an officer or court of competent jurisdiction that there is reason to believe that a provision of this Act has been violated, officers or employees duly designated by the Administrator are empowered to obtain and to execute warrants authorizing—

(1) entry, inspection, and copying of records for purposes of this Act; and

(2) the seizure of any chemical substance, mixture, or article that is in violation of this Act.

SEC. 12. EXPORTS.

[(a) IN GENERAL.—(1) Except as provided in paragraph (2) and subsections (b) and (c), this Act (other than section 8) shall not apply to any chemical substance, mixture, or to an article containing a chemical substance or mixture, if—

[(A) it can be shown that such substance, mixture, or article is being manufactured, processed, or distributed in commerce for export from the United States, unless such substance, mixture, or article was, in fact, manufactured, processed, or distributed in commerce, for use in the United States, and

[(B) such substance, mixture, or article (when distributed in commerce), or any container in which it is enclosed (when so distributed), bears a stamp or label stating that such substance, mixture, or article is intended for export.

[(2) Paragraph (1) shall not apply to any chemical substance, mixture, or article if the Administrator finds that the substance, mixture, or article will present an unreasonable risk of injury to health within the United States or to the environment of the United States. The Administrator may require, under section 4, testing of any chemical substance or mixture exempted from this Act by paragraph (1) for the purpose of determining whether or not such substance or mixture presents an unreasonable risk of injury

to health within the United States or to the environment of the United States.]

[(b)] *(a)* NOTICE.—(1) If any person exports [or intends to export] to a foreign country a chemical substance or mixture for which the submission of data is required under [section 4 or 5(b)] *section 4, 5, or 6(b)*, such person shall notify the Administrator of such exportation [or intent to export] *, not later than 30 days after the date of exportation of the substance or mixture,* and the Administrator shall *promptly thereafter* furnish to the government of such country notice of the availability of the data submitted to the Administrator under such section for such substance or mixture.

(2) If any person exports [or intends to export] to a foreign country a chemical substance or mixture for which [an order has been issued under section 5 or a rule has been proposed or promulgated under section 5 or 6, or with respect to which an action is pending, or relief has been granted under section 5 or 7] *an action has been taken pursuant to section 6 or 7*, such person shall notify the Administrator of such exportation [or intent to export] *, not later than 30 days after the date of exportation of the substance or mixture,* and the Administrator shall *promptly thereafter* furnish to the government of such country notice of [such rule, order, action, or relief] *the action taken pursuant to section 6 or 7*.

(3) CHANGE IN EXPORT STATUS.—

(A) IN GENERAL.—Any person that has notified the Administrator of the exportation of a chemical substance or mixture under this section shall notify the Administrator of any change in the export status of the substance or mixture by not later than 30 days after such a change in status.

(B) UPDATED NOTICE.—The Administrator shall promptly furnish an updated notice to the governments that have been notified pursuant to paragraphs (1) and (2) regarding the exportation of any chemical substance or mixture subject to this section if—

(i) data for the substance or mixture have been received by the Administrator pursuant to section 4, 5, 6(b), or 8;

(ii) a change has occurred in the export status of the substance or mixture; or

(iii) a change has been made in any risk management action taken pursuant to section 6 or 7 for the substance or mixture.

[(c)] *(b)* PROHIBITION ON EXPORT OF ELEMENTAL MERCURY.—

(1) PROHIBITION.—Effective January 1, 2013, the export of elemental mercury from the United States is prohibited.

[(2) INAPPLICABILITY OF SUBSECTION (a).—Subsection (a) shall not apply to this subsection.]

[(3)]*(2)* REPORT TO CONGRESS ON MERCURY COMPOUNDS.—

(A) REPORT.—Not later than one year after the date of enactment of the Mercury Export Ban Act of 2008, the Administrator shall publish and submit to Congress a report on mercuric chloride, mercurous chloride or calomel, mercuric oxide, and other mercury compounds, if any, that may currently be used in significant quantities in products or processes. Such report shall include an analysis of—

(i) the sources and amounts of each of the mercury compounds imported into the United States or manufactured in the United States annually;

(ii) the purposes for which each of these compounds are used domestically, the amount of these compounds currently consumed annually for each purpose, and the estimated amounts to be consumed for each purpose in 2010 and beyond;

(iii) the sources and amounts of each mercury compound exported from the United States annually in each of the last three years;

(iv) the potential for these compounds to be processed into elemental mercury after export from the United States; and

(v) other relevant information that Congress should consider in determining whether to extend the export prohibition to include one or more of these mercury compounds.

(B) PROCEDURE.—For the purpose of preparing the report under this paragraph, the Administrator may utilize the information gathering authorities of this title, including sections 10 and 11.

[(4)]*(3)* ESSENTIAL USE EXEMPTION.—(A) Any person residing in the United States may petition the Administrator for an exemption from the prohibition in paragraph (1), and the Administrator may grant by rule, after notice and opportunity for comment, an exemption for a specified use at an identified foreign facility if the Administrator finds that—

(i) nonmercury alternatives for the specified use are not available in the country where the facility is located;

(ii) there is no other source of elemental mercury available from domestic supplies (not including new mercury mines) in the country where the elemental mercury will be used;

(iii) the country where the elemental mercury will be used certifies its support for the exemption;

(iv) the export will be conducted in such a manner as to ensure the elemental mercury will be used at the identified facility as described in the petition, and not otherwise diverted for other uses for any reason;

(v) the elemental mercury will be used in a manner that will protect human health and the environment, taking into account local, regional, and global human health and environmental impacts;

(vi) the elemental mercury will be handled and managed in a manner that will protect human health and the environment, taking into account local, regional, and global human health and environmental impacts; and

(vii) the export of elemental mercury for the specified use is consistent with international obligations of the United States intended to reduce global mercury supply, use, and pollution.

(B) Each exemption issued by the Administrator pursuant to this paragraph shall contain such terms and conditions as are

necessary to minimize the export of elemental mercury and ensure that the conditions for granting the exemption will be fully met, and shall contain such other terms and conditions as the Administrator may prescribe. No exemption granted pursuant to this paragraph shall exceed three years in duration and no such exemption shall exceed 10 metric tons of elemental mercury.

(C) The Administrator may by order suspend or cancel an exemption under this paragraph in the case of a violation described in subparagraph (D).

(D) A violation of this subsection or the terms and conditions of an exemption, or the submission of false information in connection therewith, shall be considered a prohibited act under section 15, and shall be subject to penalties under section 16, injunctive relief under section 17, and citizen suits under section 20.

[(5)**]***(4)* CONSISTENCY WITH TRADE OBLIGATIONS.—Nothing in this subsection affects, replaces, or amends prior law relating to the need for consistency with international trade obligations.

[(6)**]***(5)* EXPORT OF COAL.—Nothing in this subsection shall be construed to prohibit the export of coal.

(c) PUBLIC RECORDS.—The Administrator shall—

(1) maintain copies of all current notices provided to other governments under this section; and

(2) make such copies available to the public in electronic format.

SEC. 13. ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES.

(a) IN GENERAL.—(1) The **[**Secretary of the Treasury**]** *Secretary of Homeland Security* shall refuse entry into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States) of any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry **[**if—**]**

[(A) it fails to comply with any rule in effect under this Act, or

[(B) it is offered for entry in violation of section 5, 6, or title IV a rule or order under section 5, 6, or title IV or an order issued in a civil action brought under section 5, 7 or title IV.**]** *if the substance, mixture, or article fails to comply with or is offered for entry in violation of any rule or order in effect under this Act.*

(2) If a chemical substance, mixture, or article is refused entry under paragraph (1), the **[**Secretary of the Treasury**]** *Secretary of Homeland Security* shall notify the consignee of such entry refusal, shall not release it to the consignee, and shall cause its disposal or storage (under such rules as the **[**Secretary of the Treasury**]** *Secretary of Homeland Security* may prescribe) if it has not been exported by the consignee within 90 days from the date of receipt of notice of such refusal, except that the **[**Secretary of the Treasury**]** *Secretary of Homeland Security* may, pending a review by the Administrator of the entry refusal, release to the consignee such substance, mixture, or article on execution of bond for the amount of the full invoice of such substance, mixture, or article (as such value is set forth in the customs entry), together with the duty

thereon. On failure to return such substance, mixture, or article for any cause to the custody of the [Secretary of the Treasury] *Secretary of Homeland Security* when demanded, such consignee shall be liable to the United States for liquidated damages equal to the full amount of such bond. All charges for storage, cartage, and labor on and for disposal of substances, mixtures, or articles which are refused entry or released under this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future entry made by such owner or consignee.

(3) IMPORT AS PART OF AN ARTICLE.—*Chemical substances and mixtures imported as part of an article shall be subject to the same requirements under this Act as if the substances and mixtures had been imported in bulk, except as the Administrator may provide by rule under this Act, or as the Secretary of Homeland Security may provide by rule under subsection (b).*

(b) RULES.—The [Secretary of the Treasury] , *Secretary of Homeland Security* after consultation with the Administrator, shall issue rules for the administration of subsection (a) of this section.

[SEC. 14. DISCLOSURE OF DATA.

[(a) IN GENERAL.—Except as provided by subsection (b), any information reported to, or otherwise obtained by, the Administrator (or any representative of the Administrator) under this Act, which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section, shall, notwithstanding the provisions of any other section of this Act, not be disclosed by the Administrator or by any officer or employee of the United States, except that such information—

[(1) shall be disclosed to any officer or employee of the United States—

[(A) in connection with the official duties of such officer or employee under any law for the protection of health or the environment, or

[(B) for specific law enforcement purposes;

[(2) shall be disclosed to contractors with the United States and employees of such contractors if in the opinion of the Administrator such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States entered into on or after the date of enactment of this Act for the performance of work in connection with this Act and under such conditions as the Administrator may specify;

[(3) shall be disclosed if the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment; or

[(4) may be disclosed when relevant in any proceeding under this Act, except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding.

In any proceeding under section 552(a) of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 552(b)(3) of such title to sustain the Administrator's action.

[(b) DATA FROM HEALTH AND SAFETY STUDIES.—(1) Subsection (a) does not prohibit the disclosure of—

[(A) any health and safety study which is submitted under this Act with respect to—

[(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, or

[(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5, and

[(B) any data reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

[(2) If a request is made to the Administrator under subsection (a) of section 552 of title 5, United States Code, for information which is described in the first sentence of paragraph (1) and which is not information described in the second sentence of such paragraph, the Administrator may not deny such request on the basis of subsection (b)(4) of such section.

[(c) DESIGNATION AND RELEASE OF CONFIDENTIAL DATA.—(1) In submitting data under this Act, a manufacturer, processor, or distributor in commerce may (A) designate the data which such person believes is entitled to confidential treatment under subsection (a), and (B) submit such designated data separately from other data submitted under this Act. A designation under this paragraph shall be made in writing and in such manner as the Administrator may prescribe.

[(2)(A) Except as provided by subparagraph (B), if the Administrator proposes to release for inspection data which has been designated under paragraph (1)(A), the Administrator shall notify, in writing and by certified mail, the manufacturer, processor, or distributor in commerce who submitted such data of the intent to release such data. If the release of such data is to be made pursuant to a request made under section 552(a) of title 5, United States Code, such notice shall be given immediately upon approval of such request by the Administrator. The Administrator may not release such data until the expiration of 30 days after the manufacturer, processor, or distributor in commerce submitting such data has received the notice required by this subparagraph.

[(B)(i) Subparagraph (A) shall not apply to the release of information under paragraph (1), (2), (3), or (4) of subsection (a), except that the Administrator may not release data under paragraph (3) of subsection (a) unless the Administrator has notified each manufacturer, processor, and distributor in commerce who submitted such data of such release. Such notice shall be made in writing by certified mail at least 15 days before the release of such data, except that if the Administrator determines that the release of such data is necessary to protect against an imminent, unreasonable

risk of injury to health or the environment, such notice may be made by such means as the Administrator determines will provide notice at least 24 hours before such release is made.

[(ii) Subparagraph (A) shall not apply to the release of information described in subsection (b)(1) other than information described in the second sentence of such subsection.

[(d) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.—(1) Any officer or employee of the United States or former officer or employee of the United States, who by virtue of such employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a), and who knowing that disclosure of such material is prohibited by such subsection, willfully disclosures the material in any manner to any person not entitled to receive it, shall be guilty of a misdemeanor and fined not more than $5,000 or imprisoned for not more than one year, or both. Section 1905 of title 18, United States Code, does not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this Act.

[(2) For the purposes of paragraph (1), any contractor with the United States who is furnished information as authorized by subsection (a)(2), and any employee of any such contractor, shall be considered to be an employee of the United States.

[(e) ACCESS BY CONGRESS.—Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, upon written request of any duly authorized committee of the Congress, to such committee.]

SEC. 14. DISCLOSURE OF DATA.

(a) APPLICABILITY.—

(1) IN GENERAL.—Subject to paragraph (2) and except as provided under subsections (b) and (e), any information reported to, or otherwise obtained by, the Administrator (or any representative of the Administrator) that is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, (commonly known as the "Freedom of Information Act") under subsection (b)(4) of that section, shall not be disclosed by the Administrator or by any officer or employee of the United States, unless the designation of the information as exempt from disclosure is prohibited under Federal law.

(2) EXEMPTIONS.—

(A) MANDATORY EXEMPTIONS.—Notwithstanding any other provision of law, the Administrator shall disclose the information described in paragraph (1)—

(i) to any officer or employee of the United States—

(I) in connection with the official duties of that officer or employee under any law for the protection of human health or the environment; or

(II) for specific law enforcement purposes;

(ii) to a contractor with the United States and employees of that contractor if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with

the United States entered into on or after the date of enactment of the Safe Chemicals Act of 2011 for the performance of work in connection with this Act and under such conditions as the Administrator may specify;

(iii) if the Administrator determines that the disclosure is necessary to protect human health or the environment;

(iv) on request, to a State or tribal government for the purpose of development or potential development, administration, or enforcement of a law, if 1 or more applicable agreements ensure that the recipient government will take appropriate steps, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to those which the Administrator uses to safeguard the information;

(v) on request, to public health or environmental health professionals or medical personnel if the Administrator determines that—

(I) disclosure is in the public interest;

(II) the recipient does not have a conflict of interest or competitive interest with respect to the submitter of the information; and

(III) 1 or more applicable agreements are in place to ensure that the recipient of the information provides comparable protections to those provided by the Administrator to maintain the confidentiality of the information.

(B) OPTIONAL EXEMPTIONS.—Notwithstanding any other provision of law, the Administrator may disclose the information described in paragraph (1) if relevant, in any proceeding under this Act, except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding.

(3) EFFECT ON OTHER LAWS.—In any proceeding under section 552(a) of title 5, United States Code (commonly referred to as the 'Freedom of Information Act'), to obtain information, the disclosure of which has been denied pursuant to this section, the Administrator may not rely on subsection (b)(3) of that section to sustain the action of the Administrator.

(b) CATEGORIES OF CONFIDENTIAL BUSINESS INFORMATION.—

(1) INFORMATION THAT IS ALWAYS ELIGIBLE FOR PROTECTION.—Subject to subsection (a)(2) and any other applicable provision of Federal law, the Administrator shall review and approve a request that conforms to the requirements described in subsection (c)(2) to treat as confidential under this section the following information:

(A) Precise information describing the manufacture, processing, or distribution of a chemical substance or mixture.

(B) Marketing and sales information.

(C) Information identifying the customers of a manufacturer, processor, or distributor.

(D) Details of the full composition of a mixture of a particular manufacturer or processor.

(E) Precise information about the use, function, or application of a chemical substance or mixture in a process, mixture, or product of a particular manufacturer or processor.

(F) Precise production or import volumes of a particular manufacturer, processor, or distributor.

(2) INFORMATION THAT MAY BE ELIGIBLE FOR PROTECTION.—

(A) IN GENERAL.—Subject to subsection (a) and any other applicable provision of Federal law, and except as provided in paragraphs (1) and (3), information submitted by a manufacturer, processor, or distributor to the Administrator may be protected if the manufacturer, processor, or distributor complies with subsection (c)(2) and the Administrator determines that a request to maintain the confidentiality of the information meets the applicable requirements of this subsection and any rule promulgated by the Administrator under subsection (c)(1).

(B) IDENTITIES OF CERTAIN CHEMICAL SUBSTANCES.—

(i) IN GENERAL.—Notwithstanding subparagraph (A), the Administrator shall not disclose precise information on the identity of a chemical substance if—

(I) the manufacturer or processor of the substance has, in accordance with subsection (c)(2)—

(aa) included in a notice under section 5(b) a request, including a justification and documentation for the request, that the identity of the substance be treated as confidential business information; or

(bb) submitted to the Administrator not later than 180 days after the date of enactment of the Safe Chemicals Act of 2011 a request, including a justification and documentation for the request, that the identity of a substance for which a notice has been submitted under section 5(b) as of the date of enactment of the Safe Chemicals Act of 2011 be treated as confidential business information; and

(II) the Administrator determines that—

(aa) the request complies with all applicable requirements of this section;

(bb) the chemical identity is not readily discoverable through reverse engineering;

(cc) the manufacturer or processor takes reasonable measures to protect the confidentiality of the chemical substance;

(dd) no other Federal statute requires disclosure;

(ee) disclosure of the identity of the chemical substance would cause financial or competitive harm to the manufacturer or processor;

(ff) the chemical substance is not, based on information that is initially available or that

later becomes available to the Administrator, a known or probable reproductive, developmental, neurological, or immunological toxicant, carcinogen, or mutagen;

(gg) the chemical substance is not persistent, bioaccumulative, and toxic; and

(hh) if a safety standard determination has been made for a chemical substance, the Administrator determines that the chemical substance meets the applicable safety standard either under current conditions or under additional conditions required by the Administrator.

(ii) NOTICE.—In cases where all of the requirements specified in clause (i) are met—

(I) the notice required to be made public by the Administrator under section 5(f)(3) shall include a justification for the determination of the Administrator and identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest; and

(II) as part of a claim to protect the identity of a chemical substance under subsection (c)(2), a manufacturer or processor may provide a 'public name' for the chemical substance for use by the Administrator when sharing information on the chemical substance under this subsection. The public names should disclose a maximum amount of information on the chemical structure of the substance, while protecting those features of the chemical structure that are considered confidential and the disclosure of which would potentially harm the owner of that information.

(iii) DURATION OF PROTECTION FOR CHEMICAL IDENTITY.—Notwithstanding subsection (c)(1)(B)(iv), the identity of a chemical substance for which a request has been submitted pursuant to clause (i)(I) and meets the requirements of clause (i) shall be protected as confidential business information—

(I) for such period of time as the Administrator, after reviewing the request, determines to be reasonable; and

(II) upon expiration of a time period specified under this clause, for an additional 5-year period, if the Administrator, after reviewing the request, determines that the request for protection continues to meet the criteria established in this subparagraph.

(iv) PUBLICATION REQUIREMENT.—The Administrator shall annually publish a notice that—

(I) includes an updated, cumulative list of each new chemical substance for which the Administrator has approved a request to protect informa-

tion under this paragraph, identified by a unique identifier, other than the precise chemical identity, and including the period of time for which the protection applies; and

(II) for each chemical substance for which the protection provided under this paragraph has expired, provides the precise identity of the chemical substance, and provides public access to any information that had been submitted to the Administrator which concealed the identity of the chemical substance in accordance with this paragraph.

(C) IMPURITIES.—Notwithstanding subparagraph (A), the Administrator may determine not to disclose information relating to the degree of purity or the identity of impurities present in a chemical substance or mixture if the Administrator determines that knowledge of the information would reveal processes used in the manufacturing or processing of the chemical substance or mixture.

(3) INFORMATION THAT IS NEVER ELIGIBLE FOR PROTECTION.—

(A) IN GENERAL.—Except as provided in paragraph (2), the Administrator shall disclose the following information:

(i) The identity of a chemical substance.

(ii) Any safety standard determination developed under section 6, including supporting analysis developed by the Administrator.

(iii) Any health and safety study data that is submitted under this Act with respect to—

(I) any chemical substance or mixture—

(aa) that has been offered for commercial distribution as of the date on which the study is to be disclosed; or

(bb) for which testing is required under section 4 or for which notification is required under section 5; and

(II) any data reported to, or otherwise obtained by, the Administrator from a health and safety study that relates to a chemical substance or mixture described in subclause (I).

(iv) Health and safety data in notices of substantial risk submitted pursuant to section 8(l) and in the underlying studies.

(v) General information describing the manufacturing volumes, expressed in ranges, and industrial, commercial, or consumer functions and uses of a chemical substance or mixture.

(vi) Any information indicating the presence of a chemical substance in consumer products intended for use, or reasonably expected to be used, by children aged 14 years or younger, if—

(I) the Administrator, or another authoritative body, has determined that the chemical substance—

(aa) is a known or probable reproductive, developmental, neurological, or immunological toxicant, carcinogen, or mutagen; or

(bb) is persistent, bioaccumulative, and toxic; or

(II) for a chemical substance for which a safety standard determination has been made, the Administrator has not found that the chemical substance meets the safety standard.

(B) PROHIBITION.—Nothing in this paragraph authorizes the release of any data that discloses a process used in the manufacturing or processing of a chemical substance or mixture, or in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

(C) APPLICABILITY OF OTHER LAWS.—Except as provided in paragraph (2), if the Administrator receives a request for information under section 552(a) of title 5, United States Code, (commonly known as the 'Freedom of Information Act') for information described in subparagraph (A), which is not information described in subparagraph (B), the Administrator shall not deny the request under subsection (b)(4) of that section.

(c) DESIGNATION AND TREATMENT OF CONFIDENTIAL BUSINESS INFORMATION.—

(1) DUTIES OF THE ADMINISTRATOR.—

(A) RULES.—Not later than 1 year after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall promulgate rules that specify—

(i) the acceptable bases on which written requests to maintain confidentiality of information may be approved, which shall be consistent with the requirements of this section;

(ii) the nature of the documentation and justification that must accompany such a request; and

(iii) the types of information the Administrator determines warrant protection for an indefinite period of time, for which the term of confidentiality specified in subparagraph (B)(iv)(I) shall not apply.

(B) REVIEW OF REQUESTS.—

(i) IN GENERAL.—Not later than 90 days after the date of receipt of information under paragraph (2), the Administrator shall review a request to maintain confidentiality of information submitted under this Act and determine whether to approve, modify, or deny that request based on the regulations promulgated by the Administrator under subparagraph (A).

(ii) PROCESS.—The Administrator shall, in accordance with clause (i)—

(I) review all requests received to maintain confidentiality of submitted information; or

(II) if it is not feasible for the Administrator to review all of the requests—

(aa) review all requests relating to information described in subsection (b)(2)(B); and

(bb) review a representative subset that includes not less than 25 percent of all other requests received; and

(III) publish in the Federal Register on at least an annual basis a description of the number and types of requests received and reviewed by the Administrator.

(iii) DENIALS.—If a request to maintain confidentiality of submitted information is denied in accordance with subparagraph (D), the Administrator shall promptly make the information available to the public in accordance with section 8(i)(2).

(iv) APPROVALS.—If a request to maintain confidentiality of submitted information is approved, the Administrator shall—

(I) except with respect to requests subject to a rule issued pursuant to subparagraph (A)(iii) and requests submitted pursuant to subsection (b)(2)(B)(i)(I), specify a time period not to exceed 5 years for which the submitted information shall be kept confidential, unless the information otherwise becomes available to the public during the period; and

(II) upon the expiration of the protection period, make the information available to the public unless the manufacturer, processor, or distributor has submitted, documented, and justified to the satisfaction of the Administrator and in accordance with this subsection the basis for a renewal of the protection, for a time period not to exceed 5 years.

(C) AUTHORITY OF THE ADMINISTRATOR.—Nothing in subparagraph (A) or (B) limits the authority of the Administrator to determine that particular information, previously treated as confidential, is no longer entitled to confidential treatment.

(D) NOTIFICATIONS.—

(i) IN GENERAL.—Except as provided in clause (ii), if the Administrator proposes to release information for which a request for confidential treatment has been approved under this section, the Administrator shall electronically notify the manufacturer, processor, or distributor in commerce who submitted the request of the intent of the Administrator to release the information not less than 15 days prior to the release of the information.

(ii) ADMINISTRATION.—The Administrator shall release the information described in clause (i) in accordance with the disclosure and procedural requirements of section 552 of title 5, United States Code (commonly known as the 'Freedom of Information Act'), except that—

(I) if the release of the information is to be made pursuant to a request made under section 552(a) of title 5, United States Code, the notice shall be given immediately upon approval of the request by the Administrator;

(II) if the Administrator determines that the release of information pursuant to subsection (a)(2)(A)(iii) is necessary to protect against imminent and substantial harm to human health or the environment, no notice shall be required; and

(III) the requirements of this subparagraph shall not apply to the release of information under—

(aa) clauses (i) through (iii) of subsection (a)(2)(A); or

(bb) subsection (b)(3)(A).

(2) DUTIES OF MANUFACTURERS, PROCESSORS, AND DISTRIBUTORS.—

(A) IN GENERAL.—In submitting data under this Act, a manufacturer, processor, or distributor in commerce may—

(i) designate information, other than information described in subsection (b)(3), for which the manufacturer, processor, or distributor requests confidential treatment under subsection (a) or (b); and

(ii) submit the designated data separately from other data submitted under this Act.

(B) REQUIREMENTS.—A designation under this paragraph shall be made in writing and in such manner as the Administrator may prescribe, and shall include—

(i) documentation and justification for each request for confidentiality, except for requests relating to the information described in subsection (b)(1);

(ii) the period of time for which maintenance of confidentiality of the information is requested except with respect to requests subject to a rule issued pursuant to subsection (c)(1)(A)(iii);

(iii) a certification that the information is not otherwise publicly available;

(iv) separate copies of all submitted information, with 1 copy containing and 1 copy excluding the information to which the request applies; and

(v) any additional information required by the Administrator.

(C) REQUEST FOR RENEWAL.—Prior to the expiration of the specified time period determined by the Administrator under paragraph (1)(B)(iv), a manufacturer, processor, or distributor may submit a request for renewal of protection for protected information. This request for renewal shall follow the same procedures and requirements as the initial submission under subparagraphs (A) and (B).

(d) CIVIL PENALTY FOR WRONGFUL DISCLOSURE OR WRONGFUL REQUESTS FOR PROTECTION.—

(1) IN GENERAL.—Any officer or employee of the United States or former officer or employee of the United States, who, by virtue of employment or official position has obtained possession

of, or has access to, material the disclosure of which is prohibited by subsection (a), and who knowing that disclosure of the material is prohibited by that subsection, willfully discloses the material in any manner to any person not entitled to receive the information, shall be subject to appropriate disciplinary action and subject to a civil money penalty of not more than $10,000 for each violation.

(2) APPLICABILITY OF OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known, or making available of, information reported or otherwise obtained under this Act.

(3) CONTRACTORS.—For the purposes of paragraph (1), any contractor with the United States who is furnished information as authorized by subsection (a)(2), including any employee of such a contractor, shall be considered to be an employee of the United States.

(4) FALSE REQUESTS.—Any officer or employee of a company that submits information under this Act who willfully designates information as eligible for confidential treatment, knowing that the information is ineligible for such treatment, shall be subject to a civil money penalty of not more than $10,000 for each such violation.

(e) ACCESS BY CONGRESS.—Notwithstanding this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, on written request of any duly authorized committee of Congress, to that committee.

(f) RISK INFORMATION FOR WORKERS.—The Administrator shall facilitate the sharing of information that pertains to chemical substances or mixtures or articles containing chemical substances that workers may come into contact with or may otherwise be exposed to during the course of work with those workers and representatives of each certified or recognized bargaining agent representing those workers. Nothing in this subsection authorizes disclosure of information other than those disclosures that may be made pursuant to subsections (a) through (e).

SEC. 15. PROHIBITED ACTS.

It shall be unlawful for any person to—

[(1) fail or refuse to comply with (A) any rule promulgated or order issued under section 4, (B) any requirement prescribed by section 5 or 6, (C) any rule promulgated or order issued under section 5 or 6, or (D) any requirement of title II or any rule promulgated or order issued under title II;]

(1) fail or refuse to comply with any rule, order, prohibition, restriction, or other requirement imposed by this Act or by the Administrator under this Act;

(2) [use] *manufacture, process, distribute in commerce, use, or dispose of* for commercial purposes a chemical substance [or mixture] *, mixture, or article*[which such person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 or 6, a rule or order under section 5 or 6, or an order issued in action brought under section 5 or 7] *any rule, order, prohibition, restriction, or other re-*

quirement imposed by this Act or by the Administrator under this Act;

(3) fail or refuse to (A) establish or maintain *acurate and complete* records, (B) submit *or make accurate and complete* reports, notices, *information submissions, disclosures, declarations, certifications,* or other information, or (C) permit access to or copying of records, as required by this Act or a rule thereunder; **[**or**]**

(4) fail or refuse to permit entry or inspection as required by section 11**[**.**]***;*

(5) make or submit a statement, declaration, disclosure, certification, writing, data set, or representation that is materially false, in whole or in part, or to falsify or conceal any material fact, in taking any action or making any communication pursuant to this Act or pursuant to any rule or order promulgated or issued under this Act; or

(6) take any action prohibited by this Act.

SEC. 16. PENALTIES.

(a) CIVIL.—(1) Any person who violates a provision of *this Act or a rule or order promulgated or issued pursuant to this Act, as described in*section 15 or 409 shall be liable to the United States for a civil penalty in an amount not to exceed **[**$25,000**]** *$37,500* for each such violation. Each day such a violation continues shall, for purposes of this subsection, constitute a separate **[**violation of section 15 or 409**]** *violation of this Act*.

(2) In the case of any violation described in paragraph (1), the Administrator may commence a civil action in the appropriate United States district court to assess penalties pursuant to that paragraph.

[(2)**]***(3)*(A) A civil penalty for a violation of *this Act, as described in* section 15 or 409 shall be assessed by the Administrator by an order made on the record after opportunity (provided in accordance with this subparagraph) for a hearing in accordance with section 554 of title 5, United States Code. Before issuing such an order, the Administrator shall give written notice to the person to be assessed a civil penalty under such order of the Administrator's proposal to issue such order and provide such person an opportunity to request, **[**within 15 days of**]** *not later than 15 days after* the date the notice is received by such person, such a hearing on the order.

(B) In determining the amount of a civil penalty, the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Administrator may compromise, modify, or remit, with or without conditions, any civil penalty which may be imposed under this subsection. The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

[(3)**]***(4)* Any person who requested in accordance with **[**paragraph (2)(A)**]** *paragraph (3)(A)* a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such

order with [the United States Court of Appeals for the District of Columbia Circuit or for any other circuit] *the appropriate district court of the United States for the district* in which such person resides or transacts business. Such a petition may only be filed within the 30-day period beginning on the date the order making such assessment was issued.

[(4)]*(5)* If any person fails to pay an assessment of a civil penalty—

(A) after the order making the assessment has become a final order and if such person does not file a petition for judicial review of the order in accordance with [paragraph (3)] *paragraph (4)*, or

(B) after a court in an action brought under [paragraph (3)] *paragraph (4)* has entered a final judgment in favor of the Administrator,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 30-day period referred to in [paragraph (3)] *paragraph (4)* or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(b) CRIMINAL.—[Any person]

(1) IN GENERAL.—Any person who knowingly [or willfully] violates any provision of *this Act, as described in* section 15 or 409 shall, in addition to or in lieu of any civil penalty which may be imposed under subsection (a) of this section for such violation, be subject, upon conviction, to a fine of not more than [$25,000] *$50,000* for each day of violation, or to imprisonment for not more than [one year] *5 years*, or both.

(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

(A) IN GENERAL.—Any individual who knowingly violates any provision of this Act and who knows at the time that the violation places another person in imminent danger of death or serious bodily injury shall upon conviction be subject to a fine of not more than $250,000, or imprisonment of not more than 15 years, or both.

(B) OTHER PERSONS.—A person that is not an individual shall, upon conviction of violating this paragraph, be subject to a fine of not more than $1,000,000.

SEC. 17. SPECIFIC ENFORCEMENT AND SEIZURE.

(a) SPECIFIC ENFORCEMENT.—[(1) The district courts of the United States shall have jurisdiction over civil actions to—

[(A) restrain any violation of section 15 or 409,

[(B) restrain any person from taking any action prohibited by section 5, 6, or title IV, or by a rule or order under section 5, 6, or title IV,

[(C) compel the taking of any action required by or under this Act, or]

(1) AUTHORITY OF THE ADMINISTRATOR.—

(A) IN GENERAL.—The Administrator may commence a civil action in the appropriate United States district court to compel compliance of any person with any provision of

this Act or any rule or order promulgated pursuant to this Act.

(B) ENFORCEMENT.—The authority of the Administrator to enforce this Act includes the authority—

(i) to seek civil or criminal penalties under section 16 for any violation of this Act, as described in sections 15 and 409;

(ii) to enjoin any violation of this Act, or of a rule or order promulgated or issued under this Act, as described in sections 15 and 409;

(iii) to order the compliance of any person with any provision of this Act, or with any rule or order promulgated or issued under this Act, through an administrative proceeding (which may proceed concurrently with action under this section), in which the Administrator may levy penalties under section 16

[(D) direct any manufacturer**]**

*(iv) to order any manufacturer;*or processor of a chemical substance, mixture, or **[**product subject to title IV**]** *article subject to this Act* manufactured or processed in violation **[**of section 5, 6, or title IV**]** *this Act*, or a rule or order **[**under section 5, 6, or title IV**]** *promulgated and issued under this Act, as described in section 15 or 409,* and distributed in commerce,**[**(i)**]**

(I) to give notice of such fact to distributors in commerce of such substance, mixture, or **[**product**]** *article* and, to the extent reasonably ascertainable, to other persons in possession of such substance, mixture, or **[**product**]** *article* or exposed to such substance, mixture, or **[**product**]** *article*, **[**(ii)**]**

(II) to give public notice of such risk of injury, and **[**(iii)**]**

(III) to either replace or repurchase such substance, mixture, or **[**product**]** *article*, whichever the person to which the requirement is directed elects.

[(2) A civil action described in paragraph (1) may be brought—

[(A) in the case of a civil action described in subparagraph (A) of such paragraph**]**

(2) CIVIL ACTIONS.—

(A) IN GENERAL.—The district courts of the United States shall have jurisdiction over a civil action described in paragraph (1).

(B) REQUIREMENTS.—A civil action described in paragraph (1) may be brought—

(i) in the case of a civil action described in subparagraphs (A) and (B) of paragraph (1), in the United States district court for the judicial district wherein any act, omission, or transaction constituting a violation **[**of section 15**]***of this Act, as described in section 15 or 409* occurred or wherein the defendant is found or transacts business, or

[(B)**]**

(ii) in the case of any other civil action described in [such paragraph] *paragraph (1)*, in the United States district court for the judicial district wherein the defendant is found or transacts business.

(3) SERVING OF PROCESS AND SUBPOENAS.—In any [In any] such civil action process may be served on a defendant in any judicial district in which a defendant resides or may be found. Subpoenas requiring attendance of witnesses in any such action may be served in any judicial district.

(b) SEIZURE.—Any chemical substance, mixture, or [product] *article* subject to [title IV] *this Act* which was manufactured, processed, or distributed in commerce in violation of this Act or any rule promulgated or order issued under this Act or any article containing such a substance or mixture shall be liable to be proceeded against, by process of libel for the seizure and condemnation of such substance, mixture, [product,] or article, in any district court of the United States within the jurisdiction of which such substance, mixture, [product,] or article is found. Such proceeding shall conform as nearly as possible to proceedings in rem in admiralty.

[SEC. 18. PREEMPTION.

[(a) EFFECT ON STATE LAW.—(1) Except as provided in paragraph (2), nothing in this Act shall affect the authority of any State or political subdivision of a State to establish or continue in effect regulation of any chemical substance, mixture, or article containing a chemical substance or mixture.

[(2) Except as provided in subsection (b)—

[(A) if the Administrator requires by a rule promulgated under section 4 the testing of a chemical substance or mixture, no State or political subdivision may, after the effective date of such rule, establish or continue in effect a requirement for the testing of such substance or mixture for purposes similar to those for which testing is required under such rule; and

[(B) if the Administrator prescribes a rule or order under section 5 or 6 (other than a rule imposing a requirement described in subsection (a)(6) of section 6) which is applicable to a chemical substance or mixture, and which is designed to protect against a risk of injury to health or the environment associated with such substance or mixture, no State or political subdivision of a State may, after the effective date of such requirement, establish or continue in effect, any requirement which is applicable to such substance or mixture, or an article containing such substance or mixture, and which is designed to protect against such risk unless such requirement (i) is identical to the requirement prescribed by the Administrator, (ii) is adopted under the authority of the Clean Air Act or any other Federal law, or (iii) prohibits the use of such substance or mixture in such State or political subdivision (other than its use in the manufacture or processing of other substances or mixtures).

[(b) EXEMPTION.—Upon application of a State or political subdivision of a State the Administrator may by rule exempt from subsection (a)(2), under such conditions as may be prescribed in such rule, a requirement of such State or political subdivision designed

to protect against a risk of injury to health or the environment associated with a chemical substance, mixture, or article containing a chemical substance or mixture if—

[(1) compliance with the requirement would not cause the manufacturing, processing, distribution in commerce, or use of the substance, mixture, or article to be in violation of the applicable requirement under this Act described in subsection (a)(2), and

[(2) the State or political subdivision requirement (A) provides a significantly higher degree of protection from such risk than the requirement under this Act described in subsection (a)(2) and (B) does not, through difficulties in marketing, distribution, or other factors, unduly burden interstate commerce.]

Nothing in this Act affects the right of a State or a political subdivision of a State to adopt or enforce any regulation, requirement, or standard of performance that is different from, or in addition to, a regulation, requirement, liability, or standard of performance established pursuant to this Act unless compliance with both this Act and the State or political subdivision of a State regulation, requirement, or standard of performance is impossible, in which case the applicable provisions of this Act shall control.

SEC. 19. JUDICIAL REVIEW.

(a) IN GENERAL.—[(1)(A) Not later than 60 days after the date of the promulgation of a rule *or order* under section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV,]

(1) JUDICIAL REVIEW.—*Not later than 60 days after the date of the promulgation or issuance of a rule under of this Act,* any person may file a petition for judicial review of such rule *or order* with the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which such person resides or in which such person's principal place of business is located. Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review [(other than in an enforcement proceeding)] of such a rule *or order* if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

[(B) Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of an order issued under subparagraph (A) or (B) of section 6(b)(1) if any district court of the United States would have had jurisdiction of such action but for this subparagraph.]

(2) Copies of any petition filed under [paragraph (1)(A)] *paragraph (1)* shall be transmitted forthwith to the Administrator and to the Attorney General by the clerk of the court with which such petition was filed. The provisions of section 2112 of title 28, United States Code, shall apply to the filing of the rulemaking record of proceedings on which the Administrator based the rule *or order* being reviewed under this section and to the transfer of proceedings between United States courts of appeals.

[(3) For purposes of this section, the term "rulemaking record" means—

[(A) the rule being reviewed under this section;

[(B) in the case of a rule under section 4(a), the finding required by such section, in the case of a rule under section 5(b)(4), the finding required by such section, in the case of a rule under section 6(a) the finding required by section 5(f) or 6(a), as the case may be, in the case of a rule under section 6(a), the statement required by section 6(c)(1), and in the case of a rule under section 6(e), the findings required by paragraph (2)(B) or (3)(B) of such section, as the case may be[1] and in the case of a rule under title IV, the finding required for the issuance of such a rule;

[(C) any transcript required to be made of oral presentations made in proceedings for the promulgation of such rule;

[(D) any written submission of interested parties respecting the promulgation of such rule; and

[(E) any other information which the Administrator considers to be relevant to such rule and which the Administrator identified, on or before the date of the promulgation of such rule, in a notice published in the Federal Register.]

(b) ADDITIONAL SUBMISSIONS AND PRESENTATIONS; MODIFICATIONS.—If in an action under this section to review a rule *or order* the petitioner or the Administrator applies to the court for leave to make additional oral submissions or written presentations respecting such rule *or order* and shows to the satisfaction of the court that such submissions and presentations would be material and that there were reasonable grounds for the submissions and failure to make such submissions and presentations in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity to make such submissions and presentations. The Administrator may modify or set aside the rule *or order* being reviewed or make a new rule *or order* by reason of the additional submissions and presentations and shall file such modified or new rule *or order* with the return of such submissions and presentations. The court shall thereafter review such new or modified rule *or order*.

(c) STANDARD OF REVIEW.—[(1)(A) Upon the filing of a petition under subsection (a)(1) for judicial review of a rule, the court shall have jurisdiction (i) to grant appropriate relief, including interim relief, as provided in chapter 7 of title 5, United States Code, and (ii) except as otherwise provided in subparagraph (B), to review such rule in accordance with chapter 7 of title 5, United States Code.

[(B) Section 706 of title 5, United States Code, shall apply to review of a rule under this section, except that—

[(i) in the case of review of a rule under section 4(a), 5(b)(4), 6(a), or 6(e), the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;

[1] So in law. Probably should be followed by a comma.

[(ii) in the case of review of a rule under section 6(a), the court shall hold unlawful and set aside such rule if it finds that—

[(I) a determination by the Administrator under section 6(c)(3) that the petitioner seeking review of such rule is not entitled to conduct (or have conducted) cross-examination or to present rebuttal submissions, or

[(II) a rule of, or ruling by, the Administrator under section 6(c)(3) limiting such petitioner's cross-examination or oral presentations,

has precluded disclosure of disputed material facts which was necessary to a fair determination by the Administrator of the rulemaking proceeding taken as a whole; and section 706(2)(D) shall not apply with respect to a determination, rule, or ruling referred to in subclause (I) or (II); and

[(iii) the court may not review the contents and adequacy of—

[(I) any statement required to be made pursuant to section 6(c)(1), or

[(II) any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule

[except as part of a review of the rulemaking record taken as a whole.

The term "evidence" as used in clause (i) means any matter in the rulemaking record.

[(C) A determination, rule, or ruling of the Administrator described in subparagraph (B)(ii) may be reviewed only in an action under this section and only in accordance with such subparagraph.]

(1) IN GENERAL.—Upon the filing of a petition under subsection (a)(1) for judicial review of a rule or order, the court shall have jurisdiction—

(A) to grant appropriate relief, including interim relief, as provided in chapter 7 of title 5, United States Code; and

(B) to review the rule or order in accordance with that chapter.

(2) The judgment of the court affirming or setting aside, in whole or in part, any rule reviewed in accordance with this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

(d) FEES AND COSTS.—The decision of the court in an action commenced under subsection (a), or of the Supreme Court of the United States on review of such a decision, may include an award of costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate.

(e) OTHER REMEDIES.—The remedies as provided in this section shall be in addition to and not in lieu of any other remedies provided by law.

SEC. 20. CITIZENS' CIVIL ACTIONS.

(a) IN GENERAL.—Except as provided in subsection (b), any person may commence a civil action—

(1) against any person (including (A) the United States, and (B) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of this Act or any rule promulgated [under section 4, 5, or 6, or title II or IV, or order issued under section 5 or title II or IV to restrain such violation,] *or order issued under this Act;*

(2) against the Administrator to compel the Administrator to perform any act or duty under this Act which is not discretionary.

Any civil action under paragraph (1) shall be brought in the United States district court for the district in which the alleged violation occurred or in which the defendant resides or in which the defendant's principal place of business is located. Any action brought under paragraph (2) shall be brought in the United States District Court for the District of Columbia, or the United States district court for the judicial district in which the plaintiff is domiciled. The district courts of the United States shall have jurisdiction over suits brought under this section, without regard to the amount in controversy or the citizenship of the parties *, to enforce this Act or any rule promulgated or order issued under this Act, or to order the Administrator to perform an act or duty described in this Act, as the case may be*. In any civil action under this subsection process may be served on a defendant in any judicial district in which the defendant resides or may be found and subpoenas for witnesses may be served in any judicial district.

(b) LIMITATION.—No civil action may be commenced—

(1) under subsection (a)(1) [to restrain] *respecting* a violation of this Act or rule or order under this Act—

(A) before the expiration of 60 days after the plaintiff has given notice of such violation (i) to the Administrator, and (ii) to the person who is alleged to have committed such violation, or

(B) if the Administrator has commenced and is diligently prosecuting a proceeding for the issuance of an order under section 16(a)(2) to require compliance with this Act or with such rule or order or if the Attorney General has commenced and is diligently prosecuting a civil action in a court of the United States to require compliance with this Act or with such rule or order, but if such proceeding or civil action is commenced after the giving of notice, any person giving such notice may intervene as a matter of right in such proceeding or action; or

(2) under subsection (a)(2) before the expiration of 60 days after the plaintiff has given notice to the Administrator of the alleged failure of the Administrator to perform an act or duty which is the basis for such action or, in the case of an action under such subsection for the failure of the Administrator to file an action under section 7, before the expiration of ten days after such notification.

Notice under this subsection shall be given in such manner as the Administrator shall prescribe by rule.

(c) GENERAL.—(1) In any action under this section, the Administrator, if not a party, may intervene as a matter of right.

(2) The court, in issuing any final order in any action brought pursuant to subsection (a), may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(3) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this Act or any rule or order under this Act or to seek any other relief.

(d) CONSOLIDATION.—When two or more civil actions brought under subsection (a) involving the same defendant and the same issues or violations are pending in two or more judicial districts, such pending actions, upon application of such defendants to such actions which is made to a court in which any such action is brought, may, if such court in its discretion so decides, be consolidated for trial by order (issued after giving all parties reasonable notice and opportunity to be heard) of such court and tried in—

(1) any district which is selected by such defendant and in which one of such actions is pending,

(2) a district which is agreed upon by stipulation between all the parties to such actions and in which one of such actions is pending, or

(3) a district which is selected by the court and in which one of such actions is pending.

The court issuing such an order shall give prompt notification of the order to the other courts in which the civil actions consolidated under the order are pending.

SEC. 21. CITIZENS' PETITIONS.

(a) IN GENERAL.—Any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule [under section 4, 6, or 8 or an order under section 5(e) or (6)(b)(2)] *, order, or any other action authorized under this Act*.

(b) PROCEDURES.—(1) Such petition shall be filed in the principal office of the Administrator and shall set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule [under section 4, 6, or 8 or an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)] *or order or to initiate other action authorized under this Act*.

(2) The Administrator may hold a public hearing or may conduct such investigation or proceeding as the Administrator deems appropriate in order to determine whether or not such petition should be granted.

(3) Within 90 days after filing of a petition described in paragraph (1), the Administrator shall either grant or deny the petition. If the Administrator grants such petition, the Administrator shall promptly commence an appropriate proceeding in accordance with [section 4, 5, 6, or 8] *the applicable provisions of this Act*. If the Administrator denies such petition, the Administrator shall publish in the Federal Register the Administrator's reasons for such denial.

(4)(A) If the Administrator denies a petition filed under this section (or if the Administrator fails to grant or deny such petition within the 90-day period) the petitioner may commence a civil ac-

tion in a district court of the United States to compel the Administrator to initiate [a rulemaking proceeding] *proceedings authorized under this Act* as requested in the petition. Any such action shall be filed within 60 days after the Administrator's denial of the petition or, if the Administrator fails to grant or deny the petition within 90 days after filing the petition, within 60 days after the expiration of the 90-day period.

(B) In an action under subparagraph (A) respecting a petition to initiate [a proceeding to issue a rule under section 4, 6, or 8 or an order under section 5(e) or 6(b)(2)] *proceedings authorized under this Act*, the petitioner shall be provided an opportunity to have such petition considered by the court in a de novo proceeding. *Notwithstanding the preceding sentence, in the case of a petition to delist a chemical substance under section 6(a), the delisting may not proceed except as authorized under that subsection.* If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

(i) [in the case of a petition to initiate a proceeding for the issuance of a rule under section 4 or an order under section 5(e)] *except as provided in clause (ii), in the case of a petition to initiate a proceeding for the issuance of a rule or an order under this Act*—

(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order; and

(II) in the absence of such information, the substance may present [an unreasonable risk to] *substantial endangerment* health or the environment, or the substance is or will be produced in substantial quantities and it enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to it; or

(ii) in the case of a petition to initiate a proceeding for the [issuance of a rule under section 6 or 8 or an order under section 6(b)(2)] *imposition or issuance of a restriction, use condition, or order under this chapter*, there is a reasonable basis to conclude that the issuance of such a rule or order is necessary to protect health or the environment against [an unreasonable risk of injury] *a substantial endangerment* to health or the environment; [1]

the court shall order the Administrator to initiate the action requested by the petitioner. If the court finds that the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act and there are insufficient resources available to the Administrator to take the action requested by the petitioner, the court may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes[.] *;*

[1] In Public Law 94–469, a period appears after "environment". The semicolon is shown in this print to reflect the probable intent of Congress.

(C) The court in issuing any final order in any action brought pursuant to subparagraph (A) may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(5) The remedies under this section shall be in addition to, and not in lieu of, other remedies provided by law.

* * * * * * *

SEC. 24. EMPLOYMENT EFFECTS.

(a) IN GENERAL.—The Administrator shall evaluate on a [continuing] *periodic* basis the potential effects on employment (including reductions in employment or loss of employment from threatened [plant closures) of—

(1) the issuance of a rule or order under section 4, 5, or 6, or

(2) a requirement of section 5 or 6.] *plant closures) of the implementation of this Act.*

(b)(1) INVESTIGATIONS.—Any employee (or any representative of an employee) may request the Administrator to make an investigation of—

(A) a discharge or layoff or threatened discharge or layoff of the employee, or

(B) adverse or threatened adverse effects on the employee's employment,

allegedly resulting from a rule or order under [section 4, 5, or 6 or a requirement of section 5 or 6] *this Act*. Any such request shall be made in writing, shall set forth with reasonable particularity the grounds for the request, and shall be signed by the employee, or representative of such employee, making the request.

(2)(A) Upon receipt of a request made in accordance with paragraph (1) the Administrator shall (i) conduct the investigation requested, and (ii) if requested by any interested person, hold public hearings on any matter involved in the investigation unless the Administrator, [by order issued] *in writing,* within 45 days of the date such hearings are requested, denies the request for the hearings because the Administrator determines there are no reasonable grounds for holding such hearings. If the Administrator makes such a determination, the Administrator shall notify in writing the person requesting the hearing of the determination and the reasons therefor and shall publish the determination and the reasons therefor in the Federal Register.

(B) If public hearings are to be held on any matter involved in an investigation conducted under this subsection—

(i) at least five days' notice shall be provided the person making the request for the investigation and any person identified in such request[,] *;and*

[(ii) such hearings shall be held in accordance with section 6(c)(3), and]

[(iii)] *(ii)* each employee who made or for whom was made a request for such hearings and the employer of such employee shall be required to present information respecting the applica-

ble matter referred to in paragraph (1)(A) or (1)(B) together with the basis for such information.

(3) Upon completion of an investigation under paragraph (2), the Administrator shall make findings of fact, shall make such recommendations as the Administrator deems appropriate, and shall make available to the public such findings and recommendations.

[(4) This section shall not be construed to require the Administrator to amend or repeal any rule or order in effect under this Act.]

(c) EFFECT.—Nothing in this section—

(1) requires the Administrator to amend or repeal any rule or order in effect under this Act; or

(2) conditions the authority of the Administrator to issue orders or promulgate rules under this Act.

SEC. 26. ADMINISTRATION OF THE ACT.

(a) COOPERATION OF FEDERAL AGENCIES.—Upon request by the Administrator, each Federal department and agency is authorized—

(1) to make its services, personnel, and facilities available (with or without reimbursement) to the Administrator to assist the Administrator in the administration of this Act; and

(2) to furnish to the Administrator such information, data, estimates, and statistics, and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary for the administration of this Act.

[(b) FEES.—(1) The Administrator may, by rule, require the payment of a reasonable fee from any person required to submit data under section 4 or 5 to defray the cost of administering this Act. Such rules shall not provide for any fee in excess of $2,500 or, in the case of a small business concern, any fee in excess of $100. In setting a fee under this paragraph, the Administrator shall take into account the ability to pay of the person required to submit the data and the cost to the Administrator of reviewing such data. Such rules may provide for sharing such a fee in any case in which the expenses of testing are shared under section 4 or 5.

[(2) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the persons which qualify as small business concerns for purposes of paragraph (1).]

(b) FEES.—

(1) IN GENERAL.—The Administrator may, by rule, require the payment of a reasonable fee from any person required to submit data to defray the cost of administering this Act.

(2) CONSIDERATIONS.—In setting a fee under this subsection, the Administrator shall take into account—

(A) the ability to pay of the person required to submit the data; and

(B) the cost to the Administrator of reviewing the data.

(3) FEE SHARING.—Rules described in paragraph (1) may provide for sharing a fee in any case in which the expenses of testing are shared under this Act.

(c) ACTION WITH RESPECT TO CATEGORIES *and Mixtures*.—(1) Any action authorized or required to be taken by the Administrator

under any provision of this Act with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this Act with respect to a category of chemical substances or mixtures, any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category.

(2) For purposes of paragraph (1):

(A) The term "category of chemical substances" means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

(B) The term "category of mixtures" means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological 1properties, in use, or in the mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act.

(3) MIXTURES.—*Any action authorized or required to be taken by the Administrator or any other person under any provision of this Act with respect to a chemical substance is likewise also authorized or required with respect to a mixture, if the Administrator determines that such extension is reasonable and efficient.*

(d) ASSISTANCE OFFICE.—The Administrator shall establish in the Environmental Protection Agency an identifiable office to provide technical and other nonfinancial assistance to manufacturers and processors of chemical substances and mixtures respecting the requirements of this Act applicable to such manufacturers and processors, the policy of the Agency respecting the application of such requirements to such manufacturers and processors, and the means and methods by which such manufacturers and processors may comply with such requirements.

(e) FINANCIAL DISCLOSURES.—(1) Except as provided under paragraph (3), each officer or employee of the Environmental Protection Agency and the Department of Health, Education, and Welfare who—

(A) performs any function or duty under this Act, and

(B) has any known financial interest (i) in any person subject to this Act or any rule or order in effect under this Act, or (ii) in any person who applies for or receives any grant or contract under this Act,

shall, on February 1, 1978, and on February 1 of each year thereafter, file with the Administrator or the Secretary of Health, Education, and Welfare (hereinafter in this subsection referred to as the "Secretary"), as appropriate, a written statement concerning all such interests held by such officer or employee during the pre-

ceding calendar year. Such statement shall be made available to the public.

(2) The Administrator and the Secretary shall—

(A) act within 90 days of the effective date of this Act—

(i) to define the term "known financial interests" for purposes of paragraph (1), and

(ii) to establish the methods by which the requirement to file written statements specified in paragraph (1) will be monitored and enforced, including appropriate provisions for review by the Administrator and the Secretary of such statements; and

(B) report to the Congress on June 1, 1978, and on June 1 of each year thereafter with respect to such statements and the actions taken in regard thereto during the preceding calendar year.

(3) The Administrator may by rule identify specific positions with the Environmental Protection Agency, and the Secretary may by rule identify specific positions with the Department of Health, Education, and Welfare, which are of a nonregulatory or nonpolicy-making nature, and the Administrator and the Secretary may by rule provide that officers or employees occupying such positions shall be exempt from the requirements of paragraph (1).

(4) This subsection does not supersede any requirement of chapter 11 of title 18, United States Code.

(5) Any officer or employee who is subject to, and knowingly violates, this subsection or any rule issued thereunder, shall be fined not more than $2,500 or imprisoned not more than one year, or both.

(f) STATEMENT OF BASIS AND PURPOSE.—Any final order issued under this Act shall be accompanied by a statement of its basis and purpose. The contents and adequacy of any such statement shall not be subject to judicial review in any respect.

(g) ASSISTANT ADMINISTRATOR.—(1) The President, by and with the advice and consent of the Senate, shall appoint an Assistant Administrator for Toxic Substances of the Environmental Protection Agency. Such Assistant Administrator shall be a qualified individual who is, by reason of background and experience, especially qualified to direct a program concerning the effects of chemicals on human health and the environment. Such Assistant Administrator shall be responsible for (A) the collection of data, (B) the preparation of studies, (C) the making of recommendations to the Administrator for regulatory and other actions to carry out the purposes and to facilitate the administration of this Act, and (D) such other functions as the Administrator may assign or delegate.

(2) The Assistant Administrator to be appointed under paragraph (1) shall be in addition to the Assistant Administrators of the Environmental Protection Agency authorized by section 1(d) of Reorganization Plan No. 3 of 1970.

(h) RULEMAKING OR ORDERS.—In carrying out this Act, the Administrator may issue such orders and prescribe such regulations as are necessary to carry out this Act.

* * * * * * *

SEC. 28. STATE PROGRAMS.

(a) IN GENERAL.—For the purpose of complementing (but not reducing) the authority of, or actions taken by, the Administrator under this Act, the Administrator may make grants to States for the establishment and operation of programs to prevent or eliminate [unreasonable] risks within the States to health or the environment which are associated with a chemical substance or mixture and with respect to which the Administrator [is unable or is not likely to take] *has not taken* action under this Act for their prevention or elimination. The amount of a grant under this subsection shall be determined by the Administrator, except that no grant for any State program may exceed 75 per centum of the establishment and operation costs (as determined by the Administrator) of such program during the period for which the grant is made.

(b) COORDINATION.—*The Administrator shall establish a process to coordinate with States, on an on-going basis, to share data and priorities relating to the management of chemical substances under this title and under programs operated by States, in accordance with section 14.*

[(b)] *(c)* APPROVAL BY ADMINISTRATOR.—(1) No grant may be made under subsection (a) unless an application therefor is submitted to and approved by the Administrator. Such an application shall be submitted in such form and manner as the Administrator may require and shall—

(A) set forth the need of the applicant for a grant under subsection (a),

(B) identify the agency or agencies of the State which shall establish or operate, or both, the program for which the application is submitted,

(C) describe the actions proposed to be taken under such program,

(D) contain or be supported by assurances satisfactory to the Administrator that such program shall, to the extent feasible, be integrated with other programs of the applicant for environmental and public health protection,

(E) provide for the making of such reports and evaluations as the Administrator may require, and

(F) contain such other information as the Administrator may prescribe.

(2) The Administrator may approve an application submitted in accordance with paragraph (1) only if the applicant has established to the satisfaction of the Administrator a priority need, as determined under rules of the Administrator, for the grant for which the application has been submitted. Such rules shall take into consideration the seriousness of the health effects in a State which are associated with chemical substances or mixtures, [including cancer, birth defects, and gene mutations,] the extent of the exposure in a state of human beings and the environment to chemical substances and mixtures, and the extent to which chemical substances and mixtures are manufactured, processed, used, and disposed of in a State.

[(c)] *(d)* ANNUAL REPORTS.—Not later than six months after the end of each of the fiscal years 1979, 1980, and 1981, the Adminis-

trator shall submit to the Congress a report respecting the programs assisted by grants under subsection (a) in the preceding fiscal year and the extent to which the Administrator has disseminated information respecting such programs.

[(d)] *(e)* AUTHORIZATION.—For the purpose of making grants under subsection (a), there are authorized to be appropriated $1,500,000 for each of the fiscal years 1982 and 1983. Sums appropriated under this subsection shall remain available until expended.

SEC. 29. CHILDREN'S ENVIRONMENTAL HEALTH RESEARCH PROGRAM.

(a) CHILDREN'S ENVIRONMENTAL HEALTH RESEARCH PROGRAM.—

(1) ESTABLISHMENT.—Not later than 90 days after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall establish within the Environmental Protection Agency a program to be known as the 'Children's Environmental Health Research Program' (referred to in this subsection as the 'Program').

(2) PURPOSE.—Subject to amounts made available in advance in appropriations Acts, the Administrator may enter into contracts and make grants under the Program to further understanding of the vulnerability of children to chemical substances and mixtures.

(3) CONSULTATION.—Contracts and grants under this section shall be provided in consultation with the Interagency Science Advisory Board on Children's Health Research established under subsection (b)(1).

(b) INTERAGENCY SCIENCE ADVISORY BOARD ON CHILDREN'S HEALTH RESEARCH.—

(1) ESTABLISHMENT.—Not later than 90 days after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall establish an advisory board to be known as the 'Interagency Science Advisory Board on Children's Health Research' (referred to in this subsection as the 'Board').

(2) PURPOSE.—The purpose of the Board shall be to provide independent advice, expert consultation, and peer review, on request of the Administrator or Congress, with respect to the scientific and technical aspects of issues relating to the implementation of this title with respect to research on protecting children's health.

(3) COMPOSITION.—The Administrator shall—

(A) appoint the members of the Board, including, at a minimum, representatives of—

(i) the National Institute of Environmental Health Sciences;

(ii) the Centers for Disease Control and Prevention;

(iii) the National Toxicology Program;

(iv) the National Cancer Institute;

(v) the National EPA-Tribal Science Council; and

(vi) not fewer than 3 centers of children's health at leading institutions of higher education;

(B) ensure that at least 1/3 of the members of the Board have specific scientific expertise in the relationship of chemical exposures to prenatal, infant, and children's health; and

(C) ensure that no individual appointed to serve on the Board has a conflict of interest that is relevant to the functions performed by the Board, unless—

(i) the individual promptly and publicly discloses the conflict; and

(ii) the Administrator determines that the conflict is unavoidable.

(4) APPLICABLE LAW.—The Board shall be subject to subchapter II of chapter 5, and chapter 7, of title 5, United States Code (commonly known as the 'Administrative Procedure Act').

(c) PRENATAL AND INFANT EXPOSURES.—

(1) MONITORING.—If, through studies performed under subsection (a) or section 4 or in any other available research, the Administrator identifies a chemical substance that may be present in human biological media that may have adverse effects on early childhood development, the Administrator shall coordinate with the Secretary of Health and Human Services to conduct, not later than 2 years after the date on which the Administrator identifies the chemical substance, a biomonitoring study to determine the presence of the chemical substance in human biological media in, at a minimum, pregnant women and infants.

(2) PUBLICATION.—On completion of any study conducted under paragraph (1), the Secretary of Health and Human Services shall—

(A) notify the Administrator of the results of the study; and

(B) publish the results of the study in a publicly available electronic format.

(3) POSITIVE RESULTS.—

(A) MANUFACTURE DISCLOSURE.—If a chemical substance or mixture is determined to be present in a study conducted under paragraph (1), the manufacturers and processors of the chemical substance or mixture shall, not later than 180 days after the date of publication of the study, disclose to the Administrator, commercial customers of the manufacturers and processors, consumers, and the public—

(i) all known uses of the chemical substance or mixture; and

(ii) all articles in which the chemical substance or mixture is, or is expected to be, present.

(B) COST AND FORM OF DISCLOSURE.—Information under clauses (i) and (ii) of subparagraph (A) shall be—

(i) made available by the Administrator in electronic format; and

(ii) made readily accessible and free of charge by each applicable manufacturer and processor in electronic format to the commercial customers of such manufacturer or processor, consumers, and the public.

SEC. 30. REDUCTION OF ANIMAL-BASED TESTING.

(a) ADMINISTRATION.—The Administrator shall take action to minimize the use of animals in testing of chemical substances or mixtures, including—

(1) encouraging and facilitating, to the maximum extent practicable—

(A) the use of existing data of sufficient scientific quality;

(B) the use of test methods that eliminate or reduce the use of animals while providing data of high scientific quality;

(C) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of 1 chemical substance would provide reliable and useful data on others in the category;

(D) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

(E) the parallel submission of data from animal-based studies and from emerging methods and models; and

(2) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

(b) INTERAGENCY SCIENCE ADVISORY BOARD ON ALTERNATIVE TESTING METHODS.—

(1) ESTABLISHMENT.—Not later than 90 days after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall establish an advisory board to be known as the 'Interagency Science Advisory Board on Alternative Testing Methods' (referred to in this subsection and subsection (c) as the 'Board').

(2) COMPOSITION.—The Administrator shall—

(A) appoint the members of the Board, including, at a minimum, representatives of—

(i) the National Institute of Environmental Health Sciences;

(ii) the Centers for Disease Control and Prevention;

(iii) the National Toxicology Program;

(iv) the National Cancer Institute; and

(v) the National EPA-Tribal Science Council; and

(B) ensure that no individual appointed to serve on the Board has a conflict of interest that is relevant to the functions to be performed, unless—

(i) the individual promptly and publicly discloses the conflict; and

(ii) the Administrator determines that the conflict is unavoidable.

(3) PURPOSE.—The purpose of the Board shall be to provide independent advice and peer review to Congress and the Administrator on the scientific and technical aspects of issues relating to the implementation of this title with respect to minimizing the use of animals in testing chemical substances or mixtures.

(4) APPLICABLE LAW.—The Board shall be subject to subchapter II of chapter 5, and chapter 7, of title 5, United States Code (commonly known as the 'Administrative Procedure Act').

(5) REPORT.—Not later than 1 year after the date of enactment of the Safe Chemicals Act of 2011, and every 3 years thereafter, the Administrator, in consultation with the Board, shall publish in the Federal Register a list of testing methods that reduce the use of animals in testing under section 4.

(c) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not animal-based, the Administrator shall—

(1) in consultation with the Board, and after providing an opportunity for public comment, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information used for safety standard determinations under section 6(b) that do not use animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

(2) beginning on the date that is 2 years after the date of enactment of the Safe Chemicals Act of 2011 and every 2 years thereafter, submit to Congress a report that describes the progress made in implementing this section; and

(3) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that are not animal-based for use in safety standard determinations under section 6(b).

(d) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct animal-based testing of a chemical substance or mixture under this title, the Administrator may adapt or waive the animal testing requirement if the Administrator determines that—

(1) there is a sufficient weight of evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property, in any case in which the information from each individual source alone is regarded as insufficient to support the conclusion;

(2) because of 1 or more physical or chemical properties of the chemical substance or mixture, testing for a specific endpoint is technically not practicable to conduct; or

(3) a chemical substance or mixture cannot be tested in animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as potential to cause severe corrosion or severe irritation to tissues.

SEC. 31. SAFER ALTERNATIVES AND GREEN CHEMISTRY AND ENGINEERING.

(a) SAFER ALTERNATIVES PROGRAM.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall establish a program to create market incentives for the development of safer alternatives to existing chemical substances that reduce or avoid the use and generation of hazardous substances.

(2) REQUIREMENTS.—The program established under paragraph (1) shall include—

(A) expedited review of new chemical substances for which the manufacturer or processor submits an alternatives analysis indicating that the new chemical sub-

stance is the safer alternative for a particular use than existing chemical substances used for the same purpose;

(B) recognition for a chemical substance or product determined by the Administrator to be a safer alternative for a particular use by means of a special designation intended for use in marketing the safer alternative, and periodic public awards or rewards; and

(C) such other incentives, as the Administrator considers to be appropriate to encourage the development, marketing, and use of chemical substances or products determined by the Administrator to be safer alternatives for the particular uses, such as job training and worker assistance.

(b) GREEN CHEMISTRY RESEARCH NETWORK.—The Administrator shall establish a network of not less than 4 green chemistry and engineering centers, located in various regions of the United States, to support the development and adoption of safer alternatives to chemical substances, particularly chemical substances listed under section 6(a).

(c) GREEN CHEMISTRY AND ENGINEERING RESEARCH GRANTS.—The Administrator shall make grants to promote and support the research, development, and adoption of safer alternatives to hazardous substances.

(d) GREEN CHEMISTRY WORKFORCE EDUCATION AND TRAINING PROGRAM.—

(1) IN GENERAL.—The Administrator shall establish a program to facilitate the development of a workforce, including industrial and scientific workers, that produces safer alternatives to existing chemical substances.

(2) GOALS.—The goals of the program established under paragraph (1) are to provide workforce training on skills that would—

(A) facilitate the expansion of green chemistry;

(B) develop scientific and technical leadership in green chemistry;

(C) facilitate the successful and safe integration of green chemistry into infrastructure projects;

(D) inform and engage communities about green chemistry; and

(E) promote innovation and strong public health and environmental protections.

(3) IMPLEMENTATION.—The Administrator shall implement the program to achieve the goals of this Act, including by—

(A) helping to develop a broad range of skills relevant to the production and use of the safer alternatives, including the design, manufacturing, use, and disposal of the alternatives;

(B) offering to develop partnerships with educational institutions, training organizations, private sector companies, and community organizations; and

(C) providing grants to States, units of local government, and the partnerships developed under subparagraph (B) to promote and support activities consistent with achieving the goals of the program established under this subsection.

SEC. 32. COOPERATION WITH INTERNATIONAL EFFORTS.

In cooperation with the Secretary of State and the head of any other appropriate Federal agency (as determined by the Administrator), the Administrator shall cooperate with international efforts as appropriate—

(1) to develop a common protocol or electronic database relating to chemical substances; or

(2) to develop safer alternatives for chemical substances.

SEC. 33. RELIABLE INFORMATION AND ADVICE.

Not later than 18 months after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall, by order, establish and implement procedures to ensure data reliability including, at a minimum, requirements that the Administrator—

(1) not less than annually randomly inspect laboratories that develop the data required under this title on the various properties and characteristics of a chemical substance;

(2) annually perform a comprehensive data audit on a subset, as chosen by the Administrator, of the data submissions under this title;

(3) establish and maintain a registry of all health- and safety-related studies initiated in response to requirements under this title;

(4) have access to all records of health- and safety-related studies initiated in response to requirements under this title; and

(5) require the submitter of any research study conducted by a third party in response to requirements under this title to disclose to the Administrator and the public, at the time of submission, the sources of any funding used for the conduct or publication of the study received by the researchers who conducted the study.

SEC. 34. HOT SPOTS.

(a) DEFINITIONS.—In this section:

(1) DISPROPORTIONATE EXPOSURE.—The term 'disproportionate exposure' means residential population exposure to 1 or more toxic chemical substances or mixtures at levels that are significantly greater than the average exposure in the United States, as defined and identified by the Administrator in accordance with the criteria established under subsection (b).

(2) LOCALITY.—The term 'locality' means any geographical area (including a county, city, town, neighborhood, census tract, zip code area, or other commonly understood political or geographical subdivision) in which the Administrator identifies disproportionate exposure.

(b) CRITERIA.—Not later than 180 days after the date of enactment of the Safe Chemicals Act of 2011, the Administrator shall promulgate a rule to establish criteria consistent with this section that—

(1) defines disproportionate exposure; and

(2) identifies any locality that is disproportionately exposed.

(c) IDENTIFICATION.—

(1) IN GENERAL.—Not later than 120 days after the date on which the rule is promulgated under subsection (b), the Admin-

istrator shall identify localities in the United States that are subject to disproportionate exposure.

(2) USE OF DATA.—In identifying localities under paragraph (1), the Administrator—

(A) shall use data contained in the National Air Toxic Assessment Database; and

(B) may use other data available to the Administrator, including data developed under—

(i) the Safe Drinking Water Act (42 U.S.C. 300f et seq.);

(ii) the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.);

(iii) the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601 et seq.); and

(iv) the Emergency Planning and Community Right-to-Know Act of 1986 (42 U.S.C. 11001 et seq.).

(3) PUBLIC PARTICIPATION.—The Administrator shall provide an opportunity for members of the public to nominate localities in which disproportionate exposure may be found for inclusion in the identification of localities under paragraph (1).

(d) LOCALITY LIST.—

(1) IN GENERAL.—Not later than 180 days after completing the identification of localities under subsection (c)(1), the Administrator, after notice and consultation with applicable State, local, county health, and environmental officials, State, local, and county legislators, and other elected officials, shall—

(A) publish a list of the localities subject to disproportionate exposure identified under that subsection in the Federal Register; and

(B) make the list published under subparagraph (A) available electronically.

(2) UPDATED LIST.—

(A) IN GENERAL.—Subject to subparagraph (B), not later than 5 years after the date on which the list is published under paragraph (1)(A), and at least once every 5 years thereafter, the Administrator shall update and republish the list.

(B) DISCRETIONARY UPDATES.—The Administrator may update and republish the list under paragraph (1) more frequently than every 5 years—

(i) to add new localities that meet the criteria established under subsection (b); or

(ii) to remove localities, if the Administrator determines that the exposure reduction has been achieved and no further action is needed after actions are taken under subsection (f).

(C) NOTIFICATION.—The Administrator shall notify all applicable State, local, county health, and environmental officials, State, local, and county legislators, and other elected officials of the updated listing.

(e) NO JUDICIAL REVIEW; NONDISCRETIONARY DUTY.—

(1) NO JUDICIAL REVIEW.—The following actions under this section shall not be subject to judicial review:

(A) A decision to include on the list published under subsection (d)(1) a locality identified under subsection (c)(1).

(B) A decision in response to nominations submitted under subsection (c)(3).

(C) A decision to list localities under subsection (d)(1) or update the list under subsection (d)(2).

(2) NONDISCRETIONARY DUTY.—Notwithstanding paragraph (1), the failure of the Administrator to publish or update the list of localities in accordance with this section shall be—

(A) considered to be a failure to perform a nondiscretionary duty; and

(B) subject to judicial review.

(f) ACTION PLANS.—

(1) IN GENERAL.—Not later than 1 year after the date on which the list is published or updated under subsection (d), the Administrator shall develop and publish, for each locality identified on the list, an action plan that includes—

(A) an identification of the chemical substances and mixtures that contribute to the disproportionate exposure (including exposure levels, sources, and pathways); and

(B) a description of actions planned by the Administrator to reduce disproportionate exposure in the locality.

(2) GOALS.—The goal of each action plan under this subsection shall be to reduce disproportionate exposure in the locality by establishing—

(A) a percentage exposure reduction goal for each chemical substance and mixture; and

(B) a timeline to achieve the percentage exposure reduction goal.

(g) REPORT TO CONGRESS.—The Administrator shall—

(1) submit to Congress an annual report that identifies—

(A) each locality added to the list in the prior year under subsection (d);

(B) each action plan developed in the prior year under subsection (f); and

(C) the progress on each action plan to date; and

(2) make the report available to the public in electronic format.

SEC. 35. APPLICATION OF THIS ACT TO FEDERAL AGENCIES.

(a) IN GENERAL.—Except as provided in subsection (e), each Federal agency, and any officer, agent, or employee of a Federal agency, shall be subject to, and comply with, all applicable requirements of this Act described in subsection (b), both substantive and procedural, in the same manner, and to the same extent, as any person subject to the requirements.

(b) DESCRIPTION OF REQUIREMENTS.—The substantive and procedural requirements referred to in this subsection include—

(1) any administrative order;

(2) any civil or administrative penalty or fine, regardless of whether the penalty or fine is—

(A) punitive or coercive in nature; or

(B) imposed for isolated, intermittent, or continuing violations;

(3) any requirement for reporting;

(4) any provision for injunctive relief and sanctions that may be imposed by a court to enforce such relief; and

(5) payment of reasonable service charges.

(c) WAIVER OF IMMUNITY.—The United States expressly waives any immunity otherwise applicable to the United States with respect to any substantive or procedural requirement referred to under subsection (a).

(d) CIVIL PENALTIES.—No agent, employee, or officer of the United States shall be personally liable for any civil penalty under this title with respect to any act or omission within the scope of the official duties of the agent, employee, or officer.

(e) CRIMINAL SANCTIONS.—An agent, employee, or officer of the United States shall be subject to any criminal sanction (including any fine or imprisonment) under this Act, but no department, agency, or instrumentality of the executive, legislative, or judicial branch of the Federal Government shall be subject to such sanction.

(f) EXEMPTION.—

(1) IN GENERAL.—If the President determines it is in the paramount interest of the United States, the President may grant an exemption for any Federal agency from compliance with any requirement of this Act.

(2) LACK OF APPROPRIATION.—No exemption shall be granted under paragraph (1) due to lack of appropriation unless—

(A) the President has specifically requested the appropriation as a part of the budgetary process; and

(B) Congress has failed to make the requested appropriation available.

(3) PERIOD OF EXEMPTION.—Any exemption granted under paragraph (1) shall be for a period of not more than 1 year, but additional exemptions may be granted for periods not to exceed 1 year, if the President makes a subsequent determination that the exemption is in the paramount interest of the United States.

(4) REPORT.—Each January after the date of enactment of this section, the President shall submit to Congress a report that describes—

(A) all exemptions granted under this subsection during the preceding calendar year; and

(B) the reason for granting each exemption.

(g) ADMINISTRATIVE ENFORCEMENT ACTIONS.—

(1) IN GENERAL.—The Administrator may initiate an administrative enforcement action against any Federal agency—

(A) in accordance with the enforcement authorities of this Act; and

(B) in the same manner and under the same circumstances as an action would be initiated against another person.

(2) SETTLEMENT.—Any voluntary resolution or settlement of an administrative enforcement action initiated under this subsection shall be set forth in a consent order.

(3) FINALITY OF ADMINISTRATIVE ORDER.—No administrative order issued to a Federal department, agency, or instrumentality under this subsection shall become final until the Federal department, agency, or instrumentality has had the opportunity to confer with the Administrator.

SEC. 36. IMPLEMENTATION OF STOCKHOLM CONVENTION, THE LRTAP POPS PROTOCOL, AND THE ROTTERDAM CONVENTION.

(a) DEFINITIONS.—In this section:

(1) CHEMICAL.—The term 'chemical' includes any substance or mixture of substances, including a substance that is part of an article.

(2) LRTAP CONVENTION.—The term 'LRTAP Convention' means the Convention on Long-Range Transboundary Air Pollution, done at Geneva on November 13, 1979 (TIAS 10541), and any subsequent amendments to which the United States is a party.

(3) LRTAP POPS CHEMICAL.—The term 'LRTAP POPs chemical' means any chemical listed on any Annex of the LRTAP POPs Protocol, if such listing has entered into force for the United States.

(4) LRTAP POPS PROTOCOL.—The term 'LRTAP POPs Protocol' means the Protocol on Persistent Organic Pollutants to the LRTAP Convention, done at Aarhus on June 24, 1998, and any subsequent amendment to which the United States is a party.

(5) MEETING OF THE PARTIES.—The term 'meeting of the parties' means—

(A) the Conference of the Parties established by and operating under Article 19 of the Stockholm Convention;

(B) the Executive Body established by and operating under Article 10 of the LRTAP POPs Convention; and

(C) the Conference of the Parties established by and operating under Article 18 of the Rotterdam Convention.

(6) PIC CHEMICAL.—The term 'PIC chemical' means any chemical identified by notification to the Secretariat of the Rotterdam Convention by the United States as banned or severely restricted in the United States, and any chemical listed on any Annex of the Rotterdam Convention, if such listing has entered into force for the United States.

(7) POPS CHEMICAL.—The term 'POPs chemical' means any chemical that is listed on any Annex of the Stockholm Convention, if such listing has entered into force for the United States.

(8) ROTTERDAM CONVENTION.—The term 'Rotterdam Convention' means the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, done at Rotterdam on September 10, 1998, and any subsequent amendment to which the United States is a party.

(9) STOCKHOLM CONVENTION.—The term 'Stockholm Convention' means the Stockholm Convention on Persistent Organic Pollutants, done at Stockholm on May 22, 2001, and any subsequent amendment to which the United States is a party.

(b) IMPLEMENTATION OF INTERNATIONAL AGREEMENTS.—

(1) IN GENERAL.—The Administrator, in cooperation with appropriate Federal agencies, shall implement and support the implementation by the United States of the provisions of the Stockholm Convention, the LRTAP POPs Protocol, and the Rotterdam Convention that have entered into effect for the United States.

(2) PROHIBITIONS.—Notwithstanding any other provision of law, no person may manufacture, process, distribute in commerce, use, dispose of, or take any other action with respect to a POPs chemical, LRTAP POPs chemical, or PIC chemical in a manner inconsistent with applicable obligations for that chemical under the Stockholm Convention, LRTAP POPs Protocol, or Rotterdam Convention.

(3) PUBLIC NOTICE AND COMMENT.—

(A) IN GENERAL.—The Administrator shall provide timely public notice and opportunity to comment on a chemical proposed for listing to any Annex to the Stockholm Convention, the LRTAP POPs Protocol, or the Rotterdam Convention.

(B) CONTENTS.—The Administrator shall identify in the notice under subparagraph (A) any relevant toxicity, exposure, and risk information on the chemical known to the Administrator, and any domestic activities involving the chemical known to the Administrator.

(C) NOTICE AND COMMENT.—

(i) IN GENERAL.—Any interested person may provide relevant comment and information on the chemical in response to the notice under subparagraph (A).

(ii) REQUEST FOR INFORMATION.—The Administrator may require the provision of relevant information related to a proposed chemical from any person, as the Administrator determines necessary to assist the United States in the review.

(iii) PUBLIC DOCKET.—The Administrator shall consider all comments and information received under this subparagraph in the review of the proposal and include the comments and information in an established public docket.

(D) POST-RECOMMENDATION.—

(i) IN GENERAL.—The Administrator shall provide timely public notice and opportunity to comment after a recommendation is made to list a chemical on any Annex to the Stockholm Convention, the LRTAP POPs Protocol, or the Rotterdam Convention.

(ii) MEETING OF THE PARTIES.—The Administrator shall provide the notice under clause (i) in advance of the meeting of the Parties at which the recommendation is to be considered.

(iii) REQUEST FOR INFORMATION.—The Administrator shall request comment and information on all aspects of the recommendation and may, if the Administrator determines it to be necessary to assist the United States in the review, require the provision of relevant information related to a proposed chemical from any person.

(iv) PUBLIC DOCKET.—The Administrator shall consider all comments and information received under this subparagraph in the review of the proposal and include the comments and information in an established public docket.

(E) DECISIONS.—

(i) IN GENERAL.—Not later than 30 days after a decision by the meeting of the parties, the Administrator shall provide timely public notice and opportunity to comment on any decision by the meeting of the parties to list a chemical on any Annex to the Stockholm Convention.

(ii) CONTENTS.—The Administrator shall provide in the notice under clause (i) a description of the amendments to the instruments and identify the changes to the domestic activities that the Administrator believes, based on information available to the Administrator, would be necessary if the United States chose to be bound by the listing decision.

(iii) PUBLIC COMMENT.—Any interested person may provide relevant comment and information in response to the notice under clause (i).

(iv) PUBLIC DOCKET.—The Administrator shall consider all comments and information received under this subparagraph in the review of the proposal and include the comments and information in an established public docket.

(F) RATIFICATION.—Not later than 30 days after the United States deposits the instrument of ratification for the Stockholm Convention, the LRTAP POPs Protocol, or the Rotterdam Convention, or not later than 30 days after the listing of any chemical subsequently added under those instruments has entered into force for the United States (whichever date is earlier), the Administrator—

(i) shall provide public notice of—

(I) the chemicals that are subject to those instruments; and

(II) any chemical subsequently added under those instruments; and

(ii) may specify the requirements that are applicable for individual chemicals in a public notice under this subparagraph.

(4) GENERAL RULEMAKING AUTHORITY.—The Administrator may promulgate regulations necessary to carry out the Stockholm Convention, the LRTAP POPs Protocol, or the Rotterdam Convention, or to ensure compliance with any obligations under such instruments.

(5) OBLIGATIONS.—If a chemical is subject to obligations under more than 1 of the instruments that includes the Stockholm Convention, the LRTAP POPs Protocol, or the Rotterdam Convention, the most stringent of the obligations shall apply to ensure compliance with each of the instruments.

(c) ENFORCEMENT.—The prohibitions and any other requirements of this section shall be enforced in the same manner as final rules or orders under section 6.

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TITLE I—CONTROL OF TOXIC SUBSTANCES

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SEC. [30]*37.* ANNUAL REPORT.

The Administrator shall prepare and submit to the President and the Congress on or before January 1, 1978, and on or before January 1 of each succeeding year a comprehensive report on the administration of this Act during the preceding fiscal year. Such report shall include—

(1) a list of the testing required under section 4 during the year for which the report is made and an estimate of the costs incurred during such year by the persons required to perform such tests;

(2) the number of notices received during such year under section 5, the number of such notices received during such year under such section for chemical substances subject to a section 4 rule, and a summary of any action taken during such year under section 5(g);

(3) a list of rules issued during such year under section 6;

(4) a list, with a brief statement of the issues, of completed or pending judicial actions under this Act and administrative actions under section 16 during such year;

(5) a summary of major problems encountered in the administration of this Act; and

(6) such recommendations for additional legislation as the Administrator deems necessary to carry out the purposes of this Act.

[SEC. 31. EFFECTIVE DATE.

[Except as provided in section 4(f), this Act shall take effect on January 1, 1977.]

[SEC. [29]*38.* AUTHORIZATION FOR APPROPRIATIONS.

[There are authorized to be appropriated to the Administrator for purposes of carrying out this Act (other than sections 27 and 28 and subsections (a) and (c) through (g) of section 10 thereof) $10,100,000 for the fiscal year ending September 30, 1977, $58,646,000 for the fiscal year 1982 and $62,000,000 for the fiscal year 1983. No part of the funds appropriated under this section may be used to construct any research laboratories.]

SEC. 38. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to the Administrator to carry out this Act such sums as are necessary for each of fiscal years 2011 through 2018.

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