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FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21ST CENTURY ACT

JUNE 18, 2015.—Ordered to be printed

Mr. INHOFE, from the Committee on Environment and Public
Works, submitted the following

R E P O R T

together with

MINORITY VIEWS

[To accompany S. 697]

[Including cost estimate of the Congressional Budget Office]

The Committee on Environment and Public Works, to which was referred the bill (S. 697) to amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends the bill, as amended, do pass.

GENERAL STATEMENT AND BACKGROUND

S. 697, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, amends the Toxic Substances Control Act (TSCA), the fundamental Federal law regulating the manufacture, processing, distribution in commerce, use and disposal of chemical substances.

The Act is named for the late Frank R. Lautenberg, the Senate's long time champion for effective reform of TSCA in order to protect against risks to human health and the environment. Before 2012, Senator Lautenberg (D-NJ) had introduced TSCA reform legislation in five consecutive Congresses. Beginning in early 2013, Senator Lautenberg worked closely with Senator David Vitter (R-LA) to craft the Chemical Safety Improvement Act (CSIA), which was introduced in May, 2013 (S. 1009). The bill represented the very

first bi-partisan TSCA reform proposal, and garnered the support of 26 additional members of the Senate. Sadly, Senator Lautenberg passed away shortly after S. 1009 was introduced. Although the Committee held a hearing on general TSCA reform with discussions of S. 1009, no further action on the bill was taken before the 113th Congress adjourned.

Following Senator Lautenberg's death, Senator Tom Udall (D-NM) stepped in to fill the late Senator's leadership role working to pass bipartisan TSCA reform. Senators Udall and Vitter introduced a modified version of S. 1009 on March 10, 2015, which reflected over a year of negotiations and building upon the original CSIA. The new bill, S. 697, contains many important enhancements to the framework first negotiated by Senators Lautenberg and Vitter.

On April 28, 2015, the Committee held a business meeting on S. 697. The Committee adopted an amendment in the nature of a substitute offered by Senator Vitter that won the support of Senators Whitehouse (D-RI), Merkley (D-OR), Booker (D-NJ) and Carper (D-DE). The substitute reflects additional modifications to the bill intended to address the concerns of stakeholders in several key areas. The bi-partisan substitute marks an important milestone in TSCA reform, and reflects the spirit of compromise that Frank Lautenberg championed during his tenure in the Senate.

TSCA (Pub.L. 94-469, 90 Stat. 2004, 15 U.S.C. 2601 *et seq.*) was enacted in 1976. TSCA gives EPA the authority to review new chemicals before they are manufactured, to gather information on existing chemicals in commerce, and to regulate unreasonable risks to health and the environment from the manufacture, processing, distribution in commerce, use or disposal of chemical substances. TSCA is one of many statutes that regulate chemicals; its unique focus is on industrial chemicals in commerce. TSCA does not give EPA the authority to regulate pesticides; food, drugs and cosmetics; nuclear materials, firearms and ammunition, or tobacco.

In the years since TSCA was first enacted, it has become clear that effective implementation of TSCA by the Environmental Protection Agency (EPA) has been challenged by shortcomings in the statute itself, and by several key decisions of Federal Courts and the Agency's interpretation of those decisions. S. 697, as reported by the Committee, is intended to enhance confidence in the federal chemical regulatory system, provide EPA the authority necessary for efficient and effective regulation of chemical risks, and foster safety and innovation in commercial chemistry. Importantly, S. 697 is designed to ensure that the competitive advantage of the U.S. chemical industry is not eroded by regulatory mandates and that industry is subject to a more consistent set of regulations that equally protect citizens across the nation.

S. 697 is intended to address significant concerns about the existing provisions of TSCA and its implementation.

Testing of chemical substances and mixtures

Section 4 of TSCA provides EPA the authority to require manufacturers to test chemicals, but requires EPA to justify a testing requirement based on either a finding that the substance may present an unreasonable risk of injury to health or the environment, or that the production of a substantial quantity of the substance may create exposures to humans or the environment. EPA

can require testing through test rules or through enforceable consent agreements (ECAs).

Concern has been raised that EPA's decisions to require testing must be supported by an a priori finding that is often difficult to make in the absence of the information that testing would provide. EPA has succeeded in requiring the testing under section 4 of only about 200 chemicals in TSCA's almost 40 years. In addition, the existing TSCA rulemaking process can place a significant burden on EPA, and test rules can sometimes take many years to complete. When EPA has proposed TSCA test rules, EPA has sometimes required testing based on a "checklist," rather than identifying specific information needs to inform what testing is required.

Manufacturing and processing notices

A new chemical (not on the TSCA inventory) cannot be manufactured in or imported to the U.S. without EPA review under TSCA section 5. The section also provides EPA authority to identify and review significant new uses of a chemical substance. Companies must first submit a pre-manufacture notice (PMN) and EPA must review the PMN. Current law gives the Agency the authority to deny a PMN and prevent the substance from moving into commerce. The PMN must include information on chemical identity, anticipated production volumes, intended categories of use, molecular formula and any available test data on that chemical. EPA uses this information to develop hazard and exposure/release profiles for the chemical which are based on both actual data on the notified chemical, as well as data from other structurally similar chemicals and information derived from computer modeling. EPA can determine that more testing is needed to complete its review, allow manufacture to commence with restrictions, or not allow manufacture to commence. Once manufacture commences, a chemical is added to the TSCA Inventory only after the manufacturer files a "Notice of Commencement" with EPA. At that point, other companies may manufacture, process or use the chemical without prior notification unless EPA has designated such activity as a significant new use requiring such notification.

Despite the completion of many reviews of new chemicals under section 5, concerns have been raised that it does not require EPA to make an affirmative finding that a new chemical or a significant new use is not likely to present an unreasonable risk. EPA's test rule authority constrains the Agency's ability to mandate new testing when necessary to support review of a new chemical or significant new use.

Regulation of hazardous chemical substances and mixtures

Section 6 of TSCA provides EPA broad authority to regulate existing chemicals. Based on an EPA finding that a chemical substance or mixture "presents or will present an unreasonable risk of injury to health or the environment," EPA can impose a variety of risk management measures, including use restrictions, limitations on production volumes, warning labels, recordkeeping or product or disposal bans. When EPA chooses to impose restrictions under Section 6, it must use the "least burdensome" requirements.

EPA must apply its section 6 authority through rulemaking. In applying the unreasonable risk standard, EPA must consider a va-

riety of risk-related and cost/benefit factors including: the effects of a substance on health and the magnitude of exposure of humans; the effects of a substance on the environment and the magnitude of exposure of the environment; the benefits of the substance for various uses and the availability of substitutes for such uses; and the reasonably ascertainable economic consequences of the rule, after considering the effect on the national economy, small business, technological innovation, the environment and public health.

Between 1978 and 1990, EPA successfully used Section 6 to regulate specific uses of the following chemical substances: halogenated chlorofluoroalkanes; TCDD; three new chemical substances used in metalworking fluids; and hexavalent chromium. None of these rulemakings were judicially challenged. In contrast to these rulemakings, EPA's regulation to ban asbestos from most products through a TSCA section 6(a) rule was much broader in scope and was challenged in *Corrosion Proof Fittings et al. v. U.S. EPA*. The Fifth Circuit Court of Appeals decision in this case struck down the asbestos rule, in part because of "the agency's reliance upon flawed methodology and its failure to consider factors and alternatives that TSCA explicitly requires it to consider." Despite direction from the court, EPA did not re-propose its rulemaking on asbestos and EPA has never used Section 6 since that decision.

Substantial stakeholder attention has been focused on the shortcomings in section 6, and S. 697 attempts to address these concerns. EPA's application of the "unreasonable risk" standard for regulatory action has been hampered by the statutory language itself, which suggests that cost and benefit considerations must be applied to the Agency's decisions on the health and environmental risks posed by a chemical substance. The requirement that EPA choose the "least burdensome" regulatory control for a chemical substance has been viewed as a requirement that EPA assess the costs and burdens of all possible regulatory and chemical options. Further, there is no requirement in section 6 that EPA systematically assess existing chemicals in commerce, and no direction to the Agency on how the Agency identifies what chemical substances warrant assessment.

Reporting and retention of information

Section 8 is the information gathering and reporting section of TSCA. Under the section, EPA can require companies to submit information on categories of use, quantities, by-products, and health and environmental effects of chemicals, and has used this authority to require periodic updating of chemicals on the TSCA Inventory that meet certain production volume thresholds. The section also requires EPA to compile and maintain the TSCA Inventory, which represents all chemicals commercialized under TSCA since its inception. Some chemicals may no longer be in commerce but continue to be listed on the Inventory.

The section also requires companies to record and retain allegations of significant adverse reactions to any substances; to submit, where requested by rule, lists/copies of ongoing and completed, or unpublished health and safety studies; and to immediately report information—not otherwise available to EPA—which reasonably supports the conclusion that a chemical presents a "substantial risk" to health or the environment.

Several aspects of Section 8 have been the subject of stakeholder concerns. The TSCA Inventory does not accurately reflect the number of chemicals actually in commerce, as it is a historical database containing those substances “grandfathered” into TSCA in 1979 (when EPA established the Inventory by rule) and those substances added to the Inventory after the pre-manufacturing review process. Additionally, some of the substances on the Inventory are the subject of confidentiality claims that have not been systematically reviewed by the Agency.

Disclosure of data

Section 14 of TSCA provides an affirmative, broad statement of protection from disclosure for information qualifying under the section 552(b)(4) exemption of the Freedom of Information Act (FOIA), i.e., “trade secrets and commercial or financial information obtained from a person and privileged or confidential.” Generally, EPA cannot disclose confidential business information (CBI), and where disclosure is allowed, the Agency must follow procedures designed to protect the submitter’s rights, such as advance written notice to the submitter. Section 14 does specifically permit EPA to release CBI to U.S. government employees in connection with their official duties to protect health or environment or for law enforcement purposes, to Federal contractors for work related to TSCA, when necessary to protect health or the environment from unreasonable risk of injury, or when relevant in a court proceeding under TSCA.

Section 14 also provides that the broad protection afforded CBI does not prohibit the disclosure of health and safety information in studies related a chemical or mixture that is in commercial distribution, that is the subject of a TSCA section 4 test rule, or is subject to a PMN or a significant new use notice (SNUN) requirement under section 5. Nothing in the section authorizes EPA to release any data that would disclose processes used in the manufacturing or processing of a chemical or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemicals in the mixture.

Section 14 and EPA’s implementation of it has been criticized by some for failing to require a systematic review of confidentiality claims, or up-front substantiation of confidentiality claims. Lacking any mechanism for review by EPA or for companies to declassify past CBI claims that are no longer needed, stakeholders have indicated a concern that there is an over-abundance of CBI claims, some of which may not be legitimate. Concern has also been raised that TSCA does not authorize EPA to share CBI with State governments or other professionals such as first responders, who may need access to it in the performance of their duties.

Preemption

TSCA Section 18 recognizes that States can have a role in regulating chemicals, and preempts State action only when EPA has acted on a chemical through a rule or order under TSCA. Under the section, new and existing State requirements on a chemical substance can be established or continue in effect if they are identical to the EPA requirement, if they are adopted under the authority of the Clean Air Act or any other federal law, or if they prohibit

the use of such substance or mixture in such State or political subdivision. Upon application of a State or political subdivision of a State, EPA can waive the preemptive effect of an EPA rule or order on State action, if 1) compliance with an action taken under State law would not cause violations of the EPA rule or order and 2) the State action provides a significantly higher level of protection from risk and does not unduly burden interstate commerce.

Some stakeholders have raised concern that TSCA has not fostered a robust Federal chemical regulatory system, which has resulted in a number of States becoming more active on chemical regulatory matters. In their view, a proliferation of different State requirements will create confusion for the general public, and significantly increase the cost and burden of regulatory compliance for chemical manufacturers, importers and users while failing to apply any protections to more than a relatively small number of citizens. Others have expressed concern that States not be constrained in their ability to protect health and the environment, particularly when state or local conditions associated with chemical substances subject to TSCA raise potential concerns. These stakeholders also point out that actions by even one state can affect products nationwide.

Administration

Section 26 of TSCA authorizes EPA to require the payment of a reasonable fee from any person required to submit data under sections 4 or 5. The fee is capped at \$2,500, or in the case of a small business, \$100. To date, EPA has established a fee only for the submittal of pre-manufacturing notices under section 5. In FY2014, EPA generated approximately \$1.1 million in fee revenue under this requirement. This revenue is directed to the general treasury, not directly to EPA.

All stakeholders have indicated an interest in ensuring that EPA has the resources necessary to implement a robust chemical regulatory system, including prioritization screening, safety assessments and determinations, and regulation of new and existing chemical substances where required to manage risks to health and the environment.

OBJECTIVES OF THE LEGISLATION

S. 697 would reauthorize and modernize the Toxic Substances Control Act (TSCA).

SECTION-BY-SECTION ANALYSIS

Section 1. Short title

Names S. 697 as the “Frank R. Lautenberg Chemical Safety for the 21st Century Act.” The late Senator Frank Lautenberg was an ardent proponent of modifications to TSCA during his lifetime.

Section 2. Findings, policy and intent

Section 2 of S. 697 amends Section 2 of TSCA in several respects to make clear Congressional intent for reforming TSCA to provide broad protection of human health and the environment, to improve availability of information about chemicals, and to clarify that

nothing in the bill is intended to affect common law rights and remedies.

S. 697 does not amend TSCA's existing policy provisions in Section 2(b), indicating the Committees intent to leave intact existing TSCA policy relating to the need for adequate data about chemicals, adequate authority to regulate chemicals that present an unreasonable risk, and the exercise of EPA's authority in a manner that does not create unnecessary economic barriers to technological innovation.

Section 3. Definitions

Section 3 of S. 697 incorporates several new definitions in TSCA. Definitions of "conditions of use," "potentially exposed or susceptible population", "safety assessment," "safety determination" and "safety standard" are included in the bill. S. 697 does not change other existing TSCA definitions, such as the definition of a "processor" or what is defined as or specifically excluded from the definition of a "chemical substance."

Further, S. 697 as approved by the Committee reverts to the term "injury" when used in the context of unreasonable risk, instead of the term "harm" as in the bill as introduced. This change ensures that other provisions of TSCA not amended by S. 697 require no conforming change. The Committee intends no modification of EPA's interpretation of the term "injury".

"Conditions of Use" is a term used throughout S. 697 to describe the context in which EPA will apply the safety standard in safety assessments and determinations. The term means the "intended, known, or reasonably foreseeable circumstances" under which a chemical substance is manufactured, processed, distributed in commerce, used or disposed of. The term is not intended to include "intentional misuse" of chemicals.

"Potentially exposed or susceptible population" is defined as "1 or more groups of individuals" in the general population who may be "differentially exposed" to a chemical under the conditions or use, or "susceptible to greater adverse health consequences" from chemical exposures than the general population. The definition makes clear that when identified by EPA, it may include groups such as infants, children, pregnant women, workers and the elderly. The term is used in the definition of "safety standard" to make clear that in applying the standard to a population, the population must be "relevant" to the safety assessment and determination for the substance, and that identified risks specific to such populations must be addressed.

In the context of safety assessments and determinations, if conditions of use suggest differential exposures to one or more groups of individuals or the conditions of use impact individuals who are more susceptible, EPA must take those exposures into account and establish risk management measures necessary and sufficient to protect those populations. Importantly, the definition does not mean that in applying the safety standard, EPA is required to protect each susceptible "individual" in the population or groups of individuals in all safety assessments and determinations. Rather, in safety assessments and determinations in which a population is relevant, the Administrator is to protect that population as well as the population as a whole from "unreasonable risk."

“Safety assessment” means an assessment of the risk posed by a chemical substance under the conditions of use, integrating hazard, use and exposure information about the chemical. Under S. 697, the safety assessment must precede EPA’s safety determination.

“Safety Determination” means an EPA determination as to whether a chemical substance meets the safety standard under the conditions of use. Under S. 697, if EPA makes a determination that a chemical substance does not meet the safety standard, the Agency must establish risk management measures, by rule, that ensure the safety standard is met under the conditions of use.

“Safety Standard” means “a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of injury to health or the environment will result from exposure to a chemical substance under the conditions of use . . .” This standard uses the same term as in current TSCA, but makes an important change to ensure that the standard including its reference to unreasonable risk, is to be applied by EPA without regard to cost or other non-risk factors. Furthermore, other relevant references to the term in the legislation and throughout TSCA were modified to make clear that when the term “unreasonable risk” is used, the term is to be applied without taking into account cost and other non-risk factors. This modification addresses one of the key criticisms of TSCA. The definition also makes clear that the safety standard applies to specific “conditions of use” identified by EPA. The standard is intended to ensure that EPA protects against unreasonable risks of injury to the general population as well as any potentially exposed or susceptible population that EPA has identified as “relevant” to the safety assessment and determination for the chemical.

Section 4. Policies, procedures and guidance

Section 4 of S. 697 creates a new Section 3A in TSCA. The section requires EPA to develop any necessary policies, procedures, and guidance, not later than two years after enactment. In order to ensure that EPA can quickly implement the Act, existing policies, procedures and guidance can continue to be used as the new ones are developed and are to be integrated into them to the maximum extent practicable. EPA is to review its policies, procedures and guidance every five years, and to update them to reflect emerging science. Policies, procedures and guidance are to address testing, prioritization screening, review of new chemicals and significant new uses, safety assessments and determinations, as well as use of science in making these decisions, including policies aimed at reducing animal testing. The section also establishes a new Scientific Advisory Committee on Chemicals to provide EPA independent scientific advice. The section makes clear the Committee’s intent that EPA’s policies, procedures and guidance should reflect the best available science and be transparent to the public.

It is the Committee’s intent that decision-making under TSCA be “consistent with the best available science.” The science EPA relies on to make safety determinations should describe and document any assumptions and methods used, and should address variability, uncertainty, the degree of independent verification and peer review. The section also requires that decisions be based on the

weight of the scientific evidence, by which the Committee intends that EPA consider all information in a systematic and integrative framework to consider the relevance of different information. The Committee believes there is significant value, where available and appropriate, in EPA's use of peer reviewed information, standardized test design and methods, consistent data evaluation procedures and good laboratory practices to ensure transparent, understandable, and reproducible chemical reviews. EPA guidance should also address transparency about the sources of funding for generation and assessment of information and, if appropriate, consideration of recommendations from NAS reports. The section is intended to ensure that EPA safety assessments and determinations are clear to the public, and based on credible, reliable scientific information.

The section also requires EPA to consider reasonably available information about potential hazards and exposures of a chemical substance under the conditions of use when making decisions under TSCA. The bill gives EPA the authority to require testing when needed to ensure decisions are based on sufficient information. The Committee intends that EPA systematically search for and identify relevant information that is available to inform safety assessments and determinations, both to minimize the potential for duplicative testing and unnecessary animal testing. The information EPA considers in its decision-making and the quality of that information is critical to giving the public greater confidence in EPA decisions.

The section also clarifies that EPA mandates for the generation of new information relevant to safety assessments and determinations must be science-based and driven by the need for the information. EPA is to specifically address exposure potential as a factor in decisions to require new testing.

The existing provisions of TSCA do not require EPA to systematically assess and determine the safety of priority chemicals. Consequently, there are relatively few EPA policies and procedures in place to address the safety assessment, safety determination and rulemaking requirements of Section 6. It is the Committee's intention that EPA rely on existing processes, such as those established under the Agency's TSCA Work Plan Chemical program, to manage the process as new policies and procedures are developed.

The Committee believes strongly that public confidence in the federal chemical regulatory system will be enhanced with improved public access to, and an understanding of, the information on which EPA bases its safety assessments and determinations. Under this section, EPA is required to make available to the public a nontechnical summary of each safety assessment and safety determination, to provide the public an opportunity to comment on the proposed assessment and safety determination, and to list the studies EPA considered and the policies and procedures EPA followed in the safety assessment and determination. EPA is also to describe the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the conditions of use will be considered, and explain the basis for that consideration in the final safety assessment.

The section also establishes a new Science Advisory Committee on Chemicals. The new advisory committee is intended to provide

EPA independent advice on the scientific and technical aspects of implementation. The advisory committee is subject to the requirements of the Federal Advisory Committee Act to ensure transparency, balance and public access to its deliberations. The Committee intends that the advisory committee represent a broad range of scientific expertise and interests including individuals with scientific expertise in public health and industry.

Section 5: Testing of chemical substances or mixtures

Section 5 of S. 697 amends section 4 of TSCA. The amendments provide EPA with broad authority to obtain new information on chemical substances at all stages of the safety review and evaluation process (for new chemicals; in limited circumstances for prioritization; for safety assessments and safety determinations of existing chemicals; and for any necessary risk management rule-making) and for export notification purposes.

The amendments address two significant shortcomings identified in TSCA: The requirement that testing be conducted only through rulemaking; and the “Catch-22” that EPA must first make a finding of potential “unreasonable risk” or substantial production and release or exposure before it can require testing by manufacturers or processors. Under the section, EPA can mandate new testing by rule, order and consent agreement. It is the Committee’s intent that EPA use its authority to require the development of new information judiciously, and only when needed to implement key provisions of the Act.

In order to avoid duplicative testing, the section allows one company to conduct toxicity testing on behalf of other companies and to obtain fair and equitable reimbursement for developing the data. The bill also clarifies language regarding the reimbursement period for such testing.

The section makes clear that the EPA may not establish minimum information requirements for all chemicals. It is the Committee’s expectations that testing requirements will be tailored to the nature of the chemical substances, hazards, exposures and conditions of use under consideration in the review and evaluation process.

For many years, the Committee has supported efforts to reduce the unnecessary use of animals in chemical testing. S. 697 includes extensive provisions by which EPA is to minimize the use of animals in testing chemicals under TSCA. EPA is to consider integrated testing strategies, greater efficiencies in testing through category approaches and formation of consortia, tiered testing and assessment strategies, and alternative testing methods, among others. Importantly, EPA is to develop a strategic plan to promote the development and implementation of reliable alternative test methods to reduce, refine, or replace the use of laboratory animals. The Committee takes note that EPA’s Office of Research and Development (ORD) has and is developing non-animal screening tests (including the use of computational toxicology), and continues work on application of those methodologies in chemical risk assessment.

The Committee recognizes that in some cases, suitable alternatives for animal tests are not currently available. The Committee believes, however, that where scientifically reliable alternatives exist that will generate equivalent information, EPA can request,

and in some cases should require, a non-animal test to first be used. The Committee does not intend to require manufacturers or processors to shoulder duplicative test burdens; EPA should look to the use of non-animal tests that provide reliable, high quality information that can replace or supplement animal tests. The testing requirements reflect the Committee's interest in assuring that the development of new information under a modernized TSCA should be consistent with best available science, and as informative, efficient and cost effective as possible.

Section 5 requires that voluntary testing conducted for TSCA purposes be first attempted using an alternative or non-animal test method or approach that the Administrator has determined to be scientifically reliable, relevant, and capable of providing information equivalent to that produced by a test using animals. The Committee expects EPA to be diligent in developing a list of approved non-animal test methods and strategies. The provision makes clear that the requirement does not prohibit the use of an animal test for purposes other than voluntary testing for TSCA purposes, or for subsequent tests conducted for TSCA purposes.

Section 6. Prioritization screening.

Section 6 of S. 697 creates a new section 4A in TSCA. The section requires EPA to establish a risk-based prioritization screening process, by rule, within one year of enactment. Under the prioritization screening process, EPA is to designate substances as high- or low-priority for safety assessment and determination. This section establishes a process that assures every chemical in commerce is subject to a systematic review by EPA through the screening and prioritization process.

In general, EPA is to focus the prioritization screening process on chemicals that are in active commerce in the United States. Amendments to section 8 require EPA to identify substances on the TSCA Inventory that are in active commerce or inactive. The Committee recognizes, however, that there may be exposures of concern from substances that are not currently or no longer in commerce, and the section provides EPA authority to prioritize inactive substances that meet certain criteria.

The Committee does not expect EPA to prioritize all active substances at one time. The section requires EPA to conduct prioritization screening based on EPA's ability to complete safety assessments and determinations. This approach provides appropriate notice about the substances subject to the prioritization process to interested stakeholders, and an opportunity to provide EPA information relevant to the prioritization decision and any subsequent safety assessment and determination. In the Committee's view, this is an improvement over EPA simply compiling a long list of chemical priorities that could trigger unwarranted de-selection decisions in the marketplace or become out of date because of reliance on older information.

To address concerns that EPA undertake a minimum number of reviews and increase "through-put" in the assessment process over time, EPA is to establish an initial list of at least 10 high and 10 low priority substances within 180 days of enactment. Within 3 years of enactment, EPA is to have designated additional high-priority substances sufficient to ensure that at least a total of 20 high-

priority substances have undergone or are undergoing safety assessments, and additional low-priority substances sufficient to ensure that at least a total of 20 low-priority substances have been so designated. These numbers are to increase to at least 25 high- and low-priorities no later than 5 years after enactment. The section contains explicit authority for EPA to draw on the existing TSCA Work Plan Chemical list (about 90 substances EPA has already prioritized based on hazard, exposure, persistence and bioaccumulation, using its existing TSCA authority). The Work Plan chemicals are, in effect, substances EPA has already prioritized for review; the Committee does not intend that EPA start work anew on these substances. The section requires that no less than 50% of the substances prioritized by EPA be drawn from the Work Plan Chemicals list, until safety assessments and safety determinations have been completed for all Work Plan Chemicals. As the safety assessment and determination process is completed for each high priority substance, it must be replaced by at least one new high priority chemical.

The section establishes general criteria for prioritization screening decisions, for EPA to use in establishing more specific criteria by rule. By including these mandatory criteria in the statute, it is the Committee's intent to require EPA to ensure that important, broad science-based considerations, classifications and designations drive the prioritization screening process, without locking EPA into specific designations based upon ever-changing science.

The substitute approved by the Committee modifies the criteria for prioritization designations by authorizing EPA to designate high priorities on the basis of "significant" hazard and exposure, rather than the "high" hazard and "widespread" exposure thresholds in S. 697 as introduced. A lack of information is also a sufficient basis to designate a substance as a high priority.

Persistent, bioaccumulative and toxic (PBT) substances are a class of substances with recognized health and environmental concerns arising from their particular hazard and exposure characteristics. The substitute approved by the Committee requires EPA to give a preference, in setting the priority list, to TSCA Work Plan chemicals that are both persistent and bioaccumulative. Consistent with the risk-based approach of the legislation, the persistent and bioaccumulative chemicals listed in the TSCA Work Plan chemicals were so identified because they also present potential toxicity and exposure concerns.

Prioritization screening decisions, including decisions to change a prioritization from low priority to high priority, or vice versa, are subject to public notice and comment. The substitute approved by the Committee clarifies that the public will have 90 days to comment on proposed prioritization decisions.

EPA decisions to designate a substance as a low priority must be based on information sufficient to establish that the substance is likely to meet the safety standard. The Committee intends that EPA adequately justify prioritization decisions, which it should fully describe when seeking comment on the proposed designation. All priority designations are subject to review and revision at any time, based on information available to the Administrator.

EPA is to strive to complete the prioritization process of all chemicals in active commerce in a timely manner, taking into ac-

count the resources available to complete safety assessments and determinations. Prioritization decisions may be postponed where development of additional information is needed, which EPA may request or require using its authority under section 4. Where testing was required for prioritization, the Administrator shall designate the chemical substance as a high or low priority not later than 90 days after receipt of information satisfying the requirement. The prioritization screening process is subject to review and modification every 5 years, to ensure that the process is operating efficiently and effectively.

The Committee also expects that EPA will over time increase the number of substances for which safety assessments and determinations are conducted, particularly as the Agency gains experience and expertise in applying the new process. Several provisions of this section are aimed at increasing through-put, and thereby meeting the Committee's objective of addressing the backlog of unassessed chemicals in commerce, increasing public confidence, providing more certainty for regulated manufacturers and processors, and addressing key health and environmental concerns.

The section provides manufacturers an opportunity to request that EPA designate a substance as an "additional priority" for safety assessment, subject to the payment of 100% of the costs associated with the safety assessment and determination. The substitute clarifies that granting a specific request to designate "additional priorities" is at EPA's discretion, and that such substances are in addition to substances designated by EPA as high priorities, and hence do not limit the number of high priorities required to be designated by EPA; they only add to the total number of chemicals the Agency can review. In order to ensure that a significant majority of EPA's activity is focused on the substances the Agency identified as high priorities, the substitute approved by the Committee directs that, if sufficient manufacturer requests are made, a minimum of 25 percent, and a maximum of 30 percent, of the cumulative number of high-priority chemicals in the safety evaluation process can be designated under this approach. For example, if EPA has designated 100 high priority chemicals since the date of enactment, then EPA can have designated and have conducted or be conducting safety assessments and safety determinations on a minimum of 25 and a maximum of 30 industry petitioned chemicals in addition to the 100 high priority chemicals. This approach is intended to allow EPA to review more chemicals than their appropriated resources would otherwise allow.

The section also includes a provision intended to increase EPA's safety assessment and determination of the TSCA Work Plan chemicals. For Work Plan chemicals for which EPA has not yet commenced safety assessments and determinations, manufacturers can request EPA to do so, subject to an agreement to pay 50% of the costs of the review. EPA has full discretion to approve or deny these petitions although the Committee intends for EPA to utilize this provision, resources allowing, to conduct safety assessments and determinations of all Work Plan chemicals as quickly as possible. The fees should allow for additional EPA priorities to be reviewed where the Agency would otherwise not have the necessary resources to add throughput into the system. Requiring manufac-

turers and processors to defray the costs of these reviews creates potential cost savings and efficiencies for EPA.

In order to bring to EPA's attention state governments' interest in a particular chemical substance, the section also requires States to notify EPA when they propose or take administrative action or enact a law to prohibit or restrict a chemical that EPA has not designated as a high-priority. If certain conditions are met, EPA must conduct a prioritization screening for the substance. The provision is intended to ensure that state concerns and information are entered into the national system for EPA review and, where appropriate, assessment and regulation to extend protections nationwide where they otherwise may have only been limited to an individual state, thereby serving the greater national interest. The section makes clear, however, that nothing in the state notification requirement pre-empts state law or actions, or requires EPA approval of the state law or actions.

The section also makes clear that an EPA priority designation shall not be construed to affect the manufacture, processing, distribution, use or disposal of a chemical or regulation of those activities. By this, the Committee intends to clarify that prioritization screening decisions do not have any formal regulatory effect in and of themselves. Prioritization designations are not definitive decisions on whether a chemical substance is safe for intended conditions of use or not safe and requires risk management. Prioritization designations are simply designed to identify chemical substances that are likely to meet the safety standard (in the case of low priority designations) or identify chemical substances that require further assessment (in the case of high priority designations), which in the latter case will lead to a determination as to whether a chemical substance meets the safety standard or needs regulation.

Section 7. New chemicals and significant new uses

Section 7 of S. 697 amends section 5 of TSCA. The amendment modifies the new chemical review process by requiring that EPA make the determination that a new chemical substance or a significant new use is likely to meet the safety standard before it can be commercially manufactured or processed. The section allows EPA to postpone a decision on a new chemical until additional information is generated using EPA's authority under section 4. The section also prohibits manufacture or processing of a new chemical or significant new use found not likely to meet the safety standard except in compliance with any conditions or restrictions imposed by EPA sufficient to ensure likely safety. As with other provisions of S. 697, the section ensures transparency in all EPA decisions on new chemicals or significant new uses. The section also retains EPA authority to establish or continue appropriate, long-standing exemptions.

The Committee intends the amendments to section 5 to ensure that EPA conducts an appropriate review of the potential health and environmental effects of new chemicals, while supporting the ability of manufacturers and processors to innovate and bring to market new chemicals and products through a flexible, targeted review process. The Committee notes that, in general, current law gives EPA more authority to review new chemicals than existing

chemicals, and consistent with current law the Agency should continue the practice of completing new chemical reviews within 90 days to the maximum extent practicable.

Under this section, EPA is to conduct an initial review of a pre-manufacture notice (PMN) for a new chemical substance, develop a profile of the substance and its exposure potential, and apply the safety standard. Consistent with existing law, the PMN submitter must provide EPA all available relevant information, including information on the intended conditions of use and reasonably anticipated exposures. The Committee intends that the review of the PMN should be conducted in that context.

The Committee recognizes that new chemicals may not have as robust a data set as existing chemicals. The testing authority provided to EPA under section 5 of S. 697 is intended to ensure EPA can obtain necessary information to review a PMN application. It is also the Committee's intent that EPA continue to apply its professional and scientific expertise, experience and judgment, developed through its implementation of TSCA's current new chemicals review program. EPA has pioneered the application of new approaches such as structure activity relationships, "read-across" information from other relevant chemicals, and new models and profiles in the new chemical review program to provide greater predictability and transparency. While some of these approaches can have limitations, they should assist EPA in reviewing new chemicals against the safety standard as applied in this section.

Under this section, where EPA imposes a requirement on the submitter of a notice under section 5 through a consent agreement or order, the Agency is required to consider whether to issue a Significant New Use Rule (SNUR) to extend the requirements to other manufacturers and processors of the same chemical after it is added to the TSCA Inventory. Where EPA decides not to issue a SNUR, it is required to publish a statement describing the reasons for not doing so. The Committee does not intend that EPA interpret its authority under this section to adopt a blanket policy of issuing a Significant New Use Rule (SNUR) for every new chemical substance. Rather, the Committee expects that EPA will apply its SNUR authority judiciously where appropriate and necessary to ensure protection of health and the environment.

The section clarifies that EPA may require significant new use notification (SNUN) for import or processing of a chemical as part of an article or a category of articles, if EPA makes an affirmative finding in a SNUR that the "reasonable potential for exposure" to the chemical through the article "warrants notification." The Committee intends this provision to clarify the application of SNUR notification provisions to imported articles and does not intend this provision to compel changes to EPA's general policy regarding treatment of articles in SNURs.

The section also continues current TSCA practice of not imposing a minimum data set requirement on all new chemicals; rather, any requirements to develop new information are determined on a chemical-by-chemical basis. This is consistent with the Committee's finding that, under S. 697, the information requirements of section 5, coupled with EPA's robust new chemical review process, are protective of health and the environment. With the requirement that EPA find a new chemical must be "likely to meet the safety stand-

ard,” the section provides EPA adequate authority to both review and, where warranted, regulate new chemical substances, while preserving the elements of TSCA that promote innovation in new chemistries. Although the section does not impose a minimum data requirement for new chemicals, EPA is provided with improved authority to require testing under section 5 of S. 697, without having to demonstrate potential risk to require testing. The requirements of section 5 of S. 697 to minimize animal testing also apply.

If EPA finds that a new chemical substance is not likely to meet the safety standard, EPA must apply restrictions sufficient to ensure that the chemical substance is likely to meet the safety standard under the conditions of use. Under the section, EPA also retains the authority to approve a PMN for a new chemical subject to the condition to conduct testing. In addition, the section adds a new requirement that new chemical substances that have PBT characteristics be subject to conditions that reduce potential exposure to the maximum extent practicable.

The section retains the statutory exemptions from section 5 of TSCA and the regulatory authority for EPA to continue existing exemptions, such as the polymer and low volume exemptions, among others. The Committee recognizes that appropriate exemptions are a critical component of TSCA, because they help focus EPA’s activity on high-priority potential risks to health and the environment.

Section 8. Safety assessments and safety determinations

Section 8 of S. 697 amends Section 6 of TSCA. The section requires EPA to conduct a safety assessment and safety determination for all high priority substances and additional priorities. Importantly, the section establishes strict, enforceable deadlines for EPA action under this section: Within 6 months of designation of a chemical substance as a high priority, EPA must define the scope of the assessment and determination, including the conditions of use and potentially exposed or susceptible populations that will be evaluated. Safety assessments and determinations must be completed within 3 years of designation. If EPA finds a chemical does not meet the safety standard, risk management measures must be imposed within 2 years. With the exception of the 6 month deadline for defining the scope of a safety assessment and determination, EPA is permitted, with adequate public justification, to extend the deadlines for an aggregate period not to exceed 2 years.

In order to ensure that relevant ongoing work at EPA continues, the Agency is expressly authorized to initiate assessments, or continue assessments that have already been initiated, prior to establishment of the new policies and procedures, for substances such as those identified by EPA in its TSCA Work Plan Chemical program.

In the safety assessment and determination process, EPA is to determine whether a substance meets the safety standard or does not meet the safety standard. If a substance is found not to meet the safety standard, EPA must impose the risk management measures necessary to ensure the safety standard is met. If the safety standard cannot be met through other risk management measures, a ban or phase out of the substance is generally required, but subject to certain time-limited exemptions. Consequently, the law is amended so EPA is better able to ban or phase out the substance.

All safety determinations are subject to public notice and comment, as are all risk management rules.

EPA has been able to regulate only a handful of existing chemicals under Section 6 of TSCA over its history. Some have argued that one of the causes of Section 6's failure was its blurring the lines between what should be pure safety reviews with non-risk factors. Under existing TSCA, EPA's authority to find unreasonable risk and regulate a chemical substance has been interpreted to require the consideration of cost and benefits as part of fundamental decisions on safety, to the detriment of health and environmental protection.

Section 8 of S. 697 addresses this criticism by requiring that EPA conduct a risk-based safety assessment and make a risk-based safety determination of each high-priority substance. The term "safety determination" is defined in section 3 to mean "a determination by the Administrator as to whether a chemical substance meets the safety standard under the conditions of use." The term "safety standard" is in turn defined in section 3 to mean:

"a standard that ensures, *without taking into consideration costs or other nonrisk factors*, that no unreasonable risk of injury to human health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of injury to—

(A) the general population; or

(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance."

The Committee intends that the phrase "without taking into consideration costs or other nonrisk factors" be interpreted to mean that EPA must determine that a chemical substance meets the safety standard, or not, based solely on risk to human health and the environment—the integration of hazard and exposure information about a chemical—and not on the basis of other factors such as consideration of the costs or benefits of the substance or of possible restrictions on the substance.

Thus, this section addresses one of the most significant problems identified in current TSCA. Under the definition of the safety standard in section 3 invoked in this section, cost and other factors such as technical feasibility are to play no part in EPA's safety determinations. EPA's safety determinations—whether a substance meets or does not meet the safety standard—are to be based only on health and environmental considerations. In addition, if a substance fails to meet the safety standard, the remedy EPA imposes must enable the substance to meet the safety standard under the conditions of use, which again, is based only on health and environmental considerations. The section therefore "de-couples" the Agency's science-based risk decision about a chemical's safety under its intended conditions of use from the Agency's decision on how to manage unreasonable risks where chemicals do not meet the safety standard under intended conditions of use.

EPA is authorized to postpone a determination (within the legislation's deadlines) if additional information is necessary. Consistent with current law, if the chemical substance is likely to result in a

risk of serious or widespread injury to health or the environment before the effective date of a rule, EPA is authorized to declare a proposed rule to be effective upon publication in the Federal Register. Safety determinations and associated safety assessments are considered final agency action effective upon completion and final publication (for substances found to meet the safety standard) or the date of promulgation of the final risk management rule (for substances found to not meet the safety standard).

The substitute approved by the Committee makes several improvements to the risk management provisions of S. 697. Consistent with changes made in section 7 related to new chemicals and significant new uses, section 8 requires EPA to impose risk management restrictions on persistent, bioaccumulative and toxic (PBT) substances for uses or conditions of use found not to meet the safety standard that reduce exposures “to the maximum extent practicable.” For PBT Work Plan chemicals and in assessing subsequent high priority chemicals, the Committee believes that EPA’s Framework for Metals Risk Assessment (EPA 120/R-07/001) (March 2007) should be consulted for metals and metal compounds. In addition, because the application of criteria applied in the prioritization screening process is not a definitive assessment of PBT characteristics, the Agency should consider whether substances that might otherwise be considered to have PBT characteristics should be addressed in a different way (e.g., substances that bioaccumulate but do not biomagnify), or whether substances that may not meet traditional PBT criteria should nonetheless be considered PBTs (e.g., substances that bioaccumulate in blood rather than fat tissue).

EPA is to impose risk management on articles only to the extent necessary to address the identified risks of the chemical substance from the article in order for EPA to determine that the chemical substance meets the safety standard. EPA is to exempt replacement parts that are manufactured prior to the effective date of the rule for articles that are first manufactured prior to the effective date of the rule unless it finds the replacement parts contribute significantly to the identified risk.

It is critical to a workable chemical management structure that EPA be afforded some level of discretion in implementing a ban or phase-out. However, to address concerns that the compliance date for such restrictions on a chemical substance not be unduly long, the section requires EPA to make compliance with such a rule mandatory in as short a period as practicable.

Notably, the section eliminates the controversial provision of existing TSCA that requires EPA to adopt the “least burdensome” regulatory requirement. This has been viewed by the Agency as a major road block to successful TSCA implementation because of the evidentiary and analytic burdens associated with justifying that each proposed regulatory action was the least burdensome requirement needed to ensure a chemical did not pose an unreasonable risk. While this requirement has been removed, the Committee maintains a strong continued interest in ensuring any regulatory decisions under this act undergo an implementable yet robust consideration of costs and benefits. This section requires EPA to assess the costs, benefits, and feasibility of regulatory options the Administrator has considered, and describe how that assessment influ-

enced the choice of regulatory requirements, but is not intended to establish a least burdensome requirement. EPA is authorized to exempt certain uses of a chemical substance if compliance with the regulatory restriction would harm national security, cause significant disruption of the national economy, or interfere with critical or essential uses. In the case of a ban or phase-out of a chemical substance, any exemption adopted by EPA can only last for a period of 5 years, subject to renewal.

Section 9. Imminent hazards

Section 9 of S. 697 amends section 7 of TSCA. The amendments make no substantive policy change in EPA's authority to protect against unreasonable risks associated with imminent hazards from certain chemical substances. The amendment updates and conforms the section to the new authority provided under S. 697.

Section 10: Information collection and reporting

Section 10 of S. 697 amends section 8 of TSCA, the general information collection and reporting authorities under the Act. The section ensures that EPA's information collection and reporting requirements produce a more complete picture of chemical substances in active commerce in the United States. The section also requires EPA to review all prior claims for the protection of confidential chemical identities for active substances within 5 years of enactment. The section provides authority to apply reporting and record-keeping requirements to both manufacturers and processors.

Although TSCA currently gives authority to EPA to collect information from processors, EPA has not chosen to do so. It is the Committee's intent that manufacturers (including importers) and processors have reporting obligations only where appropriate and necessary to enable EPA to understand what chemicals are actually in active commerce, to gain access to information necessary to implement this Act, and to keep the information updated. These reporting obligations should be appropriately tailored to ensure that reporting burdens on any particular sector are equitable, undue burdens on small manufacturers and processors are minimized, and reporting requirements are applied to those persons likely to have information relevant to the effective implementation of this title. The Committee expects EPA to use the information generated by periodic reporting obligations to provide relevant information on chemical uses and possible exposures, and improve the ability of the Administrator to conduct prioritization screening, safety assessments and safety determinations, and to promulgate and implement appropriate risk management rules.

TSCA requires a chemical substance to be listed on the TSCA Inventory before it is commercialized. However, TSCA does not require EPA on an ongoing basis to identify which substances on the Inventory are actually in commerce. With approximately 84,000 substances now on the Inventory—but less than 8,000 chemical substances reported under the EPA's Chemical Data Reporting Rule as being produced in volumes above the rule's reporting threshold—it is important that EPA (and the American public) have a better picture of what substances are in actual commerce at any given time. The failure to identify active substances has created confusion.

S. 697 addresses this problem by requiring that EPA categorize the substances on the TSCA Inventory as active or inactive. The categorization process is critical to the success of EPA's prioritization process, which focuses primarily on active substances. Importantly, the section does not authorize EPA to remove substances from the Inventory. Instead, manufacturers or processors who wish to designate an inactive substance as active have an obligation to notify EPA. Manufacturers of an inactive substance may return the substance to the active inventory with a simple notification to EPA, at which time the substance becomes subject to the prioritization screening, safety assessment and determination processes.

Section 10 also requires EPA to develop a plan within 1 year of enactment to review all prior claims for the protection of confidential chemical identity that manufacturers or processors of active substances wish to maintain, within 5 years after the active list is compiled. The Committee intends that EPA review all such confidentiality claims, consistent with the requirements of section 14 of this Act, to ensure that appropriate information relevant to health and safety of chemicals is publicly available.

Under TSCA, numerous nomenclature conventions exist that may prevent the efficient distribution of chemicals into commerce. It is the intent of the Committee that the provisions of section 10 related to nomenclature will resolve these issues by requiring the Administrator to develop new guidance that will establish equivalency between these conventions, while preserving certain nomenclature approaches that have significant value. It will also permit any chemical substance appearing multiple times, each with a different Chemical Abstract Service (CAS) number, to be treated by the Agency as a single chemical substance. This will help prevent duplicative safety assessments and determinations by ensuring that substantially equivalent chemicals are considered at the same time, as appropriate. The Committee believes this approach will also help enhance EPA's ability to evaluate substances from new sources against existing substances for equivalence, enabling similar substances to rely on the Inventory listing of an existing substance. The Committee also intends that EPA's guidance should address those instances where multiple, different substances share the same CAS number. These substances may have different hazard profiles, but these distinguishing characteristics are not transparent to the public and stakeholders.

Current TSCA provides EPA the authority to list a category of substances on the inventory, rather than list individually each chemical substance within a category. S. 697 maintains this authority to ensure that minor modification or variations in the formulation or structure of a chemical substance that have insignificant health or environmental consequences would not be automatically subject to the notification requirements of section 5. The Committee believes that EPA's current policy of not requiring notification for variations in naturally-occurring substances or mixtures should generally be continued.

Section 10 continues the practice under current TSCA to ensure that any substance that is exempt from the premanufacturing notification (PMN) process under Section 6 of S. 697 is exempt from designation as active or inactive on the chemical inventory.

Section 11. Relationship to other Federal laws

Section 11 amends section 9 of TSCA, which provides EPA discretionary authority to refer a concern about an unreasonable risk of injury to another Federal Agency, when the authority to address the risk may be more efficiently or effectively regulated by the other Agency. For example, if the Administrator finds that disposal of a chemical substance may pose risks that could be prevented or reduced under the Solid Waste Disposal Act, the Administrator should ensure that the relevant office of the EPA receives that information. Section 11 conforms this authority to the provisions of S. 697. It further requires EPA to share information relevant to preventing or mitigating exposures or releases of a chemical substance under another Federal law with any relevant Federal agencies or offices within EPA.

Section 12. Research, development, collection, dissemination, and utilization of data

Section 12 makes a minor conforming amendment to section 10 of TSCA to ensure an appropriate reference to the Department of Health and Human Services.

Section 13. Exports

Section 13 of S. 697 amends the export notification requirements established in section 12 of TSCA. The amendments conform the export notification requirements to the requirements of the Act by requiring prior notice of exports of substances that are not likely to meet, or that do not meet, the safety standard and are subject to proposed or final restrictions. The section requires EPA to promulgate rules to implement the notification requirements.

The substitute strikes the amendments to section 13 of TSCA that were in S. 697 as introduced. Thus, S. 697 makes no changes to the current import requirements under TSCA.

Section 14. Confidential information

Section 14 of S. 697 amends section 14 of TSCA to make several important modifications to the process by which confidential business information (CBI) can be protected against disclosure or disclosed. In general, it is the Committee's intent to balance the need for protection from disclosure for information qualifying under the section b(4) exemption of the Freedom of Information Act (FOIA) (i.e., "trade secrets and commercial or financial information obtained from a person and privileged or confidential") with the needs to ensure access to such information under appropriate conditions by those who need it to perform their duties, and to maximize public availability of health and environmental information relating to chemical substances in commerce. Striking a balance between protecting trade secrets and sensitive commercial and financial information and broadening access to information on chemicals is essential to encourage innovation and economic competitiveness within the chemical industry and those industries that use chemistry, while better informing the decisions made about chemicals by different levels of government, companies throughout the supply chain, and the general public.

Under this section, all information sought to be protected from disclosure must meet certain criteria, and all such claims must be

asserted. Section 14(b) identifies certain commercial and financial business information that has been consistently recognized as qualifying as CBI under existing TSCA. This type of information (e.g., marketing and sales information) does not require the same degree of substantiation by industry or review by EPA as other types of information, and is therefore distinguished from types of information that must be substantiated and reviewed by EPA.

Section 14(c) identifies the types of information that will not be protected from disclosure and the circumstances under which protection will not be afforded. Section 14(c)(1) retains virtually verbatim the language of existing section 14(b)(1), relating to the disclosure of confidential information in the context of a health and safety study. The adoption of this provision of existing law does not signal the Committee's intent to agree or disagree with EPA's interpretation of the provision to date. Rather, it reflects the significant debate over the scope and interpretation of the provision, which could not be successfully resolved. The section retains clear direction that the Administrator is not authorized to release any information that would disclose a process used in the manufacturing or processing of a chemical substance or mixture, or the portion of a mixture comprised by any chemical substance in the mixture. The Committee expects that EPA will ensure that health and environmental effects information from health and safety studies is disclosed, while appropriately protecting CBI contained within a study.

The section also makes clear the Committee's intent that EPA disclose all information not entitled to protection, while ensuring that all information that qualifies for protection from disclosure that is included in a submission that is otherwise not entitled to protection from disclosure be protected. This approach is intended to address the confusion that can exist when information that qualifies for protection is included in a submission that is otherwise not entitled to protection from disclosure.

The section also establishes a rebuttable presumption that CBI related to substances subject to a ban or phase-out shall be made public, with the requirement that EPA provide advance notice of the disclosure to the CBI claimant. The presumption is based on the principle that the public interest in disclosing confidential information concerning a chemical subject to a ban or phase-out can outweigh the claimant's interest. The required notice provides the CBI claimant an opportunity to rebut the presumption by appealing or legally challenging an EPA determination, and ensures that appropriate information is made public while protecting important property rights.

Under the section, all new claims for protection of information not presumed to be protected from disclosure must be substantiated by the claimant. The section is consistent with well-established criteria and requirements for the protection of trade secrets and other confidential information. For claims to protect chemical identity as confidential, the claimant must submit a structurally-descriptive generic name that is to be publicly disclosed. Generic names should disclose information such as the type, class, or family to which a chemical belongs, without revealing specific chemical identity.

Section 14(e) identifies exceptions to CBI protection. Several exceptions—for disclosure to a Federal officer or employee under any law to protect health and the environment, for disclosure to Federal contractors under certain circumstances, and for disclosure when the Administrator determines disclosure is necessary to protect health and the environment—are based on existing TSCA. These provisions signal no change in current policy on these disclosures. It is also the Committee's intent to make clear that nothing in section 14 constitutes a bar to the rules of civil or criminal procedure in cases litigated in the U.S. courts. Appropriate protections against disclosure in such cases can still be sought by litigants in a court of law.

The section reflects a change in CBI policy by authorizing EPA, for the first time, to share CBI with a State or a political subdivision of a State on written request. It is the Committee's view that sharing of CBI with State or local authorities is only authorized under this Act when the recipient establishes that it has adequate authority and sufficient mechanisms in place to protect the information, by agreement with the Administrator. The procedures applied by State or local authorities to protect confidential information must be comparable to the procedures used by the Administrator to safeguard such information. The Committee expects EPA to ensure that disclosures to State and local governments under this provision will be protected from disclosure to the same extent as under Federal law. Without those protections, EPA should not release CBI to a State or political subdivision of a State. The Administrator must also notify the person who submitted the CBI that it has been disclosed to a State or political subdivision.

The section also includes provisions on sharing CBI with health and environmental protection professionals in certain cases and under certain conditions. The provision is modeled on a similar program established in the Emergency Planning and Community Right to Know Act (EPCRA). The provision ensures that treating physicians, nurses, agents of poison control centers, public health or environmental officials of a State or political subdivision of a State, and first responders have appropriate, timely access to information, while still protecting CBI from disclosures more broadly. The Committee believes this provision will help remedy a deficiency in current TSCA by improving access to information while protecting proprietary information.

Under the current provisions of TSCA there is no effective mechanism requiring the Administrator to review and evaluate a CBI claim, or for companies to re-evaluate prior claims or to re-substantiate claims. Section 14(f) is designed to address this situation. The section provides clear direction that EPA should review and make determinations on CBI claims in a timely manner. All claims for the protection of confidential chemical identity must be reviewed, and EPA must review a representative subset of all other CBI claims.

The section also limits CBI protections for substantiated claims to an initial period of 10 years, renewable upon re-substantiation. A 10-year period for CBI claims is consistent with that provided under the vast majority of Federal CBI programs. The section specifies that the requirements to re-substantiate a prior claim are to be consistent with and no more or less burdensome than the

original substantiation. The Committee intends that there be no upper limit on the number of extensions available for CBI protection, so long as the claimant can make the appropriation substantiation of the claim.

The section also provides the Administrator authority or a mandate to require re-substantiation of CBI claims in certain circumstances. This provision does not require EPA to review all CBI claims for chemical substances designated as high priorities.

Finally, section 14 provides that information that is required to be disclosed or otherwise made public under Federal law, or is already publicly available cannot be newly protected as CBI under TSCA. This provision is consistent with current law and practice related to CBI protection.

Section 15. Prohibited acts

Section 15 of S. 697 amends section 15 of TSCA to conform to the requirements of the Act.

Section 16. Penalties

Section 16 of S. 697 amends section 16 of TSCA to increase civil penalties from \$25,000 to \$37,500 per violation to be consistent with other laws administered by EPA. The section also modifies the existing criminal penalty for violations that create an imminent danger of death or serious bodily injury, based on similar provisions in other federal environmental laws.

Section 17. State-Federal relationship

Section 17 of S. 697 makes several amendments to section 18 of TSCA to address the relationship between federal law and the laws of states or political subdivisions of states related to chemical regulation. Because TSCA regulates products manufactured for national and international commercial use, the Committee strongly intends S. 697 to establish a robust, nationally uniform program for the effective regulation of chemicals consistent with Article 1, Section 8, Clause 3 of the U.S. Constitution. It is the Committee's view that the prioritization, safety assessment and determination, and regulatory provisions establish a credible national program to protect health and the environment from the unmanaged risks of chemical substances in such a way that the need for separate state or local action may be minimized. It is the Committee's expectation that EPA will make appropriate efforts to engage State governments—particularly state agencies tasked with protecting public health and the environment—interested in chemical regulatory matters in the prioritization screening, safety assessment and determination, and risk management processes established under this Act.

The section specifically replaces the term “requirements” with the phrase “statute or administrative action” in describing the extent of preemption that would apply to state actions and any subsequent use of the word “requirements” is not intended to extend to common law tort claims or decisions. By the addition of several savings clauses, the Committee wishes to send a strong signal that preemption under section 17 of the legislation does not apply to tort claims.

The section changes in some ways the circumstances under which certain decisions or actions taken by the Administrator pre-

empt certain state actions. TSCA section 18 currently preempts state law when EPA has issued a testing rule under Section 4 or a rule or order under Sections 5 or 6 with respect to a chemical substance. More specifically, TSCA generally preempts State and local requirements applicable to the same chemical substance if the State or local requirement is designed to gather the same or similar information as the Section 4 rule, or to protect against the same risks as the Section 5 or 6 rule or order, unless the State or local requirement is identical to the EPA requirement, is adopted pursuant to another Federal law, or completely prohibits the manufacture or processing of the substance or mixture within the State or political subdivision. Under current TSCA, a State may request that EPA issue a waiver from the preemption provision.

Section 17's preemption provisions follow a framework that is in many ways similar to current law. State actions regarding testing, the notification of significant new uses, and the restriction of high-priority substances for which EPA has completed a safety determination and either has found that the substance meets the safety standard, or has found that it does not meet the safety standard and has completed a final risk management rule, would be preempted, to the extent the same uses and conditions of use are included in the scope of the EPA action. For example, if EPA has completed a safety assessment and safety determination for a chemical substance and finds the chemical substance meets the safety standard, that action preempts state restrictions on that substance only for the uses and/or conditions of use included in the EPA review. If EPA implements risk management requirements on a chemical substance, that action would also preempt state restrictions on that chemical substance, but only those state restrictions that apply to the same uses and/or conditions of use addressed by EPA's rule. Thus, the section establishes clear direction that preemptive effects on State law are limited to the specified regulatory actions taken by EPA with respect to a specific chemical substance or category of substances, and then only to the uses or conditions of use addressed by that EPA action.

The Administrator's commencement of a safety assessment of a high-priority chemical will preempt the implementation of any new state restriction on that chemical once the scope of the safety assessment has been defined and published by EPA (under section 6, no later than 6 months after designation as a high priority). The preemptive effect will continue until EPA publishes the safety determination. During this period, states can continue working on legislation and rules to restrict chemicals, but this preemption would prevent a final rule from taking effect unless a waiver is granted, the safety determination is finalized and the chemical substance is found to not meet the safety standard, or the deadline for completing the safety determination lapses also leading to the granting of a waiver. Existing state statutes or administrative actions on individual high priority chemicals are in no way preempted by this provision.

Section 17(d) makes clear that certain state laws that are not restrictions on chemical manufacturing and use are not preempted under S. 697. As under current TSCA the section makes clear that a state or local requirement adopted pursuant to another federal statute is not preempted. In addition, restrictions states put in

place under their own authority to protect air quality, water quality, or waste treatment or disposal are not pre-empted, as long as those restrictions do not address the same hazards and exposures, with respect to the same conditions of use, as those included in the scope of the safety determination but are inconsistent with the action of the Administrator or would cause a violation of an applicable action by the Administrator under section 5 or 6. This approach is appropriate for the considerable body of law regulating chemical releases to the environment, such as air and water quality, where the states have traditionally had a significant regulatory role and often have a uniquely local concern.

The section clarifies that an EPA action will not preempt state actions that do not directly prohibit or otherwise restrict the manufacturing, processing, distribution in commerce of a chemical substance, as well as where the state action is not otherwise required by or inconsistent with an action under sections 4, 5 or 6. Similarly, state chemical disclosure and other information-related obligations would not be preempted by EPA action under TSCA, as they do not directly restrict a chemical. The Committee expects that such state laws are established to enhance information on chemical substances, rather than being used to impose effective bans or other substantial restrictions on chemical manufacture, processing, distribution in commerce, use or disposal.

As in current law, the section also allows states to enforce State law requirements that are identical to requirements mandated by EPA under sections 4, 5 or 6. S. 697 provides that either a state or the Federal government can levy a penalty and sanction a violation of the law, but not both. In further ensuring equitable and consistent enforcement of federal chemical regulations, State penalties and sanctions can be no more stringent than those available to the Federal government.

The section provides that existing EPA regulations remain in force unless modified or eliminated under this Act, and that any preemptive effect of those regulations that pre-dates enactment of S. 697 continues in accordance with the preemption provisions in effect when those rules were put in place under the law. The Committee intends to make clear that nothing in S. 697 affirmatively modifies or eliminates the preemptive effect of a Federal decision in effect prior to the date of enactment, nor that EPA's ability to revisit previous rulemakings through the administrative process is in any way diminished.

In order to efficiently address the potential preemptive effect of EPA decisions on the body of existing state laws affecting chemical substances, S. 697 creates an exemption from preemption for all chemical specific actions taken prior to August 1, 2015. This provision is intended to "grandfather" existing state prohibitions or restrictions on chemical manufacturing, processing, use, distribution in commerce, or disposal of a chemical substance.

In addition, the section adopts similar language to section 231(b) of the Consumer Product Safety Improvement Act (CPSIA), which was intended to exclude California's "Proposition 65" requirements from federal preemption under that Act. It is the Committee's intent that adopting this provision in S. 697 would effectively achieve the same result.

Currently, TSCA provides states an opportunity to seek a waiver from preemption following final EPA action, under certain circumstances. S. 697 adopts a similar approach, and provides an additional waiver opportunity for states related to the preemptive effect of EPA's initiation of a safety assessment and determination on new state regulation.

When EPA has made a final decision or taken an action under section 4, 5 or 6 that has a preemptive effect, a State may seek and be granted a waiver when EPA determines that: there are compelling local health or environmental conditions; compliance with the state requirement would not unduly burden interstate commerce (consistent with the Commerce Clause of the U.S. Constitution); or cause a violation of federal law (consistent with the Supremacy Clause of the U.S. Constitution); and the requirement is consistent with sound objective scientific practices, the weight of the evidence and the best available science. This waiver opportunity is modeled on the existing provisions of section 18 of TSCA, but includes additional conditions for granting such a waiver, consistent with the Committee's intent that S. 697 establish a robust, nationally uniform program for the effective regulation of chemicals.

As noted earlier, EPA's commencement of a safety assessment preempts certain new state actions on a chemical substance, running from the date on which the scope of EPA's review is defined and published, ending on the date the safety determination is published or the maximum deadline of 5 years for a determination under Section 6 as amended is missed. Even during this interim period, a State may seek and EPA shall grant a waiver when compliance with the state requirement would not unduly burden interstate commerce (again, consistent with the Commerce Clause of the U.S. Constitution), or cause a violation of federal law (again, consistent with the Supremacy Clause of the U.S. Constitution), and the concern of the state or political subdivision is based in peer-reviewed science. The Committee's intent is that this last condition requires that a State's waiver application should be based on credible science citing one or more studies published in a peer reviewed journal, or a study by an institution like the National Academy of Sciences with a peer review process. This language does not require that a state's waiver application be evaluated on the weight of the evidence.

State waiver requests are subject to notice and comment, and EPA decisions on them must be made within a specified period of time, and are considered final agency actions subject to judicial review by any person. If a court does not act on a petition for judicial review, within 90 days, the waiver again applies and the state may proceed with implementation of its restriction. For waivers sought during the period EPA is reviewing a chemical substance, if EPA fails to adhere to the deadline established in section 6 for safety assessments and determinations, or fails to meet the deadlines for action on a waiver application, a waiver shall be automatically approved.

The Committee intends that the compelling state circumstances or interests identified in a waiver application for a state to act after final EPA action should generally follow the practice of other federal agencies applying similar provisions. For example, a Department of Energy ("DOE") regulation allows States to petition for a

preemption exemption for energy conservation standards for which there is already a federal standard. 10 C.F.R. § 431.422. The State must show that an exemption is needed to meet “unusual and compelling State or local energy interests.” This is defined to mean “interests which are substantially different in nature or magnitude from those prevailing in the U.S. generally . . .”

Similarly, under the Federal Food, Drug, and Cosmetic Act (FFDCA), the Food and Drug Administration (FDA) in reviewing medical devices can exempt a State requirement from preemption if there are “compelling local conditions.” 21 U.S.C. § 360k. The FDA’s regulations define this phrase to mean “any factors, considerations, or circumstances prevailing in, or characteristic of, the geographic area or population of the State or political subdivision that justify exemption preemption.”

The section authorizes any person to seek judicial review of an EPA decision to designate a substance as a low priority chemical. The Committee expects that if EPA applies the low priority designation based on information sufficient to establish that the chemical substance is likely to meet the safety standard, judicial review of a low priority designation will be sought infrequently, particularly as the ability of state governments to act on all chemical substances not designated as a high priority remains intact because low priority determinations have no preemptive or regulatory affect.

The section establishes several savings clauses. Federal court precedent establishes that preemption is a matter of Congressional intent. *Gade v. Nat’l Solid Wastes Mgmt Ass’n*, 505 U.S. 88, 96 (1992). The Supreme Court has given effect to saving clauses and found that they save common law tort claims from a statute’s preemption language. See, e.g., *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 868 (2000) (holding common law actions not preempted due to a saving clause despite a preemption clause that could otherwise be reasonably interpreted broadly to preempt such claims). The savings clauses in S. 697 are intended as a clear statement that the preemption provisions do not apply to tort claims.

Current section 18 of TSCA does not preempt or displace any private common law rights or statutory remedies for civil relief, or penalties for criminal conduct. Similarly, section 17 of S. 697 makes clear that nothing in the Act should be interpreted to preempt, supplant, or displace common law rights or statutorily enacted remedies for civil damages or a criminal penalty. The Committee believes that this clarification is useful to ensure that S. 697 results in no unintended contraction of any private legal rights, and particularly to further clarify that nothing in the revision of section 18 should be interpreted to apply to tort claims.

Section 18. Judicial review

Section 18 of S. 697 amends section 19 of TSCA. S. 697 makes no change to the existing standard of judicial review in section 19 of TSCA. Several other provisions of this section make changes to conform section 19 to the requirements of the Act.

Section 19. Citizens’ petitions

Section 19 of S. 697 amends section 20 of TSCA to make changes necessary to conform the citizens’ petition process to the require-

ments of the Act. No substantive or policy change is intended by these amendments.

Section 20. Employment effects

Section 20 of S. 697 makes a minor conforming change in section 21 of TSCA.

Section 21. Studies

Section 21 of S. 697 repeals section 25 of TSCA. Section 25 required the Administrator to conduct an indemnification study and a study on classification, storage and retrieval of information on chemicals. These studies are not necessary under a modernized TSCA, particularly given the widespread availability of information on chemical substances in electronic format.

Section 22. Administration

Section 22 of S. 697 amends Section 26 of TSCA to expand EPA's existing TSCA fee authority. In the Committee's view, the provisions will help ensure that funds sufficient to defray a substantial portion of EPA expenses in information collection and processing, prioritization, safety assessment and determination, and regulation under the Act are provided through user fees.

The section authorizes EPA to raise fees to defray approximately 25% of the cost of implementation, to a maximum of \$18 million. All fee revenue would be directed to a new TSCA Implementation Fund, to ensure that resources will be directly available to EPA to more efficiently run the program. Similar to user fees in several other federal product assessment programs (such as the Pesticide Registration Improvement Act), fee authority is conditioned on continued federal appropriations and to subsequent Congressional reauthorization.

The section authorizes EPA to adjust fees for inflation and to ensure that funds are sufficient to conduct the activities covered by the fees. The section also directs EPA to avoid surpluses. As provided in section 4A of S. 697, manufacturers or processors of chemicals EPA decides to assess as "additional priorities" will pay 100% of the costs of safety assessments and determinations, while 50% of the costs of conducting company-requested safety assessments and determinations on TSCA Work Plan chemicals are to be paid by the company.

The section provides that fees may not be assessed for a fiscal year unless the amount of appropriations (excluding fees) is equal to or greater than the amount of appropriations for fiscal year 2015. This provision is modeled after a similar provision in the Pesticide Registration Improvement Act. The Committee intends this provision to ensure that appropriations are not reduced because of the revenue collected through fees, but rather that the fees supplement appropriated resources available to the Agency. The payment of fees for "additional priorities" and for company-requested reviews of TSCA Work Plan chemicals should not be subject to the condition for continued federal appropriations.

The section establishes audit and transparency requirements in EPA's implementation of the fee program.

With these provisions, it is the Committee's intent to ensure that EPA has the resources it needs to implement the new and strengthened regulatory requirements of a modernized TSCA.

Section 23. Development and evaluation of test methods and sustainable chemistry

Section 23 of S. 697 amends section 27 of TSCA to establish an interagency Sustainable Chemistry program to promote and coordinate Federal sustainable chemistry research, development, demonstration, training and other activities. The interagency group is to include representatives of the National Science Foundation, the National Institute of Standards and Technology, and other agencies with interests in sustainable chemistry. The section provides no new appropriations authority, but directs the relevant agencies to coordinate their budgets to provide appropriate support to the program. Section 23 is intended to ensure that EPA and the federal government support education, research and development, into new, sustainable chemistries.

The Committee questions whether or to what extent the EPA labeling program will be needed for, or appropriately applied to, chemicals for which EPA conducts safety assessments and determinations under EPA's strengthened authorities under S. 697; specifically, the Committee is concerned that the labeling program, if applied to chemicals EPA has found meet the safety standard, could risk consumer confusion in the marketplace if another program within the Agency then identifies "safer" alternatives. It is the expectation of the Committee that, given the new authorities and responsibilities of the Agency under S. 697, the agency's toxics office will focus primarily on implementation and enforcement of S. 697, and consider use of any existing private sector voluntary consensus standards as an alternative to further expanding or utilizing certain aspects of the Safer Choice program.

Section 24. State programs

Section 24 makes a minor conforming change to section 28 of TSCA, relating to federal grants to support state programs.

Section 25. Authorization of appropriations

Section 25 of S. 697 repeals section 29 of TSCA, relating to authorized appropriations.

Section 26. Annual report

Section 26 of S. 697 amends section 30 of TSCA to add several elements to the annual report required of EPA to Congress on implementation of the Act including the number of notices received under section 5 as amended, and for chemical substances subject to a rule, testing consent agreement, or order under section 4 as amended.

Section 27. Effective date

Section 27 of S. 697 modifies Section 31 of TSCA to make clear that nothing in the Act shall be interpreted retroactively to any Federal, State, or maritime legal action commenced prior to the effective date.

LEGISLATIVE HISTORY

Senator Udall introduced S. 697 on March 10, 2015. The bill was referred to the Committee on Environment and Public Works. A legislative hearing on the bill was held on March 18, 2015. The Committee considered the bill in a business meeting on April 28, 2015. An amendment in the nature of a substitute was approved, and the Committee ordered the bill reported to the Senate.

ROLL CALL VOTES

The Committee on Environment and Public Works met to consider S. 697 on April 28, 2015. The committee favorably reported the bill, as amended by a substitute offered by Senators Vitter, Whitehouse, Merkley and Booker, by a roll call vote of 15–5.

Amendments rejected

A total of 6 amendments to the bill were offered and not approved by the Committee, as follows:

1. Gillibrand #1—Amendment striking a section of S. 697 that prohibits states from taking action in regulating high priority chemicals upon the initiation of the Safety Assessment by EPA (rejected by a roll call vote of 8 yeas, 12 nays).

2. Boxer-Sanders-Markey #2—Amendment requiring expedited consideration of the regulation of all forms of asbestos, instead of requiring a safety assessment be completed (rejected by a roll call vote of 9 yeas, 11 nays).

3. Markey #1—Amendment including a provision for chemicals requiring expedited action (rejected by a roll call vote of 8 yeas, 12 nays).

4. Markey #2—Amendment allowing additional time to comply with certain restrictions in cases of technological infeasibility (rejected by a roll call vote of 9 yeas, 11 nays).

5. Boxer-Carper #3—Amendment addressing chemical contamination of drinking water supplies by requiring consideration of whether a chemical substance is stored near drinking water sources when prioritizing chemicals for assessments (rejected by a roll call vote of 10 yeas, 10 nays).

6. Boxer-Markey-Sanders #5—Amendment strengthening protections for children and communities from disease clusters and providing community disease cluster technical assistance grants (rejected by a roll call vote of 10 yeas, 10 nays).

Final Committee vote to report

S. 697, as amended by the Vitter/Whitehouse/Merkley/Booker substitute, was approved and ordered to be reported to the full Senate. The roll call vote to report the bill was 15 to 5 in favor (Senators Inhofe, Vitter, Barrasso, Capito, Crapo, Boozman, Sessions, Wicker, Fischer, Rounds, Sullivan, Carper, Whitehouse, Merkley and Booker voted yea, and Senators Boxer, Cardin, Sanders, Gillibrand, and Markey voted nay).

REGULATORY IMPACT STATEMENT

In compliance with section 11(b) of rule XXVI of the Standing Rules of the Senate, the committee finds that S. 697 does create additional regulatory burdens on manufacturers, processors and

importers and users of chemical substances. These burdens include fees authorized under S. 697 of up to \$18 million annually. According to the Environmental Protection Agency, there are approximately 13,500 chemical manufacturing facilities in the United States owned by more than 9,000 companies. There is no information on the number of users of chemical substances. It is not practicable to quantify the number of entities affected, the precise economic impact on those entities, or the additional paperwork that may result from regulations to be promulgated under S. 697. However, the committee notes that the Congressional Budget Office has found that the cost of the mandates in the bill to private and public sector entities will not be substantial. The committee finds that S. 697 will not cause any adverse impact on the personal privacy of individuals.

MANDATES ASSESSMENT

In compliance with the Unfunded Mandates Reform Act of 1995 (Public Law 104-4), the committee notes that the Congressional Budget Office found, “S. 697 would impose intergovernmental and private-sector mandates, as defined in the Unfunded Mandates Reform Act (UMRA), on manufacturers, processors, importers, and users of chemical substances. The bill also would impose intergovernmental mandates on state agencies. CBO estimates that the aggregate cost of those mandates would fall below the annual thresholds established in UMRA for intergovernmental and private-sector mandates (\$77 million and \$154 million in 2015, respectively, adjusted annually for inflation).”

COST OF LEGISLATION

JUNE 5, 2015.

Hon. JIM INHOFE,
Chairman, Committee on Environment and Public Works,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 697, the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

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

Sincerely,

KEITH HALL.

Enclosure.

S. 697—Frank R. Lautenberg Chemical Safety for the 21st Century Act

Summary: S. 697 would modify the Toxic Substances Control Act (TSCA), the law that regulates the manufacture, importation, and processing of chemicals, with the aim of strengthening the Environmental Protection Agency’s (EPA’s) ability to evaluate and regulate potentially hazardous chemicals.

CBO estimates that EPA would incur additional administrative costs over the 2016–2020 period to meet the new requirements imposed by S. 697; however, we also estimate that under the bill EPA would collect sufficient fees from chemical manufacturers and processors to offset the cost of conducting the activities proposed under

this legislation. On net, we estimate that implementing this legislation would reduce discretionary costs by \$8 million over the next five years, assuming appropriation actions consistent with provisions of the bill.

Enacting S. 697 could affect direct spending and revenues because the bill would increase some existing civil and criminal penalties for violations of TSCA. Therefore, pay-as-you-go procedures apply. CBO estimates that any changes in revenues and direct spending would not be significant.

S. 697 would impose intergovernmental and private-sector mandates, as defined in the Unfunded Mandates Reform Act (UMRA), on manufacturers, processors, importers, and users of chemical substances. The bill also would impose intergovernmental mandates on state agencies. CBO estimates that the aggregate cost of those mandates would fall below the annual thresholds established in UMRA for intergovernmental and private-sector mandates (\$77 million and \$154 million in 2015, respectively, adjusted annually for inflation).

Major provisions: The bill's major provisions would:

- Require EPA to develop policies, procedures, and guidance to address the process for testing and evaluating the safety of chemical substances;
- Authorize EPA to obtain new information on chemical substances from manufacturers and processors at all stages of the safety evaluation process;
- Require EPA to establish and implement a risk-based prioritization process to screen all chemicals now in use;
- Address when federal actions under TSCA preempt requirements of state and local governments related to restricting and banning chemical substances;
- Require EPA to update its process for reviewing industry requests that information submitted to the agency be kept confidential; and,
- Require EPA to establish a new schedule for charging fees to chemical manufacturers who are required to submit data to the agency or who request that EPA assess certain chemicals that are not yet prioritized for review by EPA.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 697 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—					
	2016	2017	2018	2019	2020	2016–2020
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Administrative Expenses under TSCA:						
Estimated Authorization Level	17	17	17	17	17	85
Estimated Outlays	7	14	17	17	17	72
Offsetting Fee Collections:						
Estimated Authorization Level	–4	–10	–16	–25	–25	–80
Estimated Outlays	–4	–10	–16	–25	–25	–80
Total Changes:						
Estimated Budget Authority	13	7	1	–8	–8	5
Estimated Budget Outlays	3	4	1	–8	–8	–8

Note: TSCA = Toxic Substances Control Act.

Basis of estimate: For this estimate, CBO assumes that S. 697 will be enacted near the end of 2015 and that the necessary amounts will be appropriated each year.

Spending subject to appropriation

While some of the requirements in S. 697 are similar to activities currently performed by EPA under TSCA, 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 and on expectations of the additional workload provided by the agency. According to EPA, the agency currently requires, on average, an appropriation of about \$58 million annually to implement and enforce EPA's Chemical Risk Review and Reduction program under TSCA. That funding supports roughly 245 employees. Subject to the appropriation of the necessary amounts, CBO estimates that EPA would require about \$17 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 on implementing S. 697 primarily by producing guidance documents and cost-benefit analyses and performing other administrative tasks related to the rulemaking process for the review of the safety of new chemicals and substances currently in use. EPA would establish internal processes and information technology systems to prioritize the analysis of tens of thousands of chemicals. According to the agency, such activities are routinely carried out by contractors; as a result, most of the estimated \$17 million in annual funding needed over this period would cover contractor costs. By 2018, enforcement of the new provisions of TSCA would begin and CBO estimates that EPA would shift funding to cover additional government personnel. CBO estimates that spending on new administrative activities over the next five years would total \$72 million.

Under the legislation EPA would be authorized to charge two types of fees. One would be imposed on chemical manufacturers and processors who are required to submit certain types of notices or requests for exemptions under the bill. In addition, EPA could charge fees to manufacturers and processors who request that EPA conduct safety assessments and safety determinations for chemicals that have not been designated a priority for further assessment.

Under the bill total collections of fees for firms submitting notices and requests for exemptions could not exceed \$18 million annually. CBO estimates that EPA would begin collecting those fees in 2017 and that such collections would total \$6 million in that first year. By 2019, we expect that as more chemicals are reviewed by EPA, collections would reach \$18 million annually. Based on information from EPA, CBO estimates that collections from firms requesting safety assessments and determinations would begin in 2016 and would total \$4 million in that year. By 2019 we estimate that collections would total \$7 million annually. S. 697 specifies that all additional fees collected by EPA would be recorded in the budget as offsetting collections (an offset to appropriated spending).

CBO estimates that those collections would total \$80 million over the next five years. Thus, enacting this legislation would result in a net reduction in spending of \$8 million over the 2016–2020 period, assuming future appropriations acts are consistent with CBO’s estimates.

Direct spending and revenues

Enacting S. 697 also could affect direct spending and revenues because this bill would increase some existing civil and criminal penalties. 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.

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 2016–2025 period.

Intergovernmental and Private-Sector Impact: S. 697 would impose intergovernmental and private-sector mandates, as defined in UMRA, on manufacturers, processors, importers, and users of chemical substances. The bill also would impose intergovernmental mandates on state agencies. CBO estimates that the aggregate cost of those mandates would fall below the annual thresholds established in UMRA for intergovernmental and private-sector mandates (\$77 million and \$154 million in 2015, respectively, adjusted annually for inflation).

Mandates that apply to both public and private entities

S. 697 would modify the standard used to determine whether a chemical substance poses an unreasonable risk to human health or the environment and would allow EPA to regulate the manufacture, processing, distribution, use, and disposal of chemical substances to ensure the standard is met. If EPA determines that some chemical substances do not meet the standard and issues regulations for those substances, the bill would impose an intergovernmental and private-sector mandate. EPA would have the authority to adopt a range of regulatory options to address risks from chemical substances. For example, EPA could require manufacturers to put warning labels on selected chemicals. EPA also could require users of chemicals, such as public and private universities conducting research, to handle or dispose of selected chemicals in a certain way. Based on information from industry experts, CBO expects that the annual cost of any restriction would not be substantial. Also, because of the amount of time involved in assessing the risk of each chemical, any restrictions imposed would apply to few chemicals in the first five years the mandate is in effect. Therefore, CBO estimates that the cost of the mandate would be small for both public and private entities during that time.

Mandates that apply to public entities only

The bill would impose an intergovernmental mandate by preempting state regulations that conflict with the federal regulation of chemicals, but that preemption would impose no duty on states

that would result in additional spending or a loss of revenues. The bill also would impose a mandate on state agencies by requiring them to notify EPA whenever they propose an administrative action, enact a statute, or take regulatory action concerning a chemical that EPA has not designated as a high-priority substance. Information from EPA indicates that the cost of that notification mandate would be small.

Mandates that apply to private entities only

The bill would amend provisions in TSCA that apply to new and existing chemicals. The bill would impose new mandates and increase the cost of existing mandates on manufacturers, importers, and processors of chemical substances. Additionally, manufacturers and processors would be required to pay fees and submit data to EPA for use carrying out safety assessments and regulations to ensure safety. Finally, the bill could impose a mandate on importers of some items containing chemical substances.

Based on information from industry experts, CBO expects that the incremental cost of those mandates would not be substantial. The bill would limit the amount of mandatory fees that EPA could collect to \$18 million annually. Manufacturers and processors of existing chemical substances currently report information to EPA under programs such as the Chemical Data Reporting rule and the High Production Volume Challenge Program, which is voluntary. Based on information from industry experts, CBO expects that submitting new data to EPA for safety assessments could cost up to \$1 million per chemical substance. However, the annual number of existing chemicals that would be subject to the data submission requirements would be limited.

Estimate prepared by: Federal spending: Susanne Mehlman; Impact on state, local, and tribal governments: Jon Sperl; Impact on the private sector: Amy Petz.

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

MINORITY VIEWS

MINORITY VIEWS OF BOXER, CARDIN, SANDERS, GILLIBRAND, AND MARKEY ON S. 697, AS REPORTED BY THE EPW COMMITTEE

Protecting people from harmful chemicals is a fundamental goal. It is clear that our current chemical regulation law—the Toxic Substances Control Act (TSCA)—is broken. Reform of this law must avoid creating loopholes that could result in a failure once again.

In a key 1991 court decision, EPA's plan to phase out asbestos uses was overturned despite overwhelming evidence about the dangers of this chemical. Since this case, EPA has been unable to address the most dangerous chemicals being used today.

Reform of this failed law is needed. Any action by Congress must be better than current law and must ensure families have additional protections. Important clarifications and improvements are needed to ensure that S. 697, as reported by the EPW Committee, clearly addresses the threats dangerous chemicals pose.

The version of the bill reported by the EPW Committee makes vital improvements to the introduced bill, including removing preemption of state air and water laws, allowing co-enforcement of chemical restrictions by the States, allowing judicial review of chemicals designated as "low priority", and removing a harmful provision that would have undermined EPA's ability to restrict the import of dangerous chemicals from foreign countries.

This is important progress. However, the bill needs further improvement to make sure that TSCA reform addresses the most dangerous chemicals without being mired in years of litigation. That is why the following public health, labor, and environmental organizations do not support the bill reported by the EPW Committee and have called for additional changes.

- Safer Chemicals, Healthy Families Coalition (represents 450 organizations dedicated to reforming toxics laws)
- Asbestos Disease Awareness Organization
- Breast Cancer Fund
- AFL-CIO
- Center for Environmental Health
- Environmental Working Group
- California Attorney General

IMPROVEMENTS NEEDED TO S. 697

Allow States to Protect Their Citizens Until EPA Acts—The bill reported by the EPW Committee stops States from regulating a chemical as soon as EPA begins its assessment of the chemical and many years before a Federal restriction is actually put in place.

The bill creates a waiver process that would allow States to petition EPA to move forward. This process is complicated, subject to litigation, and leaves great uncertainty about the ability of States to protect their citizens before federal safeguards are finalized. States need greater certainty that they can act until Federal restrictions under TSCA are in place and effective so that they can ensure public health is protected.

Act on Known Dangers—The bill should make it clear that known chemical threats, such as asbestos and chemicals that accumulate in the body, will be addressed. The bill would encourage EPA to consider persistent and bioaccumulative chemicals, but would not require action. Furthermore, asbestos, which is estimated to kill 15,000 people every year, is not specifically addressed or prioritized in the bill despite its known dangers. The bill does not prioritize or address chemicals stored near sources of drinking water that could spill and contaminate drinking water supplies. Finally, the bill should provide the tools necessary to investigate, undertake actions, and coordinate responses to address disease clusters. Chemicals that present known threats such as these should be specifically addressed in the bill to guarantee that action is taken.

Ensure EPA Can Take Action to Address Dangerous Chemicals—The current TSCA law contains a number of flaws that make the adoption of strong public health protections against the most dangerous types of chemicals an extremely and unnecessarily difficult task. The bill reported by the EPW Committee does not sufficiently address these flaws. S. 697 maintains elements of the current “unreasonable risk” safety standard for EPA actions to ban or restrict exposure to toxic substances. The bill also maintains the “substantial evidence” legal standard that was an important reason for the failure of the current TSCA law. Legislation to reform TSCA should be clear that this legal standard does not create an unnecessary hurdle to implementing restrictions on chemicals that have been proven to be a danger.

Meaningfully Improve Scope and Speed of Chemical Reviews—The bill should do more to ensure meaningful progress to assess and act on chemicals that present a danger to public health. S. 697 requires EPA to begin studying the safety of 25 chemicals within the first 5 years. According to EPA there are at least 1,000 chemicals that are dangerous enough to require further study immediately. The bill should require EPA to address this concern and provide the resources to assess the most dangerous chemicals in commerce as quickly as possible.

As S. 697 moves forward, we stand ready to work with our colleagues to address the issues identified here and pass TSCA reform that protects our children and families from the threat of dangerous chemicals.

BARBARA BOXER.
BENJAMIN L. CARDIN.
BERNARD SANDERS.
KIRSTEN GILLIBRAND.
EDWARD MARKEY.

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:

* * * * *

TOXIC SUBSTANCES CONTROL ACT

* * * * *

SEC. 2. FINDINGS, POLICY, AND INTENT.

(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]

(1) ADMINISTRATION.—*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 en-

vironmental, economic, and social impact of any action the Administrator takes or proposes to take under this Act, *as provided under this Act.*

(2) REFORM.—[It is the intent of Congress that reform of this Act] *This Act, including reforms* in accordance with the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act—

(A) *shall be administered in a manner that—*

(i) *protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and*

(ii) *ensures that appropriate information on chemical substances and mixtures is available to public health officials and first responders in the event of an emergency; and*

(B) *shall not displace or supplant common law rights of action or remedies for civil relief.*

SEC. 3. DEFINITIONS.

As used in this Act:

(1) The² term “Administrator” means the Administrator of the Environmental Protection Agency.

(2)(A) Except as provided in subparagraph (B), 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 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 prod-

²In 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.

ucts (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).

(3) 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).

(4) CONDITIONS OF USE.—*The term ‘conditions of use’ means the intended, known, or reasonably foreseeable circumstances the Administrator determines a chemical substance is manufactured, processed, distributed in commerce, used, or disposed of.*

[(4)] (5) 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.

[(5)] (6) The term “environment” includes water, air, and land and the interrelationship which exists among and between water, air, and land and all living things.

[(6)] (7) 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 exposure 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)] (8) 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)] (9) 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)] (10) 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).

(11) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.—*The term ‘potentially exposed or susceptible population’ means 1 or more groups—*

(A) *of individuals within the general population who may be—*

(i) *differentially exposed to chemical substances under the conditions of use; or*

(ii) *susceptible to greater adverse health consequences from chemical exposures than the general population; and*

(B) *that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly.*

[(10)] (12) 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)] (13) The term “processor” means any person who processes a chemical substance or mixture.

(14) SAFETY ASSESSMENT.—*The term ‘safety assessment’ means an assessment of the risk posed by a chemical substance under the conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.*

(15) SAFETY DETERMINATION.—*The term ‘safety determination’ means a determination by the Administrator as to whether a chemical substance meets the safety standard under the conditions of use.*

(16) SAFETY STANDARD.—*The term ‘safety standard’ means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of injury to health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of injury to—*

(A) *the general population; or*

(B) *any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.*

[(12)] (17) 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)] (18) 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.

[(14)] (19) The term “United States”, when used in the geographic sense, means all of the States.

SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

(a) DEFINITION OF GUIDANCE.—*In this section, the term ‘guidance’ includes any significant written guidance of general applicability prepared by the Administrator.*

(b) DEADLINE.—*Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.*

(c) USE OF SCIENCE.—

(1) IN GENERAL.—*The Administrator shall establish policies, procedures, and guidance on the use of science in making decisions under sections 4, 4A, 5, and 6.*

(2) GOAL.—*A goal of the policies [and,] procedures, and guidance described in paragraph (1) shall be to make the basis of decisions clear to the public.*

(3) REQUIREMENTS.—*The policies, procedures, and guidance issued under this section shall describe the manner in which the Administrator shall ensure that —*

(A) *decisions made by the Administrator—*

(i) *are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;*

(ii) *take into account the extent to which—*

(I) *assumptions and methods are clearly and completely described and documented;*

(II) *variability and uncertainty are evaluated and characterized; and*

(III) *the information has been subject to independent verification and peer review; and*

(iii) *are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;*

(B) *to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;*

(C) *a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and*

(D) *if appropriate, the recommendations in reports of the National Academy of Sciences that provide advice regard-*

ing assessing the hazards, exposures, and risks of chemical substances are considered.

(d) EXISTING EPA POLICIES, PROCEDURES, AND GUIDANCE.—*The policies, procedures, and guidance described in subsection (b) shall incorporate, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.*

(e) REVIEW.—*Not later than 5 years after the date of enactment of [this section] the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and not less frequently than once every 5 years thereafter, the Administrator shall—*

(1) *review the adequacy of any policies, procedures, and guidance developed under this section, including animal, non-animal, and epidemiological test methods and procedures for assessing and determining risk under this Act; and*

(2) *after providing public notice and an opportunity for comment, revise the policies, procedures, and guidance if necessary to reflect new scientific developments or understandings.*

“(f) SOURCES OF INFORMATION.—*In [making any decision with respect to a chemical substance under section 4, 4A, 5, or] carrying out sections 4, 4A, 5, and 6, the Administrator shall take into consideration information relating to [the hazards and exposures of] a chemical substance, including hazard and exposure information, under the conditions of use that is reasonably available to the Administrator, including information that is—*

(1) *submitted to the Administrator pursuant to any rule, consent agreement, order, or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act, by—*

(A) *manufacturers or processors of a substance;*

(B) *the public;*

(C) *other Federal departments or agencies; or*

(D) *the Governor of a State or a State agency with responsibility for protecting health or the environment;*

(2) *submitted to a governmental entity in any jurisdiction pursuant to a governmental requirement relating to the protection of health or the environment; or*

(3) *identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible by the Administrator.*

(g) TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.—

(1) IN GENERAL.—*The Administrator shall establish policies and procedures for the testing of chemical substances or mixtures under section 4.*

(2) GOAL.—*A goal of the policies and procedures established under paragraph (1) shall be to make the basis of decisions clear to the public.*

(3) CONTENTS.—*The policies and procedures established under paragraph (1) shall—*

“(A) *address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of expo-*

sure information as a lack of exposure or exposure potential;

(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations;

(C) require the Administrator to consult with the Director of the National Institute for Occupational Safety and Health prior to prescribing epidemiologic studies of employees; and

(D) require that prior to making a request or adopting a requirement for testing using vertebrate animals, [require] the Administrator [to] shall take into consideration, as appropriate and to the extent practicable, reasonably available—

(i) toxicity information;

(ii) computational toxicology and bioinformatics;

(iii) high-throughput screening methods and the prediction models of those methods; and

(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.

(h) SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

(1) SCHEDULE.—

(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

(C) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall identify the substances subject to safety assessments and safety determinations to be completed that year.

(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

(A) IN GENERAL.—The Administrator shall establish, by rule, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

(C) MINIMUM REQUIREMENTS.—At a minimum, the policies and procedures under this paragraph shall—

(i) describe—

(I) the manner in which the Administrator will identify informational needs and seek that information from the public;

(II) the information (including draft safety assessments) that may be submitted by interested individuals or entities, including States; and

(III) the criteria by which that information will be evaluated;

(ii) require the Administrator—

(I)(aa) to define the scope of the safety assessment and safety determination to be conducted under section 6, including the hazards, exposures, conditions of use, and potentially exposed and susceptible populations that the Administrator expects to consider in a safety assessment;

(bb) to explain the basis for the scope of the safety assessment and safety determination; and

(cc) to accept comments regarding the scope of the safety assessment and safety determination; and

(II)(aa) to identify the items described in subclause (I) that the Administrator has considered in the final safety assessment; and

(bb) to explain the basis for the consideration of those items;

(iii) describe the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the conditions of use will be considered, and explain the basis for that consideration in the final safety assessment;

(iv) require that each safety assessment and safety determination shall include—

(I) a description of the weight of the scientific evidence of risk; and

(II) a summary of the information regarding the impact on health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies;

(v) establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination; and

(vi) when relevant information is provided or otherwise made available to the Administrator, shall consider the extent of Federal regulation under other Federal laws.

(D) GUIDANCE.—

(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop guidance to assist interested persons in developing their own draft safety assessments and other information for submission to the Administrator,

which may be considered at the discretion of the Administrator.

(ii) REQUIREMENT.—*The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing a draft safety assessment for consideration by the Administrator.*

(i) PUBLICLY AVAILABLE INFORMATION.—*Subject to section 14, the Administrator shall—*

(1) *make publicly available a nontechnical summary, and the final version, of each safety assessment and safety determination;*

(2) *provide public notice and an opportunity for comment on each proposed safety assessment and safety determination;* and

(3) *make public in a final safety assessment and safety determination—*

(A) *the list of studies considered by the Administrator in carrying out the safety assessment or safety determination;* and

(B) *the list of policies, procedures, and guidance that were followed in carrying out the safety assessment or safety determination.*

(j) CONSULTATION WITH SCIENCE ADVISORY COMMITTEE ON CHEMICALS.—

(1) ESTABLISHMENT.—*Not later than 1 year after the date of enactment of this section, the Administrator shall establish an advisory committee, to be known as the ‘Science Advisory Committee on Chemicals’ (referred to in this subsection as the ‘Committee’).*

(2) PURPOSE.—*The purpose of the Committee shall be to provide independent advice and expert consultation, on the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.*

(3) COMPOSITION.—*The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.*

(4) SCHEDULE.—*The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.*

(5) RELATIONSHIP TO OTHER LAW.—*All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).*

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 re-

peals 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 period 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 require-

ments 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.]

(a) DEVELOPMENT OF NEW INFORMATION ON CHEMICAL SUBSTANCES AND MIXTURES.—

(1) IN GENERAL.—*The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section if the Administrator determines that the information is necessary—*

(A) *to review a notice under section 5(d) or to perform a safety assessment or safety determination under section 6;*

(B) *to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4) or under a rule promulgated under section 6(d)(3);*

(C) *pursuant to section 12(a)(4); or*

(D) *at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.*

(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

(A) IN GENERAL.—*Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.*

(B) PROHIBITION.—*Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.*

(C) LIMITATION.—*The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.*

(3) FORM.—[Subject to section 3A(h),] [t] The Administrator may require the development of information described in paragraph (1) or (2) by—

(A) *promulgating a rule;*

(B) *entering into a testing consent agreement; or*

(C) *issuing an order.*

(4) CONTENTS.—

(A) IN GENERAL.—*A rule, testing consent agreement, or order issued under this subsection shall include—*

(i) *identification of the chemical substance or mixture for which testing is required;*

(ii) *identification of the persons required to conduct the testing;*

(iii) test protocols and methodologies for the development of [test data and] information for the chemical substance or mixture, including specific reference to any reliable nonanimal test procedures; and

(iv) specification of the period within which individuals and entities required to conduct the testing shall submit to the Administrator the information developed in accordance with the procedures described in clause (iii).

(B) CONSIDERATIONS.—*In determining the procedures and period to be required under subparagraph (A), the Administrator shall take into consideration—*

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

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

(b) STATEMENT OF NEED.—

(1) IN GENERAL.—*In promulgating a rule, entering into a testing consent agreement, or issuing an order for the development of additional information (including information on exposure or exposure potential) pursuant to this section, the Administrator shall—*

(A) identify the need intended to be met by the rule, agreement, or order;

(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

(C) explain the basis for any decision that requires the use of vertebrate animals.

(2) EXPLANATION IN CASE OF ORDER.—

(A) IN GENERAL.—*If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an order is warranted instead of promulgating a rule or entering into a testing consent agreement.*

(B) CONTENTS.—*A statement described in subparagraph*

(A) shall contain a description of—

(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

(ii) the extent to which the Administrator has obtained or attempted to obtain the information through voluntary submissions; and

(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

(c) REDUCTION OF TESTING ON VERTEBRATES.—

(1) IN GENERAL.—*The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—*

(A) encouraging and facilitating—

(i) the use of integrated and tiered testing and assessment strategies;

(ii) the use of best available science in existence on the date on which the test is conducted;

(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

(vi) the submission of information from—

(I) animal-based studies; and

(II) emerging methods and models; and

(B) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

(A) not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information under this title that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

(C) identify in the strategic plan developed under subparagraph (A) particular alternative test methods or testing strategies that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information of equivalent scientific reliability and quality to that which would be obtained from vertebrate animal testing;

(D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific reliability, relevance, and equivalent information and the test methods and strategies identified in subparagraph (C);

(E) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation;

(F) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing under this title; and

(G) identify synergies with the related information requirements of other jurisdictions to minimize the potential for additional or duplicative testing.

(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

(A) there is sufficient 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 if the information from each individual source alone is insufficient to support the conclusion;

(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

(i) the substance cannot be absorbed; or

(ii) testing for a specific endpoint is technically not practicable to conduct; or

(C) a chemical substance or mixture cannot be tested in vertebrate 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 a potential to cause severe corrosion or severe irritation to the tissues of the animal.

(4) VOLUNTARY TESTING.—

(A) IN GENERAL.—Any person developing information for submission under this title on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative or nonanimal test method or testing strategy that the Administrator has determined under paragraph (2)(C) to be scientifically reliable, relevant, and capable of providing equivalent information, before conducting new animal testing.

(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph—

(i) requires the Administrator to review the basis on which the person is conducting testing described in subparagraph (A);

(ii) prohibits the use of other test methods or testing strategies by any person for purposes other than developing information for submission under this title on a voluntary basis; or

(iii) prohibits the use of other test methods or testing strategies by any person, subsequent to the attempt to develop information using the test methods and testing

strategies identified by the Administrator under paragraph (2)(C).

(d) TESTING REQUIREMENTS.—

(1) IN GENERAL.—*The Administrator may require the development of information by—*

(A) *manufacturers and processors of the chemical substance or mixture; and*

(B) *subject to paragraph (3), persons that begin to manufacture or process the chemical substance or mixture—*

(i) *after the effective date of the rule, testing consent agreement, or order; but*

(ii) *before the period ending on the later of—*

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

or

(II) *the last day of the period that begins on the date referred to in clause (i) and that is equal to the period that the Administrator determines was necessary to develop the information.*

(2) DESIGNATION.—*The Administrator may permit 2 or more persons identified in subparagraph (A) or (B) of paragraph (1) to designate 1 of the persons or a qualified third party—*

(A) *to develop the information; and*

(B) *to submit the information on behalf of the persons making the designation.*

(3) EXEMPTIONS.—

(A) IN GENERAL.—*A person otherwise subject to a rule, testing consent agreement, or order under this section may submit to the Administrator an application for an exemption on the basis that the information is being developed by a person designated under paragraph (2).*

(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

(i) IN GENERAL.—*If the Administrator accepts an application submitted under subparagraph (A), the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as agreed to between the applicant and the designee.*

(ii) ARBITRATION.—*If the applicant and a person designated under paragraph (2) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.*

(C) TERMINATION.—*If, after granting an exemption under this paragraph, the Administrator determines that [a] no person [covered] by the exemption has failed to comply [designated under paragraph (2) has complied] with the rule, testing consent agreement, or order, the Administrator shall—*

(i) *by order, terminate the exemption; and*

(ii) *notify in writing each person that received an exemption of the requirements with respect to which the exemption was granted.*

(4) TIERED TESTING.—

(A) IN GENERAL.—*Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.*

(B) SCREENING-LEVEL TESTS.—

(i) IN GENERAL.—*The screening-level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.*

(ii) USE.—*Screening-level tests shall be used—*

(I) *to screen chemical substances or mixtures for potential adverse effects; and*

(II) *to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.*

(C) ADDITIONAL TESTING.—*If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for safety assessments or safety determinations, the Administrator may require more advanced tests for potential health or environmental effects or exposure potential.*

(D) ADVANCED TESTING WITHOUT SCREENING.—*The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.*

(e) TRANSPARENCY.—*Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders and all information submitted under this section.*

[(e)] (f) 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] rule, testing consent agreement, or order [under subsection (a)] under this subsection. 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, *without taking into account cost or other nonrisk factors*,

(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)】** *under this subsection* 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)】** *under this subsection*. 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 preceding³ 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, 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)】** *under this subsection* or if such a proceeding is not initiated within such period, publish in the Fed-

³So in law. Probably should be "preceding".

eral 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] *rule, testing consent agreement, or order* 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** *rule, testing consent agreement, or order* 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)] (g) 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, *without taking into account cost or other nonrisk factors*. 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. 4A. PRIORITIZATION SCREENING.

(a) **Establishment and List of Substances.** *Prioritization Screening Process*—

(1) **IN GENERAL.**—*Not later than 1 year after the date of enactment of this section, the Administrator shall establish, by rule, a risk-based screening process and explicit criteria for identifying existing chemical substances that are—*

(A) *a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances');* and

(B) *a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').*

- (2) INITIAL LIST OF HIGH- AND LOW-PRIORITY SUBSTANCES.—
- (A) IN GENERAL.—*Before the date of promulgation of the rule under paragraph (1) and not later than 180 days after the date of enactment of this section, the Administrator—*
- (i) *shall take into consideration and publish an initial list of high-priority substances and low-priority substances; and*
- (ii) *pursuant to section 6(b), may initiate or continue safety assessments and safety determinations for those high-priority substances.*
- (B) REQUIREMENTS.—
- (i) IN GENERAL.—*The initial list of chemical substances shall contain at least 10 high-priority substances, at least 5 of which are drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, and at least 10 low-priority substances.*
- (ii) SUBSEQUENTLY IDENTIFIED SUBSTANCES.—*Insofar as possible, at least 50 percent of all substances subsequently identified by the Administrator as high-priority substances shall be drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, until all Work Plan chemicals have been designated under this subsection.*
- (iii) PERSISTENCE AND BIOACCUMULATION.—*In developing the initial list and in identifying additional high-priority substances, the Administrator shall give preference to chemical substances scored as high for persistence and bioaccumulation in the October 2014 TSCA Work Plan and subsequent updates.*
- (C) ADDITIONAL CHEMICAL REVIEWS.—*The Administrator shall, as soon as practicable and not later than—*
- (i) *3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 20 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 20 low-priority substances have been designated; and*
- (ii) *5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 25 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 25 low-priority substances have been designated.*
- (3) IMPLEMENTATION.—
- (A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—
- (i) ACTIVE SUBSTANCES.—*In carrying out paragraph (1), the Administrator shall take into consideration ac-*

tive substances, as determined under section 8, which may include chemical substances on the interim list of active substances established under that section.

(ii) **INACTIVE SUBSTANCES.**—*In carrying out paragraph (1), the Administrator may take into consideration inactive substances, as determined under section 8, that the Administrator determines—*

(I)(aa) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

(bb) have the potential for high hazard and widespread exposure; or

(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

(bb) with respect to which there exists the potential for residual high hazards or widespread exposures not otherwise addressed by the regulatory or other action.

(iii) **REPOPULATION.**—

(I) IN GENERAL.—*On the completion of a safety determination under section 6 for a chemical substance, the Administrator shall remove the chemical substance from the list of high-priority substances established under this subsection.*

(II) ADDITIONS.—*The Administrator shall add at least 1 chemical substance to the list of high-priority substances for each chemical substance removed from the list of high-priority substances established under this subsection, until a safety assessment and safety determination is completed for all high-priority substances.*

(III) LOW-PRIORITY SUBSTANCES.—*If a low-priority substance is subsequently designated as a high-priority substance, the Administrator shall remove that substance from the list of low-priority substances.*

(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

(i) **IN GENERAL.**—*The Administrator shall—*

(I) except as provided under paragraph (2), not later than 180 days after the effective date of the final rule under paragraph (1), begin the prioritization screening process; and

(II) make every effort to complete the designation of all active substances as high-priority substances or low-priority substances in a timely manner.

(ii) **DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.**—*Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical sub-*

stance as a high-priority substance or low-priority substance.

(iii) CONSIDERATION.—

(I) IN GENERAL.—*The Administrator shall screen substances and designate high-priority substances taking into consideration the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in a timely manner.*

(II) ANNUAL GOAL.—*The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.*

(C) SCREENING OF CATEGORIES OF SUBSTANCES.—*The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate designations of high-priority substances and low-priority substances and safety assessments and safety determinations for high-priority substances.*

(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—*The Administrator shall keep current and publish a list of chemical substances that—*

(i) *are being considered in the prioritization screening process and the status of the chemical substances in the prioritization process, including those chemical substances for which prioritization decisions have been deferred; and*

(ii) *are designated as high-priority substances or low-priority substances, including the bases for such designations.*

(4) CRITERIA.—*The criteria described in paragraph (1) shall account for—*

(A) *the recommendation of the Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances appropriate for prioritization screening;*

(B) *the hazard and exposure potential of the chemical substance (or category of substances), including persistence, bioaccumulation, and specific scientific classifications and designations by authoritative governmental entities;*

(C) *the conditions of use or significant changes in the conditions of use of the chemical substance;*

(D) *evidence and indicators of exposure potential to humans or the environment from the chemical substance, including potentially exposed or susceptible populations;*

(E) *the volume of a chemical substance manufactured or processed;*

(F) *whether the volume of a chemical substance as reported under a rule promulgated pursuant to section 8(a) has significantly increased or decreased during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance;*

(G) *the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and*

(H) *the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a high-priority or a low-priority substance.*

(b) **PRIORITIZATION SCREENING PROCESS AND DECISIONS.—**

(1) **IN GENERAL.—***The prioritization screening process developed under subsection (a) shall include a requirement that the Administrator shall—*

(A) *identify the chemical substances being considered for prioritization;*

(B) *request interested persons to supply information regarding the chemical substances being considered;*

(C) *apply the criteria identified in subsection (a)(4); and*

(D) *subject to paragraph (5) and using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.*

(2) **INTEGRATION OF INFORMATION.—***The prioritization screening decision regarding a chemical substance shall integrate any hazard and exposure information relating to the chemical substance that is available to the Administrator.*

(3) **IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—***The Administrator—*

(A) *shall identify as a high-priority substance a chemical substance that, relative to other active chemical substances, the Administrator determines has the potential for significant hazard and significant exposure;*

(B) *may identify as a high-priority substance a chemical substance that, relative to other active chemical substances, the Administrator determines has the potential for significant hazard or significant exposure; and*

(C) *may identify as a high-priority substance an inactive substance, as determined under subsection (a)(3)(A)(ii) and section 8(b), that the Administrator determines warrants a safety assessment and safety determination under section 6.*

(4) **IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—***The Administrator shall identify as a low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that the chemical substance is likely to meet the safety standard.*

(5) **DEFERRING A DECISION.—***If the Administrator determines that additional information is required to establish the priority of a chemical substance under this section, the Administrator*

may defer the prioritization screening decision for a reasonable period—

(A) to allow for the submission of additional information by an interested person and for the Administrator to evaluate the additional information; or

(B) to require the development of information pursuant to a rule, testing consent agreement, or order issued under section 4(a)(2).

(6) DEADLINES FOR SUBMISSION OF INFORMATION.—*If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of the information.*

(7) NOTICE AND COMMENT.—*The Administrator shall—*

(A) *publish, including in the Federal Register, the proposed decisions made under paragraphs (3), (4), and (5) and the basis for the decisions; and*

(B) *provide 90 days for public comment.*

(8) REVISIONS OF PRIOR DESIGNATIONS.—

(A) IN GENERAL.—*At any time, and at the discretion of the Administrator, the Administrator may revise the designation of a chemical substance as a high-priority substance or a low-priority substance based on information available to the Administrator after the date of the determination under paragraph (3) or (4).*

(B) LIMITED AVAILABILITY.—*If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.*

(9) OTHER INFORMATION RELEVANT TO PRIORITIZATION.—

(A) IN GENERAL.—*If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State proposes an administrative action or enacts a statute or takes an administrative action to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not [as] designated as a high-priority substance, the Governor or State agency with responsibility for implementing the statute or administrative action shall notify the Administrator.*

(B) REQUESTS FOR INFORMATION.—*Following receipt of a notification provided under subparagraph (A), the Administrator may request any available information from the Governor or the State agency with respect to—*

(i) *scientific evidence related to the hazards, exposures and risks of the chemical substance under the conditions of use which the statute or administrative action is intended to address;*

(ii) *any State or local conditions which warranted the statute or administrative action;*

(iii) *the statutory or administrative authority on which the action is based; and*

(iv) any other available information relevant to the prohibition or other restriction, including information on any alternatives considered and their hazards, exposures, and risks.

(C) **PRIORITIZATION SCREENING.**—*The Administrator shall conduct a prioritization screening under this subsection for all substances that—*

(i) *are the subject of notifications received under subparagraph (A); and*

(ii) *the Administrator determines—*

(I) *are likely to have significant health or environmental impacts;*

(II) *are likely to have significant impact on interstate commerce; or*

(III) *have been subject to a prohibition or other restriction under a statute or administrative action in 2 or more States.*

(D) **AVAILABILITY TO PUBLIC.**—*Subject to section 14 and any applicable State law regarding the protection of confidential information provided to the State or to the Administrator, the Administrator shall make information received from a Governor or State agency under subparagraph (A) publicly available.*

(E) **EFFECT OF PARAGRAPH.**—*Nothing in this paragraph shall preempt a State statute or administrative action, require approval of a State statute or administrative action, or apply section 15 to a State.*

(10) **REVIEW.**—*Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Administrator shall—*

(A) *review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and*

(B) *if necessary, modify the prioritization screening process.*

(11) **EFFECT.**—*Subject to section 18, a designation by the Administrator under this section with respect to a chemical substance shall not affect—*

(A) *the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance; or*

(B) *the regulation of those activities.*

(c) **ADDITIONAL PRIORITIES FOR SAFETY ASSESSMENTS AND DETERMINATIONS.**—

(1) **REQUIREMENTS.**—

(A) **IN GENERAL.**—*The prioritization screening process developed under subsection (a) shall—*

(i) *include a process by which a manufacturer or processor of an active chemical substance that has not been designated a high-priority substance or is not in the process of a prioritization screening by the Administrator, may request that the Administrator designate the substance as an additional priority for a safety assessment and safety determination, subject to the payment of fees pursuant to section 26(b)(3)(E);*

(ii) specify the information to be provided in such requests; and

(iii) specify the criteria the Administrator shall use to determine whether or not to grant such a request, which shall include whether the substance is subject to restrictions imposed by statutes enacted or administrative actions taken by 1 or more States on the manufacture, processing, distribution in commerce, or use of the substance.

(B) PREFERENCE.—Subject to paragraph (2), in deciding whether to grant requests under this subsection the Administrator shall give a preference to requests concerning substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

(C) **Exceptions.—Requests** Exceptions.—Chemical substances for which requests have been granted under this subsection shall not be subject to subsection (a)(3)(A)(iii) or section 18(b).

(2) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

(A) if a sufficient number of additional priority requests meet the requirements of paragraph (1), not less than 25 percent, or more than 30 percent, of the cumulative number of substances designated to undergo safety assessments and safety determinations under **[this section]** subsections (a)(2) and (b)(3) are substances designated under the process and criteria pursuant to paragraph (1);

(B) the resources allocated to conducting safety assessments and safety determinations for additional priorities designated under this subsection are proportionate to the number of such substances relative to the total number of substances designated to undergo safety assessments and safety determinations under this section; and

(C) the number of additional priority requests stipulated under subparagraph (A) is in addition to the total number of high-priority **[chemicals]** substances identified under **[subsection (a)(2)(B)]** subsections (a)(2) and (b)(3).

(3) ADDITIONAL REVIEW OF WORK PLAN CHEMICALS FOR SAFETY ASSESSMENT AND SAFETY DETERMINATION.—In the case of a request under paragraph (1) with respect to a chemical substance identified by the Administrator in the October 2014 Work Plan—

(A) the 30-percent cap specified in paragraph (2)(A) shall not apply and the addition of Work Plan chemicals shall be at the discretion of the Administrator; and

(B) notwithstanding paragraph **[(6)]** (1)(C), requests for additional Work Plan chemicals under this subsection shall be considered high-priority chemicals subject to section 18(b) but not subsection (a)(3)(A)(iii).

(4) REQUIREMENTS.—

(A) IN GENERAL.—*The public shall be provided notice and an opportunity to comment on requests submitted under this subsection.*

(B) DECISION BY ADMINISTRATOR.—*Not later than 180 days after the date on which the Administrator receives a request under this subsection, the Administrator shall decide whether or not to grant the request.*

(C) ASSESSMENT AND DETERMINATION.—*If the Administrator grants a request under this subsection, the safety assessment and safety determination—*

(i) shall be conducted in accordance with the deadlines and other requirements of sections 3A(i) and 6; and

(ii) shall not be expedited or otherwise subject to special treatment relative to high-priority substances designated pursuant to subsection (b)(3) that are undergoing safety assessments and safety determinations.

[SEC. 5. MANUFACTURING AND PROCESSING NOTICES.]

SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.

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

[(a)] (b) [In General] Notices.—(1) Except as provided in **[subsection (h)] paragraph (3) and 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)] subsection (c)**, 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.

(3) ARTICLE CONSIDERATION.—*The Administrator may require the notification for the import or processing of a chemical substance as part of an article or category of articles under para-*

graph (1)(B) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification.;

[(d)] (c) CONTENT OF NOTICE; PUBLICATIONS IN THE FEDERAL REGISTER.—[(1) The notice required by subsection (a) subsection (b) 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.】

(1) IN GENERAL.—The notice required by subsection (b) shall include, with respect to a chemical substance—

(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

(B) information regarding conditions of use and reasonably anticipated exposures.

(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)] subsection (b) [(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;*and*

(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)] subsection (b) and for which the notification period prescribed by subsection (b) or (d) has not expired, and (B) each chemical sub-**

stance for which such notification period has expired since the last publication in the Federal Register of such list.

[(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) (d) 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) REVIEW OF NOTICE.—

(1) INITIAL REVIEW.—

(A) IN GENERAL.—*Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall—*

(i) conduct an initial review of the notice;

(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

(iii) make any necessary determination under paragraph (3).

(B) EXTENSION.—*Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.*

(2) INFORMATION SOURCES.—*In evaluating a notice under paragraph (1), the Administrator shall take into consideration—*

(A) any relevant information identified in subsection (c)(1); and

(B) any other relevant additional information available to the Administrator.

(3) DETERMINATIONS.—*Before the end of the applicable period for review under paragraph (1), based on the information described in paragraph (2), and subject to section 18(g), the Administrator shall determine that—*

(A) *the relevant chemical substance or significant new use is not likely to meet the safety standard, in which case the Administrator shall take appropriate action under paragraph (4);*

(B) *the relevant chemical substance or significant new use is likely to meet the safety standard, in which case the Administrator shall allow the review period to expire without additional restrictions; or*

(C) *additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under [paragraph] paragraphs (4) and (5).*

(4) RESTRICTIONS.—

(A) DETERMINATION BY ADMINISTRATOR.—

(i) IN GENERAL.—*If the Administrator makes a determination under subparagraph (A) or (C) of paragraph (3) with respect to a notice submitted under subsection (b)—*

(I) *the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, as appropriate, shall prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the restrictions specified in the consent agreement or order that the Administrator determines are sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard; and*

(II) *no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, except in compliance with the restrictions specified in the consent agreement or order.*

(ii) LIKELY TO MEET STANDARD.—*If the Administrator makes a determination under subparagraph (B) of paragraph (3) with respect to a chemical substance or significant new use for which a notice was submitted under subsection (b), at the end of the applicable period for review under paragraph (1), the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use.*

(B) REQUIREMENTS.—*Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall—*

(i) take into consideration whether to promulgate a rule pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance, or of the chemical substance for a new use, that is not in compliance with the restrictions imposed by the consent agreement or order; and

*(ii)(I) initiate a rulemaking described in clause (i); or
(II) publish a statement describing the reasons of the Administrator for not initiating a rulemaking.*

(C) INCLUSIONS.—*A prohibition or other restriction under subparagraph (A) may include, as appropriate—*

(i) subject to section 18(g), a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator

(ii) a requirement that manufacturers or processors of the chemical substance shall—

(I) make and retain records of the processes used to manufacture or process, as applicable, the chemical substance; or

(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, use, or disposal, as applicable, of the chemical substance, subject to section 4;

(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

(I) in general; or

(II) for a particular use;

(iv) a prohibition or other restriction of—

(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

(II) any method of commercial use of the chemical substance; or

(III) any method of disposal of the chemical substance; or

(v) a prohibition or other restriction on the manufacture, processing, or distribution in commerce of the chemical substance—

(I) in general; or

(II) for a particular use.

(D) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—*For a chemical substance the Administrator determines ranks high for persistence and bioaccumulation, the Ad-*

ministrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance is likely to meet the safety standard, reduce potential exposure to the substance to the maximum extent practicable.

(E) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

(F) DEFINITION OF REQUIREMENT.—For purposes of this Act, the term ‘requirement’ as used in this section does not displace common law.

(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

(C) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

(D) on receipt of information the Administrator finds supports the determination under paragraph (3), shall promptly make the determination.

[(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 Protection 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 proceeding 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.]

(e) NOTICE OF COMMENCEMENT.—

(1) IN GENERAL.—*Not later than 30 days after the date on which a manufacturer that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—*

(A) the name of the manufacturer; and

(B) the initial date of nonexempt commercial manufacture.

(2) WITHDRAWAL.—*A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.*

(f) FURTHER EVALUATION.—*The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—*

(1) *a notice of commencement for a chemical substance under subsection (c); or*

(2) *new information regarding the chemical substance.*

(g) TRANSPARENCY.—*Subject to section 14, the Administrator shall make available to the public—*

(1) *all notices, determinations, consent agreements, rules, and orders of the Administrator; and*

(2) *all information submitted or issued under this section.*

(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, *without taking into account cost or other nonrisk factors* 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) (2) The requirements of [subsections (a) and (b)] *subsection (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) (3) 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)] (4) 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)] (5) Immediately upon receipt of an application under [paragraph (1) or (5) *paragraph (1) or (4)*] 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.

[SEC. 6. REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES.]

SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.

[(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) publish 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 appro-

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 rule-making 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.]

(a) IN GENERAL.—The Administrator—

(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

(2) shall, as soon as practicable and not later than 6 months after the date on which a chemical substance is designated as a high-priority substance, define and publish the scope of the safety assessment and safety determination to be conducted pursuant to this section, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that the Administrator expects to consider;

(3) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

(4) shall complete a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

(5) shall promulgate a final rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; and

(6) may extend any deadline under [this subsection] paragraph (4) or (5) for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under [paragraphs (4) and (5) and] this subsection, plus any deferral under subsection (c)(2) does not exceed 2 years.

(b) PRIOR ACTIONS AND NOTICE OF EXISTING INFORMATION.—

(1) PRIOR-INITIATED ASSESSMENTS.—

(A) IN GENERAL.—*Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from con-*

tinuing or completing such a safety assessment or safety determination that was initiated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, prior to the effective date of the policies and procedures required to be established by the Administrator under section 3A or 4A.

(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—*As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.*

(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—*Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or rule solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure.*

(3) NOTICE OF EXISTING INFORMATION.—

(A) IN GENERAL.—*The Administrator shall, where such information is available, take notice of existing information regarding hazard and exposure published by other Federal agencies and the National Academies and incorporate the information in safety assessments and safety determinations with the objective of increasing the efficiency of the safety assessments and safety determinations.*

(B) INCLUSION OF INFORMATION.—*Existing information described in subparagraph (A) should be included to the extent practicable and where the Administrator determines the information is relevant and scientifically reliable.*

(c) SAFETY DETERMINATIONS.—

(1) IN GENERAL.—*Based on a review of the information available to the Administrator, including draft safety assessments submitted by interested persons, and subject to section 18, the Administrator shall determine that—*

(A) *the relevant chemical substance meets the safety standard;*

(B) *the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by rule under subsection (d)—*

(i) *impose restrictions necessary to ensure that the chemical substance meets the safety standard under the conditions of use; or*

(ii) *if the safety standard cannot be met with the application of restrictions, ban or phase out the chemical substance, as appropriate; or*

(C) *additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).*

(2) ADDITIONAL INFORMATION.—*If the Administrator determines that additional information is necessary to make a safety*

assessment or safety determination for a high-priority substance, the Administrator—

(A) shall provide an opportunity for interested persons to submit the additional information;

(B) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

(C) may defer, for a reasonable period consistent with the deadlines described in subsection (a), a safety assessment and safety determination until after receipt of the information; and

(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety determination, shall make a determination under paragraph (1).

(3) ESTABLISHMENT OF DEADLINE.—In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.

(d) RULE.—

(1) IMPLEMENTATION.—If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a rule establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

(2) SCOPE.—

(A) IN GENERAL.—The rule promulgated pursuant to this subsection—

(i) may apply to mixtures containing the chemical substance, as appropriate;

(ii) shall include dates by which compliance is mandatory, which—

(I) shall be as soon as practicable;

(II) in the case of a ban or phase-out of the chemical substance, shall implement the ban or phase-out in as short a period as practicable; and

(III) as determined by the Administrator, may vary for different affected persons; and

(iii) shall exempt replacement parts that are manufactured prior to the effective date of the rule for articles that are first manufactured prior to the effective date of the rule unless the Administrator finds the replacement parts contribute significantly to the identified risk; and

(iv) shall, in selecting among prohibitions and other restrictions, apply such prohibitions or other restrictions to articles containing the chemical substance only to the extent necessary to address the identified risks in order to determine that the chemical substance meets the safety standard.

(B) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines ranks high for persistence and bioaccumulation, the Administrator shall, in selecting among prohibitions and

other restrictions that the Administrator determines are sufficient to ensure that the chemical substance meets the safety standard, reduce exposure to the substance to the maximum extent practicable.

(C) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or other restriction under this subsection to address workplace exposures.

(D) DEFINITION OF REQUIREMENT.—*For the purposes of this Act, the term ‘requirement’ as used in this section does not displace common law.*

(3) RESTRICTIONS.—*A restriction under paragraph (1) may include, as appropriate—*

(A) *subject to section 18, a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator;*

(B) *a requirement that manufacturers or processors of the chemical substance shall—*

(i) *make and retain records of the processes used to manufacture or process the chemical substance;*

(ii) *describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or*

(iii) *monitor or conduct tests that are reasonably necessary to ensure compliance with the requirements of any rule under this subsection;*

(C) *a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;*

(D) *a requirement to ban or phase out, or any other rule regarding, the manufacture, processing, or distribution in commerce of the chemical substance for—*

(i) *a particular use;*

(ii) *a particular use at a concentration in excess of a level specified by the Administrator; or*

(iii) *all uses;*

(E) *a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—*

(i) *a particular use; or*

(ii) *a particular use at a concentration in excess of a level specified by the Administrator;*

(F) *a requirement to ban, phase out, or otherwise restrict any method of commercial use of the chemical substance;*

(G) *a requirement to ban, phase out, or otherwise restrict any method of disposal of the chemical substance or any article containing the chemical substance; and*

(H) *a requirement directing manufacturers or processors of the chemical substance to give notice of the Administra-*

tor's determination under subsection (c)(1)(B) to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

(4) ANALYSIS FOR RULEMAKING.—

(A) CONSIDERATIONS.—*In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.*

(B) ALTERNATIVES.—*As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.*

(C) PUBLIC AVAILABILITY.—*In proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.*

(D) STATEMENT REQUIRED.—*In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.*

(5) EXEMPTIONS.—

(A) IN GENERAL.—*The Administrator may exempt 1 or more uses of a chemical substance from any restriction in a rule promulgated under paragraph (1) if the Administrator determines that—*

(i) *the rule cannot be complied with, without—*

(I) *harming national security;*

(II) *causing significant disruption in the national economy due to the lack of availability of a chemical substance; or*

(III) *interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or*

(ii) *the use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.*

(B) EXEMPTION ANALYSIS.—*In proposing a rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall make publicly available any analysis conducted under this paragraph to assess the need for the exemption.*

(C) STATEMENT REQUIRED.—*In making final a rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall include a statement describing how the analysis considered under subparagraph (B) was taken into account.*

(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—*In determining whether an exemption should be granted under this*

paragraph for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more technically and economically feasible alternatives to the chemical substance most likely to be used in place of the chemical substance under the conditions of use if the rule is promulgated.

(E) CONDITIONS.—As part of a rule promulgated under paragraph (1), the Administrator shall include conditions in any exemption established under this paragraph, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption.

(F) DURATION.—

(i) IN GENERAL.—The Administrator shall establish, as part of a rule under paragraph (1) that contains an exemption under this paragraph, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis.

(ii) AUTHORITY OF ADMINISTRATOR.—The Administrator, by rule, may extend, modify, or eliminate the exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or is no longer necessary.

(iii) CONSIDERATIONS.—

(I) IN GENERAL.—Subject to subclause (II), the Administrator shall issue exemptions and establish time periods by considering factors determined by the Administrator to be relevant to the goals of fostering innovation and the development of alternatives that meet the safety standard.

(II) LIMITATION.—Any renewal of an exemption in the case of a rule requiring the ban or phase-out of a chemical substance shall not exceed 5 years.

(e) IMMEDIATE EFFECT.—The Administrator may declare a proposed rule under subsection (d)(1) to be effective on publication of the rule in the Federal Register and until the effective date of final action taken respecting the rule, if—

(1) the Administrator determines that—

(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to the proposed rule or any combination of those activities is likely to result in a risk of serious or widespread injury to health or the environment before the effective date; and

(B) making the proposed rule so effective is necessary to protect the public interest; and

(2) in the case of a proposed rule to prohibit the manufacture, processing, or distribution in commerce of a chemical substance or mixture because of the risk determined under paragraph

(1)(A), a court has granted relief in an action under section 7 with respect to that risk associated with the chemical substance or mixture.

(f) FINAL AGENCY ACTION.—*Under this section and subject to section 18—*

(1) *a safety determination, and the associated safety assessment, for a chemical substance that the Administrator determines under subsection (c) meets the safety standard, shall be considered to be a final agency action, effective beginning on the date of issuance of the final safety determination; and*

(2) *a final rule promulgated under subsection (d)(1), and the associated safety assessment and safety determination that a chemical substance does not meet the safety standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule.*

[(e)] (g) 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)⁴ 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).】

【(5) (4) 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) (h) 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.

⁴Section 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.

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).]

(a) CIVIL ACTIONS.—

(1) IN GENERAL.—*The Administrator may commence a civil action in an appropriate United States district court for—*

(A) seizure of an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture;

(B) relief (as authorized by subsection (b)) against any person that manufactures, processes, distributes in commerce, uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture; or

(C) both seizure described in subparagraph (A) and relief described in subparagraph (B).

(2) RULE, ORDER, OR OTHER PROCEEDING.—*A civil action may be commenced under this paragraph, notwithstanding—*

(A) the existence of a decision, rule, consent agreement, or order by the Administrator under section 4, 4A, 5, or 6 or title IV or VI; or

(B) the pendency of any administrative or judicial proceeding under any provision of this Act.

(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) Subpoenas⁵ 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)] *section* [6(c)] *6(d)*.

(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

⁵In Public Law 94-469, the word “subpoenas” is spelled “subpeonas”. The spelling is corrected in this print to reflect the probable intent of Congress.

or mixture, or that any combination of such activities, is likely to result in such injury to health or the environment before a final rule under section 6 can protect against such risk.

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)~~ 5, or 6, or an order in effect under *section 4* or *section 5(e)*, ~~5(d)(4)~~ 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).

(4) RULES.—

(A) DEADLINE.—

(i) IN GENERAL.—*Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall promulgate rules requiring the maintenance of records and the reporting of information known or reasonably ascertainable by the person making the report, including rules requiring processors to report information, so that the Administrator has the information necessary to carry out sections 4 and 6.*

(ii) MODIFICATION OF PRIOR RULES.—*In carrying out this subparagraph, the Administrator may modify, as appropriate, rules promulgated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.*

(B) CONTENTS.—*The rules promulgated pursuant to subparagraph (A)—*

(i) may impose different reporting and recordkeeping requirements on manufacturers and processors; and

(ii) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported.

(C) ADMINISTRATION.—*In implementing the reporting and recordkeeping requirements under this paragraph, the Administrator shall take measures—*

(i) to limit the potential for duplication in reporting requirements;

(ii) to minimize the impact of the rules on small manufacturers and processors; and

(iii) to apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.

(5) GUIDANCE.—*The Administrator shall develop guidance relating to the information required to be reported under the rules promulgated under this subsection.*

(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 Administrator) 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.

(3) NOMENCLATURE.—

(A) IN GENERAL.—*In carrying out paragraph (1), the Administrator shall—*

(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Sub-

stances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a); and

(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (I) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

(I) cement, Portland, chemicals, CAS No. 65997-15-1;

(II) cement, alumina, chemicals, CAS No. 65997-16-2;

(III) glass, oxide, chemicals, CAS No. 65997-17-3;

(IV) frits, chemicals, CAS No. 65997-18-4;

(V) steel manufacture, chemicals, CAS No. 65997-19-5; and

(VI) ceramic materials and wares, chemicals, CAS No. 66402-68-4.

(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature conventions, the Administrator shall—

(I) maintain the nomenclature conventions for substances; and

(II) develop new guidance that—

(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

(4) CHEMICAL SUBSTANCES IN COMMERCE.—

(A) RULES.—

(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator, by rule, shall require manufacturers and processors to notify the Administrator, by not later than 180 days after the date of promulgation of the rule, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(ii) ACTIVE SUBSTANCES.—The Administrator shall, pursuant to paragraph (5)(A), designate chemical sub-

stances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—The rule promulgated by the Administrator pursuant to subparagraph (A) shall require—

(i) the Administrator to maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

(ii) a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

(iii) the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C).

(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are notified pursuant to subparagraph (A) or identified as active substances under subsection (f)(1).

(D) REQUIREMENTS OF REVIEW PLAN.—The review plan under subparagraph (C) shall—

(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

(ii) require the Administrator, in accordance with section 14—

(I) to review each substantiation—

(aa) submitted pursuant to clause (i) to determine if the claim warrants protection from disclosure; and

(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

(II) approve, modify, or deny each claim; and

(III) except as provided in this section and section 14, protect from disclosure information for

which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

(iii) encourage manufacturers or processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

(E) TIMELINE FOR COMPLETION OF REVIEWS.—

(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

(ii) CONSIDERATIONS.—

(I) IN GENERAL.—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of applicable claims needing review and the available resources.

(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of reviews to be completed over the course of implementation of the plan.

(5) ACTIVE AND INACTIVE SUBSTANCES.—

(A) IN GENERAL.—The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).

(B) UPDATE.—The Administrator shall update the list of chemical substances designated as active substances as soon as practicable after the date of publication of the most recent data reported under—

(i) part 711 of title 40, Code of Federal Regulations (or successor regulations); and

(ii) the rules promulgated pursuant to subsection (a)(4).

(C) CHANGE TO ACTIVE STATUS.—

(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the

date on which the inactive substance is manufactured or processed.

(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—*If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the inactive substance as confidential, the person shall—*

(I) in the notice submitted under clause (i), assert the claim; and

(II) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

(iii) ACTIVE STATUS.—*On receiving a notification under clause (i), the Administrator shall—*

(I) designate the applicable chemical substance as an active substance;

(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific identity of the chemical substance and approve, modify, or deny the claim;

(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of not less than 10 years, unless, prior to the expiration of the period—

(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines to be necessary.

(D) CATEGORY STATUS.—*The list of inactive substances shall not be considered to be a category for purposes of section 26(c).*

(6) INTERIM LIST OF ACTIVE SUBSTANCES.—*Prior to the promulgation of the rule required under [this subsection] paragraph (4)(A), the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (or successor regulations), during the reporting period that most closely preceded the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as the interim list of active substances for the purposes of section 4A.*

(7) PUBLIC PARTICIPATION.—*Subject to this subsection, the Administrator shall make available to the public—*

(A) *the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—*

- (i) *an active substance; or*
- (ii) *an inactive substance;*

(B) *the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received and approved by the Administrator pursuant to section 14; and*

(C) *subject to section 14(g), the specific identity of any active substance for which—*

(i) *no claim of protection against disclosure of the specific identity of the active substance pursuant to this subsection was received;*

(ii) *a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or*

(iii) *the time period for protection against disclosure of the specific identity of the active substance has expired.*

(8) LIMITATION.—*No person may assert a new claim under this subsection for protection from disclosure of a specific identity of any active or inactive chemical substance for which a notice is received under paragraph (4)(A)(i) or (5)(C)(i) that is not on the confidential portion of the list published under paragraph (1).*

(9) CERTIFICATION.—*Under the [rule] rules promulgated under this subsection, manufacturers and processors shall be required—*

(A) *to certify that each report the manufacturer or processor submits complies with the requirements of the rule, and that any confidentiality claims are true and correct; and*

(B) *to retain a record supporting the certification for a period of 5 years beginning on the last day of the submission period.*

* * * * *

(e) NOTICE TO ADMINISTRATOR OF SUBSTANTIAL RISKS.—**[Any person]**

(1) IN GENERAL.—*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.*

(2) APPLICABILITY.—*Any person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does*

not present a substantial risk of injury to health and the environment.

(f) DEFINITIONS.—[For purposes of this section, the] *In this section:*

(1) ACTIVE SUBSTANCE.—*The term ‘active substance’ means a chemical substance—*

(A) that has been manufactured or processed for a non-exempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

(B) that is added to the list published under subsection (b)(1) after that date of enactment; or

(C) for which a notice is received under subsection (b)(5)(C).

(2) INACTIVE SUBSTANCE.—*The term ‘inactive substance’ means a chemical substance on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).*

(3) MANUFACTURE; PROCESS.—*The terms “manufacture” and “process” mean manufacture or process for commercial purposes.*

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] *does not meet the safety standard and determines, in the Administrator’s discretion, that [such risk] the risk posed by the substance or mixture 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 state-

ment 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] section 6(d) or section 7 with respect to such risk.

(3) If the Administrator has initiated action under [section 6 or 7] section 6(d) or 7 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, 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.

(d) COORDINATION.—In administering this Act, the Administrator shall consult and coordinate with the Secretary of [Health, Education, and Welfare] *Health and Human Services* 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 author-

ity under this Act with the authority granted under other Acts referred to in subsection (b).

(e) EXPOSURE INFORMATION.—*If the Administrator obtains information related to exposures or releases of a chemical substance that may be prevented or reduced under another Federal law, including laws not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.*

SEC. 10. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION AND UTILIZATION OF DATA.

(a) AUTHORITY.—The Administrator shall, in consultation and cooperation with the Secretary of **[Health, Education, and Welfare]** *Health and Human Services* and with other heads of appropriate departments and agencies, conduct such research, development, and monitoring as is necessary to carry out the purposes of this Act. The Administrator may enter into contracts and may make grants for research, development, and monitoring under this subsection. Contracts may be entered into under this subsection without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 14 U.S.C. 5).

(b) DATA SYSTEMS.—(1) The Administrator shall establish, administer, and be responsible for the continuing activities of an interagency committee which shall design, establish, and coordinate an efficient and effective system, within the Environmental Protection Agency, for the collection, dissemination to other Federal departments and agencies, and use of data submitted to the Administrator under this Act.

(2)(A) The Administrator shall, in consultation and cooperation with the Secretary of **[Health, Education, and Welfare]** *Health and Human Services* and other heads of appropriate departments and agencies design, establish, and coordinate an efficient and effective system for the retrieval of toxicological and other scientific data which could be useful to the Administrator in carrying out the purposes of this Act. Systematized retrieval shall be developed for use by all Federal and other departments and agencies with responsibilities in the area of regulation or study of chemical substances and mixtures and their effect on health or the environment.

(B) The Administrator, in consultation and cooperation with the Secretary of **[Health, Education, and Welfare]** *Health and Human Services*, may make grants and enter into contracts for the development of a data retrieval system described in subparagraph (A). Contracts may be entered into under this subparagraph without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5).

(c) SCREENING TECHNIQUES.—The Administrator shall coordinate, with the Assistant Secretary for Health of the Department of **[Health, Education, and Welfare]** *Health and Human Services*, research undertaken by the Administrator and directed toward the development of rapid, reliable, and economical screening techniques for carcinogenic, mutagenic, teratogenic, and ecological effects of chemical substances and mixtures.

(d) MONITORING.—The Administrator shall, in consultation and cooperation with the Secretary of **[Health, Education, and Welfare]** *Health and Human Services*, establish and be responsible for re-

search aimed at the development, in cooperation with local, State, and Federal agencies, of monitoring techniques and instruments which may be used in the detection of toxic chemical substances and mixtures and which are reliable, economical, and capable of being implemented under a wide variety of conditions.

(e) BASIC RESEARCH.—The Administrator shall, in consultation and cooperation with the Secretary of [Health, Education, and Welfare] *Health and Human Services*, establish research programs to develop the fundamental scientific basis of the screening and monitoring techniques described in subsections (c) and (d), the bounds of the reliability of such techniques, and the opportunities for their improvement.

(f) TRAINING.—The Administrator shall establish and promote programs and workshops to train or facilitate the training of Federal laboratory and technical personnel in existing or newly developed screening and monitoring techniques.

(g) EXCHANGE OF RESEARCH AND DEVELOPMENT RESULTS.—The Administrator shall, in consultation with the Secretary of [Health, Education, and Welfare] *Health and Human Services* and other heads of appropriate departments and agencies, establish and coordinate a system for exchange among Federal, State, and local authorities of research and development results respecting toxic chemical substances and mixtures, including a system to facilitate and promote the development of standard data format and analysis and consistent testing procedures.

* * * * *

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.]

(2) EXCEPTION.—*Paragraph (1) shall not apply to any chemical substance that the Administrator determines—*

(A) under section 5 is not likely to meet the safety standard; or

(B) under section 6 does not meet the safety standard.

(3) WAIVERS.—For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—

(A) determine that paragraph (1) shall not apply to the mixture or article; or

(B) establish a threshold concentration in a mixture or article at which paragraph (1) shall not apply.

(4) TESTING.—The Administrator may require testing under section 4 of any chemical substance or mixture exempted from this Act under paragraph (1) for the purpose of determining whether the chemical substance or mixture meets the safety standard within the United States.

[(b) 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), such person shall notify the Administrator of such exportation or intent to export and the Administrator shall 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, such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of such rule, order, action, or relief.]

(b) NOTICE.—

(1) IN GENERAL.—A person shall notify the Administrator that the person is exporting or intends to export to a foreign country—

(A) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 5 is not likely to meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

(B) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 6 does not meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

(C) a chemical substance for which the United States is obligated by treaty to provide export notification;

(D) a chemical substance or mixture subject to a significant new use rule, or a prohibition or other restriction pursuant to a rule, order, or consent agreement in effect under this Act; or

(E) a chemical substance or mixture for which the submission of information is required under section 4.

(2) RULES.—

(A) IN GENERAL.—The Administrator shall promulgate rules to carry out paragraph (1).

(B) CONTENTS.—*The rules promulgated pursuant to subparagraph (A) shall—*

(i) include such exemptions as the Administrator determines to be appropriate, which may include exemptions identified under section 5(h); and

(ii) indicate whether, or to what extent, the rules apply to articles containing a chemical substance or mixture described in paragraph (1).

(3) NOTIFICATION.—*The Administrator shall submit to the government of each country to which a chemical substance or mixture is exported—*

(A) for a chemical substance or mixture described in subparagraph (A), (B), or (D) of paragraph (1), a notice of the determination, rule, order, consent agreement, requirement, or designation;

(B) for a chemical substance described in paragraph (1)(C), a notice that satisfies the obligation of the United States under the applicable treaty; and

(C) for a chemical substance or mixture described in paragraph (1)(E), a notice of availability of the information on the chemical substance or mixture submitted to the Administrator.

(c) 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) 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 relat-

ing 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.

* * * * *

[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 discloses 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. CONFIDENTIAL INFORMATION.

(a) IN GENERAL.—*Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—*

(1) *that is reported to, or otherwise obtained by, the Administrator under this Act; and*

(2) *for which the requirements of subsection (d) are met.*

(b) INFORMATION GENERALLY PROTECTED FROM DISCLOSURE.—*The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information, or information that is the subject of subsection (g)(3), through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:*

(1) *Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.*

(2) *Marketing and sales information.*

(3) *Information identifying a supplier or customer.*

(4) *Details of the full composition of a mixture and the respective percentages of constituents.*

(5) *Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.*

(6) *Specific production or import volumes of the manufacturer and specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.*

(7) *Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if—*

(A) the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5; and

(B) the claim—

(i) is not subject to an exception under subsection (e);

or

(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (f)(2) or (g).

(c) INFORMATION NOT PROTECTED FROM DISCLOSURE.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

(1) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

(A) IN GENERAL.—Subject to subparagraph (B), subsection (a) does not prohibit the disclosure of—

(i) any health and safety study that is submitted under this Act with respect to—

(I) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

(II) any chemical substance or mixture for which—

(aa) testing is required under section 4; or

(bb) a notification is required under section 5; or

(ii) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in subclause (I) or (II) of clause (i).

(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph authorizes the release of any information that discloses—

(i) a process used in the manufacturing or processing of a chemical substance or mixture; or

(ii) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

(2) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

(3) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

(A) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

(B) A safety assessment developed, or a safety determination made, under section 6.

(C) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

(D) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

(4) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is otherwise eligible for protection under this section and contained in a submission of information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

(5) BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.

(d) REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—

(1) ASSERTION OF CLAIMS.—

(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

(i) taken reasonable measures to protect the confidentiality of the information;

(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance

that the Administrator may disclose to the public, subject to the condition that the generic name shall—

(i) conform with guidance prescribed by the Administrator under paragraph (3)(A); and

(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

(I) that are considered to be confidential; and

(II) the disclosure of which would be likely to harm the competitive position of the person.

(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in paragraphs (1) through (7) of subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and guidance issued by the Administrator.

(3) GUIDANCE.—The Administrator shall develop guidance regarding—

(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the information that has been submitted is true and correct.

(e) EXCEPTIONS TO PROTECTION FROM DISCLOSURE.—Information described in subsection (a)—

(1) shall be disclosed if the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

(A) under any law for the protection of health or the environment; or

(B) for a specific law enforcement purpose;

(2) shall be disclosed if the information is to be disclosed to a contractor of the United States and employees of that contractor—

(A) 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 for the performance of work in connection with this Act; and

(B) subject to such conditions as the Administrator may specify;

(3) shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment;

(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, if—

(A) 1 or more applicable agreements with the Administrator that conform with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; and

(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;

(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

(A) the statement of need and confidentiality agreement shall conform with the guidance issued under subsection (d)(3)(B);

(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

(i) the information is necessary for, or will assist in—

(I) the diagnosis or treatment of 1 or more individuals; or

(II) responding to an environmental release or exposure; and

(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

(i) a medical or public health or environmental emergency exists;

(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

(i) provide a written statement of need; and

(ii) agree to sign a confidentiality agreement; and

(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

(8) shall be disclosed if the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

(f) DURATION OF PROTECTION FROM DISCLOSURE.—

(1) IN GENERAL.—

(A) INFORMATION PROTECTED FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information that meets the requirements of subsection (d) for a period of 10 years, unless, prior to the expiration of the period—

(i) an affected person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

(ii) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in subsection (g)(2).

(B) EXTENSIONS.—

(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph (A), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

(ii) STATEMENT.—

(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph (A), a person reasserting

the relevant claim shall submit to the Administrator a statement substantiating, in accordance with subsection (d)(2), the need to extend the period.

(II) ACTION BY ADMINISTRATOR.—Not later than the date that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—

(aa) review the request;

(bb) make a determination regarding whether the information for which the request is made continues to meet the relevant criteria established under this section; and

(cc)(AA) grant an extension of not more than 10 years; or

(BB) deny the claim.

(C) NO LIMIT ON NUMBER OF EXTENSIONS.—*There shall be no limit on the number of extensions granted under subparagraph (B), if the Administrator determines that the relevant statement under subparagraph (B)(ii)(I)—*

(i) establishes the need to extend the period; and

(ii) meets the requirements established by the Administrator.

(2) REVIEW AND RESUBSTANTIATION.—

(A) DISCRETION OF ADMINISTRATOR.—*The Administrator may review, at any time, a claim for protection against disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—*

(i) after the chemical substance is identified as a high-priority substance under section 4A;

(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

(iii) for any inactive chemical substance identified under section 8(b)(5); or

(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating rules pursuant to section 6(d), subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d).

(B) REVIEW REQUIRED.—*The Administrator shall review a claim for protection from disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has*

claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

(i) as necessary to comply with a request for information received by the Administrator under section 552 of title 5, United States Code;

(ii) if information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met; or

(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

(i) reassert and substantiate or resubstantiate the claim; or

(ii) withdraw the claim.

(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

(3) UNIQUE IDENTIFIER.—The Administrator shall—

(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

(i) is made public; and

(ii) identifies the chemical substance using the unique identifier; and

(D) for each claim for protection of specific chemical identity that has been denied by the Administrator on expiration of the period for appeal under subsection (g)(4), that has expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

(g) DUTIES OF ADMINISTRATOR.—

(1) DETERMINATION.—

(A) IN GENERAL.—*Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.*

(B) DENIAL OR MODIFICATION.—

(i) IN GENERAL.—*Except as provided in subsections (c) and (f), the Administrator shall deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).*

(ii) REASONS FOR DENIAL OR MODIFICATION.—*The Administrator shall provide to a person that has submitted a claim described in clause (i) a written statement of the reasons for the denial or modification of the claim.*

(C) SUBSETS.—*The Administrator shall—*

(i) *except for claims described in subsection (b)(7), review all claims under this section for the protection against disclosure of the specific identity of a chemical substance; and*

(ii) *review a representative subset, comprising at least 25 percent, of all other claims for protection against disclosure.*

(D) EFFECT OF FAILURE TO ACT.—*The failure of the Administrator to make a decision regarding a claim for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim for protection against disclosure.*

(2) NOTIFICATION.—

(A) IN GENERAL.—*Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim under paragraph (1), or promulgates a rule under section 6(d) establishing a ban or phase-out of a chemical substance, the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.*

(B) RELEASE OF INFORMATION.—

(i) IN GENERAL.—*Except as provided in clause (ii), the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).*

(ii) EXCEPTIONS.—

(I) IN GENERAL.—*For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the*

environment, in which case no prior notification shall be necessary.

(II) NO NOTIFICATION.—*For information under paragraph (1), (2), (6), (7), or (9) of subsection (e), no prior notification shall be necessary.*

(3) REBUTTABLE PRESUMPTION.—

(A) IN GENERAL.—*With respect to notifications provided by the Administrator pursuant to subsection (c)(5), there shall be a rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.*

(B) REQUEST FOR NONDISCLOSURE.—*A person that receives a notification under paragraph (2) with respect to the information described in subparagraph (A) may submit to the Administrator, before the date on which the information is to be released, a request with supporting documentation describing why the person believes some or all of that information should not be disclosed.*

(C) DETERMINATION BY ADMINISTRATOR.—

(i) IN GENERAL.—*Not later than 30 days after the Administrator receives a request under subparagraph (B), the Administrator shall determine, at the discretion of the Administrator, whether the documentation provided by the person making the request rebuts or does not rebut the presumption described in subparagraph (A), for all or a portion of the information that the person has requested not be disclosed.*

(ii) OBJECTIVE.—*The Administrator shall make the determination with the objective of ensuring that information relevant to protection of health and the environment is disclosed to the maximum extent practicable.*

(D) TIMING.—*Not later than 30 days after making the determination described in subparagraph (C), the Administrator shall make public the information the Administrator has determined is not to be protected from disclosure.*

(E) NO TIMELY REQUEST RECEIVED.—*If the Administrator does not receive, before the date on which the information described in subparagraph (A) is to be released, a request pursuant to subparagraph (B), the Administrator shall promptly make public all of the information.*

(4) APPEALS.—

(A) IN GENERAL.—*If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released, the person may bring an action to restrain disclosure of the information in—*

(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

(ii) the United States District Court for the District of Columbia.

(B) NO DISCLOSURE.—*The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).*

(5) ADMINISTRATION.—*In carrying out this subsection, the Administrator shall use the procedures described in part 2 of title 40, Code of Federal Regulations (or successor regulations).*

(h) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.—

(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

(A) IN GENERAL.—*Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.*

(B) DESCRIPTION.—*A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—*

(i) *by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and*

(ii) *knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.*

(2) OTHER LAWS.—*Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.*

(3) CONTRACTORS.—*For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.*

(i) APPLICABILITY.—

(1) IN GENERAL.—*Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—*

(A) *to require the substantiation or resubstantiation of a claim for the protection from disclosure of information submitted to the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or*

(B) *to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.*

(2) PRIOR ACTIONS.—*Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Adminis-*

trator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

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—*

(A) *any rule promulgated, consent agreement entered into, or order issued under section 4;*

(B) *any requirement under section 5 or 6;*

(C) *any rule promulgated, consent agreement entered into, or order issued under section 5 or 6; or*

(D) *any requirement of, or any rule promulgated or order issued pursuant to title II;*

(2) use for commercial purposes a chemical substance or mixture 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;

(3) fail or refuse to (A) establish or maintain records, (B) submit reports, notices, 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.

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, including 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)(A) A civil penalty for a violation of 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 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) Any person who requested in accordance with paragraph (2)(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 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) 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), or

(B) after a court in an action brought under paragraph (3) 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) 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 who]

(1) IN GENERAL.—*Any person that; knowingly or willfully violates any provision of [section 15 or 409] this Act 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, or both.*

(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

(A) IN GENERAL.—*Any person that knowingly or willfully violates any provision of this Act, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be subject on conviction to a fine of not more than \$250,000, or imprisonment for not more than 15 years, or both.*

(B) ORGANIZATIONS.—*An organization that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not more than \$1,000,000 for each violation.*

(3) KNOWLEDGE OF IMMINENT DANGER OR INJURY.—*For purposes of determining whether a defendant knew that the violation placed another individual in imminent danger of death or serious bodily injury—*

(A) *the defendant shall be responsible only for actual awareness or actual belief possessed; and*

(B) knowledge possessed by an individual may not be attributed to the defendant.

* * * * *

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.]

(a) IN GENERAL.—

(1) ESTABLISHMENT OR ENFORCEMENT.—*Except as provided in subsections (c), (d), (e), (f), and (g), and subject to paragraph (2), no State or political subdivision of a State may establish or continue to enforce any of the following:*

(A) TESTING AND INFORMATION COLLECTION.—*A statute or administrative action to require the development of information on a chemical substance or category of substances that is reasonably likely to produce the same information required under section 4, 5, or 6 in—*

(i) a rule promulgated by the Administrator;

(ii) a testing consent agreement entered into by the Administrator; or

(iii) an order issued by the Administrator.

(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—*A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—*

(i) found to meet the safety standard and consistent with the scope of the determination made under section 6; or

(ii) found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

(C) SIGNIFICANT NEW USE.—*A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.*

(2) EFFECTIVE DATE OF PREEMPTION.—*Under this subsection, Federal preemption of State statutes and administrative actions applicable to specific substances shall not occur until the effective date of the applicable action described in paragraph (1) taken by the Administrator.*

(b) NEW STATUTES OR ADMINISTRATIVE ACTIONS CREATING PROHIBITIONS OR OTHER RESTRICTIONS.—

(1) IN GENERAL.—*Except as provided in subsections (c), (d), and (e), beginning on the date on which the Administrator defines the scope of a safety assessment and safety determination under section 6(a)(2) and ending on the date on which the Administrator publishes the safety determination, no State or political subdivision of a State may establish a statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance designated under section 4A.*

(2) EFFECT OF SUBSECTION.—

(A) IN GENERAL.—*This subsection does not restrict the authority of a State or political subdivision of a State to continue to enforce any State statute enacted, or administrative action taken, prior to the date on which the Administrator defines the scope of a safety assessment and safety determination under section 6(a)(2).*

(B) LIMITATION.—*Subparagraph (A) does not allow a State or political subdivision of a State to enforce any new prohibition or restriction under a State statute or administrative action described in that subparagraph, if the prohibition or restriction is established after the date described in that subparagraph.*

(c) SCOPE OF PREEMPTION.—*Federal preemption under subsections (a) and (b) of State statutes and administrative actions applicable to specific substances shall apply only to—*

(1) *the chemical substances or category of substances subject to a rule, order, or consent agreement under section 4;*

(2) *the uses or conditions of use of such substances that are identified by the Administrator as subject to review in a safety assessment and included in the scope of the safety determination made by the Administrator for the substance, or of any rule the Administrator promulgates pursuant to section 6(d); or*

(3) *the uses of such substances that the Administrator has specified as significant new uses and for which the Administrator has required notification pursuant to a rule promulgated under section 5.*

(d) EXCEPTIONS.—

(1) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—

(A) IN GENERAL.—*Nothing in this Act, nor any amendment made by this Act, nor any rule, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—*

(i) *is adopted or authorized under the authority of any other Federal law or adopted to satisfy or obtain authorization or approval under any other Federal law;*

(ii) *implements a reporting, monitoring, disclosure, or other information obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law;*

(iii) *is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, except to the extent that the action—*

(I) *imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and*

(II)(aa) *addresses the same hazards and exposures, with respect to the same conditions of use as are included in the scope of the safety determination pursuant to section 6, but is inconsistent with the action of the Administrator; or*

(bb) *would cause a violation of the applicable action by the Administrator under section 5 or 6; or*

(iv) subject to subparagraph (B), is identical to a requirement prescribed by the Administrator.

(B) IDENTICAL REQUIREMENTS.—

(i) IN GENERAL.—*The penalties and other sanctions applicable under State law in the event of noncompliance with the identical requirement shall be no more stringent than the penalties and other sanctions available to the Administrator under section 16 of this Act.*

(ii) PENALTIES.—*In the case of an identical requirement, no State may assess a penalty for a specific violation for which the Administrator has already assessed a penalty under section 16, and the Administrator may not assess a penalty under section 16 for a specific violation for which a State has already assessed a penalty.*

(2) APPLICABILITY TO CERTAIN RULES OR ORDERS.—*Notwithstanding subsection (e)—*

(A) *nothing in this section shall be construed as modifying the effect under this section, as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, of any rule or order promulgated or issued under this Act prior to that effective date; and*

(B) *with respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 6 prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act with regards to manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance, this section (as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after that effective date, unless the latter rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under [subsection (b) or (c) of] section 4A (b) or as an additional priority for safety assessment and safety determination under section [4A(d)] 4A(c).*

(e) PRESERVATION OF CERTAIN STATE LAW.—

(1) IN GENERAL.—*Nothing in this Act, subject to subsection (g) of this section, shall—*

(A) *be construed to preempt or otherwise affect the authority of a State or political subdivision of a State to continue to enforce any action taken before August 1, 2015, under the authority of a State law that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance; or*

(B) *be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003.*

(2) EFFECT OF SUBSECTION.—*This subsection does not affect, modify, or alter the relationship between State and Federal law pursuant to any other Federal law.*

(f) STATE WAIVERS.—

(1) DISCRETIONARY EXEMPTIONS.—*Upon application of a State or political subdivision of a State, the Administrator may by rule, exempt from subsection (a), under such conditions as may be prescribed in the rule, a statute or administrative action of that State or political subdivision of the State that relates to the effects of, or exposure to, a chemical substance under the conditions of use if the Administrator determines that—*

(A) *compelling State or local conditions warrant granting the waiver to protect health or the environment;*

(B) *compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;*

(C) *compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and*

(D) *based on the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is consistent with sound objective scientific practices, the weight of the evidence, and the best available science.*

(2) REQUIRED EXEMPTIONS.—*Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—*

(A) *compliance with the proposed requirement of the State will not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;*

(B) *compliance with the proposed requirement would not cause a violation of any applicable Federal law, rule, or order; and*

(C) *the State or political subdivision of a State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science.*

(3) DETERMINATION OF A STATE WAIVER REQUEST.—*The duty of the Administrator to grant or deny a waiver application shall be nondelegable and shall be exercised—*

(A) *not later than 180 days after the date on which an application under paragraph (1) is submitted; and*

(B) *not later than 90 days after the date on which an application under paragraph (2) is submitted.*

(4) FAILURE TO MAKE DETERMINATION.—*If the Administrator fails to make a determination under paragraph (3)(B) during the 90-day period beginning on the date on which an application under paragraph (2) is submitted, the State statute or administrative action that was the subject of the application shall*

not be considered to be an existing statute or administrative action for purposes of subsection [(a)] (b) by reason of the failure of the Administrator to make a determination.

(5) NOTICE AND COMMENT.—*Except in the case of an application approved under paragraph (9), the application of a State or political subdivision of the State shall be subject to public notice and comment.*

(6) FINAL AGENCY ACTION.—*The decision of the Administrator on the application of a State or political subdivision of the State shall be—*

- (A) *considered to be a final agency action; and*
- (B) *subject to judicial review.*

(7) DURATION OF WAIVERS.—

(A) IN GENERAL.—*Except as provided in subparagraph (B), a waiver granted under paragraph (2) or approved under paragraph (9) shall remain in effect—*

- (i) *until such time as the safety assessment and safety determination is completed; or*
- (ii) *subject to subparagraph (B), until judicial review of the failure of the Administrator to make a determination under paragraph (3) is sought under paragraph (8).*

(B) REINSTATEMENT OF WAIVER.—*A waiver described in subparagraph (A)(ii) shall again take effect upon the earlier of—*

- (i) *the date of approval by the Administrator of the waiver application;*
- (ii) *the effective date of a court order directing the Administrator to approve the waiver application; or*
- (iii) *90 days after the date on which judicial review under paragraph (8) is sought.*

(8) JUDICIAL REVIEW OF WAIVERS.—*Not later than 60 days after the date on which the Administrator makes a determination on an application of a State or political subdivision of the State under paragraph (1) or (2), or not later than 60 days after the date on which the Administrator fails to make a determination under paragraph (3), any person may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.*

(9) APPROVAL.—

(A) IN GENERAL.—*If the Administrator fails to meet the deadline under section 6(a)(4) (including an extension granted under section 6(a)(6)), or the deadline established under paragraph (3)(B), the application of a State or political subdivision of a State under paragraph (2) shall be automatically approved.*

(B) REQUIREMENTS.—*Notwithstanding paragraph (6), approval of a waiver application under subparagraph (A) for failure to meet the deadlines under section 6(a)(4) (including an extension granted under section 6(a)(6)) shall not be considered final agency action or be subject to judicial review or public notice and comment.*

(10) JUDICIAL REVIEW OF LOW-PRIORITY DECISIONS.—

(A) IN GENERAL.—*Not later than 60 days after the publication of a designation under section 4A(b)(4), any person may commence a civil action to challenge the designation.*

(B) JURISDICTION.—*The United States Court of Appeals for the District of Columbia Circuit shall have exclusive jurisdiction over a civil action filed under this paragraph.*

(g) SAVINGS.—

(1) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF OR CRIMINAL CONDUCT.—

(A) IN GENERAL.—*Nothing in this Act, nor any amendment made by this Act, nor any safety standard, rule, requirement, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall be construed to preempt, displace, or supplant any state or Federal common law rights or any state or Federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.*

(B) CLARIFICATION OF NO PREEMPTION.—*Notwithstanding any other provision of this Act, nothing in this Act, nor any amendments made by this Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any State law, maritime law, or Federal common law or statutory theory.*

(2) NO EFFECT ON PRIVATE REMEDIES.—

(A) IN GENERAL.—*Nothing in this Act, nor any amendments made by this Act, nor any rules, regulations, requirements, safety assessments, safety determinations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.*

(B) AUTHORITY OF COURTS.—*This Act does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, safety assessments, scientific assessments, or orders issued pursuant to this Act.*

SEC. 19. JUDICIAL REVIEW.

(a) IN GENERAL.—(1)(A) Not later than 60 days after the date of the promulgation of a rule under [section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV] section 4(a), 5(d), 6(c), 6(d), 6(g), or 8, or title II or IV, any person may file a petition for judicial review of such rule 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 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)** *an order issued under this title* 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 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 be⁶ 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 the petitioner or the Administrator applies to the court for leave to make additional oral submissions or written presentations respecting such rule 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 being reviewed or make a new rule by reason of the additional submissions and presentations and shall file such modified or new rule with the return of such submissions and presentations. The court shall thereafter review such new or modified rule.

(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

⁶So in law. Probably should be followed by a comma.

(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)** *section 4(a), 5(d), 6(d), or 6(g)*, 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;**

(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.】

(ii) the court may not review the contents and adequacy of 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 the rulemaking record, taken as a whole.

(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.

(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. 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)** *an order under section 4 or 5(d)*.

(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)** *an order under section 4 or 5(d)*.

(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. 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 action in a district court of the United States to compel the Administrator to initiate a rulemaking proceeding 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), the petitioner shall be provided an opportunity to have such petition considered by the court in a de novo proceeding. If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—]

(B) DE NOVO PROCEEDING.—

(i) IN GENERAL.—*In an action under subparagraph (A) to initiate a proceeding to promulgate a rule pursuant to section 4, 5, 6, or 8 or issue an order [issued] under section 4 or 5 (d), the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.*

(ii) DEMONSTRATION.—

(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by

the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

(aa) in the case of a petition to initiate a proceeding for the issuance of a rule or order under section 4, the information available to the Administrator is insufficient for the Administrator to perform an action described in section 4, 4A, 5, or 6(d);

(bb) in the case of a petition to issue an order under section 5(d), there is a reasonable basis to conclude that the chemical substance is not likely to meet the safety standard;

(cc) in the case of a petition to initiate a proceeding for the issuance of a rule under section 6(d), there is a reasonable basis to conclude that the chemical substance will not meet the safety standard; or

(dd) in the case of a petition to initiate a proceeding for the issuance of a rule under section 8, there is a reasonable basis to conclude that the rule is necessary to protect health or the environment or ensure that the chemical substance meets the safety standard.

(II) DEFERMENT.—The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

(aa) 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

(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.

* * * * *

SEC. 24. EMPLOYMENT EFFECTS.

(a) **IN GENERAL.**—The Administrator shall evaluate on a continuing 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.

(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. 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 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,

(ii) such hearings shall be held in accordance with [section 6(c)(3),] *the applicable requirements of this Act*; and

(iii) 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 applicable 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.

SEC. 25. STUDIES.

[(a) INDEMNIFICATION STUDY.—The Administrator shall conduct a study of all Federal laws administered by the Administrator for the purpose of determining whether and under what conditions, if any, indemnification should be accorded any person as a result of any action taken by the Administrator under any such law. The study shall—

[(1) include an estimate of the probable cost of any indemnification programs which may be recommended;

[(2) include an examination of all viable means of financing the cost of any recommended indemnification; and

[(3) be completed and submitted to Congress within two years from the effective date of enactment of this Act.

[The General Accounting Office shall review the adequacy of the study submitted to Congress pursuant to paragraph (3) and shall report the results of its review to the Congress within six months of the date such study is submitted to Congress.

[(b) CLASSIFICATION, STORAGE, AND RETRIEVAL STUDY.—The Council on Environmental Quality, in consultation with the Admin-

istrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate Federal departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical substances and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such substances. A report on such study shall be completed and submitted to Congress not later than 18 months after the effective date of enactment of 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 shall establish, not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, by rule—*

(A) the payment of 1 or more reasonable fees as a condition of submitting a notice or requesting an exemption under section 5;

(B) the payment of 1 or more reasonable fees by a manufacturer or processor that—

(i) is required to submit a notice pursuant to the rule promulgated under section 8(b)(4)(A)(i) identifying a chemical substance as active;

(ii) is required to submit a notice pursuant to section 8(b)(5)(B)(i) changing the status of a chemical substance from inactive to active;

(iii) is required to report information pursuant to the rules promulgated under section 8(a)(4); and

(iv) manufactures or processes a chemical substance subject to a safety assessment and safety determination pursuant to section 6.

(2) UTILIZATION AND COLLECTION OF FEES.—*The Administrator shall—*

(A) utilize the fees collected under paragraph (1) only to defray costs associated with the actions of the Administrator—

(i) to collect, process, review, provide access to, and protect from disclosure (where appropriate) information on chemical substances under this Act;

(ii) to review notices and make determinations for chemical substances under paragraphs (1) and (3) of section 5(d) and impose any necessary restrictions under section 5(d)(4);

(iii) to make prioritization decisions under section 4A;

(iv) to conduct and complete safety assessments and determinations under section 6; and

(v) to conduct any necessary rulemaking pursuant to section 6(d);

(B) insofar as possible, collect the fees described in paragraph (1) in advance of conducting any fee-supported activity;

(C) deposit the fees in the Fund established by paragraph (4)(A); and

(D) not collect excess fees or retain a significant amount of unused fees.

(3) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—*In setting fees under this section, the Administrator shall—*

(A) take into account the cost to the Administrator of conducting the activities described in paragraph (2);

(B) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

(C) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to defray approximately 25 percent of the costs of conducting the activities identified in paragraph (2)(A), not to exceed \$18,000,000, not including fees under subparagraph (E) of this paragraph;

(D) reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

(E) for substances designated as additional priorities pursuant to section 4A(c), establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the safety assessment and safety determination under section 6, except that for substances subject to section 4A(c)(3), the Administrator shall establish the fee at a level sufficient to defray 50 percent of those costs;

(F) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties poten-

tially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) or subchapter III of chapter 5 of title 5, United States Code, is applicable with respect to such meetings;

(G) beginning with the fiscal year that is 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives, increase or decrease the fees established under paragraph (1) as necessary—

(i) to ensure that funds deposited in the Fund are sufficient to conduct the activities identified in paragraph (2)(A) and the full cost or 50-percent portion of the costs of safety assessments and safety determinations pursuant to subparagraph (E); and

(ii) to account for inflation;

(H) adjust fees established under paragraph (1) as necessary to vary on account of differing circumstances, including reduced fees or waivers in appropriate circumstances, to reduce the burden on manufacturing or processing, remove barriers to innovation, or where the costs to the Administrator of collecting the fees exceed the fee revenue anticipated to be collected; and

(I) if a notice submitted under section 5 is refused or subsequently withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

(4) TSCA IMPLEMENTATION FUND.—

(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the ‘TSCA Implementation Fund’ (referred to in this subsection as the ‘Fund’), consisting of—

(i) such amounts as are deposited in the Fund under paragraph (2)(C); and

(ii) any interest earned on the investment of amounts in the Fund; and

(iii) any proceeds from the sale or redemption of investments held in the Fund.

(B) CREDITING AND AVAILABILITY OF FEES.—

(i) IN GENERAL.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation.

(ii) REQUIREMENTS.—Fees collected under this section shall not—

(I) be made available or obligated for any purpose other than to defray the costs of conducting the activities identified in paragraph (2)(A);

(II) otherwise be available for any purpose other than implementation of this Act; and

(III) so long as amounts in the Fund remain available, be subject to restrictions on expenditures applicable to the Federal government as a whole.

(C) UNUSED FUNDS.—Amounts in the Fund not currently needed to carry out this subsection shall be—

- (i) maintained readily available or on deposit;
- (ii) invested in obligations of the United States or guaranteed by the United States; or
- (iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

(D) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2015) of the Office of Pollution Prevention and Toxics of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for covered functions for fiscal year 2015 (excluding the amount of any fees appropriated for the fiscal year).

(5) AUDITING.—

(A) FINANCIAL STATEMENTS OF AGENCIES.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of an executive agency.

(B) COMPONENTS.—The annual audit required under sections 3515(b) and 3521 of that title of the financial statements of activities under this subsection shall include an analysis of—

- (i) the fees collected under paragraph (1) and disbursed;
- (ii) compliance with the deadlines established in section 6 of this Act;
- (iii) the amounts budgeted, appropriated, collected from fees, and disbursed to meet the requirements of sections 4, 4A, 5, 6, 8, and 14, including the allocation of full time equivalent employees to each such section or activity; and
- (iv) the reasonableness of the allocation of the overhead associated with the conduct of the activities described in paragraph (2)(A).

(C) INSPECTOR GENERAL.—The Inspector General of the Environmental Protection Agency shall—

- (i) conduct the annual audit required under this subsection; and
- (ii) report the findings and recommendations of the audit to the Administrator and to the appropriate committees of Congress.

(6) TERMINATION.—The authority provided by this section shall terminate at the conclusion of the fiscal year that is 10 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, unless otherwise reauthorized or modified by Congress.

(c) ACTION WITH RESPECT TO CATEGORIES.—(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 mix-

ture 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 properties, 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.

(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] *Health and Human Services* 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] *Health and Human Services* (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 preceding 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] *Health and Human Services*, 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) PRIOR ACTIONS.—*Nothing in this Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.*

SEC. 27. DEVELOPMENT AND EVALUATION OF TEST METHODS.

(a) IN GENERAL.—The Secretary of [Health, Education, and Welfare] *Health and Human Services* in consultation with the Administrator and acting through the Assistant Secretary for Health, may conduct, and make grants to public and nonprofit private entities and enter into contracts with public and private entities for, projects for the development and evaluation of inexpensive and efficient methods (1) for determining and evaluating the health and environmental effects of chemical substances and mixtures, and

their toxicity, persistence, and other characteristics which affect health and the environment, and (2) which may be used for the development of test data to meet the requirements of rules promulgated under section 4. The Administrator shall consider such methods in prescribing under section 4 standards for the development of test data.

(b) APPROVAL BY SECRETARY.—No grant may be made or contract entered into under subsection (a) unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be submitted in such form and manner and contain such information as the Secretary may require. The Secretary may apply such conditions to grants and contracts under subsection (a) as the Secretary determines are necessary to carry out the purposes of such subsection. Contracts may be entered into under such subsection without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

(c) SUSTAINABLE CHEMISTRY PROGRAM.—*The President shall establish an interagency Sustainable Chemistry Program to promote and coordinate Federal sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities.*

(d) PROGRAM ACTIVITIES.—*The activities of the Program shall be designed to—*

(1) *provide sustained support for sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training through—*

(A) *coordination of sustainable chemistry research, development, demonstration, and technology transfer conducted at Federal laboratories and agencies; and*

(B) *to the extent practicable, encouragement of consideration of sustainable chemistry in, as appropriate—*

(i) *the conduct of Federal and State science and engineering research and development; and*

(ii) *the solicitation and evaluation of applicable proposals for science and engineering research and development;*

(2) *examine methods by which the Federal Government can create incentives for consideration and use of sustainable chemistry processes and products, including innovative financing mechanisms;*

(3) *expand the education and training of undergraduate and graduate students and professional scientists and engineers, including through partnerships with industry, in sustainable chemistry science and engineering;*

(4) *collect and disseminate information on sustainable chemistry research, development, and technology transfer including information on—*

(A) *incentives and impediments to development, manufacturing, and commercialization;*

(B) *accomplishments;*

(C) *best practices; and*

(D) *costs and benefits;*

(5) *support (including through technical assistance, participation, financial support, or other forms of support) economic,*

legal, and other appropriate social science research to identify barriers to commercialization and methods to advance commercialization of sustainable chemistry.

(e) INTERAGENCY WORKING GROUP.—

(1) ESTABLISHMENT.—*Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the President, in consultation with the Office of Science and Technology Policy, shall establish an Interagency Working Group that shall include representatives from the National Science Foundation, the National Institute of Standards and Technology, the Department of Energy, the Environmental Protection Agency, the Department of Agriculture, the Department of Defense, the National Institutes of Health, and any other agency that the President may designate to oversee the planning, management, and coordination of the Program.*

(2) GOVERNANCE.—*The Director of the National Science Foundation and the Assistant Administrator for Research and Development of the Environmental Protection Agency, or their designees, shall serve as co-chairs of the Interagency Working Group.*

(3) RESPONSIBILITIES.—*In overseeing the planning, management, and coordination of the Program, the Interagency Working Group shall—*

(A) establish goals and priorities for the Program, in consultation with the Advisory Council;

(B) provide for interagency coordination, including budget coordination, of activities under the Program;

(C) meet not later than 90 days from its establishment and periodically thereafter; and

(D) establish and consult with an Advisory Council on a regular basis.

(4) MEMBERSHIP.—*The Advisory Council members shall not be employees of the Federal Government and shall include a diverse representation of knowledgeable individuals from the private sector (including small- and medium-sized enterprises from across the value chain), academia, State and tribal governments, and nongovernmental organizations and others who are in a position to provide expertise.*

(f) AGENCY BUDGET REQUESTS.—

(1) IN GENERAL.—*Each Federal agency and department participating in the Program shall, as part of its annual request for appropriations to the Office of Management and Budget, submit a report to the Office of Management and Budget that—*

(A) identifies the activities of the agency or department that contribute directly to the Program; and

(B) states the portion of the agency or department's request for appropriations that is allocated to those activities.

(2) ANNUAL BUDGET REQUEST TO CONGRESS.—*The President shall include in the annual budget request to Congress a statement of the portion of the annual budget request for each agency or department that will be allocated to activities undertaken pursuant to the Program.*

(g) REPORT TO CONGRESS.—

(1) IN GENERAL.—*Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Interagency Working Group shall submit a report to the Committee on Science, Space, and Technology and Committee on Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works and the Committee on Commerce, Science, and Transportation of the Senate that shall include—*

(A) *a summary of federally funded sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities;*

(B) *a summary of the financial resources allocated to sustainable chemistry initiatives;*

(C) *an analysis of the progress made toward achieving the goals and priorities of this Act the program established pursuant to subsection (c), and recommendations for future program activities;*

(D) *an assessment of the benefits of expanding existing, federally-supported regional innovation and manufacturing hubs to include sustainable chemistry and the value of directing the creation of 1 or more dedicated sustainable chemistry centers of excellence or hubs; and*

(E) *an evaluation of steps taken and future strategies to avoid duplication of efforts, streamline interagency coordination, facilitate information sharing, and spread best practices between participating agencies in the Program.*

(2) SUBMISSION TO GAO.—*The Interagency Working Group shall also submit the report described in paragraph (1) to the Government Accountability Office for consideration in future Congressional inquiries.*

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 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) 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) ANNUAL REPORTS.—Not later than six months after the end of each of the fiscal years 1979, 1980, and 1981, the Administrator 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) 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. 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. 30. 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);**]**

(2)(A) *the number of notices received during each year under section 5; and*

(B) *the number of the notices described in subparagraph (A) for chemical substances subject to a rule, testing consent agreement, or order under section 4;*

(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】

(a) **IN GENERAL.**—*This Act shall take effect on January 1, 1977.*

(b) **RETROACTIVE APPLICABILITY.**—*Nothing in this Act shall be interpreted to apply retroactively to any State, Federal, or maritime legal action commenced prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.*

**COMPREHENSIVE ENVIRONMENTAL RESPONSE,
COMPENSATION, AND LIABILITY ACT OF 1980**

* * * * *

SEC. 101. For purpose of this title—

(1)* * *

* * * * *

SEC. 104. (a)(1) Whenever (A) any hazardous substance is released or there is a substantial threat of such a release into the environment, or (B) there is a release or substantial threat of release into the environment of any pollutant or contaminant which may present an imminent and substantial danger to the public health or welfare, the President is authorized to act, consistent with the national contingency plan, to remove or arrange for the removal of, and provide for remedial action relating to such hazardous substance, pollutant, or contaminant at any time (including its removal from any contaminated natural resource), or take any other response measure consistent with the national contingency plan which the President deems necessary to protect the public health or welfare or the environment. When the President determines that such action will be done properly and promptly by the owner or operator of the facility or vessel or by any other responsible party, the President may allow such person to carry out the action, conduct the remedial investigation, or conduct the feasibility study in accordance with section 122. No remedial investigation or feasibility study (RI/FS) shall be authorized except on a determination by the President that the party is qualified to conduct the RI/FS and only if the President contracts with or arranges for a qualified person to assist the President in overseeing and reviewing the conduct of such RI/FS and if the responsible party agrees to reimburse the

Fund for any cost incurred by the President under, or in connection with, the oversight contract or arrangement. In no event shall a potentially responsible party be subject to a lesser standard of liability, receive preferential treatment, or in any other way, whether direct or indirect, benefit from any such arrangements as a response action contractor, or as a person hired or retained by such a response action contractor, with respect to the release or facility in question. The President shall give primary attention to those releases which the President deems may present a public health threat.

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(i)(1) There is hereby established within the Public Health Service an agency, to be known as the Agency for Toxic Substances and Disease Registry, which shall report directly to the Surgeon General of the United States. The Administrator of said Agency shall, with the cooperation of the Administrator of the Environmental Protection Agency, the Commissioner of the Food and Drug Administration, the Directors of the National Institute of Medicine, National Institute of Environmental Health Sciences, National Institute of Occupational Safety and Health, Centers for Disease Control and Prevention, the Administrator of the Occupational Safety and Health Administration, the Administrator of the Social Security Administration, the Secretary of Transportation, and appropriate State and local health officials, effectuate and implement the health related authorities of this Act. In addition, said Administrator shall—

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(5)(A) For each hazardous substance listed pursuant to paragraph (2), the Administrator of ATSDR (in consultation with the Administrator of EPA and other agencies and programs of the Public Health Service) shall assess whether adequate information on the health effects of such substance is available. For any such substance for which adequate information is not available (or under development), the Administrator of ATSDR, in cooperation with the Director of the National Toxicology Program, shall assure the initiation of a program of research designed to determine the health effects (and techniques for development of methods to determine such health effects) of such substance. Where feasible, such program shall seek to develop methods to determine the health effects of such substance in combination with other substances with which it is commonly found. Before assuring the initiation of such program, the Administrator of ATSDR shall consider recommendations of the Interagency Testing Committee established under [section 4(e)] *section 4(f)* of the Toxic Substances Control Act on the types of research that should be done.

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