This document contains amendments to the Toxic Substances Control Act up to and including those in H.R. 2576 – the Frank R. Lautenberg Chemical Safety for the 21st Century Act, enacted on June 22, 2016. Best efforts were made to capture all changes and formatting. This is an unofficial version and should not be cited or quoted. Bill sections 20 and 21 are included as an addendum, because they do not amend TSCA.

TOXIC SUBSTANCES CONTROL ACT[1]

[As Amended Through P.L. 114–182, Enacted June 22, 2016]

TITLE I—CONTROL OF TOXIC SUBSTANCES

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

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

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TITLE I—CONTROL OF TOXIC SUBSTANCES

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 information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such information should be the responsibility

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

of those who manufacture and those who process such chemical substances and mixtures;

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

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

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

[15 U.S.C. 2601]

SEC. 3. DEFINITIONS.

As used in this Act:

(1) The [2] 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 any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges), and

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

The term ''food'' as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act).

(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,

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

or (B) which affects trade, traffic, transportation, or commerce described in clause (A).

(4) The term "conditions of use" means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

(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.

(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.

(7) The term "guidance" means any significant written guidance of general applicability prepared by the Administrator.

(8) 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 information 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.

(9) 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.

(10) 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.

(11) 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).

(12) The term "potentially exposed or susceptible subpopulation" means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

(13) 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.

(14) The term ''processor'' means any person who processes a chemical substance or mixture.

(15) The term ''protocols and methodologies for the development of information'' 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 information for a chemical substance or mixture are to be developed and any analysis that is to be performed on such information, and

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

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

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

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

(16) 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.

(17) The term ''United States'', when used in the geographic sense, means all of the States.

[15 U.S.C. 2602]

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

(a) TESTING REQUIREMENTS.—(1) If the Administrator finds that—

(A)(i)(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 is insufficient information 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 information; or

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

(II) there is insufficient information 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 information; and

(B) 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, or, in the case of a chemical substance or mixture described in subparagraph (A)(i), by rule, order, or consent agreement, require that testing be conducted on such substance or mixture to develop information with respect to the health and environmental effects for which there is an insufficiency of information and experience and which is 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.

(2) ADDITIONAL TESTING AUTHORITY.—In addition to the authority provided under paragraph (1), the Administrator may, by rule, order, or consent agreement—

(1) require the development of new information relating to a chemical substance or mixture if the Administrator determines that the information is necessary—

(i) to review a notice under section 5 or to perform a risk evaluation under section 6(b);

(ii) to implement a requirement imposed in a rule, order, or consent agreement under subsection (e) or (f) of section 5 or in a rule promulgated under section 6(a);

(iii) at the request of a Federal implementing authority under another Federal law, to meet the regulatory testing needs of that authority with regard to toxicity and exposure; or

(iv) pursuant to section 12(a)(2); and

(B) require the development of new information for the purposes of prioritizing a chemical substance under section 6(b) only if the Administrator determines that such information is necessary to establish the priority of the substance, subject to the limitations that—

(i) not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, order, or consent agreement under this subparagraph, the Administrator shall designate the chemical substance as a high-priority substance or a low-priority substance; and

(ii) information required by the Administrator under this subparagraph shall not be required for the purposes of establishing or implementing a minimum information requirement of broader applicability.

(3) STATEMENT OF NEED.—When requiring the development of new information relating to a chemical substance or mixture under paragraph (2), the Administrator shall identify the need for the new information, describe how information reasonably available to the Administrator was used to inform the decision to require new information, explain the basis for any decision that requires the use of vertebrate animals, and, as applicable, explain why issuance of an order is warranted instead of promulgating a rule or entering into a consent agreement.

(4) TIERED TESTING.—When requiring the development of new information under this subsection, 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, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first conducting screening-level testing.

(b)(1) TESTING REQUIREMENT RULE, ORDER, OR CONSENT AGREEMENT.—A rule, order, or consent agreement under subsection (a) shall include—

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

(B) protocols and methodologies for the development of information 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 information developed in accordance with the protocols and methodologies referred to in subparagraph (B).

In determining the protocols and methodologies and period to be included, pursuant to subparagraphs (B) and (C), in a rule, order, or consent agreement

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, order, or consent agreement and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule, order, or consent agreement. Any such rule, order, or consent agreement may require the submission to the Administrator of preliminary information during the period prescribed under subparagraph (C).

(2)(A) The health and environmental effects for which protocols and methodologies for the development of information 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. Protocols and methodologies for the development of information may also be prescribed for the assessment of exposure or exposure potential to humans or the environment. The characteristics of chemical substances and mixtures for which such protocols and methodologies 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 protocols and methodologies include epidemiologic studies, serial or tiered testing, 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 protocols and methodologies for development of information prescribed in rules, orders, and consent agreements under subsection (a) and shall, if necessary, institute proceedings to make appropriate revisions of such protocols and methodologies.

(3)(A) A rule or order under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph (B) or (C), as applicable, to conduct tests and submit information 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 information on behalf of the persons making the designation.

(B) The following persons shall be required to conduct tests and submit information on a chemical substance or mixture subject to a rule under subsection (a)(1):

(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)(i)(II) or (a)(1)(A)(ii)(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)(i)(II) or (a)(1)(A)(ii)(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)(i)(II) or (a)(1)(A)(ii)(II) with respect to the distribution in commerce, use, or disposal of such substance or mixture.

(C) A rule or order under paragraph (1) or (2) of subsection (a) may require the development of information by any person who manufactures or processes, or intends to manufacture or process, a chemical substance or mixture subject to the rule or order.

(4) Any rule, order, or consent agreement under subsection (a) requiring the testing of and submission of information 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 information for such substance or

mixture unless the Administrator repeals the rule or order or modifies the consent agreement to terminate the requirement before such date; and a rule, order, or consent agreement under subsection (a) requiring the testing of and submission of information 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 information for such substance or mixture unless the Administrator before such date repeals or modifies the application of the rule, order, or consent agreement to such substance or mixture or repeals the rule or order or modifies the consent agreement to terminate the requirement.

(c) EXEMPTION.—(1) Any person required by a rule or order under subsection (a) to conduct tests and submit information 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 information has been submitted to the Administrator in accordance with a rule, order, or consent agreement under subsection (a) or for which information is being developed pursuant to such a rule, order, or consent agreement, and

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

the Administrator shall exempt, in accordance with paragraph (3) or (4), the applicant from conducting tests and submitting information on such substance or mixture under the rule or order 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 information on a chemical substance or mixture is granted on the basis of the existence of previously submitted information and if such exemption is granted during the reimbursement period for such information (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 information, for a portion of the costs incurred by such person in complying with the requirement to submit such information, 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 information for a chemical substance or mixture is a period—

(i) beginning on the date such information is submitted in accordance with a rule, order, or consent agreement 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 information,

whichever is later.

(4)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit information on a chemical substance or mixture is granted on the basis of the fact that information is being developed by one or more persons pursuant to a rule, order, or consent agreement 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 information, for a portion of the costs incurred by each such person in complying with such rule, order, or consent agreement, 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, order, or consent agreement, 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 information pursuant to a rule, order, or consent agreement under subsection (a) and if after such exemption is granted the Administrator determines that no such person has complied with such rule, order, or consent agreement, the Administrator shall (i) after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption, and (ii) notify in writing such person of the requirements of the rule or order with respect to which such exemption was granted.

(d) NOTICE.—Upon the receipt of any information pursuant to a rule, order, or consent agreement under subsection (a), the Administrator shall publish a notice of the receipt of such information 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 information has been received; (2) list the uses or intended uses of such substance or mixture and the information required by the applicable protocols and methodologies for the development of information; and (3) describe the nature of the information developed. Except as otherwise provided in section 14, such information shall be made available by the Administrator for examination by any person.

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

recommendation with respect to any chemical substance or mixture, the committee shall consider all relevant factors, including—

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

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

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

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

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

(vi) the existence of information 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 information upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted, and

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

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

(B) As soon as practicable but not later than nine months after the effective date of this Act, the committee shall publish in the Federal Register and transmit to the Administrator the list and designations required by subparagraph (A) together with the reasons for the committee's inclusion of each chemical substance or mixture on the list. At least every six months after the date of the transmission to the Administrator of the list pursuant to the preceeding[3] 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 issue an order, enter into a consent agreement, or initiate a rulemaking proceeding under subsection (a), or, if such an order or consent agreement is

[3] So in law. Probably should be ''preceding''.

not issued or such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not issuing such an order, entering into such a consent agreement, or initiating such a proceeding.

(2)(A) The committee established by paragraph (1)(A) shall consist of ten 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.

(ix) One member appointed by the Chairman of the Consumer Product Safety Commission from Commissioners or employees of the Commission.

(x) One member appointed by the Commissioner of Food and Drugs from employees of the Food and Drug Administration.

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

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

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

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

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

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

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

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

(1) any information 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 a significant risk of serious or widespread harm to human beings, the Administrator shall, within the 180-day period beginning on the date of the receipt of such information, initiate applicable 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, made without consideration of costs or other nonrisk factors, that such risk is not unreasonable. For good cause shown the Administrator may extend such period for an additional period of not more than 90 days. The Administrator shall publish in the Federal Register notice of any such extension and the reasons therefor. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review under chapter 7 of title 5, United States Code. This subsection shall not take effect until two years after the effective date of this Act.

(g) PETITION FOR PROTOCOLS AND METHODOLOGIES FOR THE DEVELOPMENT OF INFORMATION.—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, order, or consent agreement under subsection (a) to conduct tests and submit information on such substance may petition the Administrator to prescribe protocols and methodologies for the development of information 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 protocols and methodologies 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.

(h) REDUCTION OF TESTING ON VERTEBRATES.—

(1) IN GENERAL.—The Administrator shall reduce and replace, to the extent practicable, scientifically justified, and consistent with the policies of this title, the use of vertebrate animals in the testing of chemical substances or mixtures under this title by—

(A) prior to making a request or adopting a requirement for testing using vertebrate animals, and in accordance with subsection (a)(3), taking into consideration, as appropriate and to the extent practicable and scientifically justified, reasonably available existing information, including—

(i) toxicity information;

(ii) computational toxicology and bioinformatics; and

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

(B) encouraging and facilitating—

(i) the use of scientifically valid test methods and strategies that reduce or replace the use of vertebrate animals while providing information of equivalent or better scientific quality and relevance that will support regulatory decisions under this title;

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

(iii) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests, provided that such consortia make all information from such testing available to the Administrator.

(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new scientifically valid test

methods and strategies 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 strategies to reduce, refine, or replace vertebrate animal testing and provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment of chemical substances or mixtures through, for example—

(i) computational toxicology and bioinformatics;

(ii) high-throughput screening methods;

(iii) testing of categories of chemical substances;

(iv) tiered testing methods;

(v) in vitro studies;

(vi) systems biology;

(vii) new or revised methods identified by validation bodies such as the Interagency Coordinating Committee on the Validation of Alternative Methods or the Organization for Economic Co-operation and Development; or

(viii) industry consortia that develop information submitted under this title;

(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) include in the strategic plan developed under subparagraph (A) a list, which the Administrator shall update on a regular basis, of particular alternative test methods or strategies the Administrator has identified that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information of equivalent or better 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 and relevance of the test methods and strategies that may be identified pursuant to 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 the plan developed under subparagraph (A) and goals for future alternative test methods and strategies implementation; and

(F) prioritize and, to the extent consistent with available resources and the Administrator's other responsibilities under this title, carry out performance assessment, validation, and translational studies to accelerate the development of scientifically valid test methods and strategies that reduce, refine, or replace the use of vertebrate animals, including minimizing duplication, in any testing under this title.

(3) 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 test method or strategy identified by the Administrator pursuant to paragraph (2)(C), if the Administrator has identified such a test method or strategy for the development of such information, before conducting new vertebrate animal testing.

(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall, under any circumstance, limit or restrict the submission of any existing information to the Administrator.

(C) RELATIONSHIP TO OTHER LAW.—A violation of this paragraph shall not be a prohibited act under section 15.

(D) REVIEW OF MEANS.—This paragraph authorizes, but does not require, the Administrator to review the means by which a person conducted testing described in subparagraph (A).

[15 U.S.C. 2603]

SEC. 5. MANUFACTURING AND PROCESSING NOTICES.

(a) IN GENERAL.—(1)(A) Except as provided in subparagraph (B) of this paragraph and subsection (h), no person may—

(i) 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

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

(B) A person may take the actions described in subparagraph (A) if—

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

(ii) the Administrator—

(I) conducts a review of the notice; and

(II) makes a determination under subparagraph (A), (B), or (C) of paragraph (3) and takes the actions required in association with that determination under such subparagraph within the applicable review period.

(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) REVIEW AND DETERMINATION.—Within the applicable review period, subject to section 18, the Administrator shall review such notice and determine—

(A) that the relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall take the actions required under subsection (f);

(B) that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use; or

(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, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator; 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,

in which case the Administrator shall take the actions required under subsection (e); or

(C) that the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use.

(4) FAILURE TO RENDER DETERMINATION.—

(A) FAILURE TO RENDER DETERMINATION.—If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 26(b), and the Administrator shall not be relieved of any requirement to make such determination.

(B) LIMITATIONS.—(i) A refund of applicable fees under subparagraph (A) shall not be made if the Administrator certifies that the submitter has not provided information required under subsection (b) or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable review period.

(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.

(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section.

(5) ARTICLE CONSIDERATION.—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(A)(ii) 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 justifies notification.

(b) SUBMISSION OF INFORMATION.—(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 information for such substance pursuant to a rule, order, or consent agreement under section 4 before the submission of such notice, such person shall submit to the Administrator such information in accordance with such rule, order, or consent agreement 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 or order 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 information 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)(i) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(A)(ii).

(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, order, or consent agreement under section 4 before the submission of such notice to submit information for such substance,

such person may submit to the Administrator information prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

(B) Information submitted pursuant to subparagraph (A) shall be information which the person submitting the information believes shows that—

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

(3) Information submitted under paragraph (1) or (2) of this subsection or under subsection (e) 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, without consideration of costs or other nonrisk factors.

(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.

(c) EXTENSION OF REVIEW 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). Subject to section 14, such an

extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

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

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

(B) in such form and manner as the Administrator may prescribe, any information 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 information concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

Such a notice shall be made available, subject to section 14, for examination by interested persons.

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

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

(B) lists the uses of such substance identified in the notice; and

(C) in the case of the receipt of information under subsection (b), describes the nature of the tests performed on such substance and any information which was developed pursuant to subsection (b) or a rule, order, or consent agreement 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 applicable review period has not expired, and (B) each chemical substance for which such period has expired since the last publication in the Federal Register of such list.

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

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

(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, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use; 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 shall issue an order, to take effect on the expiration of the applicable review period, 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 to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, and the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, including while any required information is being developed, only in compliance with the order.

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

(f) PROTECTION AGAINST UNREASONABLE RISKS.—(1) If the Administrator determines that a chemical substance or significant new use with respect to which notice is required by subsection (a) presents an unreasonable risk of injury to health or environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use, the Administrator shall, before the expiration of the applicable review period, 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)(3)(B) shall apply with respect to such rule.

(3)(A) The Administrator may issue an order to prohibit or limit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1). Such order shall take effect on the expiration of the applicable review period.

(B) The provisions of subparagraph (B) of subsection (e)(1) shall apply with respect to an order issued under subparagraph (A).

(4) TREATMENT OF NONCONFORMING USES.—Not later than 90 days after taking an action under paragraph (2) or (3) or issuing an order under subsection (e) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the action or order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(5) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B) to address workplace exposures.

(g) STATEMENT ON ADMINISTRATOR FINDING.—If the Administrator finds in accordance with subsection (a)(3)(C) that a chemical substance or significant

new use is not likely to present an unreasonable risk of injury to health or the environment, then notwithstanding any remaining portion of the applicable review period, the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for the significant new use, and the Administrator shall make public a statement of the Administrator's finding. Such a statement shall be submitted for publication in the Federal Register as soon as is practicable before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

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

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific conditions of use identified in the application, 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 information 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 information has been submitted to the Administrator as required by subsection (b)(2), and

(ii) submission of information by the applicant on such substance would be duplicative of information which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such information on such substance. No exemption which is granted under this subparagraph with respect to the submission of information for a chemical substance may take effect before the beginning of the reimbursement period applicable to such information.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting information required under subsection (b)(2) for a chemical substance because of the existence of previously submitted information and if such exemption is granted during the reimbursement period for such information, 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 information 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 information, 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 information 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 information 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 information,

whichever is later.

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

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

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

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use.

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

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

(i) DEFINITIONS.—(1) For purposes of this section, the terms ''manufacture'' and ''process'' mean manufacturing or processing for commercial purposes.

(2) For purposes of this Act, the term "requirement" as used in this section shall not displace any statutory or common law.

(3) For purposes of this section, the term "applicable review period" means the period starting on the date the Administrator receives a notice under subsection (a)(1) and ending 90 days after that date, or on such date as is provided for in subsection (b)(1) or (c).

[15 U.S.C. 2604]

SEC. 6. PRIORITIZATION, RISK EVALUATION, AND REGULATION OF CHEMICAL SUBSTANCES AND MIXTURES.

(a) SCOPE OF REGULATION.—If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 18, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk:

(1) A requirement (A) prohibiting or otherwise restricting 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 or otherwise restricting 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 minimum 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 minimum 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 or 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 determination 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 determination, 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) RISK EVALUATIONS.—

(1) PRIORITIZATION FOR RISK EVALUATIONS.—

(A) ESTABLISHMENT OF PROCESS.—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 establish, by rule, a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time. The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.

(B) IDENTIFICATION OF PRIORITIES FOR RISK EVALUATION.—

(i) HIGH-PRIORITY SUBSTANCES.—The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.

(ii) LOW-PRIORITY SUBSTANCES.—The Administrator shall designate a chemical substance as a low-priority substance if the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance.

(C) INFORMATION REQUEST AND REVIEW AND PROPOSED AND FINAL PRIORITIZATION DESIGNATION.—The rulemaking required in subparagraph (A) shall ensure that the time required to make a priority designation of a chemical substance be no shorter than nine months and no longer than 1 year, and that the process for such designations includes—

(i) a requirement that the Administrator request interested persons to submit relevant information on a chemical substance that the Administrator has initiated the prioritization process on, before proposing a priority designation for the chemical substance, and provide 90 days for such information to be provided;

(ii) a requirement that the Administrator publish each proposed designation of a chemical substance as a high- or low-priority substance, along with an identification of the information, analysis, and basis used to make the proposed designations, and provide 90 days for public comment on each such proposed designation; and

(iii) a process by which the Administrator may extend the deadline in clause (i) for up to three months in order to receive or evaluate information required to be submitted in accordance with section 4(a)(2)(B), subject to the limitation that if the information available to the Administrator at the end of such an extension remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the chemical substance as a high-priority substance.

(2) INITIAL RISK EVALUATIONS AND SUBSEQUENT DESIGNATIONS OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

(A) INITIAL RISK EVALUATIONS.—Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall ensure that risk evaluations are being conducted on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments and shall publish the list of such chemical substances during the 180 day period.

(B) ADDITIONAL RISK EVALUATIONS.—Not later than three and one half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall ensure that risk evaluations are being conducted on at least 20 high-priority substances and that at least 20 chemical substances have been designated as low-priority substances, subject to the limitation that at least 50 percent of all chemical substances on which risk evaluations are being conducted by the Administrator are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.

(C) CONTINUING DESIGNATIONS AND RISK EVALUATIONS.—The Administrator shall continue to designate priority substances and conduct risk evaluations in accordance with this subsection at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines under paragraph (4)(G).

(D) PREFERENCE.—In designating high-priority substances, the Administrator shall give preference to—

(i) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a Persistence and Bioaccumulation Score of 3; and

(ii) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

(E) METALS AND METAL COMPOUNDS.—In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007, or a successor document that addresses metals risk assessment and is peer reviewed by the Science Advisory Board.

(3) INITIATION OF RISK EVALUATIONS; DESIGNATIONS.—

(A) RISK EVALUATION INITIATION.—Upon designating a chemical substance as a high-priority substance, the Administrator shall initiate a risk evaluation on the substance.

(B) REVISION.—The Administrator may revise the designation of a low-priority substance based on information made available to the Administrator.

(C) ONGOING DESIGNATIONS.—The Administrator shall designate at least one high-priority substance upon the completion of each risk evaluation (other than risk evaluations for chemical substances designated under paragraph (4)(C)(ii)).

(4) RISK EVALUATION PROCESS AND DEADLINES.—

(A) IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.

(B) ESTABLISHMENT OF PROCESS.—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 establish, by rule, a process to conduct risk evaluations in accordance with subparagraph (A).

(C) REQUIREMENT.—The Administrator shall conduct and publish risk evaluations, in accordance with the rule promulgated under subparagraph (B), for a chemical substance—

(i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and

(ii) subject to subparagraph (E), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (B), be subjected to a risk evaluation.

(D) SCOPE.—The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider, and, for each designation of a high-priority substance, ensure not less than 12 months between the initiation of the prioritization process for the chemical substance and the publication of the scope of the risk evaluation for the chemical substance, and for risk evaluations conducted on chemical substances that have been identified under paragraph (2)(A) or selected under subparagraph (E)(iv)(II) of this paragraph, ensure not less than 3 months before the Administrator publishes the scope of the risk evaluation.

(E) LIMITATION AND CRITERIA.—

(i) PERCENTAGE REQUIREMENTS.—The Administrator shall ensure that, of the number of chemical substances that undergo a risk evaluation under clause (i) of subparagraph (C), the number of chemical substances undergoing a risk evaluation under clause (ii) of subparagraph (C) is—

(I) not less than 25 percent, if sufficient requests are made under clause (ii) of subparagraph (C); and

(II) not more than 50 percent.

(ii) REQUESTED RISK EVALUATIONS.—Requests for risk evaluations under subparagraph (C)(ii) shall be subject to the payment of fees pursuant to section 26(b), and the Administrator shall not expedite or otherwise provide special treatment to such risk evaluations.

(iii) PREFERENCE.—In deciding whether to grant requests under subparagraph (C)(ii), the Administrator shall give preference to requests for risk evaluations on chemical 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.

(iv) EXCEPTIONS.—(I) Chemical substances for which requests have been granted under subparagraph (C)(ii) shall not be subject to section 18(b).

(II) Requests for risk evaluations on chemical substances which are made under subparagraph (C)(ii) and that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments shall be granted at the discretion of the Administrator and not be subject to clause (i)(II).

(F) REQUIREMENTS.—In conducting a risk evaluation under this subsection, the Administrator shall—

(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;

(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;

(iii) not consider costs or other nonrisk factors;

(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and

(v) describe the weight of the scientific evidence for the identified hazard and exposure.

(G) DEADLINES.—The Administrator—

(i) shall complete a risk evaluation for a chemical substance as soon as practicable, but not later than 3 years after the date on which the Administrator initiates the risk evaluation under subparagraph (C); and

(ii) may extend the deadline for a risk evaluation for not more than 6 months.

(H) NOTICE AND COMMENT.—The Administrator shall provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation.

(c) PROMULGATION OF SUBSECTION (a) RULES.—

(1) DEADLINES.—If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A), the Administrator—

(A) shall propose in the Federal Register a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published;

(B) shall publish in the Federal Register a final rule not later than 2 years after the date on which the final risk evaluation regarding the chemical substance is published; and

(C) may extend the deadlines under this paragraph for not more than 2 years, subject to the condition that the aggregate length of extensions under this subparagraph and subsection (b)(4)(G)(ii) does not exceed 2 years, and subject to the limitation that the Administrator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

(2) REQUIREMENTS FOR RULE.—

(A) STATEMENT OF EFFECTS.—In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, including consideration of—

(I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;

(II) the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and

(III) the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

(B) SELECTING REQUIREMENTS.—In selecting among prohibitions and other restrictions, the Administrator shall factor in, to the extent practicable, the considerations under subparagraph (A) in accordance with subsection (a).

(C) CONSIDERATION OF ALTERNATIVES.—Based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, the Administrator shall consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

(D) REPLACEMENT PARTS.—

(i) IN GENERAL.—The Administrator shall exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication in the Federal Register of the rule under subsection (a), unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation conducted under subsection (b)(4)(A), to the general population or to an identified potentially exposed or susceptible subpopulation.

(ii) DEFINITIONS.—In this subparagraph—

(I) the term "complex consumer goods" means electronic or mechanical devices composed of multiple manufactured components, with an intended useful life of 3 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, and the components of which would be impracticable to redesign or replace; and

(II) the term "complex durable goods" means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use.

(E) ARTICLES.—In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the

identified risks from exposure to the chemical substance or mixture from the article or category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

(3) PROCEDURES.—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 information, views, and arguments, and make all such submissions publicly available;

(C) promulgate a final rule based on the matter in the rulemaking record; and

(D) make and publish with the rule the determination described in subsection (a).

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—In any rule under subsection (a), the Administrator shall—

(A) specify the date on which it shall take effect, which date shall be as soon as practicable;

(B) except as provided in subparagraphs (C) and (D), specify mandatory compliance dates for all of the requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in a case of a use exempted under subsection (g);

(C) specify mandatory compliance dates for the start of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in the case of a use exempted under subsection (g);

(D) specify mandatory compliance dates for full implementation of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable; and

(E) provide for a reasonable transition period.

(2) VARIABILITY.—As determined by the Administrator, the compliance dates established under paragraph (1) may vary for different affected persons.

(3) (A) The Administrator may declare a proposed rule under subsection (a) to be effective, and compliance with the proposed requirements to be mandatory, upon publication in the Federal Register of the proposed rule and until the compliance dates applicable to such requirements in a final rule promulgated under section 6(a) or until the Administrator revokes such proposed rule, in accordance with subparagraph (B), 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 without consideration of costs or other non-risk factors; 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 in accordance with subsection (c), and either promulgate such rule (as proposed or with modifications) or revoke it.

(e) 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 paragraph (3) of subsection (c).

(5) This subsection does not limit the authority of the Administrator, under any other provision of this Act or any other Federal law, to take action respecting any polychlorinated biphenyl.

(f) MERCURY.—

(1) PROHIBITION ON SALE, DISTRIBUTION, OR TRANSFER OF ELEMENTAL MERCURY BY FEDERAL AGENCIES.—Except as provided in paragraph (2), effective beginning on the date of enactment of this subsection, no Federal agency shall convey, sell, or distribute to any other Federal agency, any State or local government agency, or any private individual or entity any elemental mercury under the control or jurisdiction of the Federal agency.

(2) EXCEPTIONS.—Paragraph (1) shall not apply to—

(A) a transfer between Federal agencies of elemental mercury for the sole purpose of facilitating storage of mercury to carry out this Act; or

(B) a conveyance, sale, distribution, or transfer of coal.

(3) LEASES OF FEDERAL COAL.—Nothing in this subsection prohibits the leasing of coal.

(g) EXEMPTIONS.—

(1) CRITERIA FOR EXEMPTION.—The Administrator may, as part of a rule promulgated under subsection (a), or in a separate rule, grant an exemption from a requirement of a subsection (a) rule for a specific condition of use of a chemical substance or mixture, if the Administrator finds that—

(A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;

(B) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or

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

(2) EXEMPTION ANALYSIS AND STATEMENT.—In proposing an exemption under this subsection, the Administrator shall analyze the need for the exemption, and shall make public the analysis and a statement describing how the analysis was taken into account.

(3) PERIOD OF EXEMPTION.—The Administrator shall establish, as part of a rule under this subsection, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis, and, by rule, may extend, modify, or eliminate an exemption if the

[4] Section 317(a) of Public Law 109–364 (120 Stat. 2142) amends paragraph (3) of section 6(e). Subsection (b) of section 317 of such Public Law provides as follows:

(b) SUNSET DATE.—The amendments made by subsection (a) shall cease to have effect on September 30, 2012. The termination of the authority to grant exemptions pursuant to such amendments shall not effect the validity of any exemption granted prior to such date.

Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or modification or is no longer necessary.

(4) CONDITIONS.—As part of a rule promulgated under this subsection, the Administrator shall include conditions, 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.

(h) CHEMICALS THAT ARE PERSISTENT, BIOACCUMULATIVE, AND TOXIC.—

(1) EXPEDITED ACTION.—Not later than 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall propose rules under subsection (a) with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments—

(A) that the Administrator has a reasonable basis to conclude are toxic and that with respect to persistence and bioaccumulation score high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation, initiated a review under section 5, or entered into a consent agreement under section 4, prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; and

(B) exposure to which under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator.

(2) NO RISK EVALUATION REQUIRED.—The Administrator shall not be required to conduct risk evaluations on chemical substances that are subject to paragraph (1).

(3) FINAL RULE.—Not later than 18 months after proposing a rule pursuant to paragraph (1), the Administrator shall promulgate a final rule under subsection (a).

(4) SELECTING RESTRICTIONS.—In selecting among prohibitions and other restrictions promulgated in a rule under subsection (a) pursuant to paragraph (1), the Administrator shall address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance and shall reduce exposure to the substance to the extent practicable.

(5) RELATIONSHIP TO SUBSECTION (b).—If, at any time prior to the date that is 90 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator makes a designation under subsection (b)(1)(B)(i), or receives a request under subsection (b)(4)(C)(ii), such chemical substance shall not be subject to this subsection, except that in selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a), the Administrator shall both ensure that the chemical substance meets the rulemaking standard under subsection (a) and reduce exposure to the substance to the extent practicable.

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

(1) a determination by the Administrator under subsection (b)(4)(A) that a chemical substance does not present an unreasonable risk of injury to health or the environment shall be issued by order and considered to be

a final agency action, effective beginning on the date of issuance of the order; and

(2) a final rule promulgated under subsection (a), including the associated determination by the Administrator under subsection (b)(4)(A) that a chemical substance presents an unreasonable risk of injury to health or the environment, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule.

(j) DEFINITION.—For the purposes of this Act, the term "requirement" as used in this section shall not displace statutory or common law.

[15 U.S.C. 2605]

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 imminently 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 determination under section 5 or 6, a rule under section 4, 5, or 6 or title IV, an order under section 4, 5, or 6 or title IV, or a consent agreement under section 4, 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)(3)(A)(i)) with respect to an imminently hazardous chemical substance or mixture, the Administrator shall commence in a district court of the United States with respect to such substance or mixture or article containing such substance or mixture a civil action described in subparagraph (A), (B), or (C) of paragraph (1).

(b) RELIEF AUTHORIZED.—(1) The district court of the United States in which an action under subsection (a) is brought shall have jurisdiction to grant such temporary or permanent relief as may be necessary to protect health or the environment from the unreasonable risk (as identified by the Administrator without consideration of costs or other nonrisk factors) associated with the chemical substance, mixture, or article involved in such action.

(2) In the case of an action under subsection (a) brought against a person who manufactures, processes, or distributes in commerce a chemical substance or mixture or an article containing a chemical substance or mixture, the relief authorized by paragraph (1) may include the issuance of a mandatory order requiring (A) in the case of purchasers of such substance, mixture, or article known to the defendant, notification to such purchasers of the risk associated with it; (B) public notice of such risk; (C) recall; (D) the replacement or repurchase of such substance, mixture, or article; or (E) any combination of the actions described in the preceding clauses.

(3) In the case of an action under subsection (a) against a chemical substance, mixture, or article, such substance, mixture, or article may be proceeded against by process of libel for its seizure and condemnation. Proceedings in such an action shall conform as nearly as possible to proceedings in rem in admiralty.

(c) VENUE AND CONSOLIDATION.—(1)(A) An action under subsection (a) against a person who manufactures, processes, or distributes a chemical substance or mixture or an article containing a chemical substance or mixture may be brought in the United States District Court for the District of Columbia or for any judicial district in which any of the defendants is found, resides, or

transacts business; and process in such an action may be served on a defendant in any other district in which such defendant resides or may be found. An action under subsection (a) against a chemical substance, mixture, or article may be brought in any United States district court within the jurisdiction of which the substance, mixture, or article is found.

(B) In determining the judicial district in which an action may be brought under subsection (a) in instances in which such action may be brought in more than one judicial district, the Administrator shall take into account the convenience of the parties.

(C) Subpoenas[5] requiring attendance of witnesses in an action brought under subsection (a) may be served in any judicial district.

(2) Whenever proceedings under subsection (a) involving identical chemical substances, mixtures, or articles are pending in courts in two or more judicial districts, they shall be consolidated for trial by order of any such court upon application reasonably made by any party in interest, upon notice to all parties in interest.

(d) ACTION UNDER SECTION 6.—Where appropriate, concurrently with the filing of an action under subsection (a) or as soon thereafter as may be practicable, the Administrator shall initiate a proceeding for the promulgation of a rule under section 6(a).

(e) REPRESENTATION.—Notwithstanding any other provision of law, in any action under subsection (a), the Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator in such an action.

(f) DEFINITION.—For the purposes of subsection (a), the term ''imminently hazardous chemical substance or mixture'' means a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment, without consideration of costs or other nonrisk factors. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture, or that any combination of such activities, is likely to result in such injury to health or the environment before a final rule under section 6 can protect against such risk.

[15 U.S.C. 2606]

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

[5] In Public Law 94–469, the word ''subpoenas'' is spelled ''subpeonas''. The spelling is corrected in this print to reflect the probable intent of Congress.

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 information 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.

(3)(A)(i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as the Administrator may require for publication of the first list of chemical substances required by subsection (b).

(ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture—

(I) subject to a rule proposed or promulgated under section 4, 5(b)(4), or 6, an order in effect under section 4 or 5(e), or a consent agreement under section 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).

(C) Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and not less frequently than once every 10 years thereafter, the Administrator, after consultation with the Administrator of the Small Business Administration, shall—

(i) review the adequacy of the standards prescribed under subparagraph (B); and

(ii) after providing public notice and an opportunity for comment, make a determination as to whether revision of the standards is warranted.

(4) CONTENTS.—The rules promulgated pursuant to paragraph (1)—

(A) may impose differing reporting and recordkeeping requirements on manufacturers and processors; and

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

(5) ADMINISTRATION.—In carrying out this section, the Administrator shall, to the extent feasible—

(A) not require reporting which is unnecessary or duplicative;

(B) minimize the cost of compliance with this section and the rules issued thereunder on small manufacturers and processors; and

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

(6) NEGOTIATED RULEMAKING.—(A) The Administrator shall enter into a negotiated rulemaking pursuant to subchapter III of chapter 5 of title 5, United States Code, to develop and publish, not later than 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a proposed rule providing for limiting the reporting requirements, under this subsection, for manufacturers of any inorganic byproducts, when such byproducts, whether by the byproduct manufacturer or by any other person, are subsequently recycled, reused, or reprocessed.

(2) Not later than 3 and one-half years after such date of enactment, the Administrator shall publish a final rule resulting from such negotiated rulemaking.

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

(iii) treat the individual members of the categories of chemical substances identified by the Administrator as statutory mixtures, as defined in Inventory descriptions established by the Administrator, as being included on the list established under paragraph (1).

(B) MULTIPLE NOMENCLATURE LISTINGS.—If a manufacturer or processor demonstrates to the Administrator that a chemical substance appears multiple times on the list published under paragraph (1) under different CAS numbers, the Administrator may recognize 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 may require processors, subject to the limitations under subsection (a)(5)(A), to notify the Administrator, by not later than 180 days after the date on which the final rule is published in the Federal Register, 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 designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

(iii) INACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which no notices are received under clause (i) to be inactive substances on the list published under paragraph (1).

(iv) LIMITATION.—No chemical substance on the list published under paragraph (1) shall be removed from such list by reason of the implementation of this subparagraph, or be subject to section 5(a)(1)(A)(i) by reason of a change to active status under paragraph (5)(B).

(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—In promulgating a rule under subparagraph (A), the Administrator shall—

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

(ii) require any manufacturer or processor of a chemical substance on the confidential portion of the list published under paragraph (1) that seeks to maintain an existing claim for protection against disclosure of the specific chemical identity of the chemical substance as confidential pursuant to section 14 to submit a notice under subparagraph (A) that includes such request;

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

(iv) move any active chemical substance for which no request was received to maintain an existing claim for protection against disclosure of the specific chemical identity of the chemical substance as confidential from the confidential portion of the list published under paragraph (1) to the nonconfidential portion of that list.

(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 chemical identities of chemical substances on the confidential portion of the list published under paragraph (1) that are asserted pursuant to subparagraph (B).

(D) REQUIREMENTS OF REVIEW PLAN.—In establishing the review plan under subparagraph (C), the Administrator shall—

(i) require, at a time specified by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim, in accordance with section 14, unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the last day of the time period specified by the Administrator; and

(ii) in accordance with section 14—

(I) review each substantiation—

(aa) submitted pursuant to clause (i) to determine if the claim qualifies for 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, approve in part and deny in part, 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 claim, in which case the Administrator shall not protect the information from disclosure; or

(bb) the Administrator otherwise becomes aware that the information does not qualify for protection from disclosure, in which case the Administrator shall take the actions described in section 14(g)(2).

(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 claims needing review and the available resources.

(II) ANNUAL REVIEW GOAL AND RESULTS.—At the beginning of each year, the Administrator shall publish an annual goal for reviews and the number of reviews completed in the prior year.

(5) ACTIVE AND INACTIVE SUBSTANCES.—

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

(B) 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.—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 chemical identity of the inactive substance as confidential, the person shall, consistent with the requirements of section 14—

(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 chemical identity of the chemical substance and approve, approve in part and deny in part, or deny the claim;

(III) except as provided in this section and section 14, protect from disclosure the specific chemical identity of the chemical substance for which the Administrator approves a claim under subclause (II) 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 claim, in which case the Administrator shall not protect the information from disclosure; or

(bb) the Administrator otherwise becomes aware that the information does not qualify for protection from disclosure, in which case the Administrator shall take the actions described in section 14(g)(2); and

(IV) pursuant to section 6(b), review the priority of the chemical substance as the Administrator determines to be necessary.

(C) 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 paragraph (4)(A), the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (as in effect on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act), 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 6(b).

(7) PUBLIC INFORMATION.—Subject to this subsection and section 14, the Administrator shall make available to the public—

(A) each specific chemical identity on the nonconfidential portion of the list published under paragraph (1) along with the Administrator's designation of the chemical substance as an active or inactive substance;

(B) the unique identifier assigned under section 14, 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

(C) the specific chemical identity of any active substance for which—

(i) a claim for protection against disclosure of the specific chemical identity of the active substance was not asserted, as required under this subsection or section 14;

(ii) all claims for protection against disclosure of the specific chemical identity of the active substance have been denied by the Administrator; or

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

(8) LIMITATION.—No person may assert a new claim under this subsection or section 14 for protection from disclosure of a specific chemical identity of any active or inactive substance for which a notice is received under paragraph (4)(A)(i) or (5)(B)(i) that is not on the confidential portion of the list published under paragraph (1).

(9) CERTIFICATION.—Under the rules promulgated under this subsection, manufacturers and processors, as applicable, shall be required—

(A) to certify that each notice or substantiation 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 documenting compliance with the rule and supporting confidentiality claims for a period of 5 years beginning on the last day of the submission period.

(10) MERCURY.—

(A) DEFINITION OF MERCURY.—In this paragraph, notwithstanding section 3(2)(B), the term "mercury" means—

(i) elemental mercury; and

(ii) a mercury compound.

(B) PUBLICATION.—Not later than April 1, 2017, and every 3 years thereafter, the Administrator shall carry out and publish in the Federal Register an inventory of mercury supply, use, and trade in the United States.

(C) PROCESS.—In carrying out the inventory under subparagraph (B), the Administrator shall—

(i) identify any manufacturing processes or products that intentionally add mercury; and

(ii) recommend actions, including proposed revisions of Federal law or regulations, to achieve further reductions in mercury use.

(D) REPORTING.—

(i) IN GENERAL.—To assist in the preparation of the inventory under subparagraph (B), any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process shall make periodic reports to the Administrator, at such time and including such information as the Administrator shall determine by rule promulgated not later than 2 years after the date of enactment of this paragraph.

(ii) COORDINATION.—To avoid duplication, the Administrator shall coordinate the reporting under this subparagraph with the Interstate Mercury Education and Reduction Clearinghouse.

(iii) EXEMPTION.—Clause (i) shall not apply to a person engaged in the generation, handling, or management of mercury-containing waste, unless that person manufactures or recovers mercury in the management of that waste.

(c) RECORDS.—Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture. Records of such adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. Any other record of such

adverse reactions shall be retained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record. Records required to be maintained under this subsection shall include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of any duly designated representative of the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

(d) HEALTH AND SAFETY STUDIES.—The Administrator shall promulgate rules under which the Administrator shall require any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator—

(1) lists of health and safety studies (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person, or (C) reasonably ascertainable by such person, except that the Administrator may exclude certain types or categories of studies from the requirements of this subsection if the Administrator finds that submission of lists of such studies are unnecessary to carry out the purposes of this Act; and

(2) copies of any study contained on a list submitted pursuant to paragraph (1) or otherwise known by such person.

(e) NOTICE TO ADMINISTRATOR OF SUBSTANTIAL RISKS.—Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

(f) DEFINITIONS.—For purposes of this section, the terms ''manufacture'' and ''process'' mean manufacture or process for commercial purposes.
[15 U.S.C. 2607]

SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.

(a) LAWS NOT ADMINISTERED BY THE ADMINISTRATOR.—(1) If the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator, under the conditions of use, and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—

(A)(i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and

(ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and

(B) to respond to the Administrator with respect to the matters described in subparagraph (A).

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested response within such time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made. The response of an agency shall be accompanied by a detailed statement of the findings and conclusions of the agency and shall be published in the Federal Register.

(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either—

(A) issues an order, within the time period specified by the Administrator in the report, 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) responds within the time period specified by the Administrator in the report and 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(a) or 7 with respect to such risk.

(3) The Administrator shall take the actions described in paragraph (4) if the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which the report was made does not—

(A) issue the order described in paragraph (2)(A) within the time period specified by the Administrator in the report; or

(B) (i) respond under paragraph (1) within the timeframe specified by the Administrator in the report; and

(ii) initiate action within 90 days of publication in the Federal Register of the response described in clause (i).

(4) If an agency to which a report is submitted under paragraph (1) does not take the actions described in subparagraph (A) or (B) of paragraph (3), the Administrator shall—

(A) initiate or complete appropriate action under section 6; or

(B) take any action authorized or required under section 7, as applicable.

(5) This subsection shall not relieve the Administrator of any obligation to take any appropriate action under section 6(a) or 7 to address risks from the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of those activities, that are not identified in a report issued by the Administrator under paragraph (1).

(6) If the Administrator has initiated action under section 6(a) 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.—(1) 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.

(2) In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this title with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk described in paragraph (1) and a comparison of the estimated costs and efficiencies of the action to be taken under this title and an action to be taken under such other law to protect against such risk.

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

(e) EXPOSURE INFORMATION.—In addition to the requirements of subsection (a), if the Administrator obtains information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.
[15 U.S.C. 2608]

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

(a) AUTHORITY.—The Administrator shall, in consultation and cooperation with the Secretary of 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) INFORMATION 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 information submitted to the Administrator under this Act.

(2)(A) The Administrator shall, in consultation and cooperation with the Secretary of 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 information 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 and Human Services, may make grants and enter into contracts for the development of an information 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 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 and Human Services, establish and be responsible for research 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 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 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 information format and analysis and consistent testing procedures.

[15 U.S.C. 2609]

SEC. 11. INSPECTIONS AND SUBPOENAS.

(a) IN GENERAL.—For purposes of administering this Act, the Administrator, and any duly designated representative of the Administrator, may inspect any establishment, facility, or other premises in which chemical substances, mixtures, or products subject to title IV are manufactured, processed, stored, or held before or after their distribution in commerce and any conveyance being used to transport chemical substances, mixtures, such products, or such articles in connection with distribution in commerce. Such an inspection may only be made upon the presentation of appropriate credentials and of a written notice to the owner, operator, or agent in charge of the premises or conveyance to be inspected. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness and shall be conducted at reasonable times, within reasonable limits, and in a reasonable manner.

(b) SCOPE.—(1) Except as provided in paragraph (2), an inspection conducted under subsection (a) shall extend to all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of this Act applicable to the chemical substances, mixtures, or products subject to title IV within such premises or conveyance have been complied with.

(2) No inspection under subsection (a) shall extend to— (A) financial information,

(B) sales information (other than shipment information),

(C) pricing information,

(D) personnel information, or

(E) research information (other than information required by this Act or under a rule promulgated, order issued, or consent agreement entered into thereunder),

unless, the nature and extent of such information are described with reasonable specificity in the written notice required by subsection (a) for such inspection.

(c) SUBPOENAS.—In carrying out this Act, the Administrator may by subpoena require the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, and other information that the Administrator deems necessary. Witnesses shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. In the event of contumacy, failure, or refusal of any person to obey any such subpoena, any district court of the United States in which venue is proper shall have jurisdiction to order any such person to comply with such subpoena. Any failure to obey such an order of the court is punishable by the court as a contempt thereof.

[15 U.S.C. 2610]

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 presents an unreasonable risk of injury to health within the United States or to the environment of the United States. The Administrator may require, under section 4, testing of any chemical substance or mixture exempted from this Act by paragraph (1) for the purpose of determining whether or not such substance or mixture presents an unreasonable risk of injury to health within the United States or to the environment of the United States.

(b) NOTICE.—(1) If any person exports or intends to export to a foreign country a chemical substance or mixture for which the submission of information 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 information 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.

(c) PROHIBITION ON EXPORT OF ELEMENTAL MERCURY AND MERCURY COMPOUNDS.—

(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) 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) CONSISTENCY WITH TRADE OBLIGATIONS.—Nothing in this subsection affects, replaces, or amends prior law relating to the need for consistency with international trade obligations.

(6) EXPORT OF COAL.—Nothing in this subsection shall be construed to prohibit the export of coal.

(7) PROHIBITION ON EXPORT OF CERTAIN MERCURY COMPOUNDS.—

(A) IN GENERAL.—Effective January 1, 2020, the export of the following mercury compounds is prohibited:

(i) Mercury (I) chloride or calomel.

(ii) Mercury (II) oxide.

(iii) Mercury (II) sulfate.

(iv) Mercury (II) nitrate.

(v) Cinnabar or mercury sulphide.

(vi) Any mercury compound that the Administrator adds to the list published under subparagraph (B) by rule, on determining that exporting that mercury compound for the purpose of regenerating elemental mercury is technically feasible.

(B) PUBLICATION.—Not later than 90 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and as appropriate thereafter, the Administrator shall publish in the Federal Register a list of the mercury compounds that are prohibited from export under this paragraph.

(C) PETITION.—Any person may petition the Administrator to add a mercury compound to the list published under subparagraph (B).

(D) ENVIRONMENTALLY SOUND DISPOSAL.—This paragraph does not prohibit the export of mercury compounds on the list published under subparagraph (B) to member countries of the Organization for Economic Co-operation and Development for environmentally sound disposal, on the condition that no mercury or mercury compounds so exported are to be recovered, recycled, or reclaimed for use, or directly reused, after such export.

(E) REPORT.—Not later than 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall evaluate any exports of mercury compounds on the list published under subparagraph (B) for disposal that occurred

after such date of enactment and shall submit to Congress a report that—

(i) describes volumes and sources of mercury compounds on the list published under subparagraph (B) exported for disposal;

(ii) identifies receiving countries of such exports;

(iii) describes methods of disposal used after such export;

(iv) identifies issues, if any, presented by the export of mercury compounds on the list published under subparagraph (B);

(v) includes an evaluation of management options in the United States for mercury compounds on the list published under subparagraph (B), if any, that are commercially available and comparable in cost and efficacy to methods being utilized in such receiving countries; and

(vi) makes a recommendation regarding whether Congress should further limit or prohibit the export of mercury compounds on the list published under subparagraph (B) for disposal.

(F) EFFECT ON OTHER LAW.—Nothing in this paragraph shall be construed to affect the authority of the Administrator under the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.).

[15 U.S.C. 2611]

SEC. 13. ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES.

(a) IN GENERAL.—(1) The Secretary of the Treasury shall refuse entry into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States) of any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry if—

(A) it fails to comply with any rule in effect under this Act, or

(B) it is offered for entry in violation of section 5, 6, or title IV a rule or order under section 5, 6, or title IV or an order issued in a civil action brought under section 5, 7 or title IV.

(2) If a chemical substance, mixture, or article is refused entry under paragraph (1), the Secretary of the Treasury shall notify the consignee of such entry refusal, shall not release it to the consignee, and shall cause its disposal or storage (under such rules as the Secretary of the Treasury may prescribe) if it has not been exported by the consignee within 90 days from the date of receipt of notice of such refusal, except that the Secretary of the Treasury may, pending a review by the Administrator of the entry refusal, release to the consignee such substance, mixture, or article on execution of bond for the amount of the full invoice of such substance, mixture, or article (as such value is set forth in the customs entry), together with the duty thereon. On failure to return such substance, mixture, or article for any cause to the custody of the Secretary of the Treasury when demanded, such consignee shall be liable to the United States for liquidated damages equal to the full amount of such bond. All charges for storage, cartage, and labor on and for disposal of substances, mixtures, or articles which are refused entry or released under this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future entry made by such owner or consignee.

(b) RULES.—The Secretary of the Treasury, after consultation with the Administrator, shall issue rules for the administration of subsection (a) of this section.

[15 U.S.C. 2612]

SEC. 14. CONFIDENTIAL INFORMATION.

(a) IN GENERAL.—Except as 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, by reason of 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 (c) are met.

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) INFORMATION NOT PROTECTED FROM DISCLOSURE.—

(1) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Information that is protected from disclosure under this section, and which is mixed with information that is not protected from disclosure under this section, does not lose its protection from disclosure notwithstanding that it is mixed with information that is not protected from disclosure.

(2) INFORMATION FROM HEALTH AND SAFETY STUDIES.—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 information 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 disclosure of any information, including formulas (including molecular structures) of a chemical substance or mixture, that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture.

(3) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—Subsection (a) does not prohibit the disclosure of—

(A) 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; or

(B) 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) BANS AND PHASE-OUTS.—

(A) IN GENERAL.—If the Administrator promulgates a rule pursuant to section 6(a) that establishes a ban or phase-out of a chemical substance or mixture, the protection from disclosure of any information under this section with respect to the chemical substance or mixture shall be presumed to no longer apply, subject to subsection (g)(1)(E) and subparagraphs (B) and (C) of this paragraph.

(B) LIMITATIONS.—

(i) CRITICAL USE.—In the case of a chemical substance or mixture for which a specific condition of use is subject to an exemption pursuant to section 6(g), if the Administrator establishes a ban or phase-out described in subparagraph (A) with

respect to the chemical substance or mixture, the presumption against protection under such subparagraph shall only apply to information that relates solely to any conditions of use of the chemical substance or mixture to which the exemption does not apply.

(ii) EXPORT.—In the case of a chemical substance or mixture for which there is manufacture, processing, or distribution in commerce that meets the conditions of section 12(a)(1), if the Administrator establishes a ban or phase-out described in subparagraph (A) with respect to the chemical substance or mixture, the presumption against protection under such subparagraph shall only apply to information that relates solely to any other manufacture, processing, or distribution in commerce of the chemical substance or mixture for the conditions of use subject to the ban or phase-out, unless the Administrator makes the determination in section 12(a)(2).

(iii) SPECIFIC CONDITIONS OF USE.—In the case of a chemical substance or mixture for which the Administrator establishes a ban or phase-out described in subparagraph (A) with respect to a specific condition of use of the chemical substance or mixture, the presumption against protection under such subparagraph shall only apply to information that relates solely to the condition of use of the chemical substance or mixture for which the ban or phase-out is established.

(C) REQUEST FOR NONDISCLOSURE.—

(i) IN GENERAL.—A manufacturer or processor of a chemical substance or mixture subject to a ban or phase-out described in this paragraph may submit to the Administrator, within 30 days of receiving a notification under subsection (g)(2)(A), a request, including documentation supporting such request, that some or all of the information to which the notice applies should not be disclosed or that its disclosure should be delayed, and the Administrator shall review the request under subsection (g)(1)(E).

(ii) EFFECT OF NO REQUEST OR DENIAL.—If no request for nondisclosure or delay is submitted to the Administrator under this subparagraph, or the Administrator denies such a request under subsection (g)(1)(A), the information shall not be protected from disclosure under this section.

(5) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information reported to or otherwise obtained by the Administrator under this Act that is not protected from disclosure under this subsection, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

(c) REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—

(1) ASSERTION OF CLAIMS.—

(A) IN GENERAL.—A person seeking to protect from disclosure any information that person submits under this Act (including information described in paragraph (2)) shall assert to the Administrator a claim for protection from disclosure 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) ADDITIONAL REQUIREMENTS FOR CLAIMS REGARDING CHEMICAL IDENTITY INFORMATION.—In the case of a claim under subparagraph (A) for protection from 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 such generic name shall—

(i) be consistent with guidance developed by the Administrator under paragraph (4)(A); and

(ii) describe the chemical structure of the chemical substance as specifically as practicable while protecting those features of the chemical structure—

(I) that are claimed as confidential; and

(II) the disclosure of which would be likely to cause substantial harm to the competitive position of the person.

(2) INFORMATION GENERALLY NOT SUBJECT TO SUBSTANTIATION REQUIREMENTS.—Subject to subsection (f), the following information shall not be subject to substantiation requirements under paragraph (3):

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

(B) Marketing and sales information.

(C) Information identifying a supplier or customer.

(D) In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents.

(E) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article.

(F) Specific production or import volumes of the manufacturer or processor.

(G) Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under section 5.

(3) SUBSTANTIATION REQUIREMENTS.—Except as provided in paragraph (2), a person asserting a claim to protect information from disclosure under this section shall substantiate the claim, in accordance with such rules as the Administrator has promulgated or may promulgate pursuant to this section.

(4) GUIDANCE.—The Administrator shall develop guidance regarding—

(A) the determination of structurally descriptive generic names, in the case of claims for the protection from 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 (d).

(5) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the statement required to assert a claim submitted pursuant to paragraph (1)(B), and any information required to

substantiate a claim submitted pursuant to paragraph (3), are true and correct.

(d) EXCEPTIONS TO PROTECTION FROM DISCLOSURE.—Information described in subsection (a) —

(1) shall be disclosed to an officer or employee of the United States—

(A) in connection with the official duties of that person under any Federal law for the protection of health or the environment; or

(B) for a specific Federal law enforcement purpose;

(2) shall 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 against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use;

(4) shall be disclosed to a State, political subdivision of a State, or tribal government, on written request, for the purpose of administration or enforcement of a law, if such entity has 1 or more applicable agreements with the Administrator that are consistent with the guidance developed under subsection (c)(4)(B) and ensure that the entity 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;

(5) shall be disclosed to a health or environmental professional employed by a Federal or State agency or tribal government or a treating physician or nurse in a nonemergency situation if such person 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 are consistent with the guidance developed under subsection (c)(4)(B);

(B) the 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 or mixture concerned, or an environmental release of or exposure to the chemical substance or mixture concerned has occurred; and

(C) 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 who has a claim under this section with respect to the information;

(6) shall be disclosed in the event of an emergency to a treating or responding physician, nurse, agent of a poison control center, public health or environmental official of a State, political subdivision of a State, or tribal government, or first responder (including any individual duly authorized by a Federal agency, State, political subdivision of a State, or tribal government who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical

technician) if such person requests the information, subject to the conditions that such person shall—

(A) have a reasonable basis to suspect that—

(i) a medical, 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 or mixture concerned, or a serious environmental release of or exposure to the chemical substance or mixture concerned has occurred; and

(B) if requested by a person who has a claim with respect to the information under this section—

(i) provide a written statement of need and agree to sign a confidentiality agreement, as described in paragraph (5); and

(ii) submit to the Administrator such statement of need and confidentiality agreement 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 is made in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding;

(8) shall be disclosed if the information is required to be made public under any other provision of Federal law; and

(9) shall be disclosed as required pursuant to discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law.

(e) DURATION OF PROTECTION FROM DISCLOSURE.—

(1) IN GENERAL.—Subject to paragraph (2), subsection (f)(3), and section 8(b), the Administrator shall protect from disclosure information described in subsection (a)—

(A) in the case of information described in subsection (c)(2), until such time as—

(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the information shall not be protected from disclosure under this section; or

(ii) the Administrator becomes aware that the information does not qualify for protection from disclosure under this section, in which case the Administrator shall take any actions required under subsections (f) and (g); and

(B) in the case of information other than information described in subsection (c)(2)—

(i) for a period of 10 years from the date on which the person asserts the claim with respect to the information submitted to the Administrator; or

(ii) if applicable before the expiration of such 10-year period, until such time as—

(I) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the information shall not be protected from disclosure under this section; or

(II) the Administrator becomes aware that the information does not qualify for protection from disclosure under this section, in which case the Administrator shall take any actions required under subsections (f) and (g).

(2) EXTENSIONS.—

(A) IN GENERAL.—In the case of information other than information described in subsection (c)(2), not later than the date that is 60 days before the expiration of the period described in paragraph (1)(B)(i), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

(B) REQUEST.—

(i) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in paragraph (1)(B)(i), a person reasserting the relevant claim shall submit to the Administrator a request for extension substantiating, in accordance with subsection (c)(3), the need to extend the period.

(ii) ACTION BY ADMINISTRATOR.—Not later than the date of expiration of the period described in paragraph (1)(B)(i), the Administrator shall, in accordance with subsection (g)(1)—

(I) review the request submitted under clause (i);

(II) make a determination regarding whether the claim for which the request was submitted continues to meet the relevant requirements of this section; and

(III) (aa) grant an extension of 10 years; or

(bb) deny the request.

(C) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under this paragraph, if the Administrator determines that the relevant request under subparagraph (B)(i)—

(i) establishes the need to extend the period; and

(ii) meets the requirements established by the Administrator.

(f) REVIEW AND RESUBSTANTIATION.—

(1) DISCRETION OF ADMINISTRATOR.—The Administrator may require any person that has claimed protection for information from disclosure under this section, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to reassert and substantiate or resubstantiate the claim in accordance with this section—

(A) after the chemical substance is designated as a high-priority substance under section 6(b);

(B) for any chemical substance designated as an active substance under section 8(b)(5)(B)(iii); or

(C) if the Administrator determines that disclosure of certain information currently protected from disclosure would be important to assist the Administrator in conducting risk evaluations or promulgating rules under section 6.

(2) REVIEW REQUIRED.—The Administrator shall review a claim for protection of information from disclosure under this section 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 reassert and substantiate or resubstantiate the claim in accordance with this section—

(A) as necessary to determine whether the information qualifies for an exemption from disclosure in connection with a request for information received by the Administrator under section 552 of title 5, United States Code;

(B) if the Administrator has a reasonable basis to believe that the information does not qualify for protection from disclosure under this section; or

(C) for any chemical substance the Administrator determines under section 6(b)(4)(A) presents an unreasonable risk of injury to health or the environment.

(3) PERIOD OF PROTECTION.—If the Administrator requires a person to reassert and substantiate or resubstantiate a claim under this subsection, and determines that the claim continues to meet the relevant requirements of this section, the Administrator shall protect the information subject to the claim from disclosure for a period of 10 years from the date of such determination, subject to any subsequent requirement by the Administrator under this subsection.

(g) DUTIES OF ADMINISTRATOR.—

(1) DETERMINATION.—

(A) IN GENERAL.—Except for claims regarding information described in subsection (c)(2), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (c), and not later than 30 days after the receipt of a request for extension of a claim under subsection (e) or a request under subsection (b)(4)(C), review and approve, approve in part and deny in part, or deny the claim or request.

(B) REASONS FOR DENIAL.—If the Administrator denies or denies in part a claim or request under subparagraph (A) the Administrator shall provide to the person that asserted the claim or submitted the request a written statement of the reasons for the denial or denial in part of the claim or request.

(C) SUBSETS.—The Administrator shall—

(i) except with respect to information described in subsection (c)(2)(G), review all claims or requests under this section for the protection from disclosure of the specific chemical identity of a chemical substance; and

(ii) review a representative subset, comprising at least 25 percent. of all other claims or requests for protection from disclosure under this section.

(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim or request for protection from disclosure or extension under this section shall not have the effect of denying or eliminating a claim or request for protection from disclosure.

(E) DETERMINATION OF REQUESTS UNDER SUBSECTION (b)(4)(C).—With respect to a request submitted under subsection (b)(4)(C), the Administrator shall, with the objective of ensuring that information relevant to the protection of health and the environment is disclosed to the extent practicable, determine whether the documentation provided by the person rebuts what shall be the presumption of the Administrator that the public interest in the disclosure of the information outweighs the public or proprietary interest in maintaining the protection for all or a portion of the information that the person has requested not be disclosed or for which disclosure be delayed.

(2) NOTIFICATION.—

(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (b), (d), and (e), if the Administrator denies or denies in part a claim or request under paragraph (1), concludes, in accordance with this section, that the information does not qualify for protection from disclosure, intends to disclose information pursuant to subsection (d), or promulgates a rule under section 6(a) establishing a ban or phase-out with respect to a chemical substance or mixture, the Administrator shall notify, in writing, the person that asserted the claim or submitted the request of the intent of the Administrator to disclose the information or not protect the information from disclosure under this section. The notice shall be furnished by certified mail

(return receipt requested), by personal delivery, or by other means that allows verification of the fact and date of receipt.

(B) DISCLOSURE OF INFORMATION.—Except as provided in subparagraph (C), the Administrator shall not disclose information under this subsection until the date that is 30 days after the date on which the person that asserted the claim or submitted the request receives notification under subparagraph (A).

(C) EXCEPTIONS.—

(i) FIFTEEN DAY NOTIFICATION.—For information the Administrator intends to disclose under subsections (d)(3), (d)(4), (d)(5), and (j), the Administrator shall not disclose the information until the date that is 15 days after the date on which the person that asserted the claim or submitted the request receives notification under subparagraph (A), except that, with respect to information to be disclosed under subsection (d)(3), if the Administrator determines that disclosure of the information is necessary to protect against an imminent and substantial harm to health or the environment, no prior notification shall be necessary.

(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information the Administrator intends to disclose under paragraph (6) of subsection (d), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

(I) for the disclosure of information under paragraphs (1), (2), (7), or (8) of subsection (d); or

(II) for the disclosure of information for which—

(aa) the Administrator has provided to the person that asserted the claim a notice under subsection (e)(2)(A); and

(bb) such person does not submit to the Administrator a request under subsection (e)(2)(B) on or before the deadline established in subsection (e)(2)(B)(i).

(D) APPEALS.—

(i) ACTION TO RESTRAIN DISCLOSURE.—If a person receives a notification under this paragraph and believes the information is protected from disclosure under this section, before the date on which the information is to be disclosed pursuant to subparagraph (B) or (C) 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.

(ii) NO DISCLOSURE.—

(I) IN GENERAL.—Subject to subsection (d), the Administrator shall not disclose information that is the subject of an appeal under this paragraph before the date on which the applicable court rules on an action under clause (i).

(II) EXCEPTION.—Subclause (I) shall not apply to disclosure of information described under subsections (d)(4) and (j).

(3) REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that, in a format

and language that is readily accessible and understandable, allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (d).

(4) 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, which shall not be either the specific chemical identity or a 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 their unique identifiers, 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 a chemical substance included on the list published under subparagraph (B) while the specific chemical identity of the chemical substance is protected from disclosure under this section identifies the chemical substance using the unique identifier; and

(D) for each claim for protection of a specific chemical identity that has been denied by the Administrator or expired, or that has been withdrawn by the person who asserted the claim, and for which the Administrator has used a unique identifier assigned under this paragraph to protect the specific chemical identity in information that the Administrator has made public, clearly link the specific chemical identity to the unique identifier in such information to the extent practicable.

(h) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.—

(1) INDIVIDUALS SUBJECT TO PENALTY.—

(A) IN GENERAL.—Subject to subparagraph (C) and paragraph (2), an individual described in subparagraph (B) shall be fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

(B) DESCRIPTION.—An individual referred to in subparagraph (A) is an individual who—

(i) pursuant to this section, obtained possession of, or has access to, information protected from disclosure under this section; and

(ii) knowing that the information is protected from disclosure under this section, willfully discloses the information in any manner to any person not entitled to receive that information.

(C) EXCEPTION.—This paragraph shall not apply to any medical professional (including an emergency medical technician or other first responder) who discloses any information obtained under paragraph (5) or (6) of subsection (d) to a patient treated by the medical professional, or to a person authorized to make medical or health care decisions on behalf of such a patient, as needed for the diagnosis or treatment of the patient.

(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported to or otherwise obtained by the Administrator under this Act.

(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 reported to or otherwise obtained by the Administrator under this Act prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

(B) to impose substantiation or resubstantiation requirements, with respect to the protection of information described in subsection (a), under this Act that are more extensive than those required under this section.

(2) ACTIONS PRIOR TO PROMULGATION OF RULES.—Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation of, or approving, approving in part, or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(j) 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.

[15 U.S.C. 2613]

SEC. 15. PROHIBITED ACTS.

It shall be unlawful for any person to—

(1) fail or refuse to comply with any requirement of this title or any rule promulgated, order issued, or consent agreement entered into under this title, or any requirement of title II or any rule promulgated or order issued under 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.

[15 U.S.C. 2614]

SEC. 16. PENALTIES.

(a) CIVIL.—(1) Any person who violates a provision of section 15 or 409 shall be liable to the United States for a civil penalty in an amount not to exceed $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.

(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.—(1) IN GENERAL.—Any person who knowingly or willfully violates any provision of section 15 or 409 shall, in addition to or in lieu of any civil penalty which may be imposed under subsection (a) of this section for such violation, be subject, upon conviction, to a fine of not more than $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 who knowingly and willfully violates any provision of section 15 or 409, and who 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.—Notwithstanding the penalties described in subparagraph (A), an organization that commits a knowing violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation.

(C) INCORPORATION OF CORRESPONDING PROVISIONS.—Subparagraphs (B) through (F) of section 113(c)(5) of the Clean Air Act (42 U.S.C. 7413(c)(5)(B)–(F)) shall apply to the prosecution of a violation under this paragraph.

[15 U.S.C. 2615]

SEC. 17. SPECIFIC ENFORCEMENT AND SEIZURE.

(a) SPECIFIC ENFORCEMENT.—(1) The district courts of the United States shall have jurisdiction over civil actions to—

(A) restrain any violation of section 15 or 409,

(B) restrain any person from taking any action prohibited by section 5, 6, or title IV, or by a rule or order under section 5, 6, or title IV,

(C) compel the taking of any action required by or under this Act, or

(D) direct any manufacturer or processor of a chemical substance, mixture, or product subject to title IV manufactured or processed in violation of section 5, 6, or title IV, or a rule or order under section 5, 6, or title IV, and distributed in commerce, (i) to give notice of such fact to distributors in commerce of such substance, mixture, or product and, to the

extent reasonably ascertainable, to other persons in possession of such substance, mixture, or product or exposed to such substance, mixture, or product, (ii) to give public notice of such risk of injury, and (iii) to either replace or repurchase such substance, mixture, or product, whichever the person to which the requirement is directed elects.

(2) A civil action described in paragraph (1) may be brought—

(A) in the case of a civil action described in subparagraph (A) of such paragraph, in the United States district court for the judicial district wherein any act, omission, or transaction constituting a violation of section 15 occurred or wherein the defendant is found or transacts business, or

(B) in the case of any other civil action described in such paragraph, in the United States district court for the judicial district wherein the defendant is found or transacts business. In any such civil action process may be served on a defendant in any judicial district in which a defendant resides or may be found. Subpoenas requiring attendance of witnesses in any such action may be served in any judicial district.

(b) SEIZURE.—Any chemical substance, mixture, or product subject to title IV which was manufactured, processed, or distributed in commerce in violation of this Act or any rule promulgated or order issued under this Act or any article containing such a substance or mixture shall be liable to be proceeded against, by process of libel for the seizure and condemnation of such substance, mixture, product, or article, in any district court of the United States within the jurisdiction of which such substance, mixture, product, or article is found. Such proceeding shall conform as nearly as possible to proceedings in rem in admiralty.

[15 U.S.C. 2616]

SEC. 18. PREEMPTION.

(a) IN GENERAL.—

(1) ESTABLISHMENT OR ENFORCEMENT.—Except as otherwise 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) DEVELOPMENT OF INFORMATION.—A statute or administrative action to require the development of information about a chemical substance or category of chemical 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 consent agreement entered into by the Administrator; or

(iii) an order issued by the Administrator.

(B) CHEMICAL SUBSTANCES FOUND NOT TO PRESENT AN UNREASONABLE RISK OR RESTRICTED.—A statute, criminal penalty, or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

(i) for which the determination described in section 6(i)(1) is made, consistent with the scope of the risk evaluation under section (6)(b)(4)(D); or

(ii) for which a final rule is promulgated under section 6(a), after the effective date of the rule issued under section 6(a) for the chemical substance, consistent with the scope of the risk evaluation under section (6)(b)(4)(D).

(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 statutes and administrative actions applicable to specific chemical substances shall not occur until the effect date of the applicable action described in paragraph (1) taken by the Administrator.

(b) NEW STATUTES, CRIMINAL PENALTIES, OR ADMINISTRATIVE ACTIONS CREATING PROHIBITIONS OR OTHER RESTRICTIONS.—

(1) IN GENERAL.—Except as provided in subsections (c), (d), (e), (f), and (g), beginning on the date on which the Administrator defines the scope of a risk evaluation for a chemical substance under section 6(b)(4)(D) and ending on the date on which the deadline established pursuant to section 6(b)(4)(G) for completion of the risk evaluation expires, or on the date on which the Administrator publishes the risk evaluation under section 6(b)(4)(C), whichever is earlier, no State or political subdivision of a State may establish a statute, criminal penalty, or administrative action prohibiting or otherwise restricting the manufacture, processing, distribution in commerce, or use of such chemical substance that is a high-priority substance designated under section 6(b)(1)(B)(i).

(2) EFFECT OF SUBSECTION.—This subsection does not restrict the authority of a State or political subdivision of a State to continue to enforce any statute enacted, criminal penalty assessed, or administrative action taken, prior to the date on which the Administrator defines and publishes the scope of a risk evaluation under section 6(b)(4)(D).

(c) SCOPE OF PREEMPTION.—Federal preemption under subsections (a) and (b) of statutes, criminal penalties, and administrative actions applicable to specific chemical substances shall apply only to—

(1) with respect to subsection (a)(1)(A), the chemical substances or category of chemical substances subject to a rule, order, or consent agreement under section 4, 5, or 6;

(2) with respect to subsection (b), the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in the scope of the risk evaluation pursuant to section 6(b)(4)(D);

(3) with respect to subsection (a)(1)(B), the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to section 6(a) or 6(i)(1); or

(4) with respect to subsection (a)(1)(C), the uses of such chemical 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 STATUTES AND ADMINISTRATIVE ACTIONS.—

(A) IN GENERAL.—Nothing in this Act, nor any amendment made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, nor any rule, standard of performance, risk evaluation, 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, risk evaluation, scientific assessment, or any other 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, 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 of 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 risk evaluation published pursuant to section 6(b)(4)(D), 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 a law of a State or political subdivision of a State 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—

(I) a State or political subdivision of a State may not assess a penalty for a specific violation for which the Administrator has assessed an adequate penalty under section 16; and

(II) if a State or political subdivision of a State has assessed a penalty for a specific violation, the Administrator may not assess a penalty for that violation in an amount that would cause the total of the penalties assessed for the violation by the State or political subdivision of a State and the Administrator combined to exceed the maximum amount that may be assessed for that violation by the Administrator under section 16.

(2) APPLICABILITY TO CERTAIN RULES OR ORDERS.—

(A) PRIOR RULES AND ORDERS.—Nothing in this section shall be construed as modifying the preemptive 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.

(B) CERTAIN CHEMICAL SUBSTANCES AND MIXTURES.—With respect to a chemical substance or mixture for which any rule or order that 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 respect to manufacturing, processing, distribution in commerce, use, or disposal of the chemical substance or mixture, nothing in this section shall be construed as modifying the preemptive effect of this section as in effect prior to the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act of any rule or order that is promulgated or issued with respect to such chemical substance or mixture under section 6 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 section 6(b)(1)(B)(i), the identification of that chemical substance under section 6(b)(2)(A), or the selection of that chemical substance for risk evaluation under section 6(b)(4)(E)(iv)(II).

(e) PRESERVATION OF CERTAIN LAWS.—

(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 or requirement imposed or requirement enacted relating to a specific chemical substance before April 22, 2016, under the authority of a law of the State or political subdivision of the State 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 Federal law and laws of a State or political subdivision of a State pursuant to any other Federal law.

(f) 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, criminal penalty, or administrative action of that State or political subdivision of the State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

(A) compelling 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 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) in the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is designed to address a risk of a chemical substance, under the conditions of use, that was identified—

(i) consistent with the best available science;

(ii) using supporting studies conducted in accordance with sound and objective scientific practices; and

(iii) based on the weight of the scientific evidence.

(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) (i) 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;

(ii) 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

(iii) the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science; or

(B) no later than the date that is 18 months after the date on which the Administrator has initiated the prioritization process for a chemical substance under the rule promulgated pursuant to section 6(b)(1)(A), or the date on which the Administrator publishes the scope of the risk evaluation for a chemical substance under section 6(b)(4)(D), whichever is sooner, the State or political subdivision of the State has enacted a statute or proposed or finalized an administrative action

intended to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, or use of the chemical substance.

(3) DETERMINATION OF A 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 110 days after the date on which an application under paragraph (2) is submitted.

(4) FAILURE TO MAKE A DETERMINATION.—If the Administrator fails to make a determination under paragraph (3)(B) during the 110-day period beginning on the date on which an application under paragraph (2) is submitted, the statute or administrative action of the State or political subdivision of the State that was the subject of the application shall not be considered to be an existing statute or administrative action for purposes of subsection (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 a State under this subsection 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 a State shall be—

(A) considered to be a final agency action; and

(B) subject to judicial review.

(7) DURATION OF WAIVERS.—A waiver granted under paragraph (2) or approved under paragraph (9) shall remain in effect until such time as the Administrator publishes the risk evaluation under section 6(b).

(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 a State under paragraph (1) or (2), 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) AUTOMATIC APPROVAL.—If the Administrator fails to meet 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, effective on the date that is 10 days after the deadline.

(B) REQUIREMENTS.—Notwithstanding paragraph (6), approval of a waiver application under subparagraph (A) for failure to meet the deadline under paragraph (3)(B) shall not be considered final agency action or be subject to judicial review or public notice and comment.

(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 the Frank R. Lautenberg Chemical Safety for the 21st Century Act, nor any standard, rule, requirement, standard of performance, risk evaluation, 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 the Frank R. Lautenberg Chemical Safety for the 21st Century

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 the Frank R. Lautenberg Chemical Safety for the 21st Century Act, nor any rules, regulations, requirements, risk evaluations, 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, risk evaluations, scientific assessments, or orders issued pursuant to this Act.

[15 U.S.C. 2617]

SEC. 19. JUDICIAL REVIEW.

(a) IN GENERAL.—(1)(A) Except as otherwise provided in this title, not later than 60 days after the date on which a rule is promulgated under this title, title II, or title IV, or the date on which an order is issued under section 4, 5(e), 5(f), or 6(i)(1), any person may file a petition for judicial review of such rule or order with the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which such person resides or in which such person's principal place of business is located. Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of such a rule or order if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

(B) Except as otherwise provided in this title, 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 this title, other than an order under section 4, 5(e), 5(f), or 6(i)(1), if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

(C) (i) Not later than 60 days after the publication of a designation under section 6(b)(1)(B)(ii), any person may commence a civil action to challenge the designation.

(ii) The United States Court of Appeals for the District of Columbia Circuit shall have exclusive jurisdiction over a civil action filed under this subparagraph.

(2) Copies of any petition filed under paragraph (1)(A) 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 record of proceedings on which the Administrator based the rule or order being reviewed under this section and to the transfer of proceedings between United States courts of appeals.

(b) ADDITIONAL SUBMISSIONS AND PRESENTATIONS; MODIFICATIONS.—If in an action under this section to review a rule, or an order under section 4, 5(e), 5(f), or 6(i)(1), the petitioner or the Administrator applies to the court for leave to make additional oral submissions or written presentations respecting such rule or order and shows to the satisfaction of the court that such submissions and presentations would be material and that there were reasonable grounds for the submissions and failure to make such submissions and presentations in the proceeding before the Administrator, the court may order the Administrator to

provide additional opportunity to make such submissions and presentations. The Administrator may modify or set aside the rule or order being reviewed or make a new rule or order by reason of the additional submissions and presentations and shall file such modified or new rule or order with the return of such submissions and presentations. The court shall thereafter review such new or modified rule or order.

(c) STANDARD OF REVIEW.—(1)(A) Upon the filing of a petition under subsection (a)(1) for judicial review of a rule or order, the court shall have jurisdiction (i) to grant appropriate relief, including interim relief, as provided in chapter 7 of title 5, United States Code, and (ii) except as otherwise provided in subparagraph (B), to review such rule or order 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 or order under this section, except that—

(i) in the case of review of—

(I) a rule under section 4(a), 5(b)(4), 6(a) (including review of the associated determination under section 6(b)(4)(A)), or 6(e), the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole; and

(II) an order under section 4, 5(e), 5(f), or 6(i)(1), 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 order if the court finds that the order is not supported by substantial evidence in the record taken as a whole; and

(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 or order, except as part of the record, taken as a whole.

(2) The judgment of the court affirming or setting aside, in whole or in part, any rule or order 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.

[15 U.S.C. 2618]

SEC. 20. CITIZENS' CIVIL ACTIONS.

(a) IN GENERAL.—Except as provided in subsection (b), any person may commence a civil action—

(1) against any person (including (A) the United States, and (B) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of this Act or any rule promulgated under section 4, 5, or 6, or title II or IV, or order issued under section 4 or 5 or title II or IV to restrain such violation, or

(2) against the Administrator to compel the Administrator to perform any act or duty under this Act which is not discretionary.

Any civil action under paragraph (1) shall be brought in the United States district court for the district in which the alleged violation occurred or in which the defendant resides or in which the defendant's principal place of business is located. Any action brought under paragraph (2) shall be brought in the United States District Court for the District of Columbia, or the United States district

court for the judicial district in which the plaintiff is domiciled. The district courts of the United States shall have jurisdiction over suits brought under this section, without regard to the amount in controversy or the citizenship of the parties. In any civil action under this subsection process may be served on a defendant in any judicial district in which the defendant resides or may be found and subpoenas for witnesses may be served in any judicial district.

(b) LIMITATION.—No civil action may be commenced—

(1) under subsection (a)(1) to restrain a violation of this Act or rule or order under this Act—

(A) before the expiration of 60 days after the plaintiff has given notice of such violation (i) to the Administrator, and (ii) to the person who is alleged to have committed such violation, or

(B) if the Administrator has commenced and is diligently prosecuting a proceeding for the issuance of an order under section 16(a)(2) to require compliance with this Act or with such rule or order or if the Attorney General has commenced and is diligently prosecuting a civil action in a court of the United States to require compliance with this Act or with such rule or order, but if such proceeding or civil action is commenced after the giving of notice, any person giving such notice may intervene as a matter of right in such proceeding or action;

(2) under subsection (a)(2) before the expiration of 60 days after the plaintiff has given notice to the Administrator of the alleged failure of the Administrator to perform an act or duty which is the basis for such action or, in the case of an action under such subsection for the failure of the Administrator to file an action under section 7, before the expiration of ten days after such notification, except that no prior notification shall be required in the case of a civil action brought to compel a decision by the Administrator pursuant to section 18(f)(3)(B); or

(3) in the case of a civil action brought to compel a decision by the Administrator pursuant to section 18(f)(3)(B), after the date that is 60 days after the deadline specified in section 18(f)(3)(B).

Notice under this subsection shall be given in such manner as the Administrator shall prescribe by rule.

(c) GENERAL.—(1) In any action under this section, the Administrator, if not a party, may intervene as a matter of right.

(2) The court, in issuing any final order in any action brought pursuant to subsection (a), may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(3) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this Act or any rule or order under this Act or to seek any other relief.

(d) CONSOLIDATION.—When two or more civil actions brought under subsection (a) involving the same defendant and the same issues or violations are pending in two or more judicial districts, such pending actions, upon application of such defendants to such actions which is made to a court in which any such action is brought, may, if such court in its discretion so decides, be consolidated for trial by order (issued after giving all parties reasonable notice and opportunity to be heard) of such court and tried in—

(1) any district which is selected by such defendant and in which one of such actions is pending,

(2) a district which is agreed upon by stipulation between all the parties to such actions and in which one of such actions is pending, or

(3) a district which is selected by the court and in which one of such actions is pending.

The court issuing such an order shall give prompt notification of the order to the other courts in which the civil actions consolidated under the order are pending.

[15 U.S.C. 2619]

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 4 or 5(e) or (f).

(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 4 or 5(e) or (f).

(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 4 or 5(e), or (f), 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—

(i) in the case of a petition to initiate a proceeding for the issuance of a rule under section 4 or an order under section 4 or 5(e)—

(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order; and

(II) in the absence of such information, the substance may present an unreasonable risk to health or the environment, or the substance is or will be produced in substantial quantities and it enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to it; or

(ii) in the case of a petition to initiate a proceeding for the issuance of a rule under section 6(a) or 8 or an order under section 5(f), the chemical substance or mixture to be subject to such rule or order presents an unreasonable risk of injury to health or to the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use;[6]

[6] In Public Law 94–469, a period appears after ''environment''. The semicolon is shown in this print to reflect the probable intent of Congress.

the court shall order the Administrator to initiate the action requested by the petitioner. If the court finds that the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act and there are insufficient resources available to the Administrator to take the action requested by the petitioner, the court may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes.

(C) The court in issuing any final order in any action brought pursuant to subparagraph (A) may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(5) The remedies under this section shall be in addition to, and not in lieu of, other remedies provided by law.

[15 U.S.C. 2620]

SEC. 22. NATIONAL DEFENSE WAIVER.

The Administrator shall waive compliance with any provision of this Act upon a request and determination by the President that the requested waiver is necessary in the interest of national defense. The Administrator shall maintain a written record of the basis upon which such waiver was granted and make such record available for in camera examination when relevant in a judicial proceeding under this Act. Upon the issuance of such a waiver, the Administrator shall publish in the Federal Register a notice that the waiver was granted for national defense purposes, unless, upon the request of the President, the Administrator determines to omit such publication because the publication itself would be contrary to the interests of national defense, in which event the Administrator shall submit notice thereof to the Armed Services Committees of the Senate and the House of Representatives.

[15 U.S.C. 2621]

SEC. 23. EMPLOYEE PROTECTION.

(a) IN GENERAL.—No employer may discharge any employee or otherwise discriminate against any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee) has—

(1) commenced, caused to be commenced, or is about to commence or cause to be commenced a proceeding under this Act;

(2) testified or is about to testify in any such proceeding; or

(3) assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this Act.

(b) REMEDY.—(1) Any employee who believes that the employee has been discharged or otherwise discriminated against by any person in violation of subsection (a) of this section may, within 30 days after such alleged violation occurs, file (or have any person file on the employee's behalf) a complaint with the Secretary of Labor (hereinafter in this section referred to as the ''Secretary'') alleging such discharge or discrimination. Upon receipt of such a complaint, the Secretary shall notify the person named in the complaint of the filing of the complaint.

(2)(A) Upon receipt of a complaint filed under paragraph (1), the Secretary shall conduct an investigation of the violation alleged in the complaint. Within 30 days of the receipt of such complaint, the Secretary shall complete such investigation and shall notify in writing the complainant (and any person acting on behalf of the complainant) and the person alleged to have committed such violation of the results of the investigation conducted pursuant to this paragraph. Within ninety days of the receipt of such complaint the Secretary shall, unless

the proceeding on the complaint is terminated by the Secretary on the basis of a settlement entered into by the Secretary and the person alleged to have committed such violation, issue an order either providing the relief prescribed by subparagraph (B) or denying the complaint. An order of the Secretary shall be made on the record after notice and opportunity for agency hearing. The Secretary may not enter into a settlement terminating a proceeding on a complaint without the participation and consent of the complainant.

(B) If in response to a complaint filed under paragraph (1) the Secretary determines that a violation of subsection (a) of this section has occurred, the Secretary shall order (i) the person who committed such violation to take affirmative action to abate the violation, (ii) such person to reinstate the complainant to the complainant's former position together with the compensation (including back pay), terms, conditions, and privileges of the complainant's employment, (iii) compensatory damages, and (iv) where appropriate, exemplary damages. If such an order is issued, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney's fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(c) REVIEW.—(1) Any employee or employer adversely affected or aggrieved by an order issued under subsection (b) may obtain review of the order in the United States Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred. The petition for review must be filed within sixty days from the issuance of the Secretary's order. Review shall conform to chapter 7 of title 5 of the United States Code.

(2) An order of the Secretary, with respect to which review could have been obtained under paragraph (1), shall not be subject to judicial review in any criminal or other civil proceeding.

(d) ENFORCEMENT.—Whenever a person has failed to comply with an order issued under subsection (b)(2), the Secretary shall file a civil action in the United States district court for the district in which the violation was found to occur to enforce such order. In actions brought under this subsection, the district courts shall have jurisdiction to grant all appropriate relief, including injunctive relief and compensatory and exemplary damages.

(e) EXCLUSION.—Subsection (a) of this section shall not apply with respect to any employee who, acting without direction from the employee's employer (or any agent of the employer), deliberately causes a violation of any requirement of this Act.

[15 U.S.C. 2622]

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, and

(ii) each employee who made or for whom was made a request for such hearings and the employer of such employee shall be required to present information respecting the 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.

[15 U.S.C. 2623]

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, information, 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 from any person required to submit information under section 4 or a notice or other information to be reviewed by the Administrator under section 5, or who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 6(b), of a fee that is sufficient and not more than reasonably necessary to defray the cost related to such chemical substance of administering sections 4, 5, and 6, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under this title, including contractor costs incurred by the Administrator. In setting a fee under this paragraph, the Administrator shall take into account the ability to pay of the person required to pay such fee and the cost to the Administrator of carrying out the activities described in this paragraph. 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 (4).

(3) FUND.—

(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the TSCA Service Fee Fund (in this paragraph referred to as the "Fund"), consisting of such amounts as are deposited in the Fund under this paragraph.

(B) COLLECTION AND DEPOSIT OF FEES.—Subject to the conditions of subparagraph (C), the Administrator shall collect the fees described in this subsection and deposit those fees in the Fund.

(C) USE OF FUNDS BY ADMINISTRATOR.—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 for use in defraying the costs of the activities described in paragraph (1).

(D) ACCOUNTING AND AUDITING.—

(i) ACCOUNTING.—The Administrator shall biennially prepare and submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes an accounting of the fees paid to the Administrator under this paragraph and amounts disbursed from the Fund for the period covered by the report, as reflected by financial statements provided in accordance with sections 3515 and 3521 of title 31, United States Code.

(ii) AUDITING.—

(I) IN GENERAL.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of a covered executive agency.

(II) COMPONENTS OF AUDIT.—The annual audit required in accordance with sections 3515 and 3521 of title 31, United States Code, of the financial statements of activities carried out using amounts from the Fund shall include an analysis of—

(aa) the fees collected and amounts disbursed under this subsection;

(bb) the reasonableness of the fees in place as of the date of the audit to meet current and projected costs of administering the provisions of this title for which the fees may be used; and

(cc) the number of requests for a risk evaluation made by manufacturers under section 6(b)(4)(C)(ii).

(III) FEDERAL RESPONSIBILITY.—The Inspector General of the Environmental Protection Agency shall conduct the annual audit described in subclause (II) and submit to the Administrator a report that describes the findings and any recommendations of the Inspector General resulting from the audit.

(4) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—In setting fees under this section, the Administrator shall—

(A) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

(B) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to annually defray—

(i) the lower of—

(I) 25 percent of the costs to the Administrator of carrying out sections 4, 5, and 6, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under this title, other than the costs to conduct and complete risk evaluations under section 6(b); or

(II) $25,000,000 (subject to adjustment pursuant to subparagraph (F)); and

(ii) the costs of risk evaluations specified in subparagraph (D);

(C) 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;

(D) notwithstanding subparagraph (B)—

(i) except as provided in clause (ii), for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to section 6(b)(4)(C)(ii), establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the risk evaluation under section 6(b);

(ii) for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to section 6(b)(4)(C)(ii), and which are included in the 2014 update of the TSCA Work Plan for Chemical Assessments, establish the fee at a level sufficient to defray 50 percent of the costs to the Administrator of conducting the risk evaluation under section 6(b); and

(iii) apply fees collected pursuant to clauses (i) and (ii) only to defray the costs described in those clauses;

(E) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially 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 II of chapter 5 of title 5, United States Code, is applicable with respect to such meetings;

(F) 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 pursuant to subparagraph (E), increase or decrease the fees established under paragraph (1) as necessary to adjust for inflation and to ensure that funds deposited in the Fund are sufficient to defray—

(i) approximately but not more than 25 percent of the costs to the Administrator of carrying out sections 4, 5, and 6, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 14 information on chemical substances under this title, other than the costs to conduct and complete risk evaluations requested under section 6(b)(4)(C)(ii); and

(ii) the costs of risk evaluations specified in subparagraph (D); and

(G) if a notice submitted under section 5 is not reviewed or such a notice is withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

(5) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for the Chemical Risk Review and Reduction program project 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 that program project for fiscal year 2014.

(6) TERMINATION.—The authority provided by this subsection shall terminate at the conclusion of the fiscal year that is 10 years after the date of the 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 mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this Act with respect to a category of chemical substances or mixtures, any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category. (2) For purposes of paragraph (1):

(A) The term ''category of chemical substances'' means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

(B) The term ''category of mixtures'' means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological 1properties, in use, or in the mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act.

(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 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 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 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 information, (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) SCIENTIFIC STANDARDS.—In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable—

(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

(2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

(i) WEIGHT OF SCIENTIFIC EVIDENCE.—The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence.

(j) AVAILABILITY OF INFORMATION.—Subject to section 14, the Administrator shall make available to the public—

(1) all notices, determinations, findings, rules, consent agreements, and orders of the Administrator under this title;

(2) any information required to be provided to the Administrator under section 4;

(3) a nontechnical summary of each risk evaluation conducted under section 6(b);

(4) a list of the studies considered by the Administrator in carrying out each such risk evaluation, along with the results of those studies; and

(5) each designation of a chemical substance under section 6(b), along with an identification of the information, analysis, and basis used to make the designations.

(k) REASONABLY AVAILABLE INFORMATION.—In carrying out sections 4, 5, and 6, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.

(l) POLICIES, PROCEDURES, AND GUIDANCE.—

(1) DEVELOPMENT.—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 any policies, procedures, and guidance the Administrator determines are necessary to carry out the amendments to this Act made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

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

(A) review the adequacy of the policies, procedures, and guidance developed under paragraph (1), including with respect to animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this title; and

(B) revise such policies, procedures, and guidance as the Administrator determines necessary to reflect new scientific developments or understandings.

(3) TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.—The policies, procedures, and guidance developed under paragraph (1) applicable to testing chemical substances and mixtures shall—

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

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

(4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.—With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6.

(5) GUIDANCE.—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 and submitting draft risk evaluations which shall be considered by the Administrator. The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration by the Administrator.

(m) REPORT TO CONGRESS.—

(1) INITIAL REPORT.—Not later than 6 months after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall submit to the Committees on Energy and Commerce and Appropriations of the House of Representatives and the Committees on Environment and Public Works and Appropriations of the Senate a report containing an estimation of—

(A) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under section 6(b)(4)(C)(i), and the resources necessary to conduct the minimum number of risk evaluations required under section 6(b)(2);

(B) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under section 6(b)(4)(C)(ii),

the likely demand for such risk evaluations, and the anticipated schedule for accommodating that demand;

(C) the capacity of the Environmental Protection Agency to promulgate rules under section 6(a) as required based on risk evaluations conducted and published under section 6(b); and

(D) the actual and anticipated efforts of the Environmental Protection Agency to increase the Agency's capacity to conduct and publish risk evaluations under section 6(b).

(2) SUBSEQUENT REPORTS.—The Administrator shall update and resubmit the report described in paragraph (1) not less frequently than once every 5 years.

(n) ANNUAL PLAN.—

(1) IN GENERAL.—The Administrator shall inform the public regarding the schedule and the resources necessary for the completion of each risk evaluation as soon as practicable after initiating the risk evaluation.

(2) PUBLICATION OF PLAN.—At the beginning of each calendar year, the Administrator shall publish an annual plan that—

(A) identifies the chemical substances for which risk evaluations are expected to be initiated or completed that year and the resources necessary for their completion;

(B) describes the status of each risk evaluation that has been initiated but not yet completed; and

(C) if the schedule for completion of a risk evaluation has changed, includes an updated schedule for that risk evaluation.

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

(1) ESTABLISHMENT.—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 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, at 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 representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible subpopulations.

(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.

(p) PRIOR ACTIONS.—

(1) RULES, ORDERS, AND EXEMPTIONS.—Nothing in the Frank R. Lautenberg Chemical Safety for the 21st Century 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.

(2) PRIOR-INITIATED EVALUATIONS.—Nothing in this Act prevents the Administrator from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such risk evaluation, prior to the effective date of the policies, procedures, and guidance required to be developed by the Administrator pursuant to the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(3) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES, PROCEDURES, AND GUIDANCE.—Nothing in this Act requires the Administrator to revise or withdraw a completed risk evaluation, determination, or rule under this Act solely because the action was completed prior to the development of a policy, procedure, or guidance pursuant to the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

[15 U.S.C. 2625]

SEC. 27. DEVELOPMENT AND EVALUATION OF TEST METHODS.

(a) IN GENERAL.—The Secretary of 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 information to meet the requirements of rules, orders, or consent agreements under section 4. The Administrator shall consider such methods in prescribing under section 4 protocols and methodologies for the development of information.

(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).

[15 U.S.C. 2626]

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.

[15 U.S.C. 2627]

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.

[15 U.S.C. 2628]

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, order, or consent agreement, and a summary of any action taken during such year under section 5(g);

(3) a list of rules issued during such year under section 6;

(4) a list, with a brief statement of the issues, of completed or pending judicial actions under this Act and administrative actions under section 16 during such year;

(5) a summary of major problems encountered in the administration of this Act; and

(6) such recommendations for additional legislation as the Administrator deems necessary to carry out the purposes of this Act.

[15 U.S.C. 2629]

SEC. 31. EFFECTIVE DATE.

Except as provided in section 4(f), this Act shall take effect on January 1, 1977.

[15 U.S.C. 2601]

*Titles II through VI are not included in this version.

ADDENDUM—ADDITIONAL SECTIONS OF THE BILL THAT DO NOT AMEND THE TOXIC SUBSTANCES CONTROL ACT

SEC. 20. NO RETROACTIVITY.

Nothing in sections 1 through 19, or the amendments made by sections 1 through 19, shall be interpreted to apply retroactively to any State, Federal, or maritime legal action filed before the date of enactment of this Act.

*Sections 1 through 19 refer to the changes made to Title I of the Toxic Substances Control Act by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

SEC. 21. TREVOR'S LAW.

(a) PURPOSES.—The purposes of this section are—

(1) to provide the appropriate Federal agencies with the authority to help conduct investigations into potential cancer clusters;

(2) to ensure that Federal agencies have the authority to undertake actions to help address cancer clusters and factors that may contribute to the creation of potential cancer clusters; and

(3) to enable Federal agencies to coordinate with other Federal, State, and local agencies, institutes of higher education, and the public in investigating and addressing cancer clusters.

(b) DESIGNATION AND INVESTIGATION OF POTENTIAL CANCER CLUSTERS.—Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

SEC. 399V–6. DESIGNATION AND INVESTIGATION OF POTENTIAL CANCER CLUSTERS.

(a) DEFINITIONS.—In this section:

(1) CANCER CLUSTER.—The term "cancer cluster" means the incidence of a particular cancer within a population group, a geographical area, and a period of time that is greater than expected for such group, area, and period.

(2) PARTICULAR CANCER.—The term "particular cancer" means one specific type of cancer or a type of cancers scientifically proven to have the same cause.

(3) POPULATION GROUP.—The term "population group" means a group, for purposes of calculating cancer rates, defined by factors such as race, ethnicity, age, or gender.

(b) CRITERIA FOR DESIGNATION OF POTENTIAL CANCER CLUSTERS.—

(1) DEVELOPMENT OF CRITERIA.—The Secretary shall develop criteria for the designation of potential cancer clusters.

(2) REQUIREMENTS.—The criteria developed under paragraph (1) shall consider, as appropriate—

(A) a standard for cancer cluster identification and reporting protocols used to determine when cancer incidence is greater than would be typically observed;

(B) scientific screening standards that ensure that a cluster of a particular cancer involves the same type of cancer, or types of cancers;

(C) the population in which the cluster of a particular cancer occurs by factors such as race, ethnicity, age, and gender, for purposes of calculating cancer rates;

(D) the boundaries of a geographic area in which a cluster of a particular cancer occurs so as not to create or obscure a potential cluster by selection of a specific area; and

(E) the time period over which the number of cases of a particular cancer, or the calculation of an expected number of cases, occurs.

(c) GUIDELINES FOR INVESTIGATION OF POTENTIAL CANCER CLUSTERS.—The Secretary, in consultation with the Council of State and Territorial Epidemiologists and representatives of State and local health departments, shall

develop, publish, and periodically update guidelines for investigating potential cancer clusters. The guidelines shall—

(1) recommend that investigations of cancer clusters—

(A) use the criteria developed under subsection (b);

(B) use the best available science; and

(C) rely on a weight of the scientific evidence;

(2) provide standardized methods of reviewing and categorizing data, including from health surveillance systems and reports of potential cancer clusters; and

(3) provide guidance for using appropriate epidemiological and other approaches for investigations.

(d) INVESTIGATION OF CANCER CLUSTERS.—

(1) SECRETARY DISCRETION.—The Secretary—

(A) in consultation with representatives of the relevant State and local health departments, shall consider whether it is appropriate to conduct an investigation of a potential cancer cluster; and

(B) in conducting investigations shall have the discretion to prioritize certain potential cancer clusters, based on the availability of resources.

(2) COORDINATION.—In investigating potential cancer clusters, the Secretary shall coordinate with agencies within the Department of Health and Human Services and other Federal agencies, such as the Environmental Protection Agency.

(3) BIOMONITORING.—In investigating potential cancer clusters, the Secretary shall rely on all appropriate biomonitoring information collected under other Federal programs, such as the National Health and Nutrition Examination Survey. The Secretary may provide technical assistance for relevant biomonitoring studies of other Federal agencies.

(e) DUTIES.—The Secretary shall—

(1) ensure that appropriate staff of agencies within the Department of Health and Human Services are prepared to provide timely assistance, to the extent practicable, upon receiving a request to investigate a potential cancer cluster from a State or local health authority;

(2) maintain staff expertise in epidemiology, toxicology, data analysis, environmental health and cancer surveillance, exposure assessment, pediatric health, pollution control, community outreach, health education, laboratory sampling and analysis, spatial mapping, and informatics;

(3) consult with community members as investigations into potential cancer clusters are conducted, as the Secretary determines appropriate;

(4) collect, store, and disseminate reports on investigations of potential cancer clusters, the possible causes of such clusters, and the actions taken to address such clusters; and

(5) provide technical assistance for investigating cancer clusters to State and local health departments through existing programs, such as the Epi-Aids program of the Centers for Disease Control and Prevention and the Assessments of Chemical Exposures Program of the Agency for Toxic Substances and Disease Registry.

[15 U.S.C. 2601]