(i) in the matter preceding subparagraph (A), by striking "(a) or"; and

(ii) in subparagraph (A), by inserting ", without taking into account cost or other nonrisk factors" after "the environment";

(B) by striking paragraph (2);

(C) by redesignating paragraphs (3) through (6) as paragraphs (2) through (5), respectively;

(D) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking "subsections (a) and (b)" and inserting "subsection (b)";

(E) in paragraph (3) (as so redesignated)—

(i) in the first sentence, by striking "will not present an unreasonable risk of injury to health or the environment" and inserting "will meet the safety standard"; and

(ii) by striking the second sentence;

(F) in paragraph (4) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (b)"; and

(G) in paragraph (5) (as so redesignated), in the first sentence, by striking "paragraph (1) or (5)" and inserting "paragraph (1) or (4)".

SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections (g) and (h), respectively;

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

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

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

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

"(4) shall complete and publish a safety assessment and safety determination not later

than 3 years after the date on which a chemical substance is designated as a high-priority substance;

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

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

"(b) Prior Actions and Notice of Existing Information.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination prior to the effective date of the policies, procedures, and guidance required to be established by the Administrator under section 3A or 4A.

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

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

"(3) NOTICE OF EXISTING INFORMATION.—

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

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

"(c) Safety Determinations.—

"(1) IN GENERAL.—Based on a review of the information available to the Administrator, including draft safety assessments submitted by interested persons pursuant to section 3A(h)(2)(D), and subject to section 18(g), the Administrator shall determine—

"(A) by order, that the relevant chemical substance meets the safety standard;

"(B) that the relevant chemical substance does not meet the safety standard, in which

case the Administrator shall, by rule under subsection (d)—

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

"(ii) if the safety standard cannot be met with the application of other restrictions under subsection (d)(3), ban or phase out the chemical substance, as appropriate; or

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

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is necessary to make a safety assessment or safety determination for a high-priority substance, the Administrator—

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

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

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

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

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

"(d) Rule.—

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

"(2) SCOPE.—

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

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

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

"(I) shall be as soon as practicable, but not later than 4 years after the date of promulgation of the rule; except for a use exempted under subsection (d)(5);

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

"(III) as determined by the Administrator, may vary for different affected persons; ~~and~~
"(IV) following a determination by the Administrator that it is technologically or economically infeasible to comply with the timeframe in clause (i)(I), may provide up to an additional 18 months for compliance to be mandatory; and"

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

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

"(B) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines that, with respect to ~~ranks high for~~ persistence and bioaccumulation, scores 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, the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance meets the safety standard, reduce exposure to the substance to the maximum extent practicable.

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

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

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

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

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

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

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

"(iii) monitor or conduct tests that are reasonably necessary to ensure

compliance with the requirements of any rule under this subsection;

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

"(D) a requirement to ban or phase out, or otherwise restrict the manufacture, processing, or distribution in commerce of the chemical substance for—

"(i) a particular use;

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

"(iii) all uses;

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

"(i) a particular use; or

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

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

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

"(H) a requirement directing manufacturers or processors of the chemical substance to give notice of the Administrator's determination under subsection (c)(1)(B) to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

"(4) ANALYSIS FOR RULEMAKING.—

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

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

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

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

"(5) EXEMPTIONS.—

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

"(i) the restriction cannot be complied with, without—

"(I) harming national security;

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

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

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

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

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

"(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—In determining whether an exemption should be granted under this paragraph for a chemical substance for which a ban or phase-out is included in a proposed or final rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more alternatives to the chemical substance the Administrator determines to be technically and economically feasible and most likely to be used in place of the chemical substance under the conditions of use.

"(E) CONDITIONS.—As part of a rule promulgated under this paragraph, 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.

"(F) DURATION.—

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

"(ii) AUTHORITY OF ADMINISTRATOR.—The Administrator, by rule, may extend, modify, or eliminate an exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification,

the exemption warrants extension or is no longer necessary.

"(iii) CONSIDERATIONS.—

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

"(II) LIMITATION.—Any renewal of an exemption in the case of a rule under paragraph (1) requiring the ban or phase-out of a chemical substance shall not exceed 5 years.

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

"(1) the Administrator determines that—

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

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

"(2) in the case of a proposed rule to prohibit the manufacture, processing, or distribution in commerce of a chemical substance or mixture because of the risk determined under paragraph (1)(A), a court has granted relief in an action under section 7 with respect to that risk associated with the chemical substance or mixture.

"(f) Final Agency Action.—Under this section and subject to section 18—

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

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

(4) in subsection (g) (as redesignated by paragraph (2))—

(A) by striking paragraph (4); and

(B) by redesignating paragraph (5) as paragraph (4).

"(g) EXTENSION OF DEADLINES FOR CERTAIN CHEMICAL SUBSTANCES: The Administrator may not extend any deadline under subsection (a) for a chemical substance designated as a high priority that is listed in the 2014 update of the TSCA Work Plan without adequate public justification under paragraph (a)(6) that demonstrates, following a review of the

information reasonably available to the Administrator, that the Administrator cannot adequately complete a safety assessment and safety determination, or a final rule pursuant to subsection (d), without additional information regarding such substance.

SEC. 9. IMMINENT HAZARDS.

Section 7 of the Toxic Substances Control Act (15 U.S.C. 2606) is amended—

(1) by striking subsection (a) and inserting the following:

"(a) Civil Actions.—

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

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

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

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

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

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

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

(2) in subsection (b)(1), by striking "unreasonable";

(3) in subsection (d), by striking "section 6(a)" and inserting "section 6(d)"; and

(4) in subsection (f), in the first sentence, by striking "and unreasonable".

SEC. 10. INFORMATION COLLECTION AND REPORTING.

Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amended—

(1) in subsection (a)—

(A) in paragraph (3)(A)(ii)(I)—

(i) by striking "5(b)(4)" and inserting "5";

(ii) by inserting "section 4 or" after "in effect under"; and

(iii) by striking "5(e)," and inserting "5(d)(4);"; and

(B) by adding at the end the following:

"(4) RULES.—

"(A) DEADLINE.—

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

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

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

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

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

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

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

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

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

(2) in subsection (b), by adding at the end the following:

"(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 all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

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

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

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

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

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

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

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

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

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

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

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

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

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) RULES.—

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

"(ii) ACTIVE SUBSTANCES.—The Administrator shall 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).

"(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—In promulgating the rule established pursuant to 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 a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

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

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

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

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

"(ii) in accordance with section 14—

"(I) review each substantiation—

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

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

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

"(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

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

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

"(iii) encourage manufacturers or processors that have previously made claims

to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

"(E) TIMELINE FOR COMPLETION OF REVIEWS.—

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

"(ii) CONSIDERATIONS.—

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

"(II) ANNUAL REVIEW GOAL AND RESULTS.—~~The~~At the beginning of each year, the Administrator shall publish an annual goal for reviews, and the number of reviews ~~to be~~ completed in the prior year. ~~over the course of implementation of the plan.~~

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

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

"(B) CHANGE TO ACTIVE STATUS.—

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

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

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

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

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

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

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

modify, or deny the claim;

"(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of 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 promptly make the information available to the public; or

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

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

"(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 4A.

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

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

"(i) an active substance; or

"(ii) an inactive substance;

"(B) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received; and

"(C) subject to subsections (f) and (g) of section 14, the specific identity of any active substance for which—

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

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

"(iii) the time period for protection against disclosure of the specific identity of

the active substance has expired.

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

"(9) CERTIFICATION.—Under the rules promulgated under this subsection, manufacturers and processors 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 supporting the certification for a period of 5 years beginning on the last day of the submission period.";

(3) in subsection (e)—

(A) by striking "Any person" and inserting the following:

"(1) IN GENERAL.—Any person"; and

(B) by adding at the end the following:

"(2) ADDITIONAL INFORMATION.—Any person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of injury to health and the environment."; and

(4) in subsection (f), by striking "For purposes of this section, the" and inserting the following: "In this section:

"(1) ACTIVE SUBSTANCE.—The term 'active substance' means a chemical substance—

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

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

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

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

"(3) MANUFACTURE; PROCESS.—The".

SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.

Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the first sentence—

(i) by striking "presents or will present an unreasonable risk to health or the environment" and inserting "does not or will not meet the safety standard"; and

(ii) by striking "such risk" the first place it appears and inserting "the risk posed by the substance or mixture";

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting "within the time period specified by the Administrator in the report" after "issues an order";

(ii) in subparagraph (B), by inserting "responds within the time period specified by the Administrator in the report and" before "initiates, within 90 days"; and

(iii) in the matter following subparagraph (B), by striking "section 6 or 7" and inserting "section 6(d) or section 7";

(C) by redesignating paragraph (3) as paragraph (6);

(D) in paragraph (6) (as so redesignated), by striking "section 6 or 7" and inserting "section 6(d) or 7"; and

(E) by inserting after paragraph (2) the following:

"(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 time frame 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 under paragraph (1) does not take the actions described in subparagraphs (A) or (B) of paragraph (3), the Administrator shall—

"(A) if a safety assessment and safety determination for the substance under section 6 has not been completed, complete the safety assessment and safety determination;

"(B) if the Administrator has determined or determines that the chemical substance does not meet the safety standard, initiate action under section 6(d) with respect to the risk; or

"(C) take any action authorized or required under section 7, as appropriate.

"(5) This subsection shall not relieve the Administrator of any obligation to complete a safety assessment and safety determination or take any required action under section 6(d) 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).";

(2) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and inserting "Health and Human Services"; and

(3) by adding at the end the following:

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

SEC. 12. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA.

Section 10 of the Toxic Substances Control Act (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".

SEC. 13. EXPORTS.

Section 12 of the Toxic Substances Control Act (15 U.S.C. 2611) is amended—

(1) in subsection (a), by striking paragraph (2) and inserting the following:

"(2) EXCEPTION.—Paragraph (1) shall not apply to—

"(A) any new chemical substance that the Administrator determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors;

"(B) any chemical substance that the Administrator determines presents or will present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; or

"(C) any chemical substance that—

"(i) the Administrator determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; and

"(ii) is subject to restriction under section 5(d)(4).

"(3) WAIVERS FOR CERTAIN MIXTURES AND ARTICLES.—For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—

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

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

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

(2) by striking subsection (b) and inserting the following:

"(b) Notice.—

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

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

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

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

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

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

"(F) a chemical substance or mixture for which an action is pending or for which relief has been granted under section 7.

"(2) RULES.—

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

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

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

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

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

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

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

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

(3) in subsection (c)—

(A) by striking paragraph (3); and

(B) by redesignating paragraphs (4) through (6) as paragraphs (3) through (5), respectively.

SEC. 14. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

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

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

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

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

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

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

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

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

"(6) Specific production or import volumes of the manufacturer.

"(7) Specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

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

"(c) Information Not Protected From Disclosure.—

"(1) IN GENERAL.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

"(A) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

"(i) IN GENERAL.—Subject to clause (ii)—

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

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

"(bb) any chemical substance or mixture for which—

"(AA) testing is required under section 4; or

"(BB) a notification is required under section 5; or

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

"(ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph authorizes the release of any information that discloses—

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

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

"(B) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—

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

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

"(iii) 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.

"(iv) 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.

"(2) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is eligible for protection under this section and is submitted with information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for

protection against disclosure shall be disclosed.

"(3) BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.

"(4) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is subject to 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.

"(d) Requirements for Confidentiality Claims.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name shall—

"(i) be consistent with guidance issued by the Administrator under paragraph (3)(A); and

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

"(I) that are considered to be confidential; and

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

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and consistent with the guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the statement required to assert a claim submitted pursuant to paragraph (1)(B) and any information required to substantiate a claim submitted pursuant to paragraph (2) are true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a)—

"(1) shall be disclosed if the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) shall be disclosed if the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment;

"(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, if 1 or more applicable agreements with the Administrator that are consistent with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information;

"(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement are consistent with the

guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

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

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such

a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) shall be disclosed if the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

"(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION NOT SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information described in subsection (b) that meets the requirements of subsections (a) and (d), unless—

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

"(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)(2).

"(B) INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information, other than information described in subsection (b), that meets the requirements of subsections (a) and (d) for a period of 10 years, unless, prior to the expiration of the period—

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

"(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)(2).

"(C) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph (B), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph (B), a person reasserting the relevant claim shall submit to the Administrator a request for extension substantiating, in accordance with subsection (d)(2), the need to extend the

period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date of expiration of the period described in subparagraph (B), the Administrator shall, in accordance with subsection (g)(1)(C)—

"(aa) review the request submitted under subclause (I);

"(bb) make a determination regarding whether the claim for which the request was submitted continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of 10 years; or

"(BB) deny the request.

"(D) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph (C), if the Administrator determines that the relevant request under subparagraph (C)(ii)(I)—

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

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

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

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating rules pursuant to section 6(d).

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection of information against disclosure under subsection (a) and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) as necessary to 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;

"(ii) if the Administrator has a reasonable basis to believe that the information does not qualify for protection against disclosure under subsection (a); or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator or expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

"(B) REASONS FOR DENIAL OR MODIFICATION.—If Administrator denies or modifies a claim or request under subparagraph (A), the Administrator shall provide to the person that submitted the claim or request a written statement of the reasons for the denial or modification of the claim or request.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection (b)(8), review all claims or requests under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims or requests for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim or request for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim or request for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim or request under paragraph (1), intends to release information pursuant to subsection (e), or promulgates a rule under section 6(d) establishing a ban or phase-out of a chemical substance, the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

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

"(C) EXCEPTIONS.—

"(i) IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim or request receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

"(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information under paragraphs (4) and (6) of subsection (e), 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 paragraph (1), (2), (7), or (9) of subsection (e); or

"(II) for the disclosure of information for which—

"(aa) a notice under subsection (f)(1)(C)(i) was received; and

"(bb) no request was received by the Administrator on or before the date of expiration of the period for which protection from disclosure applies.

"(3) REBUTTABLE PRESUMPTION.—

"(A) IN GENERAL.—With respect to notifications provided by the Administrator under paragraph (2) with respect to information pertaining to a chemical substance subject to a rule as described in pursuant to subsection (c)(3), there shall be a rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.

"(B) REQUEST FOR NONDISCLOSURE.—A person that receives a notification under paragraph (2) with respect to the information described in subparagraph (A) may submit to the Administrator, before the date on which the information is to be released pursuant to paragraph (2)(B), a request with supporting documentation describing why the person believes some or all of that information should not be disclosed.

"(C) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—Not later than 30 days after the Administrator receives a request under subparagraph (B), the Administrator shall determine~~, at the discretion of the Administrator,~~ whether the documentation provided by the person making the request rebuts or does not rebut the presumption described in subparagraph (A), for all or a portion of the information that the person has requested not be disclosed.

"(ii) OBJECTIVE.—The Administrator shall make the determination with the objective of ensuring that information relevant to protection of health and the environment is disclosed to the maximum extent practicable.

"(D) TIMING.—Not later than 30 days after making the determination described in subparagraph (C), the Administrator shall make public the information the Administrator has determined is not to be protected from disclosure.

"(E) NO TIMELY REQUEST RECEIVED.—If the Administrator does not receive, before the date on which the information described in subparagraph (A) is to be released pursuant to paragraph (2)(B), a request pursuant to subparagraph (B), the Administrator shall promptly make public all of the information.

"(4) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released pursuant to paragraph (2)(B), the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable

court rules on an action under subparagraph (A).

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

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

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information reported to or otherwise obtained by the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

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

SEC. 15. PROHIBITED ACTS.

Section 15 of the Toxic Substances Control Act (15 U.S.C. 2614) is amended by striking

paragraph (1) and inserting the following:

"(1) fail or refuse to comply with—

"(A) any rule promulgated, consent agreement entered into, or order issued under section 4;

"(B) any requirement under section 5 or 6;

"(C) any rule promulgated, consent agreement entered into, or order issued under section 5 or 6; or

"(D) any requirement of, or any rule promulgated or order issued pursuant to title II;".

SEC. 16. PENALTIES.

Section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) is amended—

(1) in subsection (a)(1)—

(A) in the first sentence, by striking "$25,000" and inserting "$37,500"; and

(B) in the second sentence, by striking" violation of section 15 or 409" and inserting "violation of this Act"; and

(2) in subsection (b)—

(A) by striking "Any person who" and inserting the following:

"(1) IN GENERAL.—Any person that";

(B) by striking "$25,000" and inserting "$50,000"; and

(C) by adding at the end the following:

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of section 15 or 409, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

"(B) ORGANIZATIONS.—An organization that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation.

"(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)) shall apply to the prosecution of a violation under this paragraph.".

SEC. 17. STATE-FEDERAL RELATIONSHIP.

Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following:

"(a) In General.—

"(1) ESTABLISHMENT OR ENFORCEMENT.—Except as provided in subsections (c), (d), (e), (f), and (g), and subject to paragraph (2), no State or political subdivision of a State may establish or continue to enforce any of the following:

"(A) TESTING.—A statute or administrative action to require the development of information on a chemical substance or category of substances that is reasonably likely to produce the same information required under section 4, 5, or 6 in—

"(i) a rule promulgated by the Administrator;

"(ii) a testing consent agreement entered into by the Administrator; or

"(iii) an order issued by the Administrator.

"(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

"(i) found to meet the safety standard and consistent with the scope of the determination made under section 6; or

"(ii) found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

"(C) SIGNIFICANT NEW USE.—A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(2) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of statutes and administrative actions applicable to specific substances shall not occur until the effective date of the applicable action described in paragraph (1) taken by the Administrator.

"(b) New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions.—

"(1) IN GENERAL.—Except as provided in subsections (c), (d), (e), (f), and (g), beginning on the date on which the Administrator defines and publishes the scope of a safety assessment and safety determination under section 6(a)(2) and ending on the date on which the Administrator publishes the safety determination under section 6(a)(4), no State or political subdivision of a State may establish a statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance designated under section 4A.

"(2) EFFECT OF SUBSECTION.—

"(A) IN GENERAL.—This subsection does not restrict the authority of a State or political subdivision of a State to continue to enforce any statute enacted, or administrative action taken, prior to the date on which the Administrator defines and publishes the scope of a safety assessment and safety determination under section 6(a)(2).

"(B) LIMITATION.—Subparagraph (A) does not allow a State or political subdivision

of a State to enforce any new prohibition or restriction under a statute or administrative action described in that subparagraph, if the prohibition or restriction is established after the date described in that subparagraph.

"(c) Scope of Preemption.—Federal preemption under subsections (a) and (b) of statutes and administrative actions applicable to specific substances shall apply only to—

"(1) the chemical substances or category of substances subject to a rule, order, or consent agreement under section 4;

"(2) the uses or conditions of use of such substances that are identified by the Administrator as subject to review in a safety assessment and included in the scope of the safety determination made by the Administrator for the substance, or of any rule the Administrator promulgates pursuant to section 6(d); or

"(3) the uses of such substances that the Administrator has specified as significant new uses and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(d) Exceptions.—

"(1) NO PREEMPTION OF STATUTES AND ADMINISTRATIVE ACTIONS.—

"(A) IN GENERAL.—Nothing in this Act, nor any amendment made by this Act, nor any rule, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

"(i) is adopted or authorized under the authority of any other Federal law or adopted to satisfy or obtain authorization or approval under any other Federal law;

"(ii) implements a reporting, monitoring, disclosure, or other information obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law;

"(iii) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, except to the extent that the action—

"(I) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(II)(aa) addresses the same hazards and exposures, with respect to the same conditions of use as are included in the scope of the safety determination pursuant to section 6, but is inconsistent with the action of the Administrator; or

"(bb) would cause a violation of the applicable action by the Administrator under section 5 or 6; or

"(iv) subject to subparagraph (B), is identical to a requirement prescribed by the Administrator.

"(B) IDENTICAL REQUIREMENTS.—

"(i) IN GENERAL.—The penalties and other sanctions applicable under 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, no State or political subdivision of a State may assess a penalty for a specific violation for which the Administrator has already assessed a penalty under section 16, and the Administrator may not assess a penalty under section 16 for a specific violation for which a State or political subdivision of a State has already assessed a penalty.

"(2) APPLICABILITY TO CERTAIN RULES OR ORDERS.—Notwithstanding subsection (e)—

"(A) nothing in this section shall be construed as modifying the effect under this section, as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, of any rule or order promulgated or issued under this Act prior to that effective date; and

"(B) with respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 6 prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act with regards to manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance, this section (as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after that effective date, unless the latter rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under subsection (b) or (c) of section 4A or as an additional priority for safety assessment and safety determination under section 4A(c).

"(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 before August 1, 2015, 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 or administrative action of that State or political subdivision of the State that relates to the effects of, or exposure to, a chemical substance under the conditions of use if the Administrator determines that—

"(A) compelling State or local conditions warrant granting the waiver to protect health or the environment;

"(B) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(C) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

"(D) based on the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is consistent with sound objective scientific practices, the weight of the evidence, and the best available science.

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

"(A) compliance with the proposed requirement of the State 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;

"(B) 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

"(C) 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.

"(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 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 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 safety determination under section 6(a)(4).

"(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.—

"(i) If the Administrator fails to meet the deadline established under section 6(a)(4) (including an extension granted under section 6(a)(6)), the application of a State or political subdivision of a State under paragraph (2) shall be automatically approved.

"(ii) 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 deadlines under section 6(a)(4) (including an extension granted under section 6(a)(6)) or 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 this Act, nor any safety standard, rule, requirement, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall be construed to preempt, displace, or supplant any state or Federal common law rights or any state or Federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.

"(B) CLARIFICATION OF NO PREEMPTION.—Notwithstanding any other provision of this Act, nothing in this Act, nor any amendments made by this Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or

other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any State law, maritime law, or Federal common law or statutory theory.

"(2) NO EFFECT ON PRIVATE REMEDIES.—

"(A) IN GENERAL.—Nothing in this Act, nor any amendments made by this Act, nor any rules, regulations, requirements, safety assessments, safety determinations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.

"(B) AUTHORITY OF COURTS.—This Act does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, safety assessments, scientific assessments, or orders issued pursuant to this Act.".

SEC. 18. JUDICIAL REVIEW.

Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A)—

(I) in the first sentence—

(aa) by striking "Not" and inserting "Except as otherwise provided in this title, not";

(bb) by striking "section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting "this title or title II or IV, or an order under section 6(c)(1)(A)"; and

(cc) by striking "judicial review of such rule" and inserting "judicial review of such rule or order"; and

(II) in the second sentence, by striking "such a rule" and inserting "such a rule or order"; and

(ii) in subparagraph (B)—

(I) by striking "Courts" and inserting "Except as otherwise provided in this title, courts"; and

(II) by striking "an order issued under subparagraph (A) or (B) of section 6(b)(1)" and inserting "an order issued under this title";

(B) in paragraph (2), in the second sentence, by striking "the filing of the rulemaking record of proceedings on which the Administrator based the rule being reviewed" and inserting "the filing of the record of proceedings on which the Administrator based the rule or order being reviewed"; and

(C) by striking paragraph (3) and inserting the following:

"(3) JUDICIAL REVIEW OF LOW-PRIORITY DECISIONS.—

"(A) IN GENERAL.—Not later than 60 days after the publication of a designation under section 4A(b)(4), or a designation under section 4A(b)(8) of a chemical substance as a low-priority substance, any person may commence a civil action to challenge the designation.

"(B) JURISDICTION.—The United States Court of Appeals for the District of Columbia Circuit shall have exclusive jurisdiction over a civil action filed under this paragraph."; and

(2) in subsection (c)(1)(B)—

(A) in clause (i)—

(i) by striking "section 4(a), 5(b)(4), 6(a), or 6(e)" and inserting "section 4(a), 6(d), or 6(g), or an order under section 6(c)(1)(A)"; and

(ii) by striking "evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;" and inserting "evidence (including any matter) in the rulemaking record, taken as a whole; and"; and

(B) by striking clauses (ii) and (iii) and the matter following clause (iii) and inserting the following:

"(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule, except as part of the rulemaking record, taken as a whole.".

SEC. 19. CITIZENS' CIVIL ACTIONS.

Section 20 of the Toxic Substances Control Act (15 U.S.C. 2619) is amended—

(1) in subsection (a)(1), by striking "or order issued under section 5" and inserting "or order issued under section 4 or 5"; and

(2) in subsection (b)—

(A) in paragraph (1)(B), by striking "or" at the end;

(B) in paragraph (2), by striking the period at the end and inserting ", 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"; and

(C) by adding at the end the following:

"(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).".

SEC. 20. CITIZENS' PETITIONS.

Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an

order under section 4 or 5(d)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "an order under section 4 or 5(d)"; and

(B) in paragraph (4), by striking subparagraph (B) and inserting the following:

"(B) DE NOVO PROCEEDING.—

"(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to issue a rule pursuant to section 4, 5, 6, or 8 or issue an order under section 4 or 5(d), the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.

"(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a rule or order under section 4, the information is needed for a purpose identified in section 4(a);

"(bb) in the case of a petition to issue an order under section 5(d), the chemical substance is not likely to meet the safety standard;

"(cc) in the case of a petition to initiate a proceeding for the issuance of a rule under section 6(d), the chemical substance does not meet the safety standard; or

"(dd) in the case of a petition to initiate a proceeding for the issuance of a rule under section 8, there is a reasonable basis to conclude that the rule is necessary to protect health or the environment or ensure that the chemical substance meets the safety standard.

"(II) DEFERMENT.—The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

"(aa) the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act; and

"(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.".

SEC. 21. EMPLOYMENT EFFECTS.

Section 24(b)(2)(B)(ii) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)(ii)) is

amended by striking "section 6(c)(3)," and inserting "the applicable requirements of this Act;".

SEC. 22. STUDIES.

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.

SEC. 23. ADMINISTRATION.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) by striking subsection (b) and inserting the following:

"(b) Fees.—

"(1) IN GENERAL.—The Administrator shall establish, not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, by rule—

"(A) the payment of 1 or more reasonable fees as a condition of submitting a notice or requesting an exemption under section 5; and

"(B) the payment of 1 or more reasonable fees by a manufacturer or processor that—

"(i) is required to submit a notice pursuant to the rule promulgated under section 8(b)(4)(A)(i) identifying a chemical substance as active;

"(ii) is required to submit a notice pursuant to section 8(b)(5)(B)(i) changing the status of a chemical substance from inactive to active;

"(iii) is required to report information pursuant to the rules promulgated under paragraph (1) or (4) of section 8(a); or

"(iv) manufactures or processes a chemical substance subject to a safety assessment and safety determination pursuant to section 6.

"(2) UTILIZATION AND COLLECTION OF FEES.—The Administrator shall—

"(A) utilize the fees collected under paragraph (1) only to defray costs associated with the actions of the Administrator—

"(i) to collect, process, review, provide access to, and protect from disclosure (where appropriate) information on chemical substances under this Act;

"(ii) to review notices and make determinations for chemical substances under paragraphs (1) and (3) of section 5(d) and impose any necessary restrictions under section 5(d)(4);

"(iii) to make prioritization decisions under section 4A;

"(iv) to conduct and complete safety assessments and determinations under section 6; and

"(v) to conduct any necessary rulemaking pursuant to section 6(d);

"(B) insofar as possible, collect the fees described in paragraph (1) in advance of conducting any fee-supported activity;

"(C) deposit the fees in the Fund established by paragraph (4)(A); and

"(D) insofar as possible, not collect excess fees or retain a significant amount of unused fees.

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

"(A) 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 defray the lower of approximately 25 percent of the costs of conducting the activities identified in paragraph (2)(A), ~~not to exceed $18,000,000~~or $25,000,000 in total fees (subject to adjustment pursuant to subparagraph (G));

"(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) and paragraph (4)(D), for substances designated as additional priorities pursuant to section 4A(c), establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the safety assessment and safety determination under section 6, except that for substances subject to section 4A(c)(3), the Administrator shall establish the fee at a level sufficient to defray 50 percent of those costs;

"(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 III 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—

"(i) to ensure, based on the audit analysis required under paragraph (5)(B), that funds deposited in the Fund are sufficient to defray approximately 25% of the cost to conduct the activities identified in paragraph (2)(A) and defray the full costs and the 50-percent portion of the costs of safety assessments and safety determinations specified in subparagraph (D); and

"(ii) to ~~account~~ adjust the total amount of fees, and individual fees, for inflation;

"(G) adjust fees established under paragraph (1) as necessary to vary on account of differing circumstances, including reduced fees or waivers in appropriate circumstances, to reduce the burden on manufacturing or processing, remove barriers to innovation, or where the costs to the Administrator of collecting the fees exceed the fee revenue anticipated to be collected; and

"(H) if a notice submitted under section 5 is refused or subsequently withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

"(4) TSCA IMPLEMENTATION FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the 'TSCA Implementation Fund' (referred to in this subsection as the 'Fund'), consisting of—

"(i) such amounts as are deposited in the Fund under paragraph (2)(C); and

"(ii) any interest earned on the investment of amounts in the Fund; and

"(iii) any proceeds from the sale or redemption of investments held in the Fund.

"(B) CREDITING AND AVAILABILITY OF FEES.—

"(i) IN GENERAL.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation.

"(ii) REQUIREMENTS.—Fees collected under this section shall not—

"(I) be made available or obligated for any purpose other than to defray the costs of conducting the activities identified in paragraph (2)(A);

"(II) otherwise be available for any purpose other than implementation of this Act; and

"(III) so long as amounts in the Fund remain available, be subject to restrictions on expenditures applicable to the Federal government as a whole.

"(C) UNUSED FUNDS.—Amounts in the Fund not currently needed to carry out this subsection shall be—

"(i) maintained readily available or on deposit;

"(ii) invested in obligations of the United States or guaranteed by the United States; or

"(iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

"(D) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2015) of the Office of Pollution Prevention and Toxics of the Environmental Protection Agency for Chemical Risk Review and Reduction for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for covered functions for fiscal year ~~2015~~2014 (excluding the amount of any fees appropriated for the fiscal year).

"(5) AUDITING.—

"(A) FINANCIAL STATEMENTS OF AGENCIES.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of an executive

agency.

"(B) COMPONENTS.—The annual audit required under sections 3515(b) and 3521 of that title of the financial statements of activities under this subsection shall include an analysis of—

"(i) the fees collected under paragraph (1) and disbursed;

"(ii) compliance with the deadlines established in section 6 of this Act;

"(iii) the amounts budgeted, appropriated, collected from fees, and disbursed to meet the requirements of sections 4, 4A, 5, 6, 8, and 14, including the allocation of full time equivalent employees to each such section or activity; and

"(iv) the reasonableness of the allocation of the overhead associated with the conduct of the activities described in paragraph (2)(A).

"(C) INSPECTOR GENERAL.—The Inspector General of the Environmental Protection Agency shall—

"(i) conduct the annual audit required under this subsection; and

"(ii) report the findings and recommendations of the audit to the Administrator and to the appropriate committees of Congress.

"(6) TERMINATION.—The authority provided by this section shall terminate at the conclusion of the fiscal year that is 10 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, unless otherwise reauthorized or modified by Congress.";

(2) in subsection (e), by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services"; and

(3) adding at the end the following:

"(h) Prior Actions.—Nothing in this Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

SEC. 24. DEVELOPMENT AND EVALUATION OF TEST METHODS AND SUSTAINABLE CHEMISTRY.

Section 27 of the Toxic Substances Control Act (15 U.S.C. 2626) is amended—

(1) in subsection (a), in the first sentence by striking "Health, Education, and Welfare" and inserting "Health and Human Services"; and

(2) by adding at the end the following:

"(c) Sustainable Chemistry Program.—The President shall establish an interagency Sustainable Chemistry Program to promote and coordinate Federal sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities.

"(d) Program Activities.—The activities of the Program shall be designed to—

"(1) provide sustained support for sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training through—

"(A) coordination of sustainable chemistry research, development, demonstration, and technology transfer conducted at Federal laboratories and agencies; and

"(B) to the extent practicable, encouragement of consideration of sustainable chemistry in, as appropriate—

"(i) the conduct of Federal and State science and engineering research and development; and

"(ii) the solicitation and evaluation of applicable proposals for science and engineering research and development;

"(2) examine methods by which the Federal Government can create incentives for consideration and use of sustainable chemistry processes and products, including innovative financing mechanisms;

"(3) expand the education and training of undergraduate and graduate students and professional scientists and engineers, including through partnerships with industry, in sustainable chemistry science and engineering;

"(4) collect and disseminate information on sustainable chemistry research, development, and technology transfer including information on—

"(A) incentives and impediments to development, manufacturing, and commercialization;

"(B) accomplishments;

"(C) best practices; and

"(D) costs and benefits;

"(5) support (including through technical assistance, participation, financial support, or other forms of support) economic, legal, and other appropriate social science research to identify barriers to commercialization and methods to advance commercialization of sustainable chemistry.

"(e) Interagency Working Group.—

"(1) ESTABLISHMENT.—Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the President, in consultation with the Office of Science and Technology Policy, shall establish an Interagency Working Group that shall include representatives from the National Science Foundation, the National Institute of Standards and Technology, the Department of Energy, the Environmental Protection Agency, the Department of Agriculture, the Department of Defense, the National Institutes of Health, and any other agency that the President may designate to oversee the planning, management, and coordination of the Program.

"(2) GOVERNANCE.—The Director of the National Science Foundation and the Assistant Administrator for Research and Development of the Environmental Protection Agency, or their designees, shall serve as co-chairs of the Interagency Working Group.

"(3) RESPONSIBILITIES.—In overseeing the planning, management, and coordination of

the Program, the Interagency Working Group shall—

"(A) establish goals and priorities for the Program, in consultation with the Advisory Council;

"(B) provide for interagency coordination, including budget coordination, of activities under the Program;

"(C) meet not later than 90 days from its establishment and periodically thereafter; and

"(D) establish and consult with an Advisory Council on a regular basis.

"(4) MEMBERSHIP.—The Advisory Council members shall not be employees of the Federal Government and shall include a diverse representation of knowledgeable individuals from the private sector (including small- and medium-sized enterprises from across the value chain), academia, State and tribal governments, and nongovernmental organizations and others who are in a position to provide expertise.

"(f) Agency Budget Requests.—

"(1) IN GENERAL.—Each Federal agency and department participating in the Program shall, as part of its annual request for appropriations to the Office of Management and Budget, submit a report to the Office of Management and Budget that—

"(A) identifies the activities of the agency or department that contribute directly to the Program; and

"(B) states the portion of the agency or department's request for appropriations that is allocated to those activities.

"(2) ANNUAL BUDGET REQUEST TO CONGRESS.—The President shall include in the annual budget request to Congress a statement of the portion of the annual budget request for each agency or department that will be allocated to activities undertaken pursuant to the Program.

"(g) Report to Congress.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Interagency Working Group shall submit a report to the Committee on Science, Space, and Technology and Committee on Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works and the Committee on Commerce, Science, and Transportation of the Senate that shall include—

"(A) a summary of federally funded sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities;

"(B) a summary of the financial resources allocated to sustainable chemistry initiatives;

"(C) an analysis of the progress made toward achieving the goals and priorities of the program established pursuant to subsection (c), and recommendations for future program activities;

"(D) an assessment of the benefits of expanding existing, federally-supported

regional innovation and manufacturing hubs to include sustainable chemistry and the value of directing the creation of 1 or more dedicated sustainable chemistry centers of excellence or hubs; and

"(E) an evaluation of steps taken and future strategies to avoid duplication of efforts, streamline interagency coordination, facilitate information sharing, and spread best practices between participating agencies in the Program.

"(2) SUBMISSION TO GAO.—The Interagency Working Group shall also submit the report described in paragraph (1) to the Government Accountability Office for consideration in future Congressional inquiries.".

SEC. 25. STATE PROGRAMS.

Section 28 of the Toxic Substances Control Act (15 U.S.C. 2627) is amended—

(1) in subsection (b)(1)—

(A) in subparagraphs (A) through (D), by striking the comma at the end of each subparagraph and inserting a semicolon; and

(B) in subparagraph (E), by striking ", and" and inserting "; and"; and

(2) by striking subsections (c) and (d).

SEC. 26. AUTHORIZATION OF APPROPRIATIONS.

Section 29 of the Toxic Substances Control Act (15 U.S.C. 2628) is repealed.

SEC. 27. ANNUAL REPORT.

Section 30 of the Toxic Substances Control Act (15 U.S.C. 2629) is amended by striking paragraph (2) and inserting the following:

"(2)(A) the number of notices received during each year under section 5; and

"(B) the number of the notices described in subparagraph (A) for chemical substances subject to a rule, testing consent agreement, or order under section 4;".

SEC. 28. EFFECTIVE DATE.

Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601 note; Public Law 94–469) is amended—

(1) by striking "Except as provided in section 4(f), this" and inserting the following:

"(a) In General.—This"; and

(2) by adding at the end the following:

"(b) Retroactive Applicability.—Nothing in this Act shall be interpreted to apply retroactively to any State, Federal, or maritime legal action commenced prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 6/23/2015 6:38:29 PM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]; Kaiser, Sven-Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac78d3704ba94edbbd0da970921271ff-SKAISER]
Subject: FW: House TSCA bill will cost $143 million through 2025
Attachments: CBO TSCA.pdf

****Report attached**

6/23/15 2:27 PM EDT

The House's bipartisan rewrite of the Toxic Substances Control Act, H.R. 2576, will cost $143 million between 2016 and 2025, according to Congressional Budget Office cost estimatereleased this afternoon.

"CBO estimates that EPA would incur additional costs to conduct safety evaluations of chemical substances over the 2016-2020 period in order to meet the new requirements imposed by H.R. 2576," the CBO states. "[W]e estimate that implementing this legislation would cost $64 million over the next five years and $143 million over the 2016-2025 period, assuming appropriation actions consistent with the bill."

Some of the requirements in H.R. 2576 are similar to activities already done by EPA under TSCA, but CBO estimates that implementing this legislation would increase EPA's administrative workload for regulating chemical safety by about 25 percent each year.

The House is scheduled to vote on the bill during a vote series starting at 6:30 p.m. tonight. The measure has been put on the suspensions calendar, which is typically used for noncontroversial legislation and requires a two-thirds majority in order to win approval.

— *Darius Dixon*

CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

June 23, 2015

H.R. 2576
TSCA Modernization Act of 2015

As ordered reported by the House Committee on Energy and Commerce on June 3, 2015

SUMMARY

H.R. 2576 would modify the Toxic Substances Control Act (TSCA), the law that regulates the manufacture, importation, and processing of chemicals, with the aim of strengthening the Environmental Protection Agency's (EPA's) ability to evaluate and regulate potentially hazardous chemicals.

CBO estimates that EPA would incur additional costs to conduct safety evaluations of chemical substances over the 2016-2020 period in order to meet the new requirements imposed by H.R. 2576; we estimate that implementing this legislation would cost $64 million over the next five years and $143 million over the 2016-2025 period, assuming appropriation actions consistent with the bill.

Under the legislation, EPA would be authorized to charge two types of fees for some of its work under the legislation. Those fees would have different budgetary treatments. One fee would be classified as a mandatory offsetting receipt and the other would be classified as a revenue. Based on information provided by the agency, CBO estimates that enacting the legislation would increase offsetting receipts, which are treated as reductions in direct spending, by $115 million over the 2016-2025 period; revenues would increase by $121 million over the same period, net of income and payroll tax offsets. Pay-as-you-go procedures apply because the bill would affect direct spending and revenues.

H.R. 2576 would impose intergovernmental and private-sector mandates, as defined in the Unfunded Mandates Reform Act (UMRA), on manufacturers, processors, importers, and users of chemical substances. CBO estimates that the aggregate cost of those mandates would fall below the annual thresholds established in UMRA for intergovernmental and private-sector mandates ($77 million and $154 million in 2015, respectively, adjusted annually for inflation).

MAJOR PROVISIONS

The bill's major provisions would:

- Require EPA to develop policies, procedures, guidance, and rules to implement the bill;

- Authorize EPA to obtain new information from manufacturers and processors necessary to conduct risk evaluations on chemical substances;

- Require EPA to initiate at least 10 risk evaluations annually on chemical substances the agency determines may present an unreasonable risk of injury to human health or the environment;

- Require EPA to publish a list of chemicals that are considered to be persistent, bioaccumulative and toxic (PBTs) and to designate any such PBTs as a "chemical of concern" for which EPA can take regulatory action;

- Require EPA to review any renewed requests from manufacturers and processors to keep certain information confidential beginning 10 years after the original designations concerning confidentiality are made;

- Address when federal actions under TSCA preempt requirements of state and local governments related to restricting and banning chemical substances; and

- Require EPA to establish a new schedule for charging fees to chemical manufacturers who are required to submit data to the agency or who request that EPA assess certain chemicals that are not yet prioritized for review by EPA.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 2576 is shown in the following table. The costs of this legislation fall within budget function 300 (natural resources and environment).

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	By Fiscal Year, in Millions of Dollars											
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2016-2020	2016-2025
CHANGES IN SPENDING SUBJECT TO APPROPRIATION												
Administrative Expenses under TSCA												
Estimated Authorization Level	15	15	15	15	15	15	16	16	17	17	75	156
Estimated Outlays	6	13	15	15	15	15	15	16	16	17	64	143
CHANGES IN DIRECT SPENDING												
PMN Fee Collections												
Estimated Budget Authority	0	-7	-10	-14	-14	-14	-14	-14	-14	-14	-45	-115
Estimated Outlays	0	-7	-10	-14	-14	-14	-14	-14	-14	-14	-45	-115
CHANGES IN REVENUES												
Estimated Revenues	2	7	7	15	15	15	15	15	15	15	46	121
NET INCREASE OR DECREASE (-) IN THE DEFICIT FROM CHANGES IN DIRECT SPENDING AND REVENUES												
Net Change in the Deficit	-2	-14	-17	-29	-29	-29	-29	-29	-29	-29	-91	-236

Notes: TSCA = Toxic Substances Control Act; PMN = Premanufacturing Notice.

For direct spending, a negative number in indicates a decrease in outlays; for revenue, a positive number indicates an increase in revenues.

BASIS OF ESTIMATE

For this estimate, CBO assumes that H.R. 2576 will be enacted near the end of 2015 and that the necessary amounts will be appropriated each year.

Spending Subject to Appropriation

CBO estimates that implementing H.R. 2576 would cost $64 million over the 2016-2020 period, subject to appropriation of the necessary amounts. While some of the requirements in H.R. 2576 are similar to activities currently performed by EPA under TSCA, CBO estimates that implementing this legislation would increase EPA's administrative workload for regulating chemical safety by about 25 percent each year. That estimate is based on historical information about how other large regulatory programs have been implemented by EPA and on estimates that were provided by the agency of the additional workload under the bill. According to EPA, the agency currently requires, on average, an appropriation of about $58 million annually to implement and enforce EPA's Chemical Risk Review and Reduction program under TSCA. That funding supports roughly 245 employees. Subject to appropriation of the necessary amounts, CBO estimates that EPA

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would require about $15 million annually over the next five years to cover the costs of additional personnel, contractors, and other administrative activities associated with meeting the new requirements of H.R. 2576.

H.R. 2576 also specifies that all additional fees collected by EPA under the bill would be available for spending on the safety analysis of individual chemicals, subject to appropriation of those amounts. (A more detailed discussion of the fees is provided below.)

Direct Spending and Revenues

Enacting this legislation would affect one existing fee and would authorize EPA to collect a new fee. Those fees would be recorded differently in the budget, as discussed below. CBO estimates that the gross collections would total $108 million over the 2016-2020 period, and would be available for spending on chemical safety evaluations, subject to appropriation of those amounts.

Premanufacturing Notice (PMN) Fees. Under the legislation the statutory cap in TSCA on the amount EPA can charge manufacturers and processors for premanufacturing notices would be eliminated. (Manufacturers or processors who plan to use a new chemical substance for a non-exempt commercial purpose are required to provide EPA with notice before initiating the activity. EPA then performs a risk assessment on the new chemical substance.) PMN fees are currently classified in the budget as offsetting receipts (a reduction in direct spending). CBO estimates that by eliminating the cap, EPA would begin collecting additional fees in 2017 and that such collections would total $7 million in that year. By 2019, we estimate that as more chemicals are reviewed by EPA, collections would reach $14 million annually. In total CBO estimates that direct spending would be reduced by $45 million over the next five years and by $115 million over the next 10 years.

Manufacturing/Processor Requested Assessment Fees. In addition, under H.R. 2576 EPA could charge fees to manufacturers and processors who request that EPA initiate risk evaluations for chemicals that have not been designated a priority for further assessment. Those new fees would be classified as revenues because their payment would be compulsory, enforced by the federal government's sovereign authority. CBO estimates that EPA would begin collecting additional fees in 2016 and that by 2019 such revenue would total $20 million annually. We estimate that gross revenues would total $63 million over the next five years and $163 million over the next ten years. Such amounts would be available for spending on risk evaluations, subject to future appropriation action. However, the amount of revenue attributable to this bill would be approximately 25 percent less to account for income and payroll tax offsets. Net of those offsets, CBO estimates that enacting H.R. 2576 would increase revenues by $121 million over the 2016-2025 period.

Enacting H.R. 2576 also could affect direct spending and revenues because this bill would establish new authority for EPA to assess civil and criminal penalties against persons who

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receive confidential business information and then improperly use or disclose such information. Criminal penalties are recorded as revenues, then deposited in the Crime Victims Fund, and later spent; civil penalties are recorded as revenues. CBO estimates that any increase in criminal or civil penalties under the bill would not be significant.

PAY-AS-YOU-GO CONSIDERATIONS

The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. CBO estimates that any fee collections over the 2016-2025 period would result in a decrease in direct spending and an increase in revenues as shown in the following table.

CBO Estimate of Pay-As-You-Go Effects for H.R. 2576, as ordered reported by the House Committee on Energy and Commerce on June 3, 2015

	By Fiscal Year, in Millions of Dollars												
	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2015-2020	2015-2025
NET INCREASE OR DECREASE (-) IN THE DEFICIT													
Statutory Pay-As-You-Go Impact	0	-2	-14	-17	-29	-29	-29	-29	-29	-29	-29	-91	-236
Memorandum:													
Changes in Outlays	0	0	-7	-10	-14	-14	-14	-14	-14	-14	-14	-45	-115
Changes in Revenues	0	2	7	7	15	15	15	15	15	15	15	46	121

INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

H.R. 2576 would impose intergovernmental and private-sector mandates, as defined in UMRA, on manufacturers, processors, importers, and users of chemical substances. CBO estimates that the aggregate cost of those mandates would fall below the annual thresholds established in UMRA for intergovernmental and private-sector mandates ($77 million and $154 million in 2015, respectively, adjusted annually for inflation).

Mandates That Apply to Both Public and Private Entities

H.R. 2576 would modify the standard used to determine whether a chemical substance presents an unreasonable risk to human health or the environment and would allow EPA to regulate the manufacture, processing, distribution, use, and disposal of chemical substances to ensure the standard is met. If EPA determines that some chemical substances do not meet the standard and issues regulations for those substances, the bill would impose

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an intergovernmental and private-sector mandate. The bill also would impose an intergovernmental and private-sector mandate if EPA uses its authority under the bill to expedite the regulation of any chemical substance determined to be persistent, bioaccumulative, and toxic. EPA would have the authority to adopt a range of regulatory options to address risks from chemical substances. For example, EPA could limit the amount manufactured or require manufacturers to put warning labels on selected chemicals. EPA also could require users of chemicals, such as public and private universities conducting research, to handle or dispose of selected chemicals in a certain way. Based on information from industry experts, CBO expects that the annual cost of any restriction would not be substantial. Also, because of the amount of time involved in evaluating the risk of each chemical, any restrictions imposed would apply to few chemicals in the first five years the mandate is in effect. Therefore, CBO estimates that the cost of the mandate would be small for both public and private entities during that time.

Mandates That Apply to Public Entities Only

The bill would impose an intergovernmental mandate by preempting state regulations that conflict with the federal regulation of chemicals, but that preemption would impose no duty on states that would result in additional spending or a loss of revenues.

Mandates That Apply to Private Entities Only

The bill would impose additional private-sector mandates on manufacturers, importers, and processors of chemical substances. By removing the cap on fees assessed by EPA when manufacturers and importers submit premanufacture notices, the bill would increase the cost of an existing mandate to pay those fees. CBO estimates that the increase in fees would start in 2017 and would reach $14 million annually beginning in 2019. The bill also would require manufacturers and processors of chemical substances to submit data to EPA for use in carrying out risk evaluations. Manufacturers and processors also would have to include additional information along with any data to substantiate a request that EPA protect their data as confidential business information. Based on information from industry experts, CBO expects that the cost to submit those data would not be substantial.

PREVIOUS CBO ESTIMATE

On June 5, 2015, CBO transmitted a cost estimate for S. 697, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as ordered reported by the Senate Committee on Environment and Public Works on April 28, 2015. Both S. 697 and H.R. 2576 would increase EPA's administrative workload by roughly equivalent amounts to meet new requirements under TSCA and both bills would enable EPA to charge fees to chemical manufacturers and processors for certain activities, though the types of fees charged and the amounts collected would vary between the two bills. Furthermore, because the

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classification of fees under the two bills differs, collections under the bills would have different budgetary implications. Under S. 697 the fees collected would be classified as offsetting collections and would more than offset the additional discretionary spending estimated under S. 697. In contrast, the fees collected under H.R. 2576 would result in a reduction in direct spending and an increase in revenues. The cost estimates for the two bills reflect the different budgetary treatment.

ESTIMATE PREPARED BY:

Federal Spending: Susanne Mehlman
Impact on State, Local, and Tribal Governments: Jon Sperl
Impact on the Private Sector: Amy Petz

ESTIMATE APPROVED BY

Theresa Gullo
Assistant Director for Budget Analysis

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Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 6/23/2015 3:13:11 PM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]; Kaiser, Sven-Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac78d3704ba94edbbd0da970921271ff-SKAISER]
Subject: RE: 1 item: S.697
Attachments: CRPT-114srpt67.pdf

Report attached

-----Original Message-----
From: Black, Jonathan (Tom Udall)
Sent: Friday, June 19, 2015 8:38 AM
To: 'Jones.Jim@epa.gov'; 'Kaiser.Sven-Erik@epamail.epa.gov'
Subject: Fw: 1 item: S.697

----- Original Message -----
From: LIS ALERT [mailto:lisalert@loc.gov]
Sent: Friday, June 19, 2015 08:10 AM
To: Black, Jonathan (Tom Udall)
Subject: 1 item: S.697

1 item (1 changed) in Bill Summary & Status

Bill(s) with changes in the parameters you selected:

1. S.697 - A bill to amend the Toxic Substances Control Act
   to reauthorize and modernize that Act, and for other purposes.
   Sponsor:Sen Udall, Tom [D-NM] (introduced 3/10/2015)
   Bill Status: 6/18/2015: By Senator Inhofe from Committee
      on Environment and Public Works filed written report.
      Report No. 114-67. Minority views filed.
   http://www.lis.gov/cgi-lis/bdquery/z?d114:SN00697:/

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Calendar No. 121

114TH CONGRESS, *1st Session* | SENATE | REPORT 114–67

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

JUNE 18, 2015.—Ordered to be printed

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

REPORT

together with

MINORITY VIEWS

[To accompany S. 697]

[Including cost estimate of the Congressional Budget Office]

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

GENERAL STATEMENT AND BACKGROUND

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

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

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

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

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

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

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

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

Testing of chemical substances and mixtures

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

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

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

Manufacturing and processing notices

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

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

Regulation of hazardous chemical substances and mixtures

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

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

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

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

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

Reporting and retention of information

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

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

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

Disclosure of data

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

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

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

Preemption

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

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

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

Administration

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

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

OBJECTIVES OF THE LEGISLATION

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

SECTION-BY-SECTION ANALYSIS

Section 1. Short title

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

Section 2. Findings, policy and intent

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

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

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

Section 3. Definitions

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

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

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

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

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

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

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

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

Section 4. Policies, procedures and guidance

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

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

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

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

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

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

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

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

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

Section 5: Testing of chemical substances or mixtures

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

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

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

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

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

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

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

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

Section 6. Prioritization screening.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 7. New chemicals and significant new uses

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

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

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

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

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

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

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

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

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

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

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

Section 8. Safety assessments and safety determinations

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

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

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

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

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

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

> "a standard that ensures, *without taking into consideration costs or other nonrisk factors,* that no unreasonable risk of injury to human health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of injury to—
> (A) the general population; or
> (B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance."

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

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

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

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

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

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

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

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

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

Section 9. Imminent hazards

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

Section 10: Information collection and reporting

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

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

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

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

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

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

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

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

Section 11. Relationship to other Federal laws

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

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

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

Section 13. Exports

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

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

Section 14. Confidential information

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 15. Prohibited acts

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

Section 16. Penalties

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

Section 17. State-Federal relationship

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 18. Judicial review

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

Section 19. Citizens' petitions

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

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

Section 20. Employment effects

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

Section 21. Studies

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

Section 22. Administration

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

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

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

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

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

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

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

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

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

Section 24. State programs

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

Section 25. Authorization of appropriations

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

Section 26. Annual report

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

Section 27. Effective date

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

LEGISLATIVE HISTORY

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

ROLL CALL VOTES

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

Amendments rejected

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

1. Gillibrand #1—Amendment striking a section of S. 697 that prohibits states from taking action in regulating high priority chemicals upon the initiation of the Safety Assessment by EPA (rejected by a roll call vote of 8 yeas, 12 nays).
2. Boxer-Sanders-Markey #2—Amendment requiring expedited consideration of the regulation of all forms of asbestos, instead of requiring a safety assessment be completed (rejected by a roll call vote of 9 yeas, 11 nays).
3. Markey #1—Amendment including a provision for chemicals requiring expedited action (rejected by a roll call vote of 8 yeas, 12 nays).
4. Markey #2—Amendment allowing additional time to comply with certain restrictions in cases of technological infeasibility (rejected by a roll call vote of 9 yeas, 11 nays).
5. Boxer-Carper #3—Amendment addressing chemical contamination of drinking water supplies by requiring consideration of whether a chemical substance is stored near drinking water sources when prioritizing chemicals for assessments (rejected by a roll call vote of 10 yeas, 10 nays).
6. Boxer-Markey-Sanders #5—Amendment strengthening protections for children and communities from disease clusters and providing community disease cluster technical assistance grants (rejected by a roll call vote of 10 yeas, 10 nays).

Final Committee vote to report

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

REGULATORY IMPACT STATEMENT

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

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

MANDATES ASSESSMENT

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

COST OF LEGISLATION

JUNE 5, 2015.

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

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

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

Sincerely,

KEITH HALL.

Enclosure.

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

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

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

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

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

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

Major provisions: The bill's major provisions would:

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

Estimated cost to the Federal Government: The estimated budgetary impact of S. 697 is shown in the following table. The costs of this legislation fall within budget function 300 (natural resources and environment).

	By fiscal year, in millions of dollars—					
	2016	2017	2018	2019	2020	2016–2020
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Administrative Expenses under TSCA:						
Estimated Authorization Level	17	17	17	17	17	85
Estimated Outlays	7	14	17	17	17	72
Offsetting Fee Collections:						
Estimated Authorization Level	−4	−10	−16	−25	−25	−80
Estimated Outlays	−4	−10	−16	−25	−25	−80
Total Changes:						
Estimated Budget Authority	13	7	1	−8	−8	5
Estimated Budget Outlays	3	4	1	−8	−8	−8

Note: TSCA = Toxic Substances Control Act.

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

Spending subject to appropriation

While some of the requirements in S. 697 are similar to activities currently performed by EPA under TSCA, CBO estimates that implementing this legislation would increase EPA's workload for regulating chemical safety by about 30 percent each year. That estimate is based on historical information about how other large regulatory programs have been implemented by EPA and on expectations of the additional workload provided by the agency. According to EPA, the agency currently requires, on average, an appropriation of about $58 million annually to implement and enforce EPA's Chemical Risk Review and Reduction program under TSCA. That funding supports roughly 245 employees. Subject to the appropriation of the necessary amounts, CBO estimates that EPA would require about $17 million annually over the next five years to cover the costs of additional personnel, contractors, and other administrative activities associated with meeting the new requirements of this legislation.

Over the next two years, CBO expects that EPA would focus on implementing S. 697 primarily by producing guidance documents and cost-benefit analyses and performing other administrative tasks related to the rulemaking process for the review of the safety of new chemicals and substances currently in use. EPA would establish internal processes and information technology systems to prioritize the analysis of tens of thousands of chemicals. According to the agency, such activities are routinely carried out by contractors; as a result, most of the estimated $17 million in annual funding needed over this period would cover contractor costs. By 2018, enforcement of the new provisions of TSCA would begin and CBO estimates that EPA would shift funding to cover additional government personnel. CBO estimates that spending on new administrative activities over the next five years would total $72 million.

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

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

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

Direct spending and revenues

Enacting S. 697 also could affect direct spending and revenues because this bill would increase some existing civil and criminal penalties. Criminal penalties are recorded as revenues, then deposited in the Crime Victims Fund, and later spent; civil penalties are recorded as revenues. CBO estimates that any increase in criminal or civil penalties under the bill would not be significant.

Pay-As-You-Go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. CBO estimates that any increase in revenues and direct spending resulting from changes in criminal or civil penalties would not be significant over the 2016–2025 period.

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

Mandates that apply to both public and private entities

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

Mandates that apply to public entities only

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

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

Mandates that apply to private entities only

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

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

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

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

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

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

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

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

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

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

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

IMPROVEMENTS NEEDED TO S. 697

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

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

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

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

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

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

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

CHANGES IN EXISTING LAW

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

* * * * * * *

TOXIC SUBSTANCES CONTROL ACT

* * * * * * *

SEC. 2. FINDINGS, POLICY, AND INTENT.

(a) FINDINGS.—The Congress finds that—

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

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

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

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

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

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

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

(c) INTENT OF CONGRESS.—[It is the intent]

(1) ADMINISTRATION.—*It is the intent* of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the en-

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

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

(A) shall be administered in a manner that—

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

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

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

SEC. 3. DEFINITIONS.

As used in this Act:

(1) 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

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

The term "food" as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act), meat and meat food prod-

[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.

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

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

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

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

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

[(6)] *(7)* The term "health and safety study" means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act.

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

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

[(9)] *(10)* The term "new chemical substance" means any chemical substance which is not included in the chemical substance list compiled and published under section 8(b).

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

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

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

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

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

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

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

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

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

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

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

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

(A) the general population; or

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

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

(A) the—

(i) health and environmental effects, and

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

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

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

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

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

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

[(13)] *(18)* The term "State" means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico,

the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

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

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

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

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

(c) USE OF SCIENCE.—

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

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

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

(A) decisions made by the Administrator—

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

(ii) take into account the extent to which—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) manufacturers or processors of a substance;

(B) the public;

(C) other Federal departments or agencies; or

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

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

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

(g) TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.—

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

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

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

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

sure information as a lack of exposure or exposure potential;

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

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

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

(i) toxicity information;

(ii) computational toxicology and bioinformatics;

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

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

(h) SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

(1) SCHEDULE.—

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

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

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

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

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

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

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

(i) describe—

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

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

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

(ii) require the Administrator—

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

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

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

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

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

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

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

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

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

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

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

(D) GUIDANCE.—

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

which may be considered at the discretion of the Administrator.

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

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

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

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

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

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

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

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

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

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

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

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

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

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[(B) From time to time, but not less than once each 12 months, the Administrator shall review the adequacy of the standards for development of data prescribed in rules under subsection (a) and shall, if necessary, institute proceedings to make appropriate revisions of such standards.

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

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

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

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

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

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

peals the application of the rule to such substance or mixture or repeals the rule.

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

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

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

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

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

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

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

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

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

[In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General

and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

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

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

[(ii) ending—

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

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

whichever is later.

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

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

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

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

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

ments of the rule with respect to which such exemption was granted.

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

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

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

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

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

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

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

(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

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

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

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

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

(A) promulgating a rule;

(B) entering into a testing consent agreement; or

(C) issuing an order.

(4) CONTENTS.—

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

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

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

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

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

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

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

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

(b) STATEMENT OF NEED.—

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

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

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

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

(2) EXPLANATION IN CASE OF ORDER.—

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

(B) CONTENTS.—*A statement described in subparagraph (A) shall contain a description of—*

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

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

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

(c) REDUCTION OF TESTING ON VERTEBRATES.—

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

(A) encouraging and facilitating—

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

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

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

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

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

(vi) the submission of information from—

(I) animal-based studies; and

(II) emerging methods and models; and

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

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

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

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

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

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

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

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

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

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

(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

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

(i) the substance cannot be absorbed; or

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

(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

(4) VOLUNTARY TESTING.—

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

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

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

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

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

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

(d) TESTING REQUIREMENTS.—

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

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

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

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

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

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

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

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

(A) to develop the information; and

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

(3) EXEMPTIONS.—

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

(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

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

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

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

(i) by order, terminate the exemption; and

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

(4) TIERED TESTING.—

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

(B) SCREENING-LEVEL TESTS.—

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

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

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

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

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

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

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

[(e)] *(f)* PRIORITY LIST.—(1)(A) There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of a [rule] *rule, testing consent agreement, or order* [under subsection (a)] *under this subsection*. In making such a recommendation with respect to any chemical substance or mixture, the committee shall consider all relevant factors, including—

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

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

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

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

(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to

present an unreasonable risk of injury to health or the environment , *without taking into account cost or other nonrisk factors*,

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

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

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

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

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

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

eral Register the Administrator's reason for not initiating such a proceeding.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Act or of any [rule] *rule, testing consent agreement, or order* promulgated or order issued thereunder.

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

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

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

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

(2) any other information available to the Administrator,

which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings [from cancer, gene mutations, or birth defects], the Administrator shall, within the 180-day period beginning on the date of the receipt of such data or information, initiate appropriate action under section 5, 6, or 7 to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding that such risk is not unreasonable , *without taking into account cost or other nonrisk factors*. For good cause shown the Administrator may extend such period for an additional period of not more than 90 days. The Administrator shall publish in the Federal Register notice of any such extension and the reasons therefor. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review under chapter 7 of title 5, United States Code. [This subsection shall not take effect until two years after the effective date of this Act.]

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

SEC. 4A. PRIORITIZATION SCREENING.

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

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

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

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

(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

(A) IN GENERAL.—*Before the date of promulgation of the rule under paragraph (1) and not later than 180 days after the date of enactment of this section, the Administrator—*

(i) shall take into consideration and publish an initial list of high-priority substances and low-priority substances; and

(ii) pursuant to section 6(b), may initiate or continue safety assessments and safety determinations for those high-priority substances.

(B) REQUIREMENTS.—

(i) IN GENERAL.—*The initial list of chemical substances shall contain at least 10 high-priority substances, at least 5 of which are drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, and at least 10 low-priority substances.*

(ii) SUBSEQUENTLY IDENTIFIED SUBSTANCES.—*Insofar as possible, at least 50 percent of all substances subsequently identified by the Administrator as high-priority substances shall be drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, until all Work Plan chemicals have been designated under this subsection.*

(iii) PERSISTENCE AND BIOACCUMULATION.—*In developing the initial list and in identifying additional high-priority substances, the Administrator shall give preference to chemical substances scored as high for persistence and bioaccumulation in the October 2014 TSCA Work Plan and subsequent updates.*

(C) ADDITIONAL CHEMICAL REVIEWS.—*The Administrator shall, as soon as practicable and not later than—*

(i) 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 20 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 20 low-priority substances have been designated; and

(ii) 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 25 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 25 low-priority substances have been designated.

(3) IMPLEMENTATION.—

(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

(i) ACTIVE SUBSTANCES.—*In carrying out paragraph (1), the Administrator shall take into consideration ac-*

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

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

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

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

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

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

(iii) REPOPULATION.—

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

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

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

(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

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

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

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

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

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

(iii) CONSIDERATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) PRIORITIZATION SCREENING PROCESS AND DECISIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

may defer the prioritization screening decision for a reasonable period—

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

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

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

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

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

(B) provide 90 days for public comment.

(8) REVISIONS OF PRIOR DESIGNATIONS.—

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

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

(9) OTHER INFORMATION RELEVANT TO PRIORITIZATION.—

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

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

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

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

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

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

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

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

(ii) the Administrator determines—

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

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

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

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

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

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

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

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

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

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

(B) the regulation of those activities.

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

(1) REQUIREMENTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) REQUIREMENTS.—

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

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

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

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

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

[SEC. 5. MANUFACTURING AND PROCESSING NOTICES.]

SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.

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

[(a)] *(b)* [In General] *Notices.*—(1) Except as provided in [subsection (h)] *paragraph (3) and subsection (h)*, no person may—

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

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

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

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

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

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

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

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

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

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

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

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

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

[(C) a description of any other data concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

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

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

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

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

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

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

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

.

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

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

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

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

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

[(B) If—

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

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

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

[(2)(A) If a person—

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

[(ii) is not required by a rule promulgated under section 4 before the submission of such notice to submit test data for such substance,

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

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

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

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

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

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

presents or may present an unreasonable risk of injury to health or the environment.

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

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

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

[(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.

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

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

(d) REVIEW OF NOTICE.—

(1) INITIAL REVIEW.—

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

(i) conduct an initial review of the notice;

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

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

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

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

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

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

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

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

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

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

(4) RESTRICTIONS.—

(A) DETERMINATION BY ADMINISTRATOR.—

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

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

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

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

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

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

(ii)(I) initiate a rulemaking described in clause (i); or

(II) publish a statement describing the reasons of the Administrator for not initiating a rulemaking.

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

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

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

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

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

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

(I) in general; or

(II) for a particular use;

(iv) a prohibition or other restriction of—

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

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

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

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

(I) in general; or

(II) for a particular use.

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

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

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

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

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

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

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

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

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

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

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

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

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

the Administrator may issue a proposed order, to take effect on the expiration of the notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c), to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities.

[(B) A proposed order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c), and

(ii) unless the Administrator has, on or before the issuance of the proposed order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

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

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

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

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

the Administrator, through attorneys of the Environmental Protection Agency, shall apply to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer or processor, as the case may be, of such substance is found, resides, or transacts business for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance (or to prohibit or limit any combination of such activities).

[(ii) If the Administrator issues a proposed order under paragraph (1)(A) respecting a chemical substance but such order does not take effect because objections have been filed under paragraph (1)(C) with respect to it, the Administrator is not required to apply for an injunction under clause (i) respecting such substance if the Administrator determines, on the basis of such objections, that the determinations under paragraph (1)(A) may not be made.

[(B) A district court of the United States which receives an application under subparagraph (A)(i) for an injunction respecting a chemical substance shall issue such injunction if the court finds that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and

[(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or

[(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance.

[(C) Pending the completion of a proceeding for the issuance of an injunction under subparagraph (B) respecting a chemical substance, the court may, upon application of the Administrator made through attorneys of the Environmental Protection Agency, issue a temporary restraining order or a preliminary injunction to prohibit the manufacture, processing, distribution in commerce, use, or disposal of such a substance (or any combination of such activities) if the court finds that the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance may expire before such proceeding can be completed.

[(D) After the submission to the Administrator of test data sufficient to evaluate the health and environmental effects of a chemical substance subject to an injunction issued under subparagraph (B) and the evaluation of such data by the Administrator, the district court of the United States which issued such injunction shall, upon petition, dissolve the injunction unless the Administrator has initiated a proceeding for the issuance of a rule under section 6(a) respecting the substance. If such a proceeding has been initiated, such court shall continue the injunction in effect until the effective date of the rule promulgated in such proceeding or, if such proceeding is terminated without the promulgation of a rule, upon the termination of the proceeding, whichever occurs first.

[(f) PROTECTION AGAINST UNREASONABLE RISKS.—(1) If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance with respect to which notice is required by subsection (a), or that any combination of such activities, presents or will present an unreasonable risk of injury to health or environment before a rule promulgated under section 6 can protect against such risk, the Administrator shall, before the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

[(2) The Administrator may issue a proposed rule under section 6(a) to apply to a chemical substance with respect to which a finding was made under paragraph (1)—

[(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

[(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 6(a), or

[(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register. Section 6(d)(2)(B) shall apply with respect to such rule.

[(3)(A) The Administrator may—

[(i) issue a proposed order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1), or

[(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial

district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance.

A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance.

[(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 6 can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing or distribution in commerce of such substance or to prohibit any combination of such activities.

[(C) The provisions of subparagraphs (B) and (C) of subsection (e)(1) shall apply with respect to an order issued under clause (i) of subparagraph (A); and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B).

[(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C), the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment.

[(g) STATEMENT OF REASONS FOR NOT TAKING ACTION.—If the Administrator has not initiated any action under this section or section 6 or 7 to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, with respect to which notification or data is required by subsection (a)(1)(B) or (b), before the expiration of the notification period applicable to the manufacturing or processing of such substance, the Administrator shall publish a statement of the Administrator's reasons for not initiating such action. Such a statement shall be published in the Federal Register before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.]

(e) NOTICE OF COMMENCEMENT.—

(1) IN GENERAL.—*Not later than 30 days after the date on which a manufacturer that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—*

(A) the name of the manufacturer; and

(B) the initial date of nonexempt commercial manufacture.

(2) WITHDRAWAL.—*A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.*

(f) FURTHER EVALUATION.—*The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—*

(1) a notice of commencement for a chemical substance under subsection (c); or

(2) new information regarding the chemical substance.

(g) TRANSPARENCY.—*Subject to section 14, the Administrator shall make available to the public—*

(1) all notices, determinations, consent agreements, rules, and orders of the Administrator; and

(2) all information submitted or issued under this section.

(h) EXEMPTIONS.—(1) The Administrator may, upon application, exempt any person from any requirement of subsection [(a) or] (b) to permit such person to manufacture or process a chemical substance for test marketing purposes—

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment *, without taking into account cost or other nonrisk factors* and

(B) under such restrictions as the Administrator considers appropriate.

[(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit data for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that—

[(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which data has been submitted to the Administrator as required by subsection (b)(2), and

[(ii) submission of data by the applicant on such substance would be duplicative of data which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such data on such substance. No exemption which is granted under this subparagraph with respect to the submission of data for a chemical substance may take effect before the beginning of the reimbursement period applicable to such data.

[(B) If the Administrator exempts any person, under subparagraph (A), from submitting data required under subsection (b)(2) for a chemical substance because of the existence of previously submitted data and if such exemption is granted during the reimbursement period for such data, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

[(i) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b)(2) to submit such data, and

[(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

[(C) For purposes of this paragraph, the reimbursement period for any previously submitted data for a chemical substance is a period—

[(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such data to the Administrator, and

[(ii) ending—

[(I) five years after the date referred to in clause (i), or

[(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.]

[(3)] *(2)* The requirements of [subsections (a) and (b)] *subsection (b)* do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

[(4)] *(3)* The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment. A rule promulgated

under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (3) of section 6(c).

[(5)] *(4)* The Administrator may, upon application, make the requirements of subsections (a) and (b) inapplicable with respect to the manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

[(6)] *(5)* Immediately upon receipt of an application under [paragraph (1) or (5) *paragraph (1) or (4)* the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

[SEC. 6. REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES.]

SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.

[(a) SCOPE OF REGULATION.—If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents, or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements:

[(1) A requirement (A) prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

[(2) A requirement—

[(A) prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

[(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

[(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.

[(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

[(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

[(6)(A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.

[(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

[(7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such risk of injury, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Any requirement (or combination of requirements) imposed under this subsection may be limited in application to specified geographic areas.

[(b) QUALITY CONTROL.—If the Administrator has a reasonable basis to conclude that a particular manufacturer or processor is manufacturing or processing a chemical substance or mixture in a manner which unintentionally causes the chemical substance or mixture to present or which will cause it to present an unreasonable risk of injury to health or the environment—

[(1) the Administrator may by order require such manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of such chemical substance or mixture; and

[(2) if the Administrator determines—

[(A) that such quality control procedures are inadequate to prevent the chemical substance or mixture from presenting such risk of injury, the Administrator may order the manufacturer or processor to revise such quality control procedures to the extent necessary to remedy such inadequacy; or

[(B) that the use of such quality control procedures has resulted in the distribution in commerce of chemical substances or mixtures which present an unreasonable risk of injury to health or the environment, the Administrator may order the manufacturer or processor to (i) give notice

of such risk to processors or distributors in commerce of any such substance or mixture, or to both, and, to the extent reasonably ascertainable, to any other person in possession of or exposed to any such substance, (ii) to give public notice of such risk, and (iii) to provide such replacement or repurchase of any such substance or mixture as is necessary to adequately protect health or the environment.

A determination under subparagraph (A) or (B) of paragraph (2) shall be made on the record after opportunity for hearing in accordance with section 554 of title 5, United States Code. Any manufacturer or processor subject to a requirement to replace or repurchase a chemical substance or mixture may elect either to replace or repurchase the substance or mixture and shall take either such action in the manner prescribed by the Administrator.

[(c) PROMULGATION OF SUBSECTION (a) RULES.—(1) In promulgating any rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement with respect to—

[(A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture,

[(B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,

[(C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and

[(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule under subsection (a) to protect against such risk of injury unless the Administrator finds, in the Administrator's discretion, that it is in the public interest to protect against such risk under this Act. In making such a finding the Administrator shall consider (i) all relevant aspects of the risk, as determined by the Administrator in the Administrator's discretion, (ii) a comparison of the estimated costs of complying with actions taken under this Act and under such law (or laws), and (iii) the relative efficiency of actions under this Act and under such law (or laws) to protect against such risk of injury.

[(2) When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5, United States Code (without regard to any reference in such section to sections 556 and 557 of such title), and shall also (A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule; (B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available; (C) provide an opportunity for an informal hearing in accordance with paragraph (3); (D) promulgate, if appro-

priate, a final rule based on the matter in the rulemaking record (as defined in section 19(a)), and (E) make and publish with the rule the finding described in subsection (a).

[(3) Informal hearings required by paragraph (2)(C) shall be conducted by the Administrator in accordance with the following requirements:

[(A) Subject to subparagraph (B), an interested person is entitled—

[(i) to present such person's position orally or by documentary submissions (or both), and

[(ii) if the Administrator determines that there are disputed issues of material fact it is necessary to resolve, to present such rebuttal submissions and to conduct (or have conducted under subparagraph (B)(ii)) such cross-examination of persons as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to such issues.

[(B) The Administrator may prescribe such rules and make such rulings concerning procedures in such hearings to avoid unnecessary costs or delay. Such rules or rulings may include (i) the imposition of reasonable time limits on each interested person's oral presentations, and (ii) requirements that any cross-examination to which a person may be entitled under subparagraph (A) be conducted by the Administrator on behalf of that person in such manner as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to disputed issues of material fact.

[(C)(i) Except as provided in clause (ii), if a group of persons each of whom under subparagraphs (A) and (B) would be entitled to conduct (or have conducted) cross-examination and who are determined by the Administrator to have the same or similar interests in the proceeding cannot agree upon a single representative of such interests for purposes of cross-examination, the Administrator may make rules and rulings (I) limiting the representation of such interest for such purposes, and (II) governing the manner in which such cross-examination shall be limited.

[(ii) When any person who is a member of a group with respect to which the Administrator has made a determination under clause (i) is unable to agree upon group representation with the other members of the group, then such person shall not be denied under the authority of clause (i) the opportunity to conduct (or have conducted) cross-examination as to issues affecting the person's particular interests if (I) the person satisfies the Administrator that the person has made a reasonable and good faith effort to reach agreement upon group representation with the other members of the group and (II) the Administrator determines that there are substantial and relevant issues which are not adequately presented by the group representative.

[(D) A verbatim transcript shall be taken of any oral presentation made, and cross-examination conducted in any informal

hearing under this subsection. Such transcript shall be available to the public.

[(4)(A) The Administrator may, pursuant to rules prescribed by the Administrator, provide compensation for reasonable attorneys' fees, expert witness fees, and other costs of participating in a rulemaking proceeding for the promulgation of a rule under subsection (a) to any person—

[(i) who represents an interest which would substantially contribute to a fair determination of the issues to be resolved in the proceeding, and

[(ii) if—

[(I) the economic interest of such person is small in comparison to the costs of effective participation in the proceeding by such person, or

[(II) such person demonstrates to the satisfaction of the Administrator that such person does not have sufficient resources adequately to participate in the proceeding without compensation under this subparagraph.

In determining for purposes of clause (i) if an interest will substantially contribute to a fair determination of the issues to be resolved in a proceeding, the Administrator shall take into account the number and complexity of such issues and the extent to which representation of such interest will contribute to widespread public participation in the proceeding and representation of a fair balance of interests for the resolution of such issues.

[(B) In determining whether compensation should be provided to a person under subparagraph (A) and the amount of such compensation, the Administrator shall take into account the financial burden which will be incurred by such person in participating in the rulemaking proceeding. The Administrator shall take such action as may be necessary to ensure that the aggregate amount of compensation paid under this paragraph in any fiscal year to all persons who, in rulemaking proceedings in which they receive compensation, are persons who either—

[(i) would be regulated by the proposed rule, or

[(ii) represent persons who would be so regulated,

may not exceed 25 per centum of the aggregate amount paid as compensation under this paragraph to all persons in such fiscal year.

[(5) Paragraphs (1), (2), (3), and (4) of this subsection apply to the promulgation of a rule repealing, or making a substantive amendment to, a rule promulgated under subsection (a).

[(d) EFFECTIVE DATE.—(1) The Administrator shall specify in any rule under subsection (a) the date on which it shall take effect, which date shall be as soon as feasible.

[(2)(A) The Administrator may declare a proposed rule under subsection (a) to be effective upon its publication in the Federal Register and until the effective date of final action taken, in accordance with subparagraph (B), respecting such rule if—

[(i) the Administrator determines that—

[(I) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk

of serious or widespread injury to health or the environment before such effective date; and

[(II) making such proposed rule so effective is necessary to protect the public interest; and

[(ii) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under clause (i)(I), a court has in an action under section 7 granted relief with respect to such risk associated with such substance or mixture.

Such a proposed rule which is made so effective shall not, for purposes of judicial review, be considered final agency action.

[(B) If the Administrator makes a proposed rule effective upon its publication in the Federal Register, the Administrator shall, as expeditiously as possible, give interested persons prompt notice of such action, provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), for a hearing on such rule, and either promulgate such rule (as proposed or with modifications) or revoke it; and if such a hearing is requested, the Administrator shall commence the hearing within five days from the date such request is made unless the Administrator and the person making the request agree upon a later date for the hearing to begin, and after the hearing is concluded the Administrator shall, within ten days of the conclusion of the hearing, either promulgate such rule (as proposed or with modifications) or revoke it.]

(a) IN GENERAL.—The Administrator—

(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

(2) shall, as soon as practicable and not later than 6 months after the date on which a chemical substance is designated as a high-priority substance, define and publish the scope of the safety assessment and safety determination to be conducted pursuant to this section, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that the Administrator expects to consider;

(3) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

(4) shall complete a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

(5) shall promulgate a final rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; and

(6) may extend any deadline under [this subsection] *paragraph (4) or (5)* for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under [paragraphs (4) and (5) and] *this subsection, plus* any deferral under subsection (c)(2) does not exceed 2 years.

(b) PRIOR ACTIONS AND NOTICE OF EXISTING INFORMATION.—

(1) PRIOR-INITIATED ASSESSMENTS.—

(A) IN GENERAL.—*Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from con-*

tinuing or completing such a safety assessment or safety determination that was initiated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, prior to the effective date of the policies and procedures required to be established by the Administrator under section 3A or 4A.

(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—*As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.*

(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or rule solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure.

(3) NOTICE OF EXISTING INFORMATION.—

(A) IN GENERAL.—*The Administrator shall, where such information is available, take notice of existing information regarding hazard and exposure published by other Federal agencies and the National Academies and incorporate the information in safety assessments and safety determinations with the objective of increasing the efficiency of the safety assessments and safety determinations.*

(B) INCLUSION OF INFORMATION.—*Existing information described in subparagraph (A) should be included to the extent practicable and where the Administrator determines the information is relevant and scientifically reliable.*

(c) SAFETY DETERMINATIONS.—

(1) IN GENERAL.—*Based on a review of the information available to the Administrator, including draft safety assessments submitted by interested persons, and subject to section 18, the Administrator shall determine that—*

(A) the relevant chemical substance meets the safety standard;

(B) the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by rule under subsection (d)—

(i) impose restrictions necessary to ensure that the chemical substance meets the safety standard under the conditions of use; or

(ii) if the safety standard cannot be met with the application of restrictions, ban or phase out the chemical substance, as appropriate; or

(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).

(2) ADDITIONAL INFORMATION.—*If the Administrator determines that additional information is necessary to make a safety*

assessment or safety determination for a high-priority substance, the Administrator—

(A) shall provide an opportunity for interested persons to submit the additional information;

(B) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

(C) may defer, for a reasonable period consistent with the deadlines described in subsection (a), a safety assessment and safety determination until after receipt of the information; and

(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety determination, shall make a determination under paragraph (1).

(3) ESTABLISHMENT OF DEADLINE.—*In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.*

(d) RULE.—

(1) IMPLEMENTATION.—*If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a rule establishing restrictions necessary to ensure that the chemical substance meets the safety standard.*

(2) SCOPE.—

(A) IN GENERAL.—*The rule promulgated pursuant to this subsection—*

(i) may apply to mixtures containing the chemical substance, as appropriate;

(ii) shall include dates by which compliance is mandatory, which—

(I) shall be as soon as practicable;

(II) in the case of a ban or phase-out of the chemical substance, shall implement the ban or phase-out in as short a period as practicable; and

(III) as determined by the Administrator, may vary for different affected persons; and

(iii) shall exempt replacement parts that are manufactured prior to the effective date of the rule for articles that are first manufactured prior to the effective date of the rule unless the Administrator finds the replacement parts contribute significantly to the identified risk; and

(iv) shall, in selecting among prohibitions and other restrictions, apply such prohibitions or other restrictions to articles containing the chemical substance only to the extent necessary to address the identified risks in order to determine that the chemical substance meets the safety standard.

(B) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines ranks high for persistence and bioaccumulation, the Administrator shall, in selecting among prohibitions and

other restrictions that the Administrator determines are sufficient to ensure that the chemical substance meets the safety standard, reduce exposure to the substance to the maximum extent practicable.

(C) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or other restriction under this subsection to address workplace exposures.

(D) DEFINITION OF REQUIREMENT.—*For the purposes of this Act, the term 'requirement' as used in this section does not displace common law.*

(3) RESTRICTIONS.—*A restriction under paragraph (1) may include, as appropriate—*

(A) subject to section 18, a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator;

(B) a requirement that manufacturers or processors of the chemical substance shall—

(i) make and retain records of the processes used to manufacture or process the chemical substance;

(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or

(iii) monitor or conduct tests that are reasonably necessary to ensure compliance with the requirements of any rule under this subsection;

(C) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

(D) a requirement to ban or phase out, or any other rule regarding, the manufacture, processing, or distribution in commerce of the chemical substance for—

(i) a particular use;

(ii) a particular use at a concentration in excess of a level specified by the Administrator; or

(iii) all uses;

(E) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—

(i) a particular use; or

(ii) a particular use at a concentration in excess of a level specified by the Administrator;

(F) a requirement to ban, phase out, or otherwise restrict any method of commercial use of the chemical substance;

(G) a requirement to ban, phase out, or otherwise restrict any method of disposal of the chemical substance or any article containing the chemical substance; and

(H) a requirement directing manufacturers or processors of the chemical substance to give notice of the Administra-

tor's determination under subsection (c)(1)(B) to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

(4) ANALYSIS FOR RULEMAKING.—

(A) CONSIDERATIONS.—*In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.*

(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

(C) PUBLIC AVAILABILITY.—*In proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.*

(D) STATEMENT REQUIRED.—*In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.*

(5) EXEMPTIONS.—

(A) IN GENERAL.—*The Administrator may exempt 1 or more uses of a chemical substance from any restriction in a rule promulgated under paragraph (1) if the Administrator determines that—*

(i) the rule cannot be complied with, without—

(I) harming national security;

(II) causing significant disruption in the national economy due to the lack of availability of a chemical substance; or

(III) interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or

(ii) the use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

(B) EXEMPTION ANALYSIS.—*In proposing a rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall make publicly available any analysis conducted under this paragraph to assess the need for the exemption.*

(C) STATEMENT REQUIRED.—*In making final a rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall include a statement describing how the analysis considered under subparagraph (B) was taken into account.*

(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—*In determining whether an exemption should be granted under this*

paragraph for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more technically and economically feasible alternatives to the chemical substance most likely to be used in place of the chemical substance under the conditions of use if the rule is promulgated.

(E) CONDITIONS.—*As part of a rule promulgated under paragraph (1), the Administrator shall include conditions in any exemption established under this paragraph, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption.*

(F) DURATION.—

(i) IN GENERAL.—*The Administrator shall establish, as part of a rule under paragraph (1) that contains an exemption under this paragraph, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis.*

(ii) AUTHORITY OF ADMINISTRATOR.—*The Administrator, by rule, may extend, modify, or eliminate the exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or is no longer necessary.*

(iii) CONSIDERATIONS.—

(I) IN GENERAL.—*Subject to subclause (II), the Administrator shall issue exemptions and establish time periods by considering factors determined by the Administrator to be relevant to the goals of fostering innovation and the development of alternatives that meet the safety standard.*

(II) LIMITATION.—*Any renewal of an exemption in the case of a rule requiring the ban or phase-out of a chemical substance shall not exceed 5 years.*

(e) IMMEDIATE EFFECT.—*The Administrator may declare a proposed rule under subsection (d)(1) to be effective on publication of the rule in the Federal Register and until the effective date of final action taken respecting the rule, if—*

(1) the Administrator determines that—

(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to the proposed rule or any combination of those activities is likely to result in a risk of serious or widespread injury to health or the environment before the effective date; and

(B) making the proposed rule so effective is necessary to protect the public interest; and

(2) in the case of a proposed rule to prohibit the manufacture, processing, or distribution in commerce of a chemical substance or mixture because of the risk determined under paragraph

(1)(A), a court has granted relief in an action under section 7 with respect to that risk associated with the chemical substance or mixture.

(f) FINAL AGENCY ACTION.—*Under this section and subject to section 18—*

(1) a safety determination, and the associated safety assessment, for a chemical substance that the Administrator determines under subsection (c) meets the safety standard, shall be considered to be a final agency action, effective beginning on the date of issuance of the final safety determination; and

(2) a final rule promulgated under subsection (d)(1), and the associated safety assessment and safety determination that a chemical substance does not meet the safety standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule.

[(e)] *(g)* POLYCHLORINATED BIPHENYLS.—(1) Within six months after the effective date of this Act the Administrator shall promulgate rules to—

(A) prescribe methods for the disposal of polychlorinated biphenyls, and

(B) require polychlorinated biphenyls to be marked with clear and adequate warnings, and instructions with respect to their processing, distribution in commerce, use, or disposal or with respect to any combination of such activities.

Requirements prescribed by rules under this paragraph shall be consistent with the requirements of paragraphs (2) and (3).

(2)(A) Except as provided under subparagraph (B), effective one year after the effective date of this Act no person may manufacture, process, or distribute in commerce or use any polychlorinated biphenyl in any manner other than in a totally enclosed manner.

(B) The Administrator may by rule authorize the manufacture, processing, distribution in commerce or use (or any combination of such activities) of any polychlorinated biphenyl in a manner other than in a totally enclosed manner if the Administrator finds that such manufacture, processing, distribution in commerce, or use (or combination of such activities) will not present an unreasonable risk of injury to health or the environment.

(C) For the purposes of this paragraph, the term "totally enclosed manner" means any manner which will ensure that any exposure of human beings or the environment by the polychlorinated biphenyl will be insignificant as determined by the Administrator by rule.

(3)(A) Except as provided in subparagraphs (B), (C), and (D)—

(i) no person may manufacture any polychlorinated biphenyl after two years after the effective date of this Act, and

(ii) no person may process or distribute in commerce any polychlorinated biphenyl after two and one-half years after such date.

(B) Any person may petition the Administrator for an exemption from the requirements of subparagraph (A), and the Administrator may grant by rule such an exemption if the Administrator finds that—

(i) an unreasonable risk of injury to health or environment would not result, and

(ii) good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl.

An exemption granted under this subparagraph shall be subject to such terms and conditions as the Administrator may prescribe and shall be in effect for such period (but not more than 1 year from the date it is granted, except as provided in subparagraph (D)) as the Administrator may prescribe.

(C) Subparagraph (A) shall not apply to the distribution in commerce of any polychlorinated biphenyl if such polychlorinated biphenyl was sold for purposes other than resale before two and one-half years after the date of enactment of this Act.

(D)[4] The Administrator may extend an exemption granted pursuant to subparagraph (B) that has not yet expired for a period not to exceed 60 days for the purpose of authorizing the Secretary of Defense and the Secretaries of the military departments to provide for the transportation into the customs territory of the United States of polychlorinated biphenyls generated by or under the control of the Department of Defense for purposes of their disposal, treatment, or storage in the customs territory of the United States if those polychlorinated biphenyls are already in transit from their storage locations but the Administrator determines, in the sole discretion of the Administrator, they would not otherwise arrive in the customs territory of the United States within the period of the original exemption. The Administrator shall promptly publish notice of such extension in the Federal Register.]

[(4) Any rule under paragraph (1), (2)(B), or (3)(B) shall be promulgated in accordance with paragraphs (2), (3), and (4) of subsection (c).]

[(5)] *(4)* This subsection does not limit the authority of the Administrator, under any other provision of this Act or any other Federal law, to take action respecting any polychlorinated biphenyl.

[(f)] *(h)* MERCURY.—

(1) PROHIBITION ON SALE, DISTRIBUTION, OR TRANSFER OF ELEMENTAL MERCURY BY FEDERAL AGENCIES.—Except as provided in paragraph (2), effective beginning on the date of enactment of this subsection, no Federal agency shall convey, sell, or distribute to any other Federal agency, any State or local government agency, or any private individual or entity any elemental mercury under the control or jurisdiction of the Federal agency.

(2) EXCEPTIONS.—Paragraph (1) shall not apply to—

(A) a transfer between Federal agencies of elemental mercury for the sole purpose of facilitating storage of mercury to carry out this Act; or

(B) a conveyance, sale, distribution, or transfer of coal.

(3) LEASES OF FEDERAL COAL.—Nothing in this subsection prohibits the leasing of coal.

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[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.

SEC. 7. IMMINENT HAZARDS.

[(a) ACTIONS AUTHORIZED AND REQUIRED.—(1) The Administrator may commence a civil action in an appropriate district court of the United States—

[(A) for seizure of an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture,

[(B) for relief (as authorized by subsection (b)) against any person who manufactures, processes, distributes in commerce, or uses, or disposes of, an imminent hazardous chemical substance or mixture or any article containing such a substance or mixture, or

[(C) for both such seizure and relief.

A civil action may be commenced under this paragraph notwithstanding the existence of a rule under section 4, 5, 6, or title IV or an order under section 5 or title IV, and notwithstanding the pendency of any administrative or judicial proceeding under any provision of this Act.

[(2) If the Administrator has not made a rule under section 6(a) immediately effective (as authorized by subsection 6(d)(2)(A)(i)) with respect to an imminently hazardous chemical substance or mixture, the Administrator shall commence in a district court of the United States with respect to such substance or mixture or article containing such substance or mixture a civil action described in subparagraph (A), (B), or (C) of paragraph (1).]

(a) CIVIL ACTIONS.—

(1) IN GENERAL.—*The Administrator may commence a civil action in an appropriate United States district court for—*

(A) seizure of an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture;

(B) relief (as authorized by subsection (b)) against any person that manufactures, processes, distributes in commerce, uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture; or

(C) both seizure described in subparagraph (A) and relief described in subparagraph (B).

(2) RULE, ORDER, OR OTHER PROCEEDING.—*A civil action may be commenced under this paragraph, notwithstanding—*

(A) the existence of a decision, rule, consent agreement, or order by the Administrator under section 4, 4A, 5, or 6 or title IV or VI; or

(B) the pendency of any administrative or judicial proceeding under any provision of this Act.

(b) RELIEF AUTHORIZED.—(1) The district court of the United States in which an action under subsection (a) is brought shall have jurisdiction to grant such temporary or permanent relief as may be necessary to protect health or the environment from the [unreasonable] risk associated with the chemical substance, mixture, or article involved in such action.

(2) In the case of an action under subsection (a) brought against a person who manufactures, processes, or distributes in commerce a chemical substance or mixture or an article containing a chemical

substance or mixture, the relief authorized by paragraph (1) may include the issuance of a mandatory order requiring (A) in the case of purchasers of such substance, mixture, or article known to the defendant, notification to such purchasers of the risk associated with it; (B) public notice of such risk; (C) recall; (D) the replacement or repurchase of such substance, mixture, or article; or (E) any combination of the actions described in the preceding clauses.

(3) In the case of an action under subsection (a) against a chemical substance, mixture, or article, such substance, mixture, or article may be proceeded against by process of libel for its seizure and condemnation. Proceedings in such an action shall conform as nearly as possible to proceedings in rem in admiralty.

(c) VENUE AND CONSOLIDATION.—(1)(A) An action under subsection (a) against a person who manufactures, processes, or distributes a chemical substance or mixture or an article containing a chemical substance or mixture may be brought in the United States District Court for the District of Columbia or for any judicial district in which any of the defendants is found, resides, or transacts business; and process in such an action may be served on a defendant in any other district in which such defendant resides or may be found. An action under subsection (a) against a chemical substance, mixture, or article may be brought in any United States district court within the jurisdiction of which the substance, mixture, or article is found.

(B) In determining the judicial district in which an action may be brought under subsection (a) in instances in which such action may be brought in more than one judicial district, the Administrator shall take into account the convenience of the parties.

(C) 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)] *section* [6(c)] *6(d)*.

(e) REPRESENTATION.—Notwithstanding any other provision of law, in any action under subsection (a), the Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator in such an action.

(f) DEFINITION.—For the purposes of subsection (a), the term "imminently hazardous chemical substance or mixture" means a chemical substance or mixture which presents an imminent [and unreasonable] risk of serious or widespread injury to health or the environment. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance

[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.

or mixture, or that any combination of such activities, is likely to result in such injury to health or the environment before a final rule under section 6 can protect against such risk.

SEC. 8. REPORTING AND RETENTION OF INFORMATION.

(a) REPORTS.—(1) The Administrator shall promulgate rules under which—

(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require, and

(B) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process—

(i) a mixture, or

(ii) a chemical substance in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product,

shall maintain records and submit to the Administrator reports but only to the extent the Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of this Act.

The Administrator may not require in a rule promulgated under this paragraph the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that the maintenance of such records or the submission of such reports, or both, is necessary for the effective enforcement of this Act. For purposes of the compilation of the list of chemical substances required under subsection (b), the Administrator shall promulgate rules pursuant to this subsection not later than 180 days after the effective date of this Act.

(2) The Administrator may require under paragraph (1) maintenance of records and reporting with respect to the following insofar as known to the person making the report or insofar as reasonably ascertainable:

(A) The common or trade name, the chemical identity, and molecular structure of each chemical substance or mixture for which such a report is required.

(B) The categories or proposed categories of use of each such substance or mixture.

(C) The total amount of each substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.

(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.

(E) All existing data concerning the environmental and health effects of such substance or mixture.

(F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.

(G) In the initial report under paragraph (1) on such substance or mixture, the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method.

To the extent feasible, the Administrator shall not require under paragraph (1), any reporting which is unnecessary or duplicative.

(3)(A)(i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as the Administrator may require for publication of the first list of chemical substances required by subsection (b).

(ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture—

(I) subject to a rule proposed or promulgated under section 4, [5(b)(4)] *5*, or 6, or an order in effect under *section 4 or* section [5(e),] *5(d)(4) or*

(II) with respect to which relief has been granted pursuant to a civil action brought under section 5 or 7,

to maintain such records on such substance or mixture, and to submit to the Administrator such reports on such substance or mixture, as the Administrator may reasonably require. A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2).

(B) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of this paragraph and paragraph (1).

(4) RULES.—

(A) DEADLINE.—

(i) IN GENERAL.—*Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall promulgate rules requiring the maintenance of records and the reporting of information known or reasonably ascertainable by the person making the report, including rules requiring processors to report information, so that the Administrator has the information necessary to carry out sections 4 and 6.*

(ii) MODIFICATION OF PRIOR RULES.—*In carrying out this subparagraph, the Administrator may modify, as appropriate, rules promulgated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.*

(B) CONTENTS.—*The rules promulgated pursuant to subparagraph (A)—*

(i) may impose different reporting and recordkeeping requirements on manufacturers and processors; and

(ii) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported.

(C) ADMINISTRATION.—*In implementing the reporting and recordkeeping requirements under this paragraph, the Administrator shall take measures—*

(i) to limit the potential for duplication in reporting requirements;

(ii) to minimize the impact of the rules on small manufacturers and processors; and

(iii) to apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.

(5) GUIDANCE.—*The Administrator shall develop guidance relating to the information required to be reported under the rules promulgated under this subsection.*

(b) INVENTORY.—(1) The Administrator shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States. Such list shall at least include each chemical substance which any person reports, under section 5 or subsection (a) of this section, is manufactured or processed in the United States. Such list may not include any chemical substance which was not manufactured or processed in the United States within three years before the effective date of the rules promulgated pursuant to the last sentence of subsection (a)(1). In the case of a chemical substance for which a notice is submitted in accordance with section 5, such chemical substance shall be included in such list as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in the United States. The Administrator shall first publish such a list not later than 315 days after the effective date of this Act. The Administrator shall not include in such list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product.

(2) To the extent consistent with the purposes of this Act, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

(3) NOMENCLATURE.—

(A) IN GENERAL.—*In carrying out paragraph (1), the Administrator shall—*

(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Sub-

stances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

(I) cement, Portland, chemicals, CAS No. 65997–15–1;

(II) cement, alumina, chemicals, CAS No. 65997–16–2;

(III) glass, oxide, chemicals, CAS No. 65997–17–3;

(IV) frits, chemicals, CAS No. 65997–18–4;

(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

(i) IN GENERAL.—*If an existing guidance allows for multiple nomenclature conventions, the Administrator shall—*

(I) maintain the nomenclature conventions for substances; and

(II) develop new guidance that—

(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

(ii) MULTIPLE CAS NUMBERS.—*For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.*

(4) CHEMICAL SUBSTANCES IN COMMERCE.—

(A) RULES.—

(i) IN GENERAL.—*Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator, by rule, shall require manufacturers and processors to notify the Administrator, by not later than 180 days after the date of promulgation of the rule, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.*

(ii) ACTIVE SUBSTANCES.—*The Administrator shall, pursuant to paragraph (5)(A), designate chemical sub-*

stances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—The rule promulgated by the Administrator pursuant to subparagraph (A) shall require—

(i) the Administrator to maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

(ii) a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

(iii) the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C).

(C) REVIEW PLAN.—*Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are notified pursuant to subparagraph (A) or identified as active substances under subsection (f)(1).*

(D) REQUIREMENTS OF REVIEW PLAN.—The review plan under subparagraph (C) shall—

(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

(ii) require the Administrator, in accordance with section 14—

(I) to review each substantiation—

(aa) submitted pursuant to clause (i) to determine if the claim warrants protection from disclosure; and

(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

(II) approve, modify, or deny each claim; and

(III) except as provided in this section and section 14, protect from disclosure information for

which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

(iii) encourage manufacturers or processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

(E) TIMELINE FOR COMPLETION OF REVIEWS.—

(i) IN GENERAL.—*The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).*

(ii) CONSIDERATIONS.—

(I) IN GENERAL.—*The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of applicable claims needing review and the available resources.*

(II) ANNUAL GOAL.—*The Administrator shall publish an annual goal for the number of reviews to be completed over the course of implementation of the plan.*

(5) ACTIVE AND INACTIVE SUBSTANCES.—

(A) IN GENERAL.—*The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).*

(B) UPDATE.—*The Administrator shall update the list of chemical substances designated as active substances as soon as practicable after the date of publication of the most recent data reported under—*

(i) part 711 of title 40, Code of Federal Regulations (or successor regulations); and

(ii) the rules promulgated pursuant to subsection (a)(4).

(C) CHANGE TO ACTIVE STATUS.—

(i) IN GENERAL.—*Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the*

date on which the inactive substance is manufactured or processed.

(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—*If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the inactive substance as confidential, the person shall—*

(I) in the notice submitted under clause (i), assert the claim; and

(II) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

(iii) ACTIVE STATUS.—*On receiving a notification under clause (i), the Administrator shall—*

(I) designate the applicable chemical substance as an active substance;

(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific identity of the chemical substance and approve, modify, or deny the claim;

(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of not less than 10 years, unless, prior to the expiration of the period—

(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines to be necessary.

(D) CATEGORY STATUS.—*The list of inactive substances shall not be considered to be a category for purposes of section 26(c).*

(6) INTERIM LIST OF ACTIVE SUBSTANCES.—*Prior to the promulgation of the rule required under* [this subsection] *paragraph (4)(A)*, the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (or successor regulations), during the reporting period that most closely preceded the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as the interim list of active substances for the purposes of section 4A.

(7) PUBLIC PARTICIPATION.—*Subject to this subsection, the Administrator shall make available to the public—*

(A) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—

(i) an active substance; or

(ii) an inactive substance;

(B) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received and approved by the Administrator pursuant to section 14; and

(C) subject to section 14(g), the specific identity of any active substance for which—

(i) no claim of protection against disclosure of the specific identity of the active substance pursuant to this subsection was received;

(ii) a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or

(iii) the time period for protection against disclosure of the specific identity of the active substance has expired.

(8) LIMITATION.—*No person may assert a new claim under this subsection for protection from disclosure of a specific identity of any active or inactive chemical substance for which a notice is received under paragraph (4)(A)(i) or (5)(C)(i) that is not on the confidential portion of the list published under paragraph (1).*

(9) CERTIFICATION.—*Under the* [rule] *rules* promulgated under this subsection, manufacturers and processors shall be required—

(A) to certify that each report the manufacturer or processor submits complies with the requirements of the rule, and that any confidentiality claims are true and correct; and

(B) to retain a record supporting the certification for a period of 5 years beginning on the last day of the submission period.

* * * * * * *

(e) NOTICE TO ADMINISTRATOR OF SUBSTANTIAL RISKS.—[Any person]

(1) IN GENERAL.—*Any person* who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

(2) APPLICABILITY.—*Any person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does*

not present a substantial risk of injury to health and the environment.

(f) DEFINITIONS.—[For purposes of this section, the] *In this section:*

(1) ACTIVE SUBSTANCE.—*The term 'active substance' means a chemical substance—*

(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

(B) that is added to the list published under subsection (b)(1) after that date of enactment; or

(C) for which a notice is received under subsection (b)(5)(C).

(2) INACTIVE SUBSTANCE.—*The term 'inactive substance' means a chemical substance on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).*

(3) MANUFACTURE; PROCESS.—*The*terms "manufacture" and "process" mean manufacture or process for commercial purposes.

SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.

(a) LAWS NOT ADMINISTERED BY THE ADMINISTRATOR.—(1) If the Administrator has reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, [presents or will present an unreasonable risk of injury to health or the environment] *does not meet the safety standard* and determines, in the Administrator's discretion, that [such risk] *the risk posed by the substance or mixture* may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—

(A)(i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and

(ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and

(B) to respond to the Administrator with respect to the matters described in subparagraph (A).

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested response within such time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made. The response of an agency shall be accompanied by a detailed state-

ment of the findings and conclusions of the agency and shall be published in the Federal Register.

(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either—

(A) issues an order declaring that the activity or combination of activities specified in the description of the risk described in the report does not present the risk described in the report, or

(B) initiates, within 90 days of the publication in the Federal Register of the response of the agency under paragraph (1), action under the law (or laws) administered by such agency to protect against such risk associated with such activity or combination of activities,

the Administrator may not take any action under [section 6 or 7] *section 6(d) or section 7* with respect to such risk.

(3) If the Administrator has initiated action under [section 6 or 7] *section 6(d) or 7* with respect to a risk associated with a chemical substance or mixture which was the subject of a report made to an agency under paragraph (1), such agency shall before taking action under the law (or laws) administered by it to protect against such risk consult with the Administrator for the purpose of avoiding duplication of Federal action against such risk.

(b) LAWS ADMINISTERED BY THE ADMINISTRATOR.—The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

(c) OCCUPATIONAL SAFETY AND HEALTH.—In exercising any authority under this Act, the Administrator shall not, for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

(d) COORDINATION.—In administering this Act, the Administrator shall consult and coordinate with the Secretary of [Health, Education, and Welfare] *Health and Human Services* and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes. The Administrator shall, in the report required by section 30, report annually to the Congress on actions taken to coordinate with such other Federal departments, agencies, or instrumentalities, and on actions taken to coordinate the author-

ity under this Act with the authority granted under other Acts referred to in subsection (b).

(e) EXPOSURE INFORMATION.—*If the Administrator obtains information related to exposures or releases of a chemical substance that may be prevented or reduced under another Federal law, including laws not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.*

SEC. 10. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION AND UTILIZATION OF DATA.

(a) AUTHORITY.—The Administrator shall, in consultation and cooperation with the Secretary of [Health, Education, and Welfare] *Health and Human Services* and with other heads of appropriate departments and agencies, conduct such research, development, and monitoring as is necessary to carry out the purposes of this Act. The Administrator may enter into contracts and may make grants for research, development, and monitoring under this subsection. Contracts may be entered into under this subsection without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 14 U.S.C. 5).

(b) DATA SYSTEMS.—(1) The Administrator shall establish, administer, and be responsible for the continuing activities of an interagency committee which shall design, establish, and coordinate an efficient and effective system, within the Environmental Protection Agency, for the collection, dissemination to other Federal departments and agencies, and use of data submitted to the Administrator under this Act.

(2)(A) The Administrator shall, in consultation and cooperation with the Secretary of [Health, Education, and Welfare] *Health and Human Services* and other heads of appropriate departments and agencies design, establish, and coordinate an efficient and effective system for the retrieval of toxicological and other scientific data which could be useful to the Administrator in carrying out the purposes of this Act. Systematized retrieval shall be developed for use by all Federal and other departments and agencies with responsibilities in the area of regulation or study of chemical substances and mixtures and their effect on health or the environment.

(B) The Administrator, in consultation and cooperation with the Secretary of [Health, Education, and Welfare] *Health and Human Services*, may make grants and enter into contracts for the development of a data retrieval system described in subparagraph (A). Contracts may be entered into under this subparagraph without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5).

(c) SCREENING TECHNIQUES.—The Administrator shall coordinate, with the Assistant Secretary for Health of the Department of [Health, Education, and Welfare] *Health and Human Services*, research undertaken by the Administrator and directed toward the development of rapid, reliable, and economical screening techniques for carcinogenic, mutagenic, teratogenic, and ecological effects of chemical substances and mixtures.

(d) MONITORING.—The Administrator shall, in consultation and cooperation with the Secretary of [Health, Education, and Welfare] *Health and Human Services*, establish and be responsible for re-

search aimed at the development, in cooperation with local, State, and Federal agencies, of monitoring techniques and instruments which may be used in the detection of toxic chemical substances and mixtures and which are reliable, economical, and capable of being implemented under a wide variety of conditions.

(e) BASIC RESEARCH.—The Administrator shall, in consultation and cooperation with the Secretary of [Health, Education, and Welfare] *Health and Human Services*, establish research programs to develop the fundamental scientific basis of the screening and monitoring techniques described in subsections (c) and (d), the bounds of the reliability of such techniques, and the opportunities for their improvement.

(f) TRAINING.—The Administrator shall establish and promote programs and workshops to train or facilitate the training of Federal laboratory and technical personnel in existing or newly developed screening and monitoring techniques.

(g) EXCHANGE OF RESEARCH AND DEVELOPMENT RESULTS.—The Administrator shall, in consultation with the Secretary of [Health, Education, and Welfare] *Health and Human Services* and other heads of appropriate departments and agencies, establish and coordinate a system for exchange among Federal, State, and local authorities of research and development results respecting toxic chemical substances and mixtures, including a system to facilitate and promote the development of standard data format and analysis and consistent testing procedures.

* * * * * * *

SEC. 12. EXPORTS.

(a) IN GENERAL.—(1) Except as provided in paragraph (2) and subsections (b) and (c), this Act (other than section 8) shall not apply to any chemical substance, mixture, or to an article containing a chemical substance or mixture, if—

(A) it can be shown that such substance, mixture, or article is being manufactured, processed, or distributed in commerce for export from the United States, unless such substance, mixture, or article was, in fact, manufactured, processed, or distributed in commerce, for use in the United States, and

(B) such substance, mixture, or article (when distributed in commerce), or any container in which it is enclosed (when so distributed), bears a stamp or label stating that such substance, mixture, or article is intended for export.

[(2) Paragraph (1) shall not apply to any chemical substance, mixture, or article if the Administrator finds that the substance, mixture, or article will present an unreasonable risk of injury to health within the United States or to the environment of the United States. The Administrator may require, under section 4, testing of any chemical substance or mixture exempted from this Act by paragraph (1) for the purpose of determining whether or not such substance or mixture presents an unreasonable risk of injury to health within the United States or to the environment of the United States.]

(2) EXCEPTION.—*Paragraph (1) shall not apply to any chemical substance that the Administrator determines—*

(A) under section 5 is not likely to meet the safety standard; or

(B) under section 6 does not meet the safety standard.

(3) WAIVERS.—*For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—*

(A) determine that paragraph (1) shall not apply to the mixture or article; or

(B) establish a threshold concentration in a mixture or article at which paragraph (1) shall not apply.

(4) TESTING.—*The Administrator may require testing under section 4 of any chemical substance or mixture exempted from this Act under paragraph (1) for the purpose of determining whether the chemical substance or mixture meets the safety standard within the United States.*

[(b) NOTICE.—[(1) If any person exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under section 4 or 5(b), such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of the availability of the data submitted to the Administrator under such section for such substance or mixture.

[(2) If any person exports or intends to export to a foreign country a chemical substance or mixture for which an order has been issued under section 5 or a rule has been proposed or promulgated under section 5 or 6, or with respect to which an action is pending, or relief has been granted under section 5 or 7, such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of such rule, order, action, or relief.]

(b) NOTICE.—

(1) IN GENERAL.—*A person shall notify the Administrator that the person is exporting or intends to export to a foreign country—*

(A) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 5 is not likely to meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

(B) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 6 does not meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

(C) a chemical substance for which the United States is obligated by treaty to provide export notification;

(D) a chemical substance or mixture subject to a significant new use rule, or a prohibition or other restriction pursuant to a rule, order, or consent agreement in effect under this Act; or

(E) a chemical substance or mixture for which the submission of information is required under section 4.

(2) RULES.—

(A) IN GENERAL.—*The Administrator shall promulgate rules to carry out paragraph (1).*

(B) CONTENTS.—*The rules promulgated pursuant to subparagraph (A) shall—*

(i) include such exemptions as the Administrator determines to be appropriate, which may include exemptions identified under section 5(h); and

(ii) indicate whether, or to what extent, the rules apply to articles containing a chemical substance or mixture described in paragraph (1).

(3) NOTIFICATION.—*The Administrator shall submit to the government of each country to which a chemical substance or mixture is exported—*

(A) for a chemical substance or mixture described in subparagraph (A), (B), or (D) of paragraph (1), a notice of the determination, rule, order, consent agreement, requirement, or designation;

(B) for a chemical substance described in paragraph (1)(C), a notice that satisfies the obligation of the United States under the applicable treaty; and

(C) for a chemical substance or mixture described in paragraph (1)(E), a notice of availability of the information on the chemical substance or mixture submitted to the Administrator.

(c) PROHIBITION ON EXPORT OF ELEMENTAL MERCURY.—

(1) PROHIBITION.—Effective January 1, 2013, the export of elemental mercury from the United States is prohibited.

(2) INAPPLICABILITY OF SUBSECTION (a).—Subsection (a) shall not apply to this subsection.

[(3) REPORT TO CONGRESS ON MERCURY COMPOUNDS.—

[(A) REPORT.—Not later than one year after the date of enactment of the Mercury Export Ban Act of 2008, the Administrator shall publish and submit to Congress a report on mercuric chloride, mercurous chloride or calomel, mercuric oxide, and other mercury compounds, if any, that may currently be used in significant quantities in products or processes. Such report shall include an analysis of—

[(i) the sources and amounts of each of the mercury compounds imported into the United States or manufactured in the United States annually;

[(ii) the purposes for which each of these compounds are used domestically, the amount of these compounds currently consumed annually for each purpose, and the estimated amounts to be consumed for each purpose in 2010 and beyond;

[(iii) the sources and amounts of each mercury compound exported from the United States annually in each of the last three years;

[(iv) the potential for these compounds to be processed into elemental mercury after export from the United States; and

[(v) other relevant information that Congress should consider in determining whether to extend the export prohibition to include one or more of these mercury compounds.

[(B) PROCEDURE.—For the purpose of preparing the report under this paragraph, the Administrator may utilize the information gathering authorities of this title, including sections 10 and 11.]

[(4)] *(3)* ESSENTIAL USE EXEMPTION.—(A) Any person residing in the United States may petition the Administrator for an exemption from the prohibition in paragraph (1), and the Administrator may grant by rule, after notice and opportunity for comment, an exemption for a specified use at an identified foreign facility if the Administrator finds that—

(i) nonmercury alternatives for the specified use are not available in the country where the facility is located;

(ii) there is no other source of elemental mercury available from domestic supplies (not including new mercury mines) in the country where the elemental mercury will be used;

(iii) the country where the elemental mercury will be used certifies its support for the exemption;

(iv) the export will be conducted in such a manner as to ensure the elemental mercury will be used at the identified facility as described in the petition, and not otherwise diverted for other uses for any reason;

(v) the elemental mercury will be used in a manner that will protect human health and the environment, taking into account local, regional, and global human health and environmental impacts;

(vi) the elemental mercury will be handled and managed in a manner that will protect human health and the environment, taking into account local, regional, and global human health and environmental impacts; and

(vii) the export of elemental mercury for the specified use is consistent with international obligations of the United States intended to reduce global mercury supply, use, and pollution.

(B) Each exemption issued by the Administrator pursuant to this paragraph shall contain such terms and conditions as are necessary to minimize the export of elemental mercury and ensure that the conditions for granting the exemption will be fully met, and shall contain such other terms and conditions as the Administrator may prescribe. No exemption granted pursuant to this paragraph shall exceed three years in duration and no such exemption shall exceed 10 metric tons of elemental mercury.

(C) The Administrator may by order suspend or cancel an exemption under this paragraph in the case of a violation described in subparagraph (D).

(D) A violation of this subsection or the terms and conditions of an exemption, or the submission of false information in connection therewith, shall be considered a prohibited act under section 15, and shall be subject to penalties under section 16, injunctive relief under section 17, and citizen suits under section 20.

[(5)] *(4)* CONSISTENCY WITH TRADE OBLIGATIONS.—Nothing in this subsection affects, replaces, or amends prior law relat-

ing to the need for consistency with international trade obligations.

[(6)] *(5)* EXPORT OF COAL.—Nothing in this subsection shall be construed to prohibit the export of coal.

* * * * * * *

[SEC. 14. DISCLOSURE OF DATA.

[(a) IN GENERAL.—Except as provided by subsection (b), any information reported to, or otherwise obtained by, the Administrator (or any representative of the Administrator) under this Act, which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section, shall, notwithstanding the provisions of any other section of this Act, not be disclosed by the Administrator or by any officer or employee of the United States, except that such information—

[(1) shall be disclosed to any officer or employee of the United States—

[(A) in connection with the official duties of such officer or employee under any law for the protection of health or the environment, or

[(B) for specific law enforcement purposes;

[(2) shall be disclosed to contractors with the United States and employees of such contractors if in the opinion of the Administrator such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States entered into on or after the date of enactment of this Act for the performance of work in connection with this Act and under such conditions as the Administrator may specify;

[(3) shall be disclosed if the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment; or

[(4) may be disclosed when relevant in any proceeding under this Act, except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding.

[In any proceeding under section 552(a) of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 552(b)(3) of such title to sustain the Administrator's action.

[(b) DATA FROM HEALTH AND SAFETY STUDIES.—(1) Subsection (a) does not prohibit the disclosure of—

[(A) any health and safety study which is submitted under this Act with respect to—

[(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, or

[(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5, and

[(B) any data reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

[(2) If a request is made to the Administrator under subsection (a) of section 552 of title 5, United States Code, for information which is described in the first sentence of paragraph (1) and which is not information described in the second sentence of such paragraph, the Administrator may not deny such request on the basis of subsection (b)(4) of such section.

[(c) DESIGNATION AND RELEASE OF CONFIDENTIAL DATA.—[(1) In submitting data under this Act, a manufacturer, processor, or distributor in commerce may (A) designate the data which such person believes is entitled to confidential treatment under subsection (a), and (B) submit such designated data separately from other data submitted under this Act. A designation under this paragraph shall be made in writing and in such manner as the Administrator may prescribe.

[(2)(A) Except as provided by subparagraph (B), if the Administrator proposes to release for inspection data which has been designated under paragraph (1)(A), the Administrator shall notify, in writing and by certified mail, the manufacturer, processor, or distributor in commerce who submitted such data of the intent to release such data. If the release of such data is to be made pursuant to a request made under section 552(a) of title 5, United States Code, such notice shall be given immediately upon approval of such request by the Administrator. The Administrator may not release such data until the expiration of 30 days after the manufacturer, processor, or distributor in commerce submitting such data has received the notice required by this subparagraph.

[(B)(i) Subparagraph (A) shall not apply to the release of information under paragraph (1), (2), (3), or (4) of subsection (a), except that the Administrator may not release data under paragraph (3) of subsection (a) unless the Administrator has notified each manufacturer, processor, and distributor in commerce who submitted such data of such release. Such notice shall be made in writing by certified mail at least 15 days before the release of such data, except that if the Administrator determines that the release of such data is necessary to protect against an imminent, unreasonable risk of injury to health or the environment, such notice may be made by such means as the Administrator determines will provide notice at least 24 hours before such release is made.

[(ii) Subparagraph (A) shall not apply to the release of information described in subsection (b)(1) other than information described in the second sentence of such subsection.

[(d) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.—[(1) Any officer or employee of the United States or former officer or employee of the United States, who by virtue of such employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a), and who knowing that disclosure of such material is prohibited by such subsection, willfully disclosures the material in any manner to any person not entitled to receive it, shall be guilty of a misdemeanor

and fined not more than $5,000 or imprisoned for not more than one year, or both. Section 1905 of title 18, United States Code, does not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this Act.

[(2) For the purposes of paragraph (1), any contractor with the United States who is furnished information as authorized by subsection (a)(2), and any employee of any such contractor, shall be considered to be an employee of the United States.

[(e) ACCESS BY CONGRESS.—Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, upon written request of any duly authorized committee of the Congress, to such committee.]

SEC. 14. CONFIDENTIAL INFORMATION.

(a) IN GENERAL.—*Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—*

(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

(2) for which the requirements of subsection (d) are met.

(b) INFORMATION GENERALLY PROTECTED FROM DISCLOSURE.—*The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information, or information that is the subject of subsection (g)(3), through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:*

(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

(2) Marketing and sales information.

(3) Information identifying a supplier or customer.

(4) Details of the full composition of a mixture and the respective percentages of constituents.

(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

(6) Specific production or import volumes of the manufacturer and specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

(7) Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if—

(A) the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5; and

(B) the claim—

(i) is not subject to an exception under subsection (e); or

(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (f)(2) or (g).

(c) INFORMATION NOT PROTECTED FROM DISCLOSURE.—*Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:*

(1) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

(A) IN GENERAL.—*Subject to subparagraph (B), subsection (a) does not prohibit the disclosure of—*

(i) any health and safety study that is submitted under this Act with respect to—

(I) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

(II) any chemical substance or mixture for which—

(aa) testing is required under section 4; or

(bb) a notification is required under section 5; or

(ii) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in subclause (I) or (II) of clause (i).

(B) EFFECT OF PARAGRAPH.—*Nothing in this paragraph authorizes the release of any information that discloses—*

(i) a process used in the manufacturing or processing of a chemical substance or mixture; or

(ii) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

(2) CERTAIN REQUESTS.—*If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.*

(3) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

"(A) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

(B) A safety assessment developed, or a safety determination made, under section 6.

(C) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

(D) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

(4) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION *.—Any information that is otherwise eligible for protection under this section and contained in a submission of information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.*

(5) BAN OR PHASE-OUT.*—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.*

(d) REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—

(1) ASSERTION OF CLAIMS.—

(A) IN GENERAL.*—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.*

(B) INCLUSION.*—An assertion of a claim under subparagraph (A) shall include a statement that the person has—*

(i) taken reasonable measures to protect the confidentiality of the information;

(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

(C) SPECIFIC CHEMICAL IDENTITY.*—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance*

that the Administrator may disclose to the public, subject to the condition that the generic name shall—

(i) conform with guidance prescribed by the Administrator under paragraph (3)(A); and

(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

(I) that are considered to be confidential; and

(II) the disclosure of which would be likely to harm the competitive position of the person.

(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—*Except for information described in paragraphs (1) through (7) of subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and guidance issued by the Administrator.*

(3) GUIDANCE.—*The Administrator shall develop guidance regarding—*

(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

(4) CERTIFICATION.—*An authorized official of a person described in paragraph (1)(A) shall certify that the information that has been submitted is true and correct.*

(e) EXCEPTIONS TO PROTECTION FROM DISCLOSURE.—*Information described in subsection (a)—*

(1) shall be disclosed if the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

(A) under any law for the protection of health or the environment; or

(B) for a specific law enforcement purpose;

(2) shall be disclosed if the information is to be disclosed to a contractor of the United States and employees of that contractor—

(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

(B) subject to such conditions as the Administrator may specify;

(3) shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment;

(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, if—

(A) 1 or more applicable agreements with the Administrator that conform with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; and

(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;

(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

(A) the statement of need and confidentiality agreement shall conform with the guidance issued under subsection (d)(3)(B);

(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

(i) the information is necessary for, or will assist in—

(I) the diagnosis or treatment of 1 or more individuals; or

(II) responding to an environmental release or exposure; and

(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

(i) a medical or public health or environmental emergency exists;

(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

(i) provide a written statement of need; and

(ii) agree to sign a confidentiality agreement; and

(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

(8) shall be disclosed if the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

(f) DURATION OF PROTECTION FROM DISCLOSURE.—

(1) IN GENERAL.—

(A) INFORMATION PROTECTED FROM DISCLOSURE.—*Subject to paragraph (2), the Administrator shall protect from disclosure information that meets the requirements of subsection (d) for a period of 10 years, unless, prior to the expiration of the period—*

(i) an affected person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

(ii) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in subsection (g)(2).

(B) EXTENSIONS.—

(i) IN GENERAL.—*Not later than the date that is 60 days before the expiration of the period described in subparagraph (A), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.*

(ii) STATEMENT.—

(I) IN GENERAL.—*Not later than the date that is 30 days before the expiration of the period described in subparagraph (A), a person reasserting*

the relevant claim shall submit to the Administrator a statement substantiating, in accordance with subsection (d)(2), the need to extend the period.

(II) ACTION BY ADMINISTRATOR.—Not later than the date that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—

(aa) review the request;

(bb) make a determination regarding whether the information for which the request is made continues to meet the relevant criteria established under this section; and

(cc)(AA) grant an extension of not more than 10 years; or

(BB) deny the claim.

(C) NO LIMIT ON NUMBER OF EXTENSIONS.—*There shall be no limit on the number of extensions granted under subparagraph (B), if the Administrator determines that the relevant statement under subparagraph (B)(ii)(I)—*

(i) establishes the need to extend the period; and

(ii) meets the requirements established by the Administrator.

(2) REVIEW AND RESUBSTANTIATION.—

(A) DISCRETION OF ADMINISTRATOR.—*The Administrator may review, at any time, a claim for protection against disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—*

(i) after the chemical substance is identified as a high-priority substance under section 4A;

(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

(iii) for any inactive chemical substance identified under section 8(b)(5); or

(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating rules pursuant to section 6(d), subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d).

(B) REVIEW REQUIRED.—*The Administrator shall review a claim for protection from disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has*

claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

(i) as necessary to comply with a request for information received by the Administrator under section 552 of title 5, United States Code;

(ii) if information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met; or

(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

(C) ACTION BY RECIPIENT.—*If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—*

(i) reassert and substantiate or resubstantiate the claim; or

(ii) withdraw the claim.

(D) PERIOD OF PROTECTION.—*Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.*

(3) UNIQUE IDENTIFIER.—*The Administrator shall—*

(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

(i) is made public; and

(ii) identifies the chemical substance using the unique identifier; and

(D) for each claim for protection of specific chemical identity that has been denied by the Administrator on expiration of the period for appeal under subsection (g)(4), that has expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

(g) DUTIES OF ADMINISTRATOR.—

(1) DETERMINATION.—

(A) IN GENERAL.—*Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.*

(B) DENIAL OR MODIFICATION.—

(i) IN GENERAL.—*Except as provided in subsections (c) and (f), the Administrator shall deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).*

(ii) REASONS FOR DENIAL OR MODIFICATION.—*The Administrator shall provide to a person that has submitted a claim described in clause (i) a written statement of the reasons for the denial or modification of the claim.*

(C) SUBSETS.—*The Administrator shall—*

(i) except for claims described in subsection (b)(7), review all claims under this section for the protection against disclosure of the specific identity of a chemical substance; and

(ii) review a representative subset, comprising at least 25 percent, of all other claims for protection against disclosure.

(D) EFFECT OF FAILURE TO ACT.—*The failure of the Administrator to make a decision regarding a claim for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim for protection against disclosure.*

(2) NOTIFICATION.—

(A) IN GENERAL.—*Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim under paragraph (1), or promulgates a rule under section 6(d) establishing a ban or phase-out of a chemical substance, the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.*

(B) RELEASE OF INFORMATION.—

(i) IN GENERAL.—*Except as provided in clause (ii), the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).*

(ii) EXCEPTIONS.—

(I) IN GENERAL.—*For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the*

environment, in which case no prior notification shall be necessary.

(II) NO NOTIFICATION.—*For information under paragraph (1), (2), (6), (7), or (9) of subsection (e), no prior notification shall be necessary.*

(3) REBUTTABLE PRESUMPTION.—

(A) IN GENERAL.—*With respect to notifications provided by the Administrator pursuant to subsection (c)(5), there shall be a rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.*

(B) REQUEST FOR NONDISCLOSURE.—*A person that receives a notification under paragraph (2) with respect to the information described in subparagraph (A) may submit to the Administrator, before the date on which the information is to be released, a request with supporting documentation describing why the person believes some or all of that information should not be disclosed.*

(C) DETERMINATION BY ADMINISTRATOR.—

(i) IN GENERAL.—*Not later than 30 days after the Administrator receives a request under subparagraph (B), the Administrator shall determine, at the discretion of the Administrator, whether the documentation provided by the person making the request rebuts or does not rebut the presumption described in subparagraph (A), for all or a portion of the information that the person has requested not be disclosed.*

(ii) OBJECTIVE.—*The Administrator shall make the determination with the objective of ensuring that information relevant to protection of health and the environment is disclosed to the maximum extent practicable.*

(D) TIMING.—*Not later than 30 days after making the determination described in subparagraph (C), the Administrator shall make public the information the Administrator has determined is not to be protected from disclosure.*

(E) NO TIMELY REQUEST RECEIVED.—*If the Administrator does not receive, before the date on which the information described in subparagraph (A) is to be released, a request pursuant to subparagraph (B), the Administrator shall promptly make public all of the information.*

(4) APPEALS.—

(A) IN GENERAL.—*If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released, the person may bring an action to restrain disclosure of the information in—*

(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

(ii) the United States District Court for the District of Columbia.

(B) NO DISCLOSURE.—*The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).*

(5) ADMINISTRATION.—*In carrying out this subsection, the Administrator shall use the procedures described in part 2 of title 40, Code of Federal Regulations (or successor regulations).*

(h) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.—

(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

(A) IN GENERAL.—*Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.*

(B) DESCRIPTION.—*A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—*

(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

(2) OTHER LAWS.—*Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.*

(3) CONTRACTORS.—*For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.*

(i) APPLICABILITY.—

(1) IN GENERAL.—*Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—*

(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information submitted to the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

(2) PRIOR ACTIONS.—*Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Adminis-*

trator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

SEC. 15. PROHIBITED ACTS.

It shall be unlawful for any person to—

[(1) fail or refuse to comply with (A) any rule promulgated or order issued under section 4, (B) any requirement prescribed by section 5 or 6, (C) any rule promulgated or order issued under section 5 or 6, or (D) any requirement of title II or any rule promulgated or order issued under title II;]

(1) fail or refuse to comply with—

(A) any rule promulgated, consent agreement entered into, or order issued under section 4;

(B) any requirement under section 5 or 6;

(C) any rule promulgated, consent agreement entered into, or order issued under section 5 or 6; or

(D) any requirement of, or any rule promulgated or order issued pursuant to title II;

(2) use for commercial purposes a chemical substance or mixture which such person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 or 6, a rule or order under section 5 or 6, or an order issued in action brought under section 5 or 7;

(3) fail or refuse to (A) establish or maintain records, (B) submit reports, notices, or other information, or (C) permit access to or copying of records, as required by this Act or a rule thereunder; or

(4) fail or refuse to permit entry or inspection as required by section 11.

SEC. 16. PENALTIES.

(a) CIVIL.—(1) Any person who violates a provision of *this Act or a rule or order promulgated or issued pursuant to this Act, including* section 15 or 409 shall be liable to the United States for a civil penalty in an amount not to exceed [$25,000] *$37,500* for each such violation. Each day such a violation continues shall, for purposes of this subsection, constitute a separate [violation of section 15 or 409] *violation of this Act.*

(2)(A) A civil penalty for a violation of section 15 or 409 shall be assessed by the Administrator by an order made on the record after opportunity (provided in accordance with this subparagraph) for a hearing in accordance with section 554 of title 5, United States Code. Before issuing such an order, the Administrator shall give written notice to the person to be assessed a civil penalty under such order of the Administrator's proposal to issue such order and provide such person an opportunity to request, within 15 days of the date the notice is received by such person, such a hearing on the order.

(B) In determining the amount of a civil penalty, the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Administrator may compromise, modify, or remit, with or without conditions, any civil penalty which may be imposed under this subsection. The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(3) Any person who requested in accordance with paragraph (2)(A) a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 30-day period beginning on the date the order making such assessment was issued.

(4) If any person fails to pay an assessment of a civil penalty—

(A) after the order making the assessment has become a final order and if such person does not file a petition for judicial review of the order in accordance with paragraph (3), or

(B) after a court in an action brought under paragraph (3) has entered a final judgment in favor of the Administrator,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 30-day period referred to in paragraph (3) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(b) CRIMINAL.—[Any person who]

(1) IN GENERAL.—*Any person that*; knowingly or willfully violates any provision of [section 15 or 409] *this Act* shall, in addition to or in lieu of any civil penalty which may be imposed under subsection (a) of this section for such violation, be subject, upon conviction, to a fine of not more than [$25,000] *$50,000* for each day of violation, or to imprisonment for not more than one year, or both.

(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

(A) IN GENERAL.—*Any person that knowingly or willfully violates any provision of this Act, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.*

(B) ORGANIZATIONS.—*An organization that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation.*

(3) KNOWLEDGE OF IMMINENT DANGER OR INJURY.—*For purposes of determining whether a defendant knew that the violation placed another individual in imminent danger of death or serious bodily injury—*

(A) the defendant shall be responsible only for actual awareness or actual belief possessed; and

(B) knowledge possessed by an individual may not be attributed to the defendant.

* * * * * * *

SEC. 18. PREEMPTION.

[(a) EFFECT ON STATE LAW.—(1) Except as provided in paragraph (2), nothing in this Act shall affect the authority of any State or political subdivision of a State to establish or continue in effect regulation of any chemical substance, mixture, or article containing a chemical substance or mixture.

[(2) Except as provided in subsection (b)—

[(A) if the Administrator requires by a rule promulgated under section 4 the testing of a chemical substance or mixture, no State or political subdivision may, after the effective date of such rule, establish or continue in effect a requirement for the testing of such substance or mixture for purposes similar to those for which testing is required under such rule; and

[(B) if the Administrator prescribes a rule or order under section 5 or 6 (other than a rule imposing a requirement described in subsection (a)(6) of section 6) which is applicable to a chemical substance or mixture, and which is designed to protect against a risk of injury to health or the environment associated with such substance or mixture, no State or political subdivision of a State may, after the effective date of such requirement, establish or continue in effect, any requirement which is applicable to such substance or mixture, or an article containing such substance or mixture, and which is designed to protect against such risk unless such requirement (i) is identical to the requirement prescribed by the Administrator, (ii) is adopted under the authority of the Clean Air Act or any other Federal law, or (iii) prohibits the use of such substance or mixture in such State or political subdivision (other than its use in the manufacture or processing of other substances or mixtures).

[(b) EXEMPTION.—Upon application of a State or political subdivision of a State the Administrator may by rule exempt from subsection (a)(2), under such conditions as may be prescribed in such rule, a requirement of such State or political subdivision designed to protect against a risk of injury to health or the environment associated with a chemical substance, mixture, or article containing a chemical substance or mixture if—

[(1) compliance with the requirement would not cause the manufacturing, processing, distribution in commerce, or use of the substance, mixture, or article to be in violation of the applicable requirement under this Act described in subsection (a)(2), and

[(2) the State or political subdivision requirement (A) provides a significantly higher degree of protection from such risk than the requirement under this Act described in subsection (a)(2) and (B) does not, through difficulties in marketing, distribution, or other factors, unduly burden interstate commerce.]

(a) IN GENERAL.—

(1) ESTABLISHMENT OR ENFORCEMENT.—*Except as provided in subsections (c), (d), (e), (f), and (g), and subject to paragraph (2), no State or political subdivision of a State may establish or continue to enforce any of the following:*

(A) TESTING AND INFORMATION COLLECTION.—*A statute or administrative action to require the development of information on a chemical substance or category of substances that is reasonably likely to produce the same information required under section 4, 5, or 6 in—*

(i) a rule promulgated by the Administrator;

(ii) a testing consent agreement entered into by the Administrator; or

(iii) an order issued by the Administrator.

(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

(i) found to meet the safety standard and consistent with the scope of the determination made under section 6; or

(ii) found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

(C) SIGNIFICANT NEW USE.—*A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.*

(2) EFFECTIVE DATE OF PREEMPTION.—*Under this subsection, Federal preemption of State statutes and administrative actions applicable to specific substances shall not occur until the effective date of the applicable action described in paragraph (1) taken by the Administrator.*

(b) NEW STATUTES OR ADMINISTRATIVE ACTIONS CREATING PROHIBITIONS OR OTHER RESTRICTIONS.—

(1) IN GENERAL.—*Except as provided in subsections (c), (d), and (e), beginning on the date on which the Administrator defines the scope of a safety assessment and safety determination under section 6(a)(2) and ending on the date on which the Administrator publishes the safety determination, no State or political subdivision of a State may establish a statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance designated under section 4A.*

(2) EFFECT OF SUBSECTION.—

(A) IN GENERAL.—*This subsection does not restrict the authority of a State or political subdivision of a State to continue to enforce any State statute enacted, or administrative action taken, prior to the date on which the Administrator defines the scope of a safety assessment and safety determination under section 6(a)(2).*

(B) LIMITATION.—*Subparagraph (A) does not allow a State or political subdivision of a State to enforce any new prohibition or restriction under a State statute or administrative action described in that subparagraph, if the prohibition or restriction is established after the date described in that subparagraph.*

(c) SCOPE OF PREEMPTION.—*Federal preemption under subsections (a) and (b) of State statutes and administrative actions applicable to specific substances shall apply only to—*

(1) the chemical substances or category of substances subject to a rule, order, or consent agreement under section 4;

(2) the uses or conditions of use of such substances that are identified by the Administrator as subject to review in a safety assessment and included in the scope of the safety determination made by the Administrator for the substance, or of any rule the Administrator promulgates pursuant to section 6(d); or

(3) the uses of such substances that the Administrator has specified as significant new uses and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

(d) EXCEPTIONS.—

(1) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—

(A) IN GENERAL.—*Nothing in this Act, nor any amendment made by this Act, nor any rule, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—*

(i) is adopted or authorized under the authority of any other Federal law or adopted to satisfy or obtain authorization or approval under any other Federal law;

(ii) implements a reporting, monitoring, disclosure, or other information obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law;

(iii) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, except to the extent that the action—

(I) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

(II)(aa) addresses the same hazards and exposures, with respect to the same conditions of use as are included in the scope of the safety determination pursuant to section 6, but is inconsistent with the action of the Administrator; or

(bb) would cause a violation of the applicable action by the Administrator under section 5 or 6; or

(iv) subject to subparagraph (B), is identical to a requirement prescribed by the Administrator.

(B) IDENTICAL REQUIREMENTS.—

(i) IN GENERAL.—*The penalties and other sanctions applicable under State law in the event of noncompliance with the identical requirement shall be no more stringent than the penalties and other sanctions available to the Administrator under section 16 of this Act.*

(ii) PENALTIES.—*In the case of an identical requirement, no State may assess a penalty for a specific violation for which the Administrator has already assessed a penalty under section 16, and the Administrator may not assess a penalty under section 16 for a specific violation for which a State has already assessed a penalty.*

(2) APPLICABILITY TO CERTAIN RULES OR ORDERS.—*Notwithstanding subsection (e)—*

(A) nothing in this section shall be construed as modifying the effect under this section, as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, of any rule or order promulgated or issued under this Act prior to that effective date; and

(B) with respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 6 prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act with regards to manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance, this section (as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after that effective date, unless the latter rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under [subsection (b) or (c) of] section 4A *(b)* or as an additional priority for safety assessment and safety determination under section [4A(d)] *4A(c).*

(e) PRESERVATION OF CERTAIN STATE LAW.—

(1) IN GENERAL.—*Nothing in this Act, subject to subsection (g) of this section, shall—*

(A) be construed to preempt or otherwise affect the authority of a State or political subdivision of a State to continue to enforce any action taken before August 1, 2015, under the authority of a State law that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance; or

(B) be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003.

(2) EFFECT OF SUBSECTION.—*This subsection does not affect, modify, or alter the relationship between State and Federal law pursuant to any other Federal law.*

(f) STATE WAIVERS.—

(1) DISCRETIONARY EXEMPTIONS.—*Upon application of a State or political subdivision of a State, the Administrator may by rule, exempt from subsection (a), under such conditions as may be prescribed in the rule, a statute or administrative action of that State or political subdivision of the State that relates to the effects of, or exposure to, a chemical substance under the conditions of use if the Administrator determines that—*

(A) compelling State or local conditions warrant granting the waiver to protect health or the environment;

(B) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

(C) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

(D) based on the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is consistent with sound objective scientific practices, the weight of the evidence, and the best available science.

(2) REQUIRED EXEMPTIONS.—*Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—*

(A) compliance with the proposed requirement of the State will not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

(B) compliance with the proposed requirement would not cause a violation of any applicable Federal law, rule, or order; and

(C) the State or political subdivision of a State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science.

(3) DETERMINATION OF A STATE WAIVER REQUEST.—*The duty of the Administrator to grant or deny a waiver application shall be nondelegable and shall be exercised—*

(A) not later than 180 days after the date on which an application under paragraph (1) is submitted; and

(B) not later than 90 days after the date on which an application under paragraph (2) is submitted.

(4) FAILURE TO MAKE DETERMINATION.—*If the Administrator fails to make a determination under paragraph (3)(B) during the 90-day period beginning on the date on which an application under paragraph (2) is submitted, the State statute or administrative action that was the subject of the application shall*

not be considered to be an existing statute or administrative action for purposes of subsection [(a)] *(b)* by reason of the failure of the Administrator to make a determination.

(5) NOTICE AND COMMENT.—*Except in the case of an application approved under paragraph (9), the application of a State or political subdivision of the State shall be subject to public notice and comment.*

(6) FINAL AGENCY ACTION.—*The decision of the Administrator on the application of a State or political subdivision of the State shall be—*

(A) considered to be a final agency action; and

(B) subject to judicial review.

(7) DURATION OF WAIVERS.—

(A) IN GENERAL.—*Except as provided in subparagraph (B), a waiver granted under paragraph (2) or approved under paragraph (9) shall remain in effect—*

(i) until such time as the safety assessment and safety determination is completed; or

(ii) subject to subparagraph (B), until judicial review of the failure of the Administrator to make a determination under paragraph (3) is sought under paragraph (8).

(B) REINSTATEMENT OF WAIVER.—*A waiver described in subparagraph (A)(ii) shall again take effect upon the earlier of—*

(i) the date of approval by the Administrator of the waiver application;

(ii) the effective date of a court order directing the Administrator to approve the waiver application; or

(iii) 90 days after the date on which judicial review under paragraph (8) is sought.

(8) JUDICIAL REVIEW OF WAIVERS.—*Not later than 60 days after the date on which the Administrator makes a determination on an application of a State or political subdivision of the State under paragraph (1) or (2), or not later than 60 days after the date on which the Administrator fails to make a determination under paragraph (3), any person may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.*

(9) APPROVAL.—

(A) IN GENERAL.—*If the Administrator fails to meet the deadline under section 6(a)(4) (including an extension granted under section 6(a)(6)), or the deadline established under paragraph (3)(B), the application of a State or political subdivision of a State under paragraph (2) shall be automatically approved.*

(B) REQUIREMENTS.—*Notwithstanding paragraph (6), approval of a waiver application under subparagraph (A) for failure to meet the deadlines under section 6(a)(4) (including an extension granted under section 6(a)(6)) shall not be considered final agency action or be subject to judicial review or public notice and comment.*

(10) JUDICIAL REVIEW OF LOW-PRIORITY DECISIONS.—

(A) IN GENERAL.—*Not later than 60 days after the publication of a designation under section 4A(b)(4), any person may commence a civil action to challenge the designation.*

(B) JURISDICTION.—*The United States Court of Appeals for the District of Columbia Circuit shall have exclusive jurisdiction over a civil action filed under this paragraph.*

(g) SAVINGS.—

(1) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF OR CRIMINAL CONDUCT.—

(A) IN GENERAL.—*Nothing in this Act, nor any amendment made by this Act, nor any safety standard, rule, requirement, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall be construed to preempt, displace, or supplant any state or Federal common law rights or any state or Federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.*

(B) CLARIFICATION OF NO PREEMPTION.—*Notwithstanding any other provision of this Act, nothing in this Act, nor any amendments made by this Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any State law, maritime law, or Federal common law or statutory theory.*

(2) NO EFFECT ON PRIVATE REMEDIES.—

(A) IN GENERAL.—*Nothing in this Act, nor any amendments made by this Act, nor any rules, regulations, requirements, safety assessments, safety determinations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.*

(B) AUTHORITY OF COURTS.—*This Act does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, safety assessments, scientific assessments, or orders issued pursuant to this Act.*

SEC. 19. JUDICIAL REVIEW.

(a) IN GENERAL.—(1)(A) Not later than 60 days after the date of the promulgation of a rule under [section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV] *section 4(a), 5(d), 6(c), 6(d), 6(g), or 8, or title II or IV*, any person may file a petition for judicial review of such rule with the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which such person resides or in which such person's principal place of business is located. Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of such a rule if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

(B) Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an

enforcement proceeding) of [an order issued under subparagraph (A) or (B) of section 6(b)(1)] *an order issued under this title* if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

(2) Copies of any petition filed under [paragraph (1)(A)] *paragraph (1)* shall be transmitted forthwith to the Administrator and to the Attorney General by the clerk of the court with which such petition was filed. The provisions of section 2112 of title 28, United States Code, shall apply to the filing of the rulemaking record of proceedings on which the Administrator based the rule being reviewed under this section and to the transfer of proceedings between United States courts of appeals.

[(3) For purposes of this section, the term "rulemaking record" means—

[(A) the rule being reviewed under this section;

[(B) in the case of a rule under section 4(a), the finding required by such section, in the case of a rule under section 5(b)(4), the finding required by such section, in the case of a rule under section 6(a) the finding required by section 5(f) or 6(a), as the case may be, in the case of a rule under section 6(a), the statement required by section 6(c)(1), and in the case of a rule under section 6(e), the findings required by paragraph (2)(B) or (3)(B) of such section, as the case may be[6] and in the case of a rule under title IV, the finding required for the issuance of such a rule;

[(C) any transcript required to be made of oral presentations made in proceedings for the promulgation of such rule;

[(D) any written submission of interested parties respecting the promulgation of such rule; and

[(E) any other information which the Administrator considers to be relevant to such rule and which the Administrator identified, on or before the date of the promulgation of such rule, in a notice published in the Federal Register.]

(b) ADDITIONAL SUBMISSIONS AND PRESENTATIONS; MODIFICATIONS.—If in an action under this section to review a rule the petitioner or the Administrator applies to the court for leave to make additional oral submissions or written presentations respecting such rule and shows to the satisfaction of the court that such submissions and presentations would be material and that there were reasonable grounds for the submissions and failure to make such submissions and presentations in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity to make such submissions and presentations. The Administrator may modify or set aside the rule being reviewed or make a new rule by reason of the additional submissions and presentations and shall file such modified or new rule with the return of such submissions and presentations. The court shall thereafter review such new or modified rule.

(c) STANDARD OF REVIEW.—(1)(A) Upon the filing of a petition under subsection (a)(1) for judicial review of a rule, the court shall have jurisdiction (i) to grant appropriate relief, including interim relief, as provided in chapter 7 of title 5, United States Code, and

[6] So in law. Probably should be followed by a comma.

(ii) except as otherwise provided in subparagraph (B), to review such rule in accordance with chapter 7 of title 5, United States Code.

(B) Section 706 of title 5, United States Code, shall apply to review of a rule under this section, except that—

(i) in the case of review of a rule under [section 4(a), 5(b)(4), 6(a), or 6(e)] *section 4(a), 5(d), 6(d), or 6(g)*, the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial [evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;]

[(ii) in the case of review of a rule under section 6(a), the court shall hold unlawful and set aside such rule if it finds that—

[(I) a determination by the Administrator under section 6(c)(3) that the petitioner seeking review of such rule is not entitled to conduct (or have conducted) cross-examination or to present rebuttal submissions, or

[(II) a rule of, or ruling by, the Administrator under section 6(c)(3) limiting such petitioner's cross-examination or oral presentations,

has precluded disclosure of disputed material facts which was necessary to a fair determination by the Administrator of the rulemaking proceeding taken as a whole; and section 706(2)(D) shall not apply with respect to a determination, rule, or ruling referred to in subclause (I) or (II); and

[(iii) the court may not review the contents and adequacy of—

[(I) any statement required to be made pursuant to section 6(c)(1), or

[(II) any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule]

[except as part of a review of the rulemaking record taken as a whole.

[The term "evidence" as used in clause (i) means any matter in the rulemaking record.]

(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule, except as part of the rulemaking record, taken as a whole.

(C) A determination, rule, or ruling of the Administrator described in subparagraph (B)(ii) may be reviewed only in an action under this section and only in accordance with such subparagraph.

(2) The judgment of the court affirming or setting aside, in whole or in part, any rule reviewed in accordance with this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

(d) FEES AND COSTS.—The decision of the court in an action commenced under subsection (a), or of the Supreme Court of the United States on review of such a decision, may include an award

of costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate.

(e) OTHER REMEDIES.—The remedies as provided in this section shall be in addition to and not in lieu of any other remedies provided by law.

* * * * * * *

SEC. 21. CITIZENS' PETITIONS.

(a) IN GENERAL.—Any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 6, or 8 or [an order under section 5(e) or (6)(b)(2)] *an order under section 4 or 5(d).*

(b) PROCEDURES.—(1) Such petition shall be filed in the principal office of the Administrator and shall set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under section 4, 6, or 8 or [an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)] *an order under section 4 or 5(d).*

(2) The Administrator may hold a public hearing or may conduct such investigation or proceeding as the Administrator deems appropriate in order to determine whether or not such petition should be granted.

(3) Within 90 days after filing of a petition described in paragraph (1), the Administrator shall either grant or deny the petition. If the Administrator grants such petition, the Administrator shall promptly commence an appropriate proceeding in accordance with section 4, 5, 6, or 8. If the Administrator denies such petition, the Administrator shall publish in the Federal Register the Administrator's reasons for such denial.

(4)(A) If the Administrator denies a petition filed under this section (or if the Administrator fails to grant or deny such petition within the 90-day period) the petitioner may commence a civil action in a district court of the United States to compel the Administrator to initiate a rulemaking proceeding as requested in the petition. Any such action shall be filed within 60 days after the Administrator's denial of the petition or, if the Administrator fails to grant or deny the petition within 90 days after filing the petition, within 60 days after the expiration of the 90-day period.

[(B) In an action under subparagraph (A) respecting a petition to initiate a proceeding to issue a rule under section 4, 6, or 8 or an order under section 5(e) or 6(b)(2), the petitioner shall be provided an opportunity to have such petition considered by the court in a de novo proceeding. If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—]

(B) DE NOVO PROCEEDING.—

(i) IN GENERAL.—*In an action under subparagraph (A) to initiate a proceeding to promulgate a rule pursuant to section 4, 5, 6, or 8 or issue* an order [issued] under section 4 or 5 *(d)*, the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.

(ii) DEMONSTRATION.—

(I) IN GENERAL.—*The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by*

the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

(aa) in the case of a petition to initiate a proceeding for the issuance of a rule or order under section 4, the information available to the Administrator is insufficient for the Administrator to perform an action described in section 4, 4A, 5, or 6(d);

(bb) in the case of a petition to issue an order under section 5(d), there is a reasonable basis to conclude that the chemical substance is not likely to meet the safety standard;

(cc) in the case of a petition to initiate a proceeding for the issuance of a rule under section 6(d), there is a reasonable basis to conclude that the chemical substance will not meet the safety standard; or

(dd) in the case of a petition to initiate a proceeding for the issuance of a rule under section 8, there is a reasonable basis to conclude that the rule is necessary to protect health or the environment or ensure that the chemical substance meets the safety standard.

(II) DEFERMENT.—*The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—*

(aa) the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act; and

(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.

* * * * * * *

SEC. 24. EMPLOYMENT EFFECTS.

(a) IN GENERAL.—The Administrator shall evaluate on a continuing basis the potential effects on employment (including reductions in employment or loss of employment from threatened plant closures) of—

(1) the issuance of a rule or order under section 4, 5, or 6, or

(2) a requirement of section 5 or 6.

(b)(1) INVESTIGATIONS.—Any employee (or any representative of an employee) may request the Administrator to make an investigation of—

(A) a discharge or layoff or threatened discharge or layoff of the employee, or

(B) adverse or threatened adverse effects on the employee's employment,

allegedly resulting from a rule or order under section 4, 5, or 6 or a requirement of section 5 or 6. Any such request shall be made in writing, shall set forth with reasonable particularity the grounds for the request, and shall be signed by the employee, or representative of such employee, making the request.

(2)(A) Upon receipt of a request made in accordance with paragraph (1) the Administrator shall (i) conduct the investigation requested, and (ii) if requested by any interested person, hold public hearings on any matter involved in the investigation unless the Administrator, by order issued within 45 days of the date such hearings are requested, denies the request for the hearings because the Administrator determines there are no reasonable grounds for holding such hearings. If the Administrator makes such a determination, the Administrator shall notify in writing the person requesting the hearing of the determination and the reasons therefor and shall publish the determination and the reasons therefor in the Federal Register.

(B) If public hearings are to be held on any matter involved in an investigation conducted under this subsection—

(i) at least five days' notice shall be provided the person making the request for the investigation and any person identified in such request,

(ii) such hearings shall be held in accordance with [section 6(c)(3),] *the applicable requirements of this Act;* and

(iii) each employee who made or for whom was made a request for such hearings and the employer of such employee shall be required to present information respecting the applicable matter referred to in paragraph (1)(A) or (1)(B) together with the basis for such information.

(3) Upon completion of an investigation under paragraph (2), the Administrator shall make findings of fact, shall make such recommendations as the Administrator deems appropriate, and shall make available to the public such findings and recommendations.

(4) This section shall not be construed to require the Administrator to amend or repeal any rule or order in effect under this Act.

SEC. 25. STUDIES.

[(a) INDEMNIFICATION STUDY.—The Administrator shall conduct a study of all Federal laws administered by the Administrator for the purpose of determining whether and under what conditions, if any, indemnification should be accorded any person as a result of any action taken by the Administrator under any such law. The study shall—

[(1) include an estimate of the probable cost of any indemnification programs which may be recommended;

[(2) include an examination of all viable means of financing the cost of any recommended indemnification; and

[(3) be completed and submitted to Congress within two years from the effective date of enactment of this Act.

[The General Accounting Office shall review the adequacy of the study submitted to Congress pursuant to paragraph (3) and shall report the results of its review to the Congress within six months of the date such study is submitted to Congress.

[(b) CLASSIFICATION, STORAGE, AND RETRIEVAL STUDY.—The Council on Environmental Quality, in consultation with the Admin-

istrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate Federal departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical substances and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such substances. A report on such study shall be completed and submitted to Congress not later than 18 months after the effective date of enactment of this Act.]

SEC. 26. ADMINISTRATION OF THE ACT.

(a) COOPERATION OF FEDERAL AGENCIES.—Upon request by the Administrator, each Federal department and agency is authorized—

(1) to make its services, personnel, and facilities available (with or without reimbursement) to the Administrator to assist the Administrator in the administration of this Act; and

(2) to furnish to the Administrator such information, data, estimates, and statistics, and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary for the administration of this Act.

[(b) FEES.—[(1) The Administrator may, by rule, require the payment of a reasonable fee from any person required to submit data under section 4 or 5 to defray the cost of administering this Act. Such rules shall not provide for any fee in excess of $2,500 or, in the case of a small business concern, any fee in excess of $100. In setting a fee under this paragraph, the Administrator shall take into account the ability to pay of the person required to submit the data and the cost to the Administrator of reviewing such data. Such rules may provide for sharing such a fee in any case in which the expenses of testing are shared under section 4 or 5.

[(2) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the persons which qualify as small business concerns for purposes of paragraph (1).]

(b) FEES.—

(1) IN GENERAL.—*The Administrator shall establish, not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, by rule—*

(A) the payment of 1 or more reasonable fees as a condition of submitting a notice or requesting an exemption under section 5;

(B) the payment of 1 or more reasonable fees by a manufacturer or processor that—

(i) is required to submit a notice pursuant to the rule promulgated under section 8(b)(4)(A)(i) identifying a chemical substance as active;

(ii) is required to submit a notice pursuant to section 8(b)(5)(B)(i) changing the status of a chemical substance from inactive to active;

(iii) is required to report information pursuant to the rules promulgated under section 8(a)(4); and

(iv) manufactures or processes a chemical substance subject to a safety assessment and safety determination pursuant to section 6.

(2) UTILIZATION AND COLLECTION OF FEES.—*The Administrator shall—*

(A) utilize the fees collected under paragraph (1) only to defray costs associated with the actions of the Administrator—

(i) to collect, process, review, provide access to, and protect from disclosure (where appropriate) information on chemical substances under this Act;

(ii) to review notices and make determinations for chemical substances under paragraphs (1) and (3) of section 5(d) and impose any necessary restrictions under section 5(d)(4);

(iii) to make prioritization decisions under section 4A;

(iv) to conduct and complete safety assessments and determinations under section 6; and

(v) to conduct any necessary rulemaking pursuant to section 6(d);

(B) insofar as possible, collect the fees described in paragraph (1) in advance of conducting any fee-supported activity;

(C) deposit the fees in the Fund established by paragraph (4)(A); and

(D) not collect excess fees or retain a significant amount of unused fees.

(3) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—*In setting fees under this section, the Administrator shall—*

(A) take into account the cost to the Administrator of conducting the activities described in paragraph (2);

(B) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

(C) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to defray approximately 25 percent of the costs of conducting the activities identified in paragraph (2)(A), not to exceed $18,000,000, not including fees under subparagraph (E) of this paragraph;

(D) reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

(E) for substances designated as additional priorities pursuant to section 4A(c), establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the safety assessment and safety determination under section 6, except that for substances subject to section 4A(c)(3), the Administrator shall establish the fee at a level sufficient to defray 50 percent of those costs;

(F) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties poten-

tially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) or subchapter III of chapter 5 of title 5, United States Code, is applicable with respect to such meetings;

(G) beginning with the fiscal year that is 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives, increase or decrease the fees established under paragraph (1) as necessary—

(i) to ensure that funds deposited in the Fund are sufficient to conduct the activities identified in paragraph (2)(A) and the full cost or 50-percent portion of the costs of safety assessments and safety determinations pursuant to subparagraph (E); and

(ii) to account for inflation;

(H) adjust fees established under paragraph (1) as necessary to vary on account of differing circumstances, including reduced fees or waivers in appropriate circumstances, to reduce the burden on manufacturing or processing, remove barriers to innovation, or where the costs to the Administrator of collecting the fees exceed the fee revenue anticipated to be collected; and

(I) if a notice submitted under section 5 is refused or subsequently withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

(4) TSCA IMPLEMENTATION FUND.—

(A) ESTABLISHMENT.—*There is established in the Treasury of the United States a fund, to be known as the 'TSCA Implementation Fund' (referred to in this subsection as the 'Fund'), consisting of—*

(i) such amounts as are deposited in the Fund under paragraph (2)(C); and

(ii) any interest earned on the investment of amounts in the Fund; and

(iii) any proceeds from the sale or redemption of investments held in the Fund.

(B) CREDITING AND AVAILABILITY OF FEES.—

(i) IN GENERAL.—*Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation.*

(ii) REQUIREMENTS.—*Fees collected under this section shall not—*

(I) be made available or obligated for any purpose other than to defray the costs of conducting the activities identified in paragraph (2)(A);

(II) otherwise be available for any purpose other than implementation of this Act; and

(III) so long as amounts in the Fund remain available, be subject to restrictions on expenditures applicable to the Federal government as a whole.

(C) UNUSED FUNDS.—*Amounts in the Fund not currently needed to carry out this subsection shall be—*

(i) maintained readily available or on deposit;

(ii) invested in obligations of the United States or guaranteed by the United States; or

(iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

(D) MINIMUM AMOUNT OF APPROPRIATIONS.—*Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2015) of the Office of Pollution Prevention and Toxics of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for covered functions for fiscal year 2015 (excluding the amount of any fees appropriated for the fiscal year).*

(5) AUDITING.—

(A) FINANCIAL STATEMENTS OF AGENCIES.—*For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of an executive agency.*

(B) COMPONENTS.—*The annual audit required under sections 3515(b) and 3521 of that title of the financial statements of activities under this subsection shall include an analysis of—*

(i) the fees collected under paragraph (1) and disbursed;

(ii) compliance with the deadlines established in section 6 of this Act;

(iii) the amounts budgeted, appropriated, collected from fees, and disbursed to meet the requirements of sections 4, 4A, 5, 6, 8, and 14, including the allocation of full time equivalent employees to each such section or activity; and

(iv) the reasonableness of the allocation of the overhead associated with the conduct of the activities described in paragraph (2)(A).

(C) INSPECTOR GENERAL.—*The Inspector General of the Environmental Protection Agency shall—*

(i) conduct the annual audit required under this subsection; and

(ii) report the findings and recommendations of the audit to the Administrator and to the appropriate committees of Congress.

(6) TERMINATION.—*The authority provided by this section shall terminate at the conclusion of the fiscal year that is 10 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, unless otherwise reauthorized or modified by Congress.*

(c) ACTION WITH RESPECT TO CATEGORIES.—(1) Any action authorized or required to be taken by the Administrator under any provision of this Act with respect to a chemical substance or mix-

ture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this Act with respect to a category of chemical substances or mixtures, any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category.

(2) For purposes of paragraph (1):

(A) The term "category of chemical substances" means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

(B) The term "category of mixtures" means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological 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, Education, and Welfare] *Health and Human Services* who—

(A) performs any function or duty under this Act, and

(B) has any known financial interest (i) in any person subject to this Act or any rule or order in effect under this Act, or (ii) in any person who applies for or receives any grant or contract under this Act,

shall, on February 1, 1978, and on February 1 of each year thereafter, file with the Administrator or the Secretary of [Health, Education, and Welfare] *Health and Human Services* (hereinafter in this subsection referred to as the "Secretary"), as appropriate, a written statement concerning all such interests held by such officer or employee during the preceding calendar year. Such statement shall be made available to the public.

(2) The Administrator and the Secretary shall—

(A) act within 90 days of the effective date of this Act—

(i) to define the term "known financial interests" for purposes of paragraph (1), and

(ii) to establish the methods by which the requirement to file written statements specified in paragraph (1) will be

monitored and enforced, including appropriate provisions for review by the Administrator and the Secretary of such statements; and

(B) report to the Congress on June 1, 1978, and on June 1 of each year thereafter with respect to such statements and the actions taken in regard thereto during the preceding calendar year.

(3) The Administrator may by rule identify specific positions with the Environmental Protection Agency, and the Secretary may by rule identify specific positions with the Department of [Health, Education, and Welfare] *Health and Human Services*, which are of a nonregulatory or nonpolicy-making nature, and the Administrator and the Secretary may by rule provide that officers or employees occupying such positions shall be exempt from the requirements of paragraph (1).

(4) This subsection does not supersede any requirement of chapter 11 of title 18, United States Code.

(5) Any officer or employee who is subject to, and knowingly violates, this subsection or any rule issued thereunder, shall be fined not more than $2,500 or imprisoned not more than one year, or both.

(f) STATEMENT OF BASIS AND PURPOSE.—Any final order issued under this Act shall be accompanied by a statement of its basis and purpose. The contents and adequacy of any such statement shall not be subject to judicial review in any respect.

(g) ASSISTANT ADMINISTRATOR.—(1) The President, by and with the advice and consent of the Senate, shall appoint an Assistant Administrator for Toxic Substances of the Environmental Protection Agency. Such Assistant Administrator shall be a qualified individual who is, by reason of background and experience, especially qualified to direct a program concerning the effects of chemicals on human health and the environment. Such Assistant Administrator shall be responsible for (A) the collection of data, (B) the preparation of studies, (C) the making of recommendations to the Administrator for regulatory and other actions to carry out the purposes and to facilitate the administration of this Act, and (D) such other functions as the Administrator may assign or delegate.

(2) The Assistant Administrator to be appointed under paragraph (1) shall be in addition to the Assistant Administrators of the Environmental Protection Agency authorized by section 1(d) of Reorganization Plan No. 3 of 1970.

(h) PRIOR ACTIONS.—*Nothing in this Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.*

SEC. 27. DEVELOPMENT AND EVALUATION OF TEST METHODS.

(a) IN GENERAL.—The Secretary of [Health, Education, and Welfare] *Health and Human Services* in consultation with the Administrator and acting through the Assistant Secretary for Health, may conduct, and make grants to public and nonprofit private entities and enter into contracts with public and private entities for, projects for the development and evaluation of inexpensive and efficient methods (1) for determining and evaluating the health and environmental effects of chemical substances and mixtures, and

their toxicity, persistence, and other characteristics which affect health and the environment, and (2) which may be used for the development of test data to meet the requirements of rules promulgated under section 4. The Administrator shall consider such methods in prescribing under section 4 standards for the development of test data.

(b) APPROVAL BY SECRETARY.—No grant may be made or contract entered into under subsection (a) unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be submitted in such form and manner and contain such information as the Secretary may require. The Secretary may apply such conditions to grants and contracts under subsection (a) as the Secretary determines are necessary to carry out the purposes of such subsection. Contracts may be entered into under such subsection without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

(c) SUSTAINABLE CHEMISTRY PROGRAM.—*The President shall establish an interagency Sustainable Chemistry Program to promote and coordinate Federal sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities.*

(d) PROGRAM ACTIVITIES.—*The activities of the Program shall be designed to—*

(1) provide sustained support for sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training through—

(A) coordination of sustainable chemistry research, development, demonstration, and technology transfer conducted at Federal laboratories and agencies; and

(B) to the extent practicable, encouragement of consideration of sustainable chemistry in, as appropriate—

(i) the conduct of Federal and State science and engineering research and development; and

(ii) the solicitation and evaluation of applicable proposals for science and engineering research and development;

(2) examine methods by which the Federal Government can create incentives for consideration and use of sustainable chemistry processes and products, including innovative financing mechanisms;

(3) expand the education and training of undergraduate and graduate students and professional scientists and engineers, including through partnerships with industry, in sustainable chemistry science and engineering;

(4) collect and disseminate information on sustainable chemistry research, development, and technology transfer including information on—

(A) incentives and impediments to development, manufacturing, and commercialization;

(B) accomplishments;

(C) best practices; and

(D) costs and benefits;

(5) support (including through technical assistance, participation, financial support, or other forms of support) economic,

legal, and other appropriate social science research to identify barriers to commercialization and methods to advance commercialization of sustainable chemistry.

(e) INTERAGENCY WORKING GROUP.—

(1) ESTABLISHMENT.—*Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the President, in consultation with the Office of Science and Technology Policy, shall establish an Interagency Working Group that shall include representatives from the National Science Foundation, the National Institute of Standards and Technology, the Department of Energy, the Environmental Protection Agency, the Department of Agriculture, the Department of Defense, the National Institutes of Health, and any other agency that the President may designate to oversee the planning, management, and coordination of the Program.*

(2) GOVERNANCE.—*The Director of the National Science Foundation and the Assistant Administrator for Research and Development of the Environmental Protection Agency, or their designees, shall serve as co-chairs of the Interagency Working Group.*

(3) RESPONSIBILITIES.—*In overseeing the planning, management, and coordination of the Program, the Interagency Working Group shall—*

(A) establish goals and priorities for the Program, in consultation with the Advisory Council;

(B) provide for interagency coordination, including budget coordination, of activities under the Program;

(C) meet not later than 90 days from its establishment and periodically thereafter; and

(D) establish and consult with an Advisory Council on a regular basis.

(4) MEMBERSHIP.—*The Advisory Council members shall not be employees of the Federal Government and shall include a diverse representation of knowledgeable individuals from the private sector (including small- and medium-sized enterprises from across the value chain), academia, State and tribal governments, and nongovernmental organizations and others who are in a position to provide expertise.*

(f) AGENCY BUDGET REQUESTS.—

(1) IN GENERAL.—*Each Federal agency and department participating in the Program shall, as part of its annual request for appropriations to the Office of Management and Budget, submit a report to the Office of Management and Budget that—*

(A) identifies the activities of the agency or department that contribute directly to the Program; and

(B) states the portion of the agency or department's request for appropriations that is allocated to those activities.

(2) ANNUAL BUDGET REQUEST TO CONGRESS.—*The President shall include in the annual budget request to Congress a statement of the portion of the annual budget request for each agency or department that will be allocated to activities undertaken pursuant to the Program.*

(g) REPORT TO CONGRESS.—

(1) IN GENERAL.—*Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Interagency Working Group shall submit a report to the Committee on Science, Space, and Technology and Committee on Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works and the Committee on Commerce, Science, and Transportation of the Senate that shall include—*

(A) a summary of federally funded sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities;

(B) a summary of the financial resources allocated to sustainable chemistry initiatives;

(C) an analysis of the progress made toward achieving the goals and priorities of this Act the program established pursuant to subsection (c), and recommendations for future program activities;

(D) an assessment of the benefits of expanding existing, federally-supported regional innovation and manufacturing hubs to include sustainable chemistry and the value of directing the creation of 1 or more dedicated sustainable chemistry centers of excellence or hubs; and

(E) an evaluation of steps taken and future strategies to avoid duplication of efforts, streamline interagency coordination, facilitate information sharing, and spread best practices between participating agencies in the Program.

(2) SUBMISSION TO GAO.—*The Interagency Working Group shall also submit the report described in paragraph (1) to the Government Accountability Office for consideration in future Congressional inquiries.*

SEC. 28. STATE PROGRAMS.

(a) IN GENERAL.—For the purpose of complementing (but not reducing) the authority of, or actions taken by, the Administrator under this Act, the Administrator may make grants to States for the establishment and operation of programs to prevent or eliminate unreasonable risks within the States to health or the environment which are associated with a chemical substance or mixture and with respect to which the Administrator is unable or is not likely to take action under this Act for their prevention or elimination. The amount of a grant under this subsection shall be determined by the Administrator, except that no grant for any State program may exceed 75 per centum of the establishment and operation costs (as determined by the Administrator) of such program during the period for which the grant is made.

(b) APPROVAL BY ADMINISTRATOR.—(1) No grant may be made under subsection (a) unless an application therefor is submitted to and approved by the Administrator. Such an application shall be submitted in such form and manner as the Administrator may require and shall—

(A) set forth the need of the applicant for a grant under subsection (a)**[,]** *;*

(B) identify the agency or agencies of the State which shall establish or operate, or both, the program for which the application is submitted**[,]** *;*

(C) describe the actions proposed to be taken under such program[,] ;

(D) contain or be supported by assurances satisfactory to the Administrator that such program shall, to the extent feasible, be integrated with other programs of the applicant for environmental and public health protection[,] ;

(E) provide for the making of such reports and evaluations as the Administrator may require[, and]

(F) contain such other information as the Administrator may prescribe.

(2) The Administrator may approve an application submitted in accordance with paragraph (1) only if the applicant has established to the satisfaction of the Administrator a priority need, as determined under rules of the Administrator, for the grant for which the application has been submitted. Such rules shall take into consideration the seriousness of the health effects in a State which are associated with chemical substances or mixtures, including cancer, birth defects, and gene mutations, the extent of the exposure in a state of human beings and the environment to chemical substances and mixtures, and the extent to which chemical substances and mixtures are manufactured, processed, used, and disposed of in a State.

[(c) ANNUAL REPORTS.—Not later than six months after the end of each of the fiscal years 1979, 1980, and 1981, the Administrator shall submit to the Congress a report respecting the programs assisted by grants under subsection (a) in the preceding fiscal year and the extent to which the Administrator has disseminated information respecting such programs.

[(d) AUTHORIZATION.—For the purpose of making grants under subsection (a), there are authorized to be appropriated $1,500,000 for each of the fiscal years 1982 and 1983. Sums appropriated under this subsection shall remain available until expended.]

[SEC. 29. AUTHORIZATION FOR APPROPRIATIONS.

[There are authorized to be appropriated to the Administrator for purposes of carrying out this Act (other than sections 27 and 28 and subsections (a) and (c) through (g) of section 10 thereof) $10,100,000 for the fiscal year ending September 30, 1977, $58,646,000 for the fiscal year 1982 and $62,000,000 for the fiscal year 1983. No part of the funds appropriated under this section may be used to construct any research laboratories.]

SEC. 30. ANNUAL REPORT.

The Administrator shall prepare and submit to the President and the Congress on or before January 1, 1978, and on or before January 1 of each succeeding year a comprehensive report on the administration of this Act during the preceding fiscal year. Such report shall include—

(1) a list of the testing required under section 4 during the year for which the report is made and an estimate of the costs incurred during such year by the persons required to perform such tests;

[(2) the number of notices received during such year under section 5, the number of such notices received during such year under such section for chemical substances subject to a section

4 rule, and a summary of any action taken during such year under section 5(g);]

(2)(A) the number of notices received during each year under section 5; and

(B) the number of the notices described in subparagraph (A) for chemical substances subject to a rule, testing consent agreement, or order under section 4;

(3) a list of rules issued during such year under section 6;

(4) a list, with a brief statement of the issues, of completed or pending judicial actions under this Act and administrative actions under section 16 during such year;

(5) a summary of major problems encountered in the administration of this Act; and

(6) such recommendations for additional legislation as the Administrator deems necessary to carry out the purposes of this Act.

SEC. 31. EFFECTIVE DATE.

[Except as provided in section 4(f), this]

(a) IN GENERAL.—*This*Act shall take effect on January 1, 1977.

(b) RETROACTIVE APPLICABILITY.—*Nothing in this Act shall be interpreted to apply retroactively to any State, Federal, or maritime legal action commenced prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.*

COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY ACT OF 1980

* * * * * * *

SEC. 101. For purpose of this title—

(1)* * *

* * * * * * *

SEC. 104. (a)(1) Whenever (A) any hazardous substance is released or there is a substantial threat of such a release into the environment, or (B) there is a release or substantial threat of release into the environment of any pollutant or contaminant which may present an imminent and substantial danger to the public health or welfare, the President is authorized to act, consistent with the national contingency plan, to remove or arrange for the removal of, and provide for remedial action relating to such hazardous substance, pollutant, or contaminant at any time (including its removal from any contaminated natural resource), or take any other response measure consistent with the national contingency plan which the President deems necessary to protect the public health or welfare or the environment. When the President determines that such action will be done properly and promptly by the owner or operator of the facility or vessel or by any other responsible party, the President may allow such person to carry out the action, conduct the remedial investigation, or conduct the feasibility study in accordance with section 122. No remedial investigation or feasibility study (RI/FS) shall be authorized except on a determination by the President that the party is qualified to conduct the RI/FS and only if the President contracts with or arranges for a qualified person to assist the President in overseeing and reviewing the conduct of such RI/FS and if the responsible party agrees to reimburse the

Fund for any cost incurred by the President under, or in connection with, the oversight contract or arrangement. In no event shall a potentially responsible party be subject to a lesser standard of liability, receive preferential treatment, or in any other way, whether direct or indirect, benefit from any such arrangements as a response action contractor, or as a person hired or retained by such a response action contractor, with respect to the release or facility in question. The President shall give primary attention to those releases which the President deems may present a public health threat.

* * * * * * *

(i)(1) There is hereby established within the Public Health Service an agency, to be known as the Agency for Toxic Substances and Disease Registry, which shall report directly to the Surgeon General of the United States. The Administrator of said Agency shall, with the cooperation of the Administrator of the Environmental Protection Agency, the Commissioner of the Food and Drug Administration, the Directors of the National Institute of Medicine, National Institute of Environmental Health Sciences, National Institute of Occupational Safety and Health, Centers for Disease Control and Prevention, the Administrator of the Occupational Safety and Health Administration, the Administrator of the Social Security Administration, the Secretary of Transportation, and appropriate State and local health officials, effectuate and implement the health related authorities of this Act. In addition, said Administrator shall—

* * * * * * *

(5)(A) For each hazardous substance listed pursuant to paragraph (2), the Administrator of ATSDR (in consultation with the Administrator of EPA and other agencies and programs of the Public Health Service) shall assess whether adequate information on the health effects of such substance is available. For any such substance for which adequate information is not available (or under development), the Administrator of ATSDR, in cooperation with the Director of the National Toxicology Program, shall assure the initiation of a program of research designed to determine the health effects (and techniques for development of methods to determine such health effects) of such substance. Where feasible, such program shall seek to develop methods to determine the health effects of such substance in combination with other substances with which it is commonly found. Before assuring the initiation of such program, the Administrator of ATSDR shall consider recommendations of the Interagency Testing Committee established under [section 4(e)] *section 4(f)* of the Toxic Substances Control Act on the types of research that should be done.

* * * * * * *

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Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 6/11/2015 9:45:42 PM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]; Kaiser, Sven-Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac78d3704ba94edbbd0da970921271ff-SKAISER]
Subject: Preemption report by CRS
Attachments: R44066 - CRS comparison of S.697 and H.R. 2576 Preemption.pdf

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Preemption in Proposed Amendments to the Toxic Substances Control Act (TSCA): Side-by-Side Analysis of S. 697 and H.R. 2576

Alexandra M. Wyatt
Legislative Attorney

June 11, 2015

Congressional Research Service
7-5700
www.crs.gov
R44066

CRS REPORT
Prepared for Members and
Committees of Congress

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Summary

The Toxic Substances Control Act (TSCA) was enacted in 1976 to govern the regulation of chemical substances in U.S. commerce. Its core provisions have not been significantly amended since that time. Under TSCA, the Environmental Protection Agency (EPA) has implemented a chemicals management program over the past four decades. EPA has issued a very limited number of risk management rules under TSCA to restrict chemicals it has found to present unreasonable risks of injury to human health or the environment. Meanwhile, states and, in a few cases, local subdivisions of states have enacted an increasing number of their own chemical programs and restrictions.

The federal preemption doctrine derives from the Supremacy Clause of the U.S. Constitution, which provides that federal laws "shall be the supreme Law of the Land." Congress can expressly preempt state and local laws by statute, and the scope of preemption is determined by Congress's intent. Because TSCA preemption is based on EPA's issuance of certain types of rules and orders targeting particular chemicals (subject to exceptions), state and local chemical programs and restrictions—for the most part targeting chemicals not subject to EPA risk management rules—generally have not faced preemption under TSCA. As legislative proposals to amend TSCA have been discussed in recent years, one major topic of debate has been the extent to which the scope of TSCA's preemption of state chemical regulations should be preserved, expanded, or reduced.

This report provides a brief background on preemption in current TSCA. The report then provides a side-by-side comparison of the preemption provisions of House and Senate bills in the 114th Congress to amend TSCA. S. 697, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, was ordered to be reported out of the Senate Environment and Public Works Committee on April 28, 2015, on a 15-5 vote. H.R. 2576, the TSCA Modernization Act of 2015, was first released as a discussion draft on April 7, 2015. It was introduced as H.R. 2576 and referred to the House Energy and Commerce Committee on May 26, 2015, and the committee ordered the bill to be reported on June 3, 2015, on a 47-0 vote, with one abstaining.

Both bills would expand EPA's authority to regulate chemicals in a number of ways, similar in some respects, although S. 697 is a longer and more detailed bill that would make more changes to TSCA's language than H.R. 2576. The preemption provisions of the two bills have many similarities as well, including in their overall structure, which retains TSCA's approach of only preempting state and local laws on a chemical-by-chemical basis after EPA action on a chemical. Both bills would also exclude from preemption state and some local chemical requirements in effect as of August 1, 2015, and any state or local requirements arising from long-standing state chemical laws such as California's Proposition 65. However, the bills have a number of differences with respect to preemption. For example, S. 697 would preempt new restrictions on a chemical while EPA prepared a safety assessment on that chemical, a period of up to several years; H.R. 2576 may impose somewhat broader preemption on the basis of EPA actions for new chemicals and new uses than S. 697. Various other similarities and differences between the two bills regarding preemptive EPA actions, exceptions, exemptions, and waivers are also compared.

A third proposal to amend TSCA, S. 725, the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act, would eliminate express TSCA preemption entirely. S. 725 is not included in this report's comparison.

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Introduction to Preemption in TSCA

Preemption Under the Constitution

Preemption raises complex issues of law, policy, and federalism. Under the Supremacy Clause of the U.S. Constitution,[1] state law and policy (or law and policy of local subdivisions of states, acting under state law) that conflicts with federal law must yield to the exercise of Congress's powers. Whether a certain state action is preempted by federal law is a question of congressional intent.[2] When it acts, Congress can preempt state action within a field entirely, allow for states to act freely, or permit state action to any intermediate degree. Federal statutes relating to protection of the environment and public health have taken a diverse range of approaches to preemption ranging between these two extremes of field preemption and no preemption. The Toxic Substances Control Act (TSCA),[3] which defines the authority of the Environmental Protection Agency (EPA) to assess and regulate chemical substances in U.S. commerce, takes an intermediate approach.

Overview of TSCA

An overview of TSCA as a whole is necessary to place TSCA's preemption provisions in context. For more information, see CRS Report RL31905, *The Toxic Substances Control Act (TSCA): A Summary of the Act and Its Major Requirements*, by Jerry H. Yen.

TSCA establishes a chemical regulatory program allowing EPA to review new chemical substances before they enter U.S. commerce, as well as significant new uses of chemical substances as designated by EPA (§5);[4] to regulate chemicals in commerce that EPA determines to present unreasonable risks of injury to human health or the environment, using the least burdensome requirements that adequately protect against such risks (§6);[5] and to require testing on chemicals that may present an unreasonable risk, or that merit testing by virtue of certain high production volume or high exposure potential criteria (§4).[6] TSCA also authorizes and mandates that EPA require reporting of certain information on chemicals by manufacturers (including importers), processors, and sometimes distributors, and to maintain an inventory of chemicals and substances that have commenced non-exempt manufacture or import in the United States (§8).[7] In addition, among other provisions, TSCA requires EPA to maintain confidentiality of trade secrets

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[1] U.S. CONST. art. VI, cl. 2.

[2] While this report focuses on express statutory provisions regarding preemption, preemption may be implied as well as express. "Conflict preemption" could be implied either because compliance with both the state rule and the TSCA rule would be impossible, or because the state rule would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *See generally Article VI: Prior Debts, National Supremacy, and Oaths of Office, in* S. DOC. NO. 112-9, THE CONSTITUTION OF THE UNITED STATES OF AMERICA: ANALYSIS AND INTERPRETATION, INTERIM EDITION: ANALYSIS OF CASES DECIDED BY THE SUPREME COURT OF THE UNITED STATES TO JULY 1, 2014, at 986-991, 100-1005 (Kenneth R. Thomas, ed., 2014), *available at* http://www.gpo.gov/fdsys/pkg/GPO-CONAN-REV-2014/pdf/GPO-CONAN-REV-2014-9-7.pdf.

[3] 15 U.S.C. §§2601-2697.

[4] 15 U.S.C. §2604.

[5] 15 U.S.C. §2605.

[6] 15 U.S.C. §2603.

[7] 15 U.S.C. §2607.

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and privileged or confidential business information in a particular manner (§14),[8] coordinate with other federal agencies and EPA offices (§9),[9] and respond to citizens' petitions (§21).[10] TSCA's core provisions (Title I) have not been significantly amended since the law's enactment in 1976.[11]

It is also important to note that TSCA applies to "chemical substances" (defined in §3).[12] To avoid overlapping with other federal statutes, TSCA defines this term to exclude certain categories of materials and substances from its scope. Substances when used in pesticides, foods (including ingredients and additives), food contact substances (such as containers), personal care products, tobacco, nuclear materials, firearms, and shells and cartridges are not within the scope of TSCA—or consequently, within the scope of TSCA preemption.

Preemption Under TSCA

TSCA's preemption provisions (§18)[13] base preemption on certain actions taken by EPA under a handful of specified statutory provisions. So long as EPA has not specifically addressed a chemical under TSCA, there is no preemption of state regulation of that same chemical.[14] When EPA does take certain actions regarding a chemical, TSCA provides for preemption of duplicative testing requirements and of non-identical state regulations, other than total bans or disposal regulations, unless the state regulations are adopted under other federal laws or an exemption is granted.[15] Specifically, TSCA Section 18(a) provides the following:

- If EPA promulgates a rule under TSCA Section 4 requiring manufacturers or processors of a chemical substance to conduct testing on that substance to develop data on its health and environmental effects, then a state or political subdivision cannot establish or continue its own testing requirement rule for that chemical substance "for purposes similar to those for which testing is required" by EPA.[16]

  EPA has issued testing rules for several hundred chemicals under Section 4.[17] These would preempt similar testing requirements by states, but research has uncovered no cases finding preemption of state testing requirements by EPA testing rules.[18]

[8] 15 U.S.C. §2613.

[9] 15 U.S.C. §2608.

[10] 15 U.S.C. §2620.

[11] Five titles have been added to deal with particular chemical concerns: asbestos (Title II), indoor radon (Title III), lead (Title IV), environmental exposures in schools (Title V), and formaldehyde in composite wood products (Title VI).

[12] 15 U.S.C. §2602(2)(B).

[13] 15 U.S.C. §2617.

[14] 15 U.S.C. §2617(a)(1).

[15] 15 U.S.C. §2617(a)(2), (b).

[16] 15 U.S.C. §2617(a)(2)(A).

[17] *See generally* 40 C.F.R. pt. 799.

[18] EPA also works with chemical companies to develop needed data via Enforceable Consent Agreements and Voluntary Testing Agreements; these do not have preemptive effect because TSCA's testing preemption applies only to rules, not orders or agreements. 15 U.S.C. §2617(a)(2)(A).

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- If EPA prescribes a rule or order under TSCA Section 5 (new chemicals) or Section 6 (existing chemicals), which is designed to protect against a risk of injury to health or the environment associated with a chemical substance, then a state or political subdivision cannot establish or continue any non-identical requirement applicable to the same chemical substance (or article containing such chemical substance) that is designed to protect against the same risk.[19]

  Since 1976, EPA has promulgated rules imposing restrictions to protect against risk of injury to health or the environment from six existing chemicals under Section 6 of TSCA[20] and four new chemicals under Section 5(f).[21] These few EPA rules have not preempted many state or local requirements.[22]

Because these are the only bases for preemption, EPA information-gathering rules under Section 8, or actions under any other section of TSCA, do not preempt state or local actions. Pursuant to exceptions, any preemption by EPA rules or orders under Sections 5 or 6 would *not* extend to the following:

- State regulations on the manner or method of disposal of chemicals; an EPA rule pertaining to disposal has no preemptive effect.[23]
- State requirements that are identical to federal requirements,[24] enabling states to provide additional enforcement (co-enforcement) of those requirements.
- State requirements that are adopted under the authority of any other federal law.[25]
- Complete prohibitions on the use of particular chemicals within a state's jurisdiction. However, a state cannot prohibit the chemical's use in manufacturing or processing of other substances.[26]

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[19] 15 U.S.C. §2617(a)(2)(B).

[20] The section 6 rules are a ban on manufacturing, processing, distribution in commerce and use of PCBs, 40 C.F.R. pt. 761 (specifically required by TSCA section 6(e)); a ban on manufacture, processing, distribution in commerce of chlorofluorocarbons (CFCs) for aerosol propellants, 43 Fed. Reg. 11318 (Mar. 17, 1978) (other uses of CFCs were later phased out under the Clean Air Act); a ban on storage and disposal of waste contaminated with a certain dioxin at one facility in Arkansas (revoked five years later upon the effective date of the Resource Conservation and Recovery Act (RCRA), 50 Fed. Reg. 1978 (Jan. 14, 1985)); a limit on certain uses of metalworking fluids, 40 C.F.R. pt. 747; and a ban on hexavalent chromium chemicals in comfort (i.e., non-industrial) cooling towers, 40 C.F.R. §749.68. A ban on asbestos was largely struck down in 1991 (except with respect to certain new uses), because, among other reasons, the court held that EPA had not considered less burdensome alternatives as required by TSCA section 6. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

[21] *See* EPA, TSCA Chemical Substance Inventory, 2014 version, *available at* http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/ (search of "regulatory flags" in inventory file). The new chemicals regulated under TSCA section 5(f) are all used in metalworking. *See* 40 C.F.R. pt. 747; 49 Fed. Reg. 36846 (Sep. 20, 1984); 49 Fed. Reg. 24658 (June 14, 1984); 49 Fed. Reg. 2762 (Jan. 23, 1984).

[22] EPA has also issued a number of consent orders under Section 5(e) imposing restrictions on individual manufacturers, and Significant New Use Rules under Section 5(a) requiring notification to be submitted prior to manufacturing or processing chemicals for non-ongoing uses designated as "significant" by EPA, but these actions do not appear to have been subjected to judicial analysis as to their preemptive effect on any state or local requirements.

[23] 15 U.S.C. §2617(a)(2)(B) (citing 15 U.S.C. §2605(a)(6)).

[24] 15 U.S.C. §2617(a)(2)(B)(i).

[25] 15 U.S.C. §2617(a)(2)(B)(ii) (citing Clean Air Act as an example).

[26] 15 U.S.C. §2617(a)(2)(B)(iii).

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TSCA Section 18(b) allows a state to apply to EPA for an exemption to allow a more stringent state chemical risk management regulation that would otherwise be preempted.[27] EPA may, by rule, grant such an exemption so long as compliance with the state requirement would not cause a violation of the federal requirements for the chemical; would provide a significantly higher degree of protection from risk; and would not "unduly burden interstate commerce."[28] It appears that no exemption rule has ever been issued.[29]

Section 18 of TSCA does not expressly preempt or affect lawsuits regarding chemical exposures under common law.[30] Nonetheless, courts would generally interpret preempted "requirements" to include state common law.[31] Thus, it is possible, for example, that a defendant's compliance with TSCA could provide a viable preemption defense to a lawsuit, if the common law or statutory requirement forming the basis for the lawsuit were designed to protect against the same risk as an EPA rule or order under TSCA Sections 5 or 6.[32] The division of federal and state authority over chemicals is also affected by the lack of express authority, in Section 18 or elsewhere, for EPA to share with states any trade secret information that it collects that is confidential under TSCA Section 14.

TSCA Amendment Proposals in the 114th Congress

Legislative Background and Status

Legislative efforts to revise TSCA's chemical regulatory framework date back at least to 2005.[33] The legislative proposals that have been discussed over this time generally would preserve the basic organization of TSCA Title I; for example, provisions related to testing would remain in Section 4, new chemicals and new uses in Section 5, regulation of existing chemicals in Section 6, and preemption in Section 18. They would also generally continue TSCA's exclusion of specified categories of substances regulated under other laws. Yet the proposals would make significant changes to the operation of TSCA. The proposals differ in various respects from one another, however, including with respect to preemption.

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[27] 15 U.S.C. §2617(b).

[28] *Id.*

[29] The state of Connecticut applied for an exemption to pursue a state registration program for PCB transformers. This was not granted because EPA established a national registration requirement for PCB transformers at 40 C.F.R. §761.30(a)(1)(vi). *See* 63 Fed. Reg. 35384, 35393-94 (June 29, 1998) (discussing Connecticut petition and response).

[30] 15 U.S.C. §2617. However, preemption would apply only to the extent the common law requirement was "designed to protect against" the same risk as an EPA requirement for a chemical.

[31] *See, e.g., Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008) ("Absent other indication, reference to a State's 'requirements' includes its common-law duties.").

[32] *See Anderson v. Hackett*, 646 F. Supp. 2d 1041, 1053 (S.D. Ill. 2009) (stating in dicta that a showing by the defendant chemical manufacturers that they had complied with EPA's PCB regulations under TSCA "may provide them a defense to Plaintiffs's action" seeking damages and medical monitoring for alleged releases of PCB-containing oil). There have been few or no examples of such defenses outside the PCB context.

[33] Kid Safe Chemicals Act, S. 1391, H.R. 4308, 109th Cong. (2005). *See also* GOVERNMENT ACCOUNTABILITY OFFICE, GAO NO. 05-458, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA'S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM (2005), *available at* http://www.gao.gov/new.items/d05458.pdf. The Kid Safe Chemicals Act was reintroduced with few substantive changes in 2008. S. 3040, H.R. 6100, 110th Cong. (2008).

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In the 114th Congress, S. 697, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, was introduced on March 10, 2015. A hearing on the bill was held before the Senate Environment and Public Works Committee on March 18, 2015.[34] Following a markup, an amended version of S. 697 was ordered to be reported out of the committee on April 28, 2015, on a 15-5 vote with bipartisan support. An alternate proposal, S. 725, the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act, has not been ordered to be reported out of committee. S. 725 would eliminate express preemption from TSCA entirely,[35] and is not included in this report's comparison.

In the House of Representatives, a discussion draft entitled the TSCA Modernization Act of 2015 was released in early April, and a hearing was held in the Subcommittee on Environment and the Economy of the Committee on Energy and Commerce on April 14, 2015.[36] After some revisions, the House discussion draft was approved by the subcommittee on May 14, 2015, on a 21-0 voice vote, also on a bipartisan basis. The TSCA Modernization Act of 2015 was formally introduced, with some amendments, on May 26, 2015, as H.R. 2576 and referred to the full committee on Energy and Commerce. The committee ordered the bill to be reported on June 3, 2015, on a 47-0 vote, with one abstaining.

Comparison

S. 697 and H.R. 2576 address many of the same topics and provisions of TSCA, with important similarities and differences in their approaches. For additional discussion of select issues addressed by the bills, see CRS Report R44024, *Proposed Amendments to the Toxic Substances Control Act (TSCA) in the 114th Congress: S. 697, S. 725, and a House Discussion Draft*, by Jerry H. Yen and Alexandra M. Wyatt.

S. 697 generally takes a more comprehensive and detailed approach to amending TSCA. It would add, among other new definitions, a definition of the term "safety standard" to mean a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of injury to health or the environment, including to any relevant "potentially exposed or susceptible population," will result from exposure to a chemical substance under the conditions of use.[37] EPA would be required to establish a risk-based screening process to identify chemicals as high or low priorities for assessment, and then to conduct assessments on the high priority chemicals, with at least 25 assessments initiated by five years after enactment (along with other deadlines).[38] Chemicals found not to meet the safety standard would have to be regulated; EPA would not be limited to the "least burdensome requirements" as under current TSCA, although it would have to take into account costs, benefits, and alternatives.[39] S. 697 would make changes to the new chemical provisions, including imposing new duties on EPA to review such chemicals

[34] *Frank R Lautenberg Chemical Safety for the 21st Century Act: Hearing before the S. Comm. on Env't and Public Works*, 114th Cong. (2015), *available at* http://www.epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_id=60d1e265-cdac-7629-3385-2d72dd8fe3eb.

[35] S. 725, 114th Cong. §117 (2015).

[36] *H.R. ____, the TSCA Modernization Act of 2015: Hearing before the H. Subcomm. on Env't and the Economy*, 114th Cong. (2015), *available at* http://energycommerce.house.gov/hearing/hr-tsca-modernization-act-2015.

[37] S. 697, 114th Cong. §3(4) (adding new TSCA §3(16)).

[38] *Id.* §6 (adding new TSCA §4A(a)(2)).

[39] *Id.* §8(3) (adding new TSCA §6(a)-(e)).

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against the safety standard.[40] New provisions on policies and guidance, including pertaining to use of science, would also impose duties on EPA.[41] Based on amended reporting requirements, EPA would be required to identify chemicals that have not recently been in U.S. commerce as "inactive."[42]

H.R. 2576 would make fewer changes to TSCA. Unlike S. 697, it would not change TSCA's new chemical provisions. Nor would it add a detailed new prioritization scheme for evaluating chemicals (although EPA could likely continue its existing prioritization efforts, the TSCA Work Plan for Chemical Assessments[43]). Similar to S. 697, H.R. 2576 would prohibit EPA from taking into account information on cost and other factors not directly related to health or the environment in conducting risk evaluations, give EPA a mandate and framework to conduct such risk evaluations, and remove the "least burdensome requirements" language from TSCA's risk management provisions for chemicals found to present an unreasonable risk. H.R. 2576 would instead require that chemical rules be cost-effective, unless EPA determines that additional or different requirements are necessary to protect against the identified risk.[44] EPA would have to initiate at least 10 risk evaluations per year, subject to the availability of appropriations.[45]

While doing so in different ways, both bills would also generally expand EPA's testing authority; impose certain requirements pertaining to scientific standards; modify TSCA's confidentiality provisions; expand TSCA's fee provisions; and make certain other changes and additions to other sections of the law—although as noted above, S. 697 would make substantially more changes and additions.

Table 1 below provides a side-by-side comparison of the preemption provisions and other provisions related to the state-federal relationship in these two bills.[46] **Table 1** first describes limits on the universe of state or local rules that would potentially be subject to preemption by EPA actions by comparing the bills' overall preemption scope, exceptions, and savings clauses. These are broadly similar, with some differences at the margins; most notably, both would retain TSCA's chemical-by-chemical preemption approach. **Table 1** then compares the scope and timing of preemption (subject to the exceptions) based on various EPA actions under each proposal. Here, there are somewhat larger structural differences between the bills: for example, S. 697 preempts new state restrictions while a chemical is undergoing assessment by EPA, while H.R. 2576 has somewhat broader preemption on the basis of EPA actions on new chemicals and significant new uses of chemicals. Both bills would preempt state requirements after EPA either imposed requirements on a chemical found to present an unreasonable risk, or after EPA determined that a chemical did not present an unreasonable risk. **Table 1** then compares S. 697's new waiver provisions with those of H.R. 2576, which are retained from current TSCA. Finally, **Table 1** notes several other provisions not pertaining to preemption that nonetheless relate to the federal-state relationship under TSCA.

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[40] *Id.* §7 (amending TSCA §5).

[41] *See id.* §4 (adding new TSCA §3A), §23 (adding new TSCA §27(c)-(g)).

[42] *Id.* §10 (amending TSCA §8).

[43] *See* EPA, Chemical Safety and Pollution Prevention, Existing Chemicals—Current Chemical Activities (2015), http://www.epa.gov/oppt/existingchemicals/pubs/managechemrisk.html.

[44] H.R. 2576, 114th Cong. §4 (2015) (amending TSCA §6).

[45] *Id.*

[46] *Id.* §7, S. 697 §17 (both amending TSCA §18). Detailed legal analysis whether the bills would preempt any particular state chemical regulation is beyond the scope of this memorandum.

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Table 1. Side-by-Side Comparison of TSCA Legislation in the 114th Congress: Preemption Provisions and State-Federal Relationship

Provision	S. 697, Frank R. Lautenberg Chemical Safety for the 21st Century Act (Ordered to be Reported out of Committee April 28, 2015)	H.R. 2576, the TSCA Modernization Act of 2015 (Ordered to be Reported out of Committee June 3, 2015)
State or Local Law Not Preempted—Baseline, Exceptions, and Savings Clauses		
Framework: No Preemption Until EPA Action on a Chemical	Broadly, both bills would retain the general structure of preemption under TSCA Section 18: there would be no effect on state chemical regulations or actions unless and until EPA took certain actions, and preemption would operate on a chemical-by-chemical basis. Current TSCA Section 18(a)(1) states that "[e]xcept as provided … nothing in this chapter shall affect the authority of any State or political subdivision of a State to establish or continue in effect regulation of any chemical…." While S. 697 does not retain this express language, as H.R. 2576 would, the effect of removing this provision would be minimal; it would still remain the case that nothing in TSCA as amended by S. 697 would affect state or local authority over chemicals except as specifically provided in the amended preemption provisions (or as required in narrow circumstances by the Supremacy Clause of the U.S. Constitution; see "Express Conflicts," below).	
Scope Limitation in Definition of Chemical Substances	Both bills would keep TSCA's definition of "chemical substance" and its exclusion from the scope of TSCA of categories including pesticides, tobacco products, nuclear materials, firearms, shells, cartridges, food, food contact substances in containers, drugs, medical devices, and personal care products. Thus, neither EPA actions under TSCA, nor preemption based on EPA actions, would apply to such categories.	
Preemptive Effect of EPA Actions Taken Before Enactment	S. 697 would not change the preemptive effect of any rule or order promulgated or issued by EPA prior to the date of its enactment, or of any rule or order issued after enactment for a chemical already subject to a Section 6 rule on the date of enactment, unless that post-enactment rule or order followed designation of the chemical as a high priority.	H.R. 2576 provides that nothing in it shall be construed as changing the preemptive effect of an action taken by EPA either prior to the date of its enactment, or under section 6(e) (regarding regulation of polychlorinated biphenyls or PCBs).
Express Conflicts	The Supremacy Clause of the U.S. Constitution would operate in addition to express preemption: "conflict preemption" could be implied under certain circumstances.[a] S. 697 also addresses inconsistent restrictions in its exception for requirements under certain state or local environmental laws, discussed below.	H.R. 2576 would add to the background Supremacy Clause principles, in the provisions preserving existing state chemical programs and restrictions and the other exceptions described below, language allowing preemption if EPA's requirement "actually conflicts" with the state or local requirement.[b]
Preservation of Existing State Chemical Programs and Restrictions	Under both bills, states and localities could continue to enforce actions taken before August 1, 2015, under the authority of a state law, restricting manufacturing, processing, distribution in commerce, use, or disposal of a chemical, and would not be preempted by any EPA action on that chemical. (Local ordinances issued under general local government authority, as well as requirements that are not restrictions, could be subject to preemption.) This provision would grandfather many existing state chemical restrictions from the possibility of preemption by TSCA, but not, for example, any future chemical restrictions that might be issued under states' existing green chemistry statutes. States and localities could also continue to enforce actions taken at any time under longstanding state laws in effect by August 31, 2003, such as California's Proposition 65.	

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Provision	S. 697, Frank R. Lautenberg Chemical Safety for the 21st Century Act (Ordered to be Reported out of Committee April 28, 2015)	H.R. 2576, the TSCA Modernization Act of 2015 (Ordered to be Reported out of Committee June 3, 2015)
Exceptions from Preemption for State Reporting and Monitoring Requirements	S. 697 would expressly exempt from preemption any state or local requirement or other action implementing a reporting, monitoring, disclosure, or other information obligation for the chemical substance not otherwise required under TSCA or other federal law.	To the extent state or local requirements for reporting or monitoring of chemicals were designed for information gathering, and not for testing for purposes similar to an EPA testing rule or for protection against exposure, they would not be within the scope of H.R. 2576's preemption. Courts would have to interpret whether particular state or local reporting or disclosure requirements were "designed to protect against exposure."
Exception from Preemption for State Requirements Identical to Federal Requirements	As in current TSCA, a state or local requirement identical to a requirement prescribed by EPA would not be preempted, allowing for co-enforcement. New provisions on penalties and sanctions would differ somewhat between the two bills but would generally aim to avoid duplicative penalties by preventing states from assessing a penalty for a violation for which EPA had already assessed a penalty.	
	S. 697 would cap the penalties and sanctions available to states at the level available to EPA. EPA could not assess a penalty for a violation for which a state had already assessed a penalty.	H.R. 2576 would allow available state penalties and sanctions to be more stringent than those available to EPA; it would also allow EPA to assess a penalty for a violation for which a state had already assessed a penalty so long as the combined total of the penalties did not exceed the maximum that EPA could assess. This exception would not extend to testing requirements for purposes similar to an EPA testing requirement.
Exception from Preemption for Requirements Under Other Federal Laws	State or local requirements or various other actions 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, would be shielded from preemption. This language is somewhat broader than current TSCA, which is limited to "requirement[s] … adopted under" the authority of any other federal law.	The H.R. 2576 exception would be similar to current TSCA: state or local requirements adopted under the authority of any other federal law would be shielded from preemption. However, this exception would not extend to testing requirements for purposes similar to an EPA testing requirement.

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Provision	S. 697, Frank R. Lautenberg Chemical Safety for the 21st Century Act (Ordered to be Reported out of Committee April 28, 2015)	H.R. 2576, the TSCA Modernization Act of 2015 (Ordered to be Reported out of Committee June 3, 2015)
Exceptions from Preemption for Disposal-Related Requirements or Requirements Under Certain State or Local Environmental Laws	State or local chemical requirements or actions adopted pursuant to state or local authority related to waste treatment or disposal would not be preempted; restrictions on disposal are not included within the scope of preempted actions. Requirements or actions adopted pursuant to authority under a state or local law related to water quality or air quality also would not be preempted. However, to the extent such requirement or action, in fact, imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical, it would be preempted if it (a) addresses the same hazards, exposures, and use conditions as EPA's safety determination, but is inconsistent with EPA's action; or (b) would cause a violation of the EPA action.	State or local requirements "related to waste treatment or waste disposal" would not be preempted, and EPA disposal-related requirements would not have preemptive effect. State or local chemical requirements "adopted to protect air or water quality" would not be preempted. This phrase is worded somewhat more narrowly than the comparable phrase in S. 697, because while S. 697 extends to actions under authorities "related to" air or water quality, H.R. 2576 would require the actions to be adopted "to protect" them; H.R. 2576 would thus require purpose, as opposed to relation. Like the exception above, these exceptions would not extend to any testing requirements for purposes similar to an EPA testing requirement.
Savings Clause for Various Rights, Causes of Action and Remedies	S. 697 would protect the following from being preempted by EPA actions under TSCA as amended by S. 697: - any federal or state common law rights or statute creating either a remedy for civil relief (including civil damages), or a penalty for a criminal conduct, - any cause of action for any injury based on any legal theory of liability. S. 697 does not address interpretation of contracts, except to the extent that contracts would be addressed by common law rights or statutes creating remedies or within any "legal theory of liability."	While similar in many respects to the comparable provision in S. 697, H.R. 2576's savings clause would protect the following from being preempted *or otherwise affected* by EPA actions under TSCA, as amended by H.R. 2576: - federal or state tort law or the law governing the interpretation of contracts, including any remedy for civil relief (including civil damages), whether under statutory or common law, and - any cause of action for any injury based on any "legal theory relating to tort law."
Savings Clause for Use of EPA Determinations as Evidence in Civil Actions	Actions by EPA under TSCA as amended by S. 697 (such as a determination that a chemical meets or does not meet the safety standard) cannot be interpreted as dispositive in any civil action in any federal or state court. (Note, however, that such EPA actions, while not dispositive, could still influence a federal or state court's determination if used as evidence.) TSCA as amended by S. 697 would not affect the authority of any court to make a determination in an adjudicatory proceeding with respect to the admissibility of evidence.	It is "not the intent of Congress" that actions by EPA under TSCA as amended by H.R. 2576 be interpreted as "influencing … the disposition" of any civil action for damages. However, use of EPA actions as evidence would be left to courts. In H.R. 2576, this provision is limited to state courts. As with S. 697, TSCA as amended by H.R. 2576 would not affect the authority of any state court to make a determination in an adjudicatory proceeding with respect to the admissibility of evidence.

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Provision	S. 697, Frank R. Lautenberg Chemical Safety for the 21st Century Act (Ordered to be Reported out of Committee April 28, 2015)	H.R. 2576, the TSCA Modernization Act of 2015 (Ordered to be Reported out of Committee June 3, 2015)
Scope and Timing of Preemption Based on EPA Actions		
New Chemicals	S. 697 does not provide for preemption on the basis of EPA orders or consent agreements under amended TSCA Section 5 for new chemicals, unless such actions require the development of information on the chemical (see "Testing," below). S. 697 contrasts in this respect with current TSCA, which provides that, subject to exceptions, any EPA rule or order for a new chemical under Section 5, designed to protect against a risk of injury to health or the environment, preempts state or local requirement designed to protect against that same risk.	H.R. 2576 would not substantively amend TSCA Section 5. Subject to exceptions (see above), any EPA rule or order for a new chemical under TSCA Section 5, promulgated or issued after enactment of H.R. 2576 and designed to protect against a risk of injury to health or the environment, would preempt state or local requirements designed to protect against exposure to that chemical from any use that had been identified in that chemical's premanufacture notification (PMN), as PMNs are "received by [EPA] under [TSCA] section 5(a)." This exposure- and use-based scope of preemption differs from current TSCA's preemption of requirements designed to protect against the same risk as an EPA requirement. (PMNs must contain information on proposed categories of use, to the extent known to or reasonably ascertainable by the submitter.)
Significant New Uses	Similar to current TSCA, Section 5 as amended by S. 697 would authorize EPA to declare certain non-ongoing uses of chemicals "significant new uses" by rule (Significant New Use Rule, or SNUR) and require a Significant New Use Notification (SNUN) 90 days prior to any manufacturing (including importing) or processing of that chemical for that significant new use. A SNUR issued by EPA for a chemical after enactment of S. 697 would narrowly preempt state or local requirements for notification of the use that EPA designated as a significant new use for that chemical, beginning on the effective date of the SNUR, and subject to exceptions (see above). Any state or local requirements for the chemical other than use notification requirements would not be preempted by the SNUR.	Preemption would depend in part on whether a SNUR was deemed to be "designed to protect against a risk of injury to health or the environment." If so, then subject to exceptions (see above), a SNUR for a chemical promulgated by EPA after enactment of H.R. 2576 would preempt requirements designed to protect against exposure to that chemical from "a use identified in a notice received by [EPA] under [TSCA] section 5(a)." As noted above, this would extend to ongoing uses identified in any PMN for the chemical as well as in any new uses identified in any SNUN submitted for the chemical. If a SNUR was deemed to be designed to give EPA an opportunity for evaluation and not to protect against risk, then it would not have preemptive effect. This interpretation, while possible, appears less likely given EPA's use of SNURs to date.

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Provision	S. 697, Frank R. Lautenberg Chemical Safety for the 21st Century Act (Ordered to be Reported out of Committee April 28, 2015)	H.R. 2576, the TSCA Modernization Act of 2015 (Ordered to be Reported out of Committee June 3, 2015)
Testing	If EPA promulgated a rule, issued an order, or entered into a consent agreement requiring development of information (such as by testing) on a chemical under Sections 4, 5, or 6 as amended by S. 697, that EPA requirement would preempt state or local information development requirements for that chemical that would be reasonably likely to produce the same information as the EPA requirement, subject to exceptions (see above).	H.R. 2576 would retain current TSCA Section 18(a)(2)(A), which provides that if EPA promulgates a rule under TSCA Section 4 requiring testing on a chemical, that rule would preempt state or local testing requirements for that chemical for purposes similar to those of the EPA rule. H.R. 2576 would change "rule" to "rule, order, or consent agreement" (but would not change the lack of preemptive effect of pre-enactment testing orders or consent agreements). Exceptions for identical requirements or for requirements under other federal or certain state laws would not apply, nor waivers for the most part (see below), but actions taken under state laws in effect in 2003 would be preserved (see above).
EPA Prioritization and Assessment; New State or Local Restrictions	Subject to exceptions (see above), S. 697 would preempt a state or locality from establishing a *new* restriction (other than on disposal) on a chemical designated by EPA as a high priority for safety assessment under new Section 4A, beginning when EPA defined the scope of the safety assessment, and continuing while EPA conducted the assessment. S. 697 would require EPA to publish the scope of the safety assessment and safety determination as soon as practicable and no later than six months after the date on which EPA designated the chemical a high priority. Until that publication, states and localities could enact new restrictions that would not be preempted. Preemption under this provision would last until EPA completed the safety assessment and safety determination for the chemical; at that time, preemption would either continue, if EPA found the chemical to meet the safety standard, or be temporarily lifted, if EPA found the chemical not to meet the safety standard, as described below. S. 697 would require EPA to complete a safety assessment and safety determination not later than three years after the date of a chemical's high-priority designation, subject to extension. EPA's designation of a chemical as a low priority would not preempt any state or local requirements.	No preemption provision. States and localities could establish new restrictions on chemicals during the period in which EPA evaluated a chemical. (H.R. 2576 does not set forth a specific prioritization process, although as discussed at a hearing, EPA could likely continue its existing prioritization efforts, the TSCA Work Plan for Chemical Assessments. Instead of high priority and low priority lists, EPA would be required to complete a risk evaluation within three years, subject to extension, after: - EPA determined the chemical may present an unreasonable risk of injury to health or the environment because of potential hazard and a potential route of exposure, - EPA began the evaluation on a chemical on its Work Plan, or - a manufacturer of the chemical requested a risk evaluation.)

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Provision	S. 697, Frank R. Lautenberg Chemical Safety for the 21st Century Act (Ordered to be Reported out of Committee April 28, 2015)	H.R. 2576, the TSCA Modernization Act of 2015 (Ordered to be Reported out of Committee June 3, 2015)
EPA Completion of Risk Assessment; Determination that Chemical Does Not Present Unreasonable Risk	If EPA made a final determination under amended Section 6(c) that a chemical meets the safety standard (that is, will not result in an unreasonable risk from exposure under the intended conditions of use, as further defined in S. 697), that safety determination would preempt state and local restrictions (but not disposal restrictions or other requirements) for the uses included within the scope of EPA's safety determination. Exceptions could apply (see above).	If EPA made a final determination under amended Section 6(b) that a chemical will not present an unreasonable risk under the intended condition of use, EPA's determination would preempt state and local requirements designed to protect against exposure to the chemical under intended conditions of use that EPA had considered in the risk evaluation, and to apply under such conditions of use. Requirements not designed to protect against exposure would therefore not be preempted, but state or local disposal requirements could potentially be preempted. Exceptions could apply (see above).
EPA Completion of Risk Assessment; Determination that Chemical Presents Unreasonable Risk	If EPA made a final determination under amended Section 6(c) that a chemical does not meet the safety standard (that is, presents an unreasonable risk from exposure under the intended conditions of use), the preemption of new state or local requirements by EPA's safety assessment of high priority chemicals (see above) would stop. EPA's negative safety determination would preclude preemption of new or existing state or local requirements until the effective date of an EPA rule restricting the chemical under amended TSCA Section 6(d). After a negative safety determination, EPA would be required to promulgate a rule within two years of completing the negative safety determination, subject to extension.	If EPA made a final determination under amended Section 6(b) that a chemical presents or will present an unreasonable risk from exposure under the intended conditions of use, that negative determination would *not* preempt state or local requirements. State or local requirements designed to protect against exposure to the chemical under intended conditions of use considered by EPA in the risk evaluation would *not* be preempted until the effective date of an EPA rule restricting the chemical under amended TSCA Section 6(a). After a negative determination, EPA would be required to promulgate a rule within 180 days after publication of the determination, subject to extension.
EPA Rulemaking and Imposition of Requirements on a Chemical; Scope of Preemption	If EPA imposed any requirement on a chemical by rule under amended Section 6, then any non-identical, non-disposal-related state or local prohibition or restriction also applicable to that chemical (or to an article containing the chemical) would be preempted consistent with the scope of the safety determination. Preemption would be limited to the uses or conditions of use included in the scope of the rule, but would apply to state or local requirements whether designed to protect against exposure (as under H.R. 2576) or designed to manage risk by some other means. Exceptions could apply (see above).	If EPA imposed any requirement by rule under amended Section 6 (other than a disposal-related requirement) designed to protect against a risk associated with a chemical, then any non-identical state or local requirement also applicable to that chemical (or to an article because the article contains the chemical), and designed to protect against exposure to the chemical under the intended conditions of use considered by EPA in the chemical's risk evaluation, would be preempted. The requirement would not necessarily have to be a "restriction" on the manufacture, processing, distribution in commerce or use of a chemical, as under S. 697, although presumably most "requirement[s] … designed to protect against exposure" would be restrictions. Exceptions could apply (see above).

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Provision	S. 697, Frank R. Lautenberg Chemical Safety for the 21st Century Act (Ordered to be Reported out of Committee April 28, 2015)	H.R. 2576, the TSCA Modernization Act of 2015 (Ordered to be Reported out of Committee June 3, 2015)
EPA Rulemaking and Imposition of Requirements on a Chemical; Timing of Preemption	Preemption would start on the EPA requirement's "effective date." It could be a matter of interpretation whether this would necessarily be the date that full compliance with the EPA rule's requirements would be mandatory, if EPA set an "effective date" earlier than when all requirements would be enforced. (Section 6 as amended by S. 697 would require rules under that section to include "dates by which compliance is mandatory," which must be "as soon as practicable.")	Preemption would start on the EPA requirement's "effective date" which possibly could differ from the date that compliance with all the EPA rule's requirements became mandatory. (H.R. 2576 would retain TSCA's requirement that EPA "specify in any [Section 6] rule … the date on which it shall take effect, which date shall be as soon as feasible," and would add a provision requiring that "any rule … shall provide for a reasonable transition period.")
Exemptions or Waivers from Otherwise Applicable Preemption		
Discretionary Exemptions for States or Localities	S. 697 would add a new TSCA Section 18(f) governing state exemptions (or waivers) in greater detail than current TSCA, with provisions for both discretionary and required waivers. Upon application of a state or locality, the EPA Administrator (non-delegable) could, in his or her discretion, promulgate a rule exempting from preemption a chemical restriction relating to effects of or exposure to a chemical, under such conditions as EPA would prescribe, if EPA determined that: (1) compelling state or local conditions warrant granting the waiver to protect health or the environment; (2) requirement would not unduly burden interstate commerce; (3) the requirement would not cause a violation of federal law; and (4) the requirement is consistent with sound objective scientific practices, the weight of the evidence, and the best available science. The Administrator would have to decide on an application within 180 days.	H.R. 2576 would retain current TSCA Section 18(b), which allows for discretionary waivers. EPA (not specifically limited to the Administrator in a non-delegable capacity) in its discretion, upon application of a state or locality, could issue a rule exempting a state or local chemical restriction (but not a testing requirement unless designed to protect against risk) from preemption, under such conditions as EPA may prescribe, if EPA determined that: (1) compliance with the state or local requirement would not cause a violation of the federal requirement; (2) the state or local requirement provides a significantly higher degree of protection from risk than the EPA requirement, and (3) the state or local requirement does not, through difficulties in marketing, distribution, or other factors, unduly burden interstate commerce. Unlike S. 697, there is no specific requirement for waivers to be consistent with any scientific criteria. No timeline for exemption decisions is provided.

ED_002117_00005992-00016

Provision	S. 697, Frank R. Lautenberg Chemical Safety for the 21st Century Act (Ordered to be Reported out of Committee April 28, 2015)	H.R. 2576, the TSCA Modernization Act of 2015 (Ordered to be Reported out of Committee June 3, 2015)
Required Exemptions for States or Localities	The Administrator would be required to grant an exemption application for a state or local requirement relating to the effects of exposure to a chemical if conditions (2) and (3) above were met and the state or locality "has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science." Rulemaking would not be required, although public notice and opportunity for comment generally would be. The Administrator would have to decide on an application made on this basis within 90 days, or approval would be automatic. Approval would also be automatic if EPA missed its deadline for completing a safety determination.	No comparable provision.
Judicial Review of State or Local Waiver Decisions	Any person could petition for judicial review within 60 days of a decision of the administrator on exemptions, or a failure to meet the 180 or 90 day deadline.	Judicial review of EPA's exemption decisions would be governed by the Administrative Procedure Act;[c] TSCA does not have, and H.R. 2576 would not add, any specific provision regarding judicial review of EPA decisions on state exemptions.
Critical Use Exemptions from EPA Rules; Effect on Preemption	In general, EPA would be authorized to exempt uses of a chemical from any restriction in a Section 6 rule if EPA made any of several determinations and imposed conditions in a rule exempting such uses. State and local restrictions on the exempted uses apparently still would be preempted by the rule from which the uses were exempted, unless the uses were excluded from the scope of the Section 6 rule itself.	H.R. 2576 would authorize comparable critical use exemptions, but with different EPA determinations. Also, a rule would not be required, but the exemption could be granted only after public notice and opportunity for comment. State and local restrictions on the exempted uses apparently still would be preempted by the rule from which the uses were exempted. Exclusion of any uses from the scope of the Section 6 rule also apparently would not affect preemption.

ED_002117_00005992-00017

Provision	S. 697, Frank R. Lautenberg Chemical Safety for the 21st Century Act (Ordered to be Reported out of Committee April 28, 2015)	H.R. 2576, the TSCA Modernization Act of 2015 (Ordered to be Reported out of Committee June 3, 2015)
Other Provisions Related to State-Federal Relationship		
Consideration of State Recommendations	S. 697, in a new Section 4A of TSCA on prioritization of chemicals for evaluation, would require EPA to consider information and recommendations submitted by a state governor or agency regarding a chemical in making prioritization decisions regarding that chemical.	No comparable provision.
State Notification Duty	Under new Section 4A, states would be required to inform EPA if they proposed or enacted a new restriction on a chemical EPA had not designated as high priority.	No comparable provision.
Disclosure of Confidential Information to States	Under amended Section 14, EPA would be required to disclose confidential information to a state or locality (S. 697 does not include tribes), on written request, for development, administration, or enforcement of a law if agreements ensure that the state or locality can and will protect the information, and EPA notifies the submitter of the disclosure. EPA would also have to disclose confidential information on request in emergency situations, subject to certain conditions, or to state health or environmental professionals who provided an adequate statement of need.	Under amended Section 14, EPA would be authorized to disclose confidential information to a state, on request, to a state, local, or tribal official for administration or enforcement (but not development) of a law. EPA would also have to disclose confidential information on request to state health or environmental professionals in response to an environmental release.

Source: CRS analysis of S. 697 and H.R. 2576.

Notes: S. 725, the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act, would eliminate express preemption from TSCA entirely and is not included in this Table.

a. U.S. CONST. art. VI, cl. 2; report footnote 2, *supra*.

b. An amendment changing the "[EPA action] actually conflicts with…" standard to a standard of "impossible … to comply with both the State requirement and" an EPA action was withdrawn at the committee markup. See House Energy and Commerce Committee, Full Committee Vote on the TSCA Modernization Act and FCC Process Reform Act (June 3, 2015), https://energycommerce.house.gov/ markup/full-committee-vote-tsca-modernization-act-and-fcc-process-reform-act.

c. 5 U.S.C. tit. 7.

Author Contact Information

Alexandra M. Wyatt
Legislative Attorney
awyatt@crs.loc.gov, 7-0816

ED_002117_00005992-00018

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 6/8/2015 2:35:14 PM
To: Kaiser, Sven-Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac78d3704ba94edbbd0da970921271ff-SKAISER]; Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
Subject: FW: S. 697, Frank R. Lautenberg Chemical Safety for the 21st Century Act
Attachments: s697.pdf; s697.docx

CBO score.

From: Karakitsos, Dimitri (EPW)
Sent: Friday, June 05, 2015 5:45 PM
To: Black, Jonathan (Tom Udall)
Subject: FW: S. 697, Frank R. Lautenberg Chemical Safety for the 21st Century Act

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From: Darren Young [mailto:Darren.Young@cbo.gov]
Sent: Friday, June 05, 2015 5:43 PM
To: Karakitsos, Dimitri (EPW); Cook, Chris (Budget); Merchant, Kusai (Budget); Albritton, Jason (EPW)
Cc: Susanne Mehlman
Subject: S. 697, Frank R. Lautenberg Chemical Safety for the 21st Century Act

I attached copies (a scanned copy with a signature and a copy saved in Word) of a cost estimate for S. 697 to this message. Another copy will be sent to you via inside mail, plus a copy (without the cover page) will be posted on CBO's website.

Let me know if you need anything else.

Darren

CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

June 5, 2015

S. 697
Frank R. Lautenberg Chemical Safety for the 21st Century Act

As ordered reported by the Senate Committee on Environment and Public Works on April 28, 2015

SUMMARY

S. 697 would modify the Toxic Substances Control Act (TSCA), the law that regulates the manufacture, importation, and processing of chemicals, with the aim of strengthening the Environmental Protection Agency's (EPA's) ability to evaluate and regulate potentially hazardous chemicals.

CBO estimates that EPA would incur additional administrative costs over the 2016-2020 period to meet the new requirements imposed by S. 697; however, we also estimate that under the bill EPA would collect sufficient fees from chemical manufacturers and processors to offset the cost of conducting the activities proposed under this legislation. On net, we estimate that implementing this legislation would reduce discretionary costs by $8 million over the next five years, assuming appropriation actions consistent with provisions of the bill.

Enacting S. 697 could affect direct spending and revenues because the bill would increase some existing civil and criminal penalties for violations of TSCA. Therefore, pay-as-you-go procedures apply. CBO estimates that any changes in revenues and direct spending would not be significant.

S. 697 would impose intergovernmental and private-sector mandates, as defined in the Unfunded Mandates Reform Act (UMRA), on manufacturers, processors, importers, and users of chemical substances. The bill also would impose intergovernmental mandates on state agencies. CBO estimates that the aggregate cost of those mandates would fall below the annual thresholds established in UMRA for intergovernmental and private-sector mandates ($77 million and $154 million in 2015, respectively, adjusted annually for inflation).

MAJOR PROVISIONS

The bill's major provisions would:

- Require EPA to develop policies, procedures, and guidance to address the process for testing and evaluating the safety of chemical substances;

- Authorize EPA to obtain new information on chemical substances from manufacturers and processors at all stages of the safety evaluation process;

- Require EPA to establish and implement a risk-based prioritization process to screen all chemicals now in use;

- Address when federal actions under TSCA preempt requirements of state and local governments related to restricting and banning chemical substances;

- Require EPA to update its process for reviewing industry requests that information submitted to the agency be kept confidential; and,

- Require EPA to establish a new schedule for charging fees to chemical manufacturers who are required to submit data to the agency or who request that EPA assess certain chemicals that are not yet prioritized for review by EPA.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 697 is shown in the following table. The costs of this legislation fall within budget function 300 (natural resources and environment).

ED_002117_00005995-00002

	By Fiscal Year, in Millions of Dollars					
	2016	2017	2018	2019	2020	2016-2020
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Administrative Expenses under TSCA						
Estimated Authorization Level	17	17	17	17	17	85
Estimated Outlays	7	14	17	17	17	72
Offsetting Fee Collections						
Estimated Authorization Level	-4	-10	-16	-25	-25	-80
Estimated Outlays	-4	-10	-16	-25	-25	-80
Total Changes						
Estimated Budget Authority	13	7	1	-8	-8	5
Estimated Budget Outlays	3	4	1	-8	-8	-8

Note: TSCA = Toxic Substances Control Act.

BASIS OF ESTIMATE

For this estimate, CBO assumes that S. 697 will be enacted near the end of 2015 and that the necessary amounts will be appropriated each year.

Spending Subject to Appropriation

While some of the requirements in S. 697 are similar to activities currently performed by EPA under TSCA, CBO estimates that implementing this legislation would increase EPA's workload for regulating chemical safety by about 30 percent each year. That estimate is based on historical information about how other large regulatory programs have been implemented by EPA and on expectations of the additional workload provided by the agency. According to EPA, the agency currently requires, on average, an appropriation of about $58 million annually to implement and enforce EPA's Chemical Risk Review and Reduction program under TSCA. That funding supports roughly 245 employees. Subject to the appropriation of the necessary amounts, CBO estimates that EPA would require about $17 million annually over the next five years to cover the costs of additional personnel, contractors, and other administrative activities associated with meeting the new requirements of this legislation.

Over the next two years, CBO expects that EPA would focus on implementing S. 697 primarily by producing guidance documents and cost-benefit analyses and performing other administrative tasks related to the rulemaking process for the review of the safety of

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new chemicals and substances currently in use. EPA would establish internal processes and information technology systems to prioritize the analysis of tens of thousands of chemicals. According to the agency, such activities are routinely carried out by contractors; as a result, most of the estimated $17 million in annual funding needed over this period would cover contractor costs. By 2018, enforcement of the new provisions of TSCA would begin and CBO estimates that EPA would shift funding to cover additional government personnel. CBO estimates that spending on new administrative activities over the next five years would total $72 million.

Under the legislation EPA would be authorized to charge two types of fees. One would be imposed on chemical manufacturers and processors who are required to submit certain types of notices or requests for exemptions under the bill. In addition, EPA could charge fees to manufacturers and processors who request that EPA conduct safety assessments and safety determinations for chemicals that have not been designated a priority for further assessment.

Under the bill total collections of fees for firms submitting notices and requests for exemptions could not exceed $18 million annually. CBO estimates that EPA would begin collecting those fees in 2017 and that such collections would total $6 million in that first year. By 2019, we expect that as more chemicals are reviewed by EPA, collections would reach $18 million annually. Based on information from EPA, CBO estimates that collections from firms requesting safety assessments and determinations would begin in 2016 and would total $4 million in that year. By 2019 we estimate that collections would total $7 million annually. S. 697 specifies that all additional fees collected by EPA would be recorded in the budget as offsetting collections (an offset to appropriated spending). CBO estimates that those collections would total $80 million over the next five years. Thus, enacting this legislation would result in a net reduction in spending of $8 million over the 2016-2020 period, assuming future appropriations acts are consistent with CBO's estimates.

Direct Spending and Revenues

Enacting S. 697 also could affect direct spending and revenues because this bill would increase some existing civil and criminal penalties. Criminal penalties are recorded as revenues, then deposited in the Crime Victims Fund, and later spent; civil penalties are recorded as revenues. CBO estimates that any increase in criminal or civil penalties under the bill would not be significant.

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PAY-AS-YOU-GO CONSIDERATIONS

The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. CBO estimates that any increase in revenues and direct spending resulting from changes in criminal or civil penalties would not be significant over the 2016-2025 period.

INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

S. 697 would impose intergovernmental and private-sector mandates, as defined in UMRA, on manufacturers, processors, importers, and users of chemical substances. The bill also would impose intergovernmental mandates on state agencies. CBO estimates that the aggregate cost of those mandates would fall below the annual thresholds established in UMRA for intergovernmental and private-sector mandates ($77 million and $154 million in 2015, respectively, adjusted annually for inflation).

Mandates That Apply to Both Public and Private Entities

S. 697 would modify the standard used to determine whether a chemical substance poses an unreasonable risk to human health or the environment and would allow EPA to regulate the manufacture, processing, distribution, use, and disposal of chemical substances to ensure the standard is met. If EPA determines that some chemical substances do not meet the standard and issues regulations for those substances, the bill would impose an intergovernmental and private-sector mandate. EPA would have the authority to adopt a range of regulatory options to address risks from chemical substances. For example, EPA could require manufacturers to put warning labels on selected chemicals. EPA also could require users of chemicals, such as public and private universities conducting research, to handle or dispose of selected chemicals in a certain way. Based on information from industry experts, CBO expects that the annual cost of any restriction would not be substantial. Also, because of the amount of time involved in assessing the risk of each chemical, any restrictions imposed would apply to few chemicals in the first five years the mandate is in effect. Therefore, CBO estimates that the cost of the mandate would be small for both public and private entities during that time.

Mandates That Apply to Public Entities Only

The bill would impose an intergovernmental mandate by preempting state regulations that conflict with the federal regulation of chemicals, but that preemption would impose no duty on states that would result in additional spending or a loss of revenues The bill also would impose a mandate on state agencies by requiring them to notify EPA whenever they propose an administrative action, enact a statute, or take regulatory action concerning a chemical that EPA has not designated as a high-priority substance. Information from EPA indicates that the cost of that notification mandate would be small.

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Mandates That Apply to Private Entities Only

The bill would amend provisions in TSCA that apply to new and existing chemicals. The bill would impose new mandates and increase the cost of existing mandates on manufacturers, importers, and processors of chemical substances. Additionally, manufacturers and processors would be required to pay fees and submit data to EPA for use carrying out safety assessments and regulations to ensure safety. Finally, the bill could impose a mandate on importers of some items containing chemical substances.

Based on information from industry experts, CBO expects that the incremental cost of those mandates would not be substantial. The bill would limit the amount of mandatory fees that EPA could collect to $18 million annually. Manufacturers and processors of existing chemical substances currently report information to EPA under programs such as the Chemical Data Reporting rule and the High Production Volume Challenge Program, which is voluntary. Based on information from industry experts, CBO expects that submitting new data to EPA for safety assessments could cost up to $1 million per chemical substance. However, the annual number of existing chemicals that would be subject to the data submission requirements would be limited.

ESTIMATE PREPARED BY:

Federal Spending: Susanne Mehlman
Impact on State, Local, and Tribal Governments: Jon Sperl
Impact on the Private Sector: Amy Petz

ESTIMATE APPROVED BY

Theresa Gullo
Assistant Director for Budget Analysis

ED_002117_00005995-00006

June 5, 2015

Honorable Jim Inhofe
Chairman
Committee on Environment
and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The Congressional Budget Office has prepared the enclosed cost estimate for S. 697, the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Susanne S. Mehlman, who can be reached at 226-2860.

Sincerely,

Keith Hall

Enclosure

cc: Honorable Barbara Boxer
Ranking Member

CONGRESSIONAL BUDGET OFFICE
U.S. Congress
Washington, DC 20515

Keith Hall, Director

June 5, 2015

Honorable Jim Inhofe
Chairman
Committee on Environment
and Public Works
United States Senate
Washington, DC 20510

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Ranking Member

CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

June 5, 2015

S. 697
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CBO estimates that EPA would incur additional administrative costs over the 2016-2020 period to meet the new requirements imposed by S. 697; however, we also estimate that under the bill EPA would collect sufficient fees from chemical manufacturers and processors to offset the cost of conducting the activities proposed under this legislation. On net, we estimate that implementing this legislation would reduce discretionary costs by $8 million over the next five years, assuming appropriation actions consistent with provisions of the bill.

Enacting S. 697 could affect direct spending and revenues because the bill would increase some existing civil and criminal penalties for violations of TSCA. Therefore, pay-as-you-go procedures apply. CBO estimates that any changes in revenues and direct spending would not be significant.

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ED_002117_00005996-00003

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Over the next two years, CBO expects that EPA would focus on implementing S. 697 primarily by producing guidance documents and cost-benefit analyses and performing other administrative tasks related to the rulemaking process for the review of the safety of

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PAY-AS-YOU-GO CONSIDERATIONS

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INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

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S. 697 would modify the standard used to determine whether a chemical substance poses an unreasonable risk to human health or the environment and would allow EPA to regulate the manufacture, processing, distribution, use, and disposal of chemical substances to ensure the standard is met. If EPA determines that some chemical substances do not meet the standard and issues regulations for those substances, the bill would impose an intergovernmental and private-sector mandate. EPA would have the authority to adopt a range of regulatory options to address risks from chemical substances. For example, EPA could require manufacturers to put warning labels on selected chemicals. EPA also could require users of chemicals, such as public and private universities conducting research, to handle or dispose of selected chemicals in a certain way. Based on information from industry experts, CBO expects that the annual cost of any restriction would not be substantial. Also, because of the amount of time involved in assessing the risk of each chemical, any restrictions imposed would apply to few chemicals in the first five years the mandate is in effect. Therefore, CBO estimates that the cost of the mandate would be small for both public and private entities during that time.

Mandates That Apply to Public Entities Only

The bill would impose an intergovernmental mandate by preempting state regulations that conflict with the federal regulation of chemicals, but that preemption would impose no duty on states that would result in additional spending or a loss of revenues The bill also would impose a mandate on state agencies by requiring them to notify EPA whenever they propose an administrative action, enact a statute, or take regulatory action concerning a chemical that EPA has not designated as a high-priority substance. Information from EPA indicates that the cost of that notification mandate would be small.

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Mandates That Apply to Private Entities Only

The bill would amend provisions in TSCA that apply to new and existing chemicals. The bill would impose new mandates and increase the cost of existing mandates on manufacturers, importers, and processors of chemical substances. Additionally, manufacturers and processors would be required to pay fees and submit data to EPA for use carrying out safety assessments and regulations to ensure safety. Finally, the bill could impose a mandate on importers of some items containing chemical substances.

Based on information from industry experts, CBO expects that the incremental cost of those mandates would not be substantial. The bill would limit the amount of mandatory fees that EPA could collect to $18 million annually. Manufacturers and processors of existing chemical substances currently report information to EPA under programs such as the Chemical Data Reporting rule and the High Production Volume Challenge Program, which is voluntary. Based on information from industry experts, CBO expects that submitting new data to EPA for safety assessments could cost up to $1 million per chemical substance. However, the annual number of existing chemicals that would be subject to the data submission requirements would be limited.

ESTIMATE PREPARED BY:

Federal Spending: Susanne Mehlman
Impact on State, Local, and Tribal Governments: Jon Sperl
Impact on the Private Sector: Amy Petz

ESTIMATE APPROVED BY

Theresa Gullo
Assistant Director for Budget Analysis

ED_002117_00005996-00007

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/26/2015 6:17:16 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; Vaught, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c30920bcb6214a91b7e3c1e7810c63e1-Vaught, Laura]; Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
Subject: Sen. Udall TSCA TA on Preemption
Attachments: Udall.TSCA Preemption TA.3.26.15.docx

Jonathan,
Please see the attached technical assistance. The TA is provided in response to your request and does not necessarily represent the policy positions of the agency and the administration on the bill, draft language and comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

-----Original Message-----
From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Monday, March 23, 2015 12:23 PM
To: Kaiser, Sven-Erik; Vaught, Laura; Jones, Jim
Cc: Black, Jonathan (Tom Udall)
Subject: Preemption Technical Assistance

Since Jim mentioned that preemption would figure prominently into the Administration's evaluation of any TSCA reform bill, I assume you can help with some technical assistance on the issue.

I need a few things:

1) Please address the "ambiguity" about whether state clean air, clean water and GHG laws are preempted.
    a) Please provide technical assistance on clarifying that this bill does not preempt those laws.
2) Please provide EPA technical assistance in drafting the following scenarios for High Priority Preemption:
    a) Allow for a prohibition (pause) on NEW state laws during the EPA's safety assessment and evaluation. BUT, lift that prohibition once a safety determination is made.
    b) Move the prohibition on NEW state laws back to the end of the safety assessment -- to the point of a safety determination.
    c) Move the prohibition on NEW state laws back to the point at which EPA circulates a "draft" safety determination for public comment.
    d) we may have some other scenarios.
3) Please provide technical assistance on the concern with "articles" that was referenced in the hearing.

Thanks,
---Jonathan

This technical assistance is provided by EPA in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency or the administration on the bill, the draft language and comments.

1) Please address the "ambiguity" about whether state clean air, clean water and GHG laws are preempted.

a) Please provide technical assistance on clarifying that this bill does not preempt those laws.

There are two principal ambiguities or issues associated with the drafting. The first is that the section 18(d)(1)(A) as drafted, read literally, will not capture most state programs authorized by EPA, since these programs are typically adopted under the authority of state law, and are authorized under (but are not required to comply with) Federal law. The second is the requirement, in 18(d)(1)(C)(ii)(II), that, to be saved from preemption, a requirement under a state air, water or waste law must not be inconsistent with the action of the Administrator. That will likely lead to the argument that virtually any action taken by the state that differs from the action of the Administrator is inconsistent with the action of the Administrator, since it reflects a different judgment. We acknowledge that the word "inconsistent" could be subject to narrower interpretations: eg, it could mean simply that compliance with the state requirement would cause a violation of the federal requirement. But that is separately specified by section 18(d)(1)(C)(ii)(III), so the requirement not to be inconsistent must mean something broader than causing federal non-compliance. But it's not clear what that would be.

Following are drafting suggestions to address these two issues, and also some suggestions to improve clarity generally.

"(d) Exceptions.—

"(1) IN GENERAL.—Subsections (a) and (b) shall not apply to a statute or administrative action of a State or a political subdivision of a State applicable to a specific chemical substance that—

"(A) is adopted **or authorized** under the authority of~~, or authorized to comply with,~~ any other Federal law**, or adopted for the purpose of satisfying or obtaining authorization or approval under any other Federal law;**

"(B) implements a reporting, monitoring, or other information collection obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, **except to the extent that such action** ~~unless~~

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~~the action taken by the State or political subdivision of a State--~~

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii)(I) **has already been imposed** ~~is already required by a decision~~ by the Administrator under section 5 or 6**; or**

~~"(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that are included in the scope of a safety determination pursuant to section 6 or the scope of a significant new use rule promulgated pursuant to section 5, but is inconsistent with the action of the Administrator; or~~

"(III) would cause a violation of a restriction established by the Administrator under section 5 or 6 **if adhered to.**

"(2) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—Nothing in this Act, nor any amendment made by this Act, nor any rule, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

"(A) is adopted under the authority of, or authorized to comply with, any other Federal law;

"(B) implements a reporting, monitoring, or other information collection obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, unless the action taken by the State or political subdivision of a State—

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii)(I) is already required by a decision by the Administrator under

Commented [A1]: Severability of preemption

Commented [A2]: Per our commentary above, the requirement that a state requirement be consistent with federal requirements gives rise to one of the two principal issues we have identified. We suggest deleting 18(d)(1)(C)(ii)(II), because simply deleting the "inconsistent with" proviso and leaving the remainder would result in few if any state laws being able to qualify for the 18(d)(1)(C) exemption. Section 18(d)(1)(C)(ii)(II) could be re-drafted based on a narrower principle than "inconsistent with," but we would need further direction on what that principle is in order to make drafting suggestions.

Commented [A3]: It appears that only difference between (1) and (2) is in the introductory language. If the reason for (2) is that there is important additional language in the introduction, then that language should be integrated into (1), rather than be the basis for a second, and largely duplicative, section.

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section 5 or 6;

"(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that are included in the scope of a safety determination pursuant to section 6 or the scope of a significant new use rule promulgated pursuant to section 5, but is inconsistent with the action of the Administrator; or

"(III) would cause a violation of the applicable action by the Administrator under section 5 or 6.

2) Please provide EPA technical assistance in drafting the following scenarios for High Priority Preemption:

a) Allow for a prohibition (pause) on NEW state laws during the EPA's safety assessment and evaluation. BUT, lift that prohibition once a safety determination is made.

No drafting changes to section 18(b) are needed to accomplish this – whether intended or not, this is what the bill text already provides. This is because section 18(b) applies to a chemical that "is a high-priority substance", as of the commencement of a safety determination. Per 4A(a)(3)(A)(iii)(I), a chemical is removed from the high priority list upon completion of a safety determination, so 18(b) preemption would cut off at that point without the need for specific language to that effect. (Although no changes are needed for this purpose, we suggest that the phrase in 18(b) "statute or administrative action prohibiting or restricting" be changed to "statute or administrative action to prohibit or otherwise restrict", to conform with changes made elsewhere in the bill – including in 18(a) – per earlier TA.)

Although no change is needed to section 18(b), we suggest dropping section 18(f)(5) addressing duration of section 18(b) waivers. This paragraph is unnecessary under this construct: since (b) preemption by its terms would last only until the safety determination is complete, there is no need to specify that waivers of (b) preemption terminate at that point. But if it is retained, these suggested conforming edits should be made.

(f) . . . "(5) DURATION OF WAIVERS.—A waiver granted under paragraph (1)(B) shall remain in effect until ~~the later of—~~

~~"(A)~~ such time as the safety assessment and safety determination is completed~~; and~~

~~"(B) the date on which compliance with an applicable rule issued under section 6(d) is required.~~

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b) Move the prohibition on NEW state laws back to the end of the safety assessment -- to the point of a safety determination.

§18(b) New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions.—Except as provided in subsections (c), (d), and (e), no State or political subdivision of a State may establish (after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) a statute or administrative action **to** prohibit~~ing~~ or **otherwise** restrict~~ing~~ the manufacture, processing, distribution in commerce or use of a chemical substance that ~~is a high-priority substance designated under section 4A~~**the Administrator determines does not meet the safety standard under section 6, during the period that** ~~as of~~

(1) **begins on** the date on which the Administrator makes such **determination, consistent with the scope of the determination; and**
(2) **ends on the effective date of the rule issued under section 6(d) for the chemical substance, subject to such further preemption as may arise under subsection 18(a)**.

…

(f) . . . "(5) DURATION OF WAIVERS.—A waiver granted under paragraph (1)(B) shall remain in effect until ~~the later of—~~

~~"(A) such time as the safety assessment and safety determination is completed; and~~

~~"(B)~~ the **effective** date **of the** ~~on which compliance with an~~ applicable rule issued under section 6(d~~) is required~~.

c) Move the prohibition on NEW state laws back to the point at which EPA circulates a "draft" safety determination for public comment.

§18(b) New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions.—Except as provided in subsections (c), (d), and (e), no State or political subdivision of a State may establish (after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) a statute or administrative action **to** prohibit~~ing~~ or **otherwise** restrict~~ing~~ the manufacture, processing, distribution in commerce or use of a chemical substance ~~that is a high-priority substance designated under section 4A,~~ **during the period that** ~~as of~~

Commented [A4]: This goes beyond the TA request but makes a fix already made elsewhere in the bill, including 18(a), per earlier TA.

Commented [A5]: Per 4A(A)(3)(iii)(I), once EPA makes a safety determination, the chemical ceases to be a high priority substance.

A post-determination chemical substance is no longer literally a high priority substance.

Commented [A6]: One only needs to address the scenario of a negative determination here. If the safety determination is positive, then 18(a) preemption governs.

Commented [A7]: As with the answer to (2)(a), above, (f)(5) could be dropped, but these conforming edit are suggested if it is retained. Note that we changed the reference to the compliance date to the effective date, to conform with the duration of the preemption. Note that this raises a point of uncertainty in the bill, as to what "effective date" refers to. See discussion under (d), below.

Commented [A8]: This goes beyond the TA request but makes a fix already made elsewhere in the bill, including 18(a), per earlier TA.

Commented [A9]: Suggest striking this, because the period could include a time during which the chemical substance is not a high priority substance.

Per 4A(A)(3)(iii)(I), once EPA makes a safety determination, the chemical ceases to be a high priority substance.

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(1) **begins on** the date on which the Administrator **publishes a public notice of a proposed safety determination under section 6, consistent with the scope of the determination; and**
(2) **ends on the date of the final determination that the chemical substance meets the safety standard or the effective date of the rule issued under section 6(d) for the chemical substance, subject to such further preemption as may arise under subsection 18(a)**.

Here, too, section 18(f)(5) ideally should be dropped as unnecessary. If retained, it should be revised as follows:

(f) . . . "(5) DURATION OF WAIVERS.—A waiver granted under paragraph (1)(B) shall remain in effect until ~~the later of—~~

"(A) **the date of the final determination that the chemical substance meets the safety standard; or** ~~such time as the safety assessment and safety determination is completed; and~~

"(B) the **effective** date **of the** ~~on which compliance with an applicable~~ rule issued under section 6(d) ~~is required~~.

d) we may have some other scenarios.

One further issue to consider is that there is ambiguity about what exactly is the "effective date" in § 18(a)(1)(B), since § 6(d)(2)(B) provides for multiple compliance deadlines. Options range from triggering 18(a) preemption (and terminating 18(b) preemption, under options (b) and (c) above):

- upon the date the rule is effective in the C.F.R. (not necessarily the same thing as the compliance deadline under the rule)
- upon the first of the compliance deadlines
- upon the last of the compliance deadlines
- for different affected persons at different times, depending on the compliance deadline for that person

"18(a)(1)(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

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"(i) found to meet the safety standard and consistent with the scope of the determination made under section 6; or

"(ii) found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

"(C) SIGNIFICANT NEW USE.—A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(2) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of State statutes and administrative actions applicable to specific substances shall not occur until the effective date of the applicable action described in paragraph (1) taken by the Administrator.

3) Please provide technical assistance on the concern with "articles" that was referenced in the hearing.

In order of centrality to the issues referenced at the hearing:

1. Section 3A(h)(3) is the central issue. Exposure to a chemical substance, in an article or otherwise, is already relevant to the safety standard under § 3 and the safety assessment procedures in § 3A(h)(2). This paragraph would likely prevent EPA from regulating to protect comprehensively against the risks from chemical substances in articles (or at least create legal vulnerabilities for EPA if it does so) except where EPA has fairly granular information about the exposure pathways associated with each specific kind of article. Striking the paragraph would resolve the concern.

2. The remaining issues relate to import certification at § 13(b). This involves the potential for EPA to require article importers to submit import certification statements that the imported articles are in compliance with TSCA. CBP's import regulations currently exempt article imports from TSCA import certifications unless EPA regulation directs otherwise. To date, EPA has not directed otherwise. TSCA itself imposes no hurdle for EPA (or CBP) to require import certification for articles.

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There are two sub-issues here:

- Where EPA requires import certification for articles, §13(b)(3)(B) gives an importer a safe harbor to rely on a foreign manufacturer's MSDS, so long as the importer's reliance is in good faith. This significantly limits the potential value of an import certification requirement, and could create an incentive for foreign manufacturers to conceal information from importers.
- §13(b)(2)(B) and (C) limit EPA's authority to require import certification for articles. They require EPA to identify specific types of articles that would be subject to certification, and to consider factors as to which EPA may not have a great deal of information (e.g., the contribution of imported articles to the risk addressed by the rule). Simplifying or eliminating these requirements would make this a more flexible tool for EPA.

Note, finally, that under current drafting, a rulemaking under § 13(b)(2)(A) would **not** be required in order for CBP to exercise its authorities under § 13(a) to refuse entry to an article on the grounds that such article contained an unsafe chemical substance. The issue we have identified pertains only to certification.

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Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 3/23/2015 4:23:12 PM
To: Kaiser, Sven-Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac78d3704ba94edbbd0da970921271ff-SKAISER]; Vaught, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c30920bcb6214a91b7e3c1e7810c63e1-Vaught, Laura]; Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Preemption Technical Assistance
Attachments: WEI15256_XML.doc

Since Jim mentioned that preemption would figure prominently into the Administration's evaluation of any TSCA reform bill, I assume you can help with some technical assistance on the issue.

I need a few things:

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    d) we may have some other scenarios.
3) Please provide technical assistance on the concern with "articles" that was referenced in the hearing.

Thanks,
---Jonathan

Your message is ready to be sent with the following file or link attachments:

WEI15256_XML

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

Title: To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act".

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(c) of the Toxic Substances Control Act (15 U.S.C. 2601(c)) is amended—

(1) by striking "It is the intent" and inserting the following:

"(1) ADMINISTRATION.—It is the intent";

(2) in paragraph (1) (as so redesignated), by inserting ", as provided under this Act" before the period at the end; and

(3) by adding at the following:

"(2) REFORM.—It is the intent of Congress that reform of this Act in accordance with the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act—

"(A) shall be administered in a manner that—

"(i) protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and

"(ii) ensures that appropriate information on chemical substances and mixtures is available to public health officials and first responders in the event of an emergency; and

"(B) shall not displace or supplant common law rights of action or remedies for civil relief.".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) by redesignating paragraphs (4), (5), (6), (7), (8), (9), (10), (11), (12), (13), and (14) as paragraphs (5), (6), (7), (8), (9), (10), (12), (13), (17), (18), and (19), respectively;

(2) by inserting after paragraph (3) the following:

"(4) CONDITIONS OF USE.—The term 'conditions of use' means the intended, known, or reasonably foreseeable circumstances the Administrator determines a chemical substance is manufactured, processed, distributed in commerce, used, or disposed of.";

(3) by inserting after paragraph (10) (as so redesignated) the following:

"(11) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.—The term 'potentially

exposed or susceptible population' means 1 or more groups—

"(A) of individuals within the general population who may be—

"(i) differentially exposed to chemical substances under the conditions of use; or

"(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

"(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; and

(4) by inserting after paragraph (13) (as so redesignated) the following:

"(14) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.

"(15) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the conditions of use.

"(16) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of harm to health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of harm to—

"(A) the general population; or

"(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

The Toxic Substances Control Act is amended by inserting after section 3 (15 U.S.C. 2602) the following:

"SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

"(a) Definition of Guidance.—In this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.

"(b) Deadline.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.

"(c) Use of Science.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance on the use of science in making decisions under sections 4, 4A, 5, and 6.

"(2) GOAL.—A goal of the policies and procedures described in paragraph (1) shall be to

make the basis of decisions clear to the public.

"(3) REQUIREMENTS.—The policies, procedures, and guidance issued under this section shall describe the manner in which the Administrator shall ensure that —

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;

"(B) to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.

"(e) Review.—Not later than 5 years after the date of enactment of this section, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(1) review the adequacy of any policies, procedures, and guidance developed under this section, including animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this Act; and

"(2) after providing public notice and an opportunity for comment, revise the policies, procedures, and guidance if necessary to reflect new scientific developments or understandings.

"(f) Sources of Information.—In making any decision with respect to a chemical substance under section 4, 4A, 5, or 6, the Administrator shall take into consideration information relating

to the hazards and exposures of a chemical substance under the conditions of use that is reasonably available to the Administrator, including information that is—

"(1) submitted to the Administrator pursuant to any rule, consent agreement, order, or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act, by—

"(A) manufacturers or processors of a substance;

"(B) the public;

"(C) other Federal departments or agencies; or

"(D) the Governor of a State or a State agency with responsibility for protecting health or the environment;

"(2) submitted to a governmental entity in any jurisdiction pursuant to a governmental requirement relating to the protection of health or the environment; or

"(3) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible by the Administrator.

"(g) Testing of Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator shall establish policies and procedures for the testing of chemical substances or mixtures under section 4.

"(2) GOAL.—A goal of the policies and procedures established under paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) CONTENTS.—The policies and procedures established under paragraph (1) shall—

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential;

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations;

"(C) require the Administrator to consult with the Director of the National Institute for Occupational Safety and Health prior to prescribing epidemiologic studies of employees; and

"(D) prior to adopting a requirement for testing using vertebrate animals, require the Administrator to take into consideration, as appropriate and to the extent practicable, reasonably available—

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

"(iii) high-throughput screening methods and the prediction models of those methods; and

"(iv) scientifically reliable and relevant alternatives to tests on animals that

would provide equivalent information.

"(4) TIERED TESTING.—

"(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.

"(B) SCREENING-LEVEL TESTS.—

"(i) IN GENERAL.—The screening-level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.

"(ii) USE.—Screening-level tests shall be used—

"(I) to screen chemical substances or mixtures for potential adverse effects; and

"(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.

"(C) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for safety assessments or safety determinations, the Administrator may require more advanced tests for potential health or environmental effects or exposure potential.

"(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

"(h) Safety Assessments and Safety Determinations.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(C) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall identify the substances subject to safety assessments and safety determinations to be completed that year.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(A) IN GENERAL.—The Administrator shall establish, by rule, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

"(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

"(C) MINIMUM REQUIREMENTS.—At a minimum, the policies and procedures under this paragraph shall—

"(i) describe—

"(I) the manner in which the Administrator will identify informational needs and seek that information from the public;

"(II) the information (including draft safety assessments) that may be submitted by interested individuals or entities, including States; and

"(III) the criteria by which that information will be evaluated;

"(ii) require the Administrator—

"(I)(aa) to define the scope of the safety assessment and safety determination to be conducted under section 6, including the hazards, exposures, conditions of use, and potentially exposed and susceptible populations that the Administrator expects to consider in a safety assessment;

"(bb) to explain the basis for the scope of the safety assessment and safety determination; and

"(cc) to accept comments regarding the scope of the safety assessment and safety determination; and

"(II)(aa) to identify the items described in subclause (I) that the Administrator has considered in the final safety assessment; and

"(bb) to explain the basis for the consideration of those items;

"(iii) describe the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the conditions of use will be considered, and explain the basis for that consideration in the final safety assessment;

"(iv) require that each safety assessment and safety determination shall include—

"(I) a description of the weight of the scientific evidence of risk; and

"(II) a summary of the information regarding the impact on health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies;

"(v) establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination; and

"(vi) when relevant information is provided or otherwise made available to the Administrator, shall consider the extent of Federal regulation under other Federal

laws.

"(D) GUIDANCE.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop guidance to assist interested persons in developing draft safety assessments and other information for submission to the Administrator, which may be considered at the discretion of the Administrator.

"(ii) REQUIREMENT.—The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing a draft assessment for consideration by the Administrator.

"(3) ARTICLES.—If the Administrator intends to prohibit or otherwise restrict an article on the basis of a chemical substance contained in that article, the Administrator shall have evidence of significant exposure to the chemical substance from such article.

"(i) Publicly Available Information.—Subject to section 14, the Administrator shall—

"(1) make publicly available a nontechnical summary, and the final version, of each safety assessment and safety determination;

"(2) provide public notice and an opportunity for comment on each proposed safety assessment and safety determination; and

"(3) make public in a final safety assessment and safety determination—

"(A) the list of studies considered by the Administrator in carrying out the safety assessment or safety determination; and

"(B) the list of policies, procedures, and guidance that were followed in carrying out the safety assessment or safety determination.

"(j) Consultation With Science Advisory Committee on Chemicals.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish an advisory committee, to be known as the 'Science Advisory Committee on Chemicals' (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, on the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(5) RELATIONSHIP TO OTHER LAW.—All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).".

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking subsections (a), (b), (c), (d), and (g);

(2) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively;

(3) in subsection (f) (as so redesignated)—

(A) by striking "rule" each place it appears and inserting "rule, testing consent agreement, or order";

(B) by striking "under subsection (a)" each place it appears and inserting "under this subsection"; and

(C) in paragraph (1)(B), in the last sentence, by striking "rulemaking";

(4) in subsection (g) (as so redesignated)—

(A) in the first sentence, by striking "from cancer, gene mutations, or birth defects"; and

(B) by striking the last sentence; and

(5) by inserting before subsection (f) (as so redesignated) the following:

"(a) Development of New Information on Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section if the Administrator determines that the information is necessary—

"(A) to review a notice under section 5(d) or to perform a safety assessment or safety determination under section 6;

"(B) to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4) or under a rule promulgated under section 6(d)(3);

"(C) pursuant to section 12(a)(4); or

"(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

"(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.

"(B) PROHIBITION.—Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.

"(C) LIMITATION.—The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

"(3) FORM.—Subject to section 3A(h), the Administrator may require the development of information described in paragraph (1) or (2) by—

"(A) promulgating a rule;

"(B) entering into a testing consent agreement; or

"(C) issuing an order.

"(4) CONTENTS.—

"(A) IN GENERAL.—A rule, testing consent agreement, or order issued under this subsection shall include—

"(i) identification of the chemical substance or mixture for which testing is required;

"(ii) identification of the persons required to conduct the testing;

"(iii) test protocols and methodologies for the development of test data and information for the chemical substance or mixture, including specific reference to reliable nonanimal test procedures; and

"(iv) specification of the period within which individuals and entities required to conduct the testing shall submit to the Administrator the information developed in accordance with the procedures described in clause (iii).

"(B) CONSIDERATIONS.—In determining the procedures and period to be required under subparagraph (A), the Administrator shall take into consideration—

"(i) the relative costs of the various test protocols and methodologies that may be required; and

"(ii) the reasonably foreseeable availability of facilities and personnel required to perform the testing.

"(b) Statement of Need.—

"(1) IN GENERAL.—In promulgating a rule, entering into a testing consent agreement, or issuing an order for the development of additional information (including information on exposure or exposure potential) pursuant to this section, the Administrator shall—

"(A) identify the need intended to be met by the rule, agreement, or order;

"(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of vertebrate animals.

"(2) EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an order is warranted instead of promulgating a rule or entering into a testing consent agreement.

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a

description of—

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

"(ii) the extent to which the Administrator has obtained or attempted to obtain the information through voluntary submissions; and

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

"(I) animal-based studies; and

"(II) emerging methods and models; and

"(B) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) after providing an opportunity for public comment, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information under this title that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

"(C) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation; and

"(D) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing under this title.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(d) Testing Requirements.—

"(1) IN GENERAL.—The Administrator may require the development of information by—

"(A) manufacturers and processors of the chemical substance or mixture; and

"(B) persons that begin to manufacture or process the chemical substance or mixture—

"(i) after the effective date of the rule, testing consent agreement, or order; but

"(ii) subject to paragraph (3), before the period ending on the date that is 180 days after the end of the period described in this section.

"(2) DESIGNATION.—The Administrator may permit 2 or more persons identified in subparagraph (A) or (B) of paragraph (1) to designate 1 of the persons or a qualified third party—

"(A) to develop the information; and

"(B) to submit the information on behalf of the persons making the designation.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—A person otherwise subject to a rule, testing consent agreement,

or order under this section may submit to the Administrator an application for an exemption on the basis that the information is being developed by a person designated under paragraph (2).

"(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

"(i) IN GENERAL.—If the Administrator accepts an application submitted under subparagraph (A), the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as agreed to between the applicant and the designee.

"(ii) ARBITRATION.—If the applicant and a person designated under paragraph (2) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.

"(C) TERMINATION.—If, after granting an exemption under this paragraph, the Administrator determines that a person covered by the exemption has failed to comply with the rule, testing consent agreement, or order, the Administrator shall—

"(i) by order, terminate the exemption; and

"(ii) notify in writing each person that received an exemption of the requirements with respect to which the exemption was granted.

"(e) Transparency.—Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders and all information submitted under this section.".

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the third sentence by striking "section 4(e)" and inserting "section 4(f)".

SEC. 6. PRIORITIZATION SCREENING.

The Toxic Substances Control Act is amended by inserting after section 4 (15 U.S.C. 2603) the following:

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) Establishment and List of Substances.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish, by rule, a risk-based screening process and explicit criteria for identifying existing chemical substances that are—

"(A) a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances'); and

"(B) a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').

"(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(A) IN GENERAL.—Before the date of promulgation of the rule under paragraph (1) and not later than 180 days after the date of enactment of this section, the

Administrator—

"(i) shall take into consideration and publish an initial list of high-priority substances and low-priority substances; and

"(ii) pursuant to section 6(b), may initiate or continue safety assessments and safety determinations for those high-priority substances.

"(B) REQUIREMENTS.—

"(i) IN GENERAL.—The initial list of chemical substances shall contain at least 10 high-priority substances, at least 5 of which are drawn from the list of chemical substances identified by the Administrator in the October, 2014 TSCA Work Plan and subsequent updates, and at least 10 low-priority substances.

"(ii) SUBSEQUENTLY IDENTIFIED SUBSTANCES.—Insofar as possible, at least 50 percent of all substances subsequently identified by the Administrator as high-priority substances shall be drawn from the list of chemical substances identified by the Administrator in the October, 2014 TSCA Work Plan and subsequent updates, until all Work Plan chemicals have been designated under this subsection.

"(C) ADDITIONAL CHEMICAL REVIEWS.—The Administrator shall—

"(i) 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 20 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 20 low-priority substances have been designated; and

"(ii) as soon as practicable and not later than 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 25 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 25 low-priority substances have been designated.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator shall take into consideration active substances, as determined under section 8, which may include chemical substances on the interim list of active substances established under that section.

"(ii) INACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator may take into consideration inactive substances, as determined under section 8, that the Administrator determines—

"(I)(aa) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) have the potential for high hazard and widespread exposure; or

"(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) with respect to which there exists the potential for residual high hazards or widespread exposures not otherwise addressed by the regulatory or other action.

"(iii) REPOPULATION.—

"(I) IN GENERAL.—On the completion of a safety determination under section 6 for a chemical substance, the Administrator shall remove the chemical substance from the list of high-priority substances established under this subsection.

"(II) ADDITIONS.—The Administrator shall add at least 1 chemical substance to the list of high-priority substances for each chemical substance removed from the list of high-priority substances established under this subsection, until a safety assessment and safety determination is completed for all high-priority substances.

"(III) LOW-PRIORITY SUBSTANCES.—If a low-priority substance is subsequently designated as a high-priority substance, the Administrator shall remove that substance from the list of low-priority substances.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) not later than 180 days after the effective date of the final rule under paragraph (1), begin the prioritization screening process; and

"(II) make every effort to complete the designation of all active substances as high-priority substances or low-priority substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical substance as a high-priority substance or low-priority substance.

"(iii) CONSIDERATION.—

"(I) IN GENERAL.—The Administrator shall screen substances and designate high-priority substances taking into consideration the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in a timely manner.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.

"(C) SCREENING OF CATEGORIES OF SUBSTANCES.—The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process

to allow for timely and adequate designations of high-priority substances and low-priority substances and safety assessments and safety determinations for high-priority substances.

"(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—Not less frequently than once each year, the Administrator shall publish a list of chemical substances that—

"(i) are being considered in the prioritization screening process and the status of the chemical substances in the prioritization process, including those chemical substances for which prioritization decisions have been deferred; and

"(ii) are designated as high-priority substances or low-priority substances, including the bases for such designations.

"(4) CRITERIA.—The criteria described in paragraph (1) shall account for—

"(A) the recommendation of the Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances appropriate for prioritization screening;

"(B) the hazard and exposure potential of the chemical substance (or category of substances), including specific scientific classifications and designations by authoritative governmental entities;

"(C) the conditions of use or significant changes in the conditions of use of the chemical substance;

"(D) evidence and indicators of exposure potential to humans or the environment from the chemical substance, including potentially exposed or susceptible populations;

"(E) the volume of a chemical substance manufactured or processed;

"(F) whether the volume of a chemical substance as reported under a rule promulgated pursuant to section 8(a) has significantly increased or decreased during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance;

"(G) the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

"(H) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a low-priority substance.

"(b) Prioritization Screening Process and Decisions.—

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall include a requirement that the Administrator shall—

"(A) identify the chemical substances being considered for prioritization;

"(B) request interested persons to supply information regarding the chemical

substances being considered;

"(C) apply the criteria identified in subsection (a)(4); and

"(D) subject to paragraph (5) and using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.

"(2) INTEGRATION OF INFORMATION.—The prioritization screening decision regarding a chemical substance shall integrate any hazard and exposure information relating to the chemical substance that is available to the Administrator.

"(3) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(A) shall identify as a high-priority substance a chemical substance that, relative to other chemical substances, the Administrator determines has the potential for high hazard and widespread exposure;

"(B) may identify as a high-priority substance a chemical substance that, relative to other chemical substances, the Administrator determines has the potential for high hazard or widespread exposure; and

"(C) may identify as a high-priority substance an inactive substance, as determined under subsection (a)(3)(A)(ii) and section 8(b), that the Administrator determines warrants a safety assessment and safety determination under section 6.

"(4) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that the chemical substance is likely to meet the applicable safety standard.

"(5) DEFERRING A DECISION.—If the Administrator determines that additional information is required to establish the priority of a chemical substance under this section, the Administrator may defer the prioritization screening decision for a reasonable period—

"(A) to allow for the submission of additional information by an interested person and for the Administrator to evaluate the additional information; or

"(B) to require the development of information pursuant to a rule, testing consent agreement, or order issued under section 4(a)(2).

"(6) DEADLINES FOR SUBMISSION OF INFORMATION.—If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of the information.

"(7) NOTICE AND COMMENT.—The Administrator shall—

"(A) publish the proposed decisions made under paragraphs (3), (4), and (5) and the basis for the decisions; and

"(B) provide an opportunity for public comment.

"(8) REVISIONS OF PRIOR DESIGNATIONS.—

"(A) IN GENERAL.—At any time, and at the discretion of the Administrator, the Administrator may revise the designation of a chemical substance as a high-priority

substance or a low-priority substance based on information available to the Administrator after the date of the determination under paragraph (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.

"(9) OTHER INFORMATION RELEVANT TO PRIORITIZATION.—

"(A) IN GENERAL.—If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State proposes an administrative action or enacts a statute or takes an administrative action to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not as designated a high-priority substance, the Governor or State agency with responsibility for implementing the statute or administrative action shall notify the Administrator.

"(B) REQUESTS FOR INFORMATION.—Following receipt of a notification provided under subparagraph (A), the Administrator may request any available information from the Governor or the State agency with respect to—

"(i) scientific evidence related to the hazards, exposures and risks of the chemical substance under the conditions of use which the statute or administrative action is intended to address;

"(ii) any State or local conditions which warranted the statute or administrative action;

"(iii) the statutory or administrative authority on which the action is based; and

"(iv) any other available information relevant to the prohibition or other restriction, including information on any alternatives considered and their hazards, exposures, and risks.

"(C) PRIORITIZATION SCREENING.—The Administrator shall conduct a prioritization screening under this subsection for all substances that—

"(i) are the subject of notifications received under subparagraph (A); and

"(ii) the Administrator determines—

"(I) are likely to have significant health or environmental impacts;

"(II) are likely to have significant impact on interstate commerce; or

"(III) have been subject to a prohibition or other restriction under a statute or administrative action in 2 or more States.

"(D) AVAILABILITY TO PUBLIC.—Subject to section 14 and any applicable State law regarding the protection of confidential information provided to the State or to the Administrator, the Administrator shall make information received from a Governor or State agency under subparagraph (A) publicly available.

"(E) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall preempt a State statute or administrative action, require approval of a State statute or administrative

action, or apply section 15 to a State.

"(10) REVIEW.—Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Administrator shall—

"(A) review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and

"(B) if necessary, modify the prioritization screening process.

"(11) EFFECT.—Subject to section 18, a designation by the Administrator under this section with respect to a chemical substance shall not affect—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance; or

"(B) the regulation of those activities.

"(c) Additional Priorities for Safety Assessments and Determinations.—

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall—

"(A) include a process by which a manufacturer or processor of an active chemical substance that has not been designated a high-priority substance, or that has not been subject to or is not in the process of a prioritization screening by the Administrator, may request that the Administrator designate the substance for a safety assessment and safety determination, subject to the payment of fees pursuant to section 26(b)(3)(E); and

"(B) provide guidance to submitters on the information to be provided in such requests, and specify the criteria the Administrator shall use to determine whether or not to grant such a request, which shall include whether the substance is subject to restrictions imposed by statutes enacted or administrative actions taken by 1 or more States on the manufacture, processing, distribution in commerce, or use of the substance.

"(2) PREFERENCE.—Subject to paragraph (3), in deciding whether to grant requests under this subsection the Administrator shall give a preference to requests concerning substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

"(3) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

"(A) not more than 15 percent of the total number of substances designated to undergo safety assessments and safety determinations under this section are substances designated under the process and criteria pursuant to paragraph (1); and

"(B) the resources allocated to conducting safety assessments and safety determinations for additional priorities designated under this subsection are proportionate to the number of such substances relative to the total number of

substances designated to undergo safety assessments and safety determinations under this section.

"(4) REQUIREMENTS.—

"(A) IN GENERAL.—The public shall be provided notice and an opportunity to comment on requests submitted under this subsection.

"(B) DECISION BY ADMINISTRATOR.—Not later than 180 days after the date on which the Administrator receives a request under this subsection, the Administrator shall decide whether or not to grant the request.

"(C) ASSESSMENT AND DETERMINATION.—If the Administrator grants a request under this subsection, the safety assessment and safety determination—

"(i) shall be conducted in accordance with the deadlines and other requirements of sections 3A(i) and 6; and

"(ii) shall not be expedited or otherwise subject to special treatment relative to high-priority substances designated pursuant to subsection (b)(3) that are undergoing safety assessments and safety determinations.

"(5) EXCEPTIONS.—Requests granted under this subsection shall not be subject to subsection (a)(3)(A)(iii) or section 18(b).".

SEC. 7. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.";

(2) by striking subsection (b);

(3) by redesignating subsection (a) as subsection (b);

(4) by redesignating subsection (i) as subsection (a) and moving the subsection so as to appear at the beginning of the section;

(5) in subsection (b) (as so redesignated)—

(A) in the subsection heading, by striking "In General" and inserting "Notices"; and

(B) in paragraph (1), in the matter following subparagraph (B)—

(i) by striking "subsection (d)" and inserting "subsection (b)"; and

(ii) by striking "and such person complies with any applicable requirement of subsection (b)";

(6) by redesignating subsections (c) and (d) as subsection (d) and (c), respectively, and moving subsection (c) (as so redesigned) so as appear after subsection (b) (as redesignated by paragraph (3));

(7) in subsection (c) (as so redesignated)—

(A) by striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—The notice required by subsection (a) shall include, with respect to a chemical substance—

"(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

"(B) information regarding conditions of use and reasonably anticipated exposures.";

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking "or of data under subsection (b)";

(ii) in subparagraph (A), by adding "and" after the semicolon at the end;

(iii) in subparagraph (B), by striking "; and" and inserting a period; and

(iv) by striking subparagraph (C); and

(C) in paragraph (3), by striking "subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "subsection (b) and for which the notification period prescribed by subsection (b) or (d)";

(8) by striking subsection (d) (as redesignated by paragraph (6)) and inserting the following:

"(d) Review of Notice.—

"(1) INITIAL REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall—

"(i) conduct an initial review of the notice;

"(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

"(iii) make any necessary determination under paragraph (3).

"(B) EXTENSION.—Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.

"(2) INFORMATION SOURCES.—In evaluating a notice under paragraph (1), the Administrator shall take into consideration—

"(A) any relevant information identified in subsection (c)(1); and

"(B) any other relevant additional information available to the Administrator.

"(3) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), based on the information described in paragraph (2), and subject to section 18(g), the Administrator shall determine that—

"(A) the relevant chemical substance or significant new use is not likely to meet the safety standard, in which case the Administrator shall take appropriate action under paragraph (4);

"(B) the relevant chemical substance or significant new use is likely to meet the safety standard, in which case the Administrator shall allow the review period to expire without additional restrictions; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (5).

"(4) RESTRICTIONS.—

"(A) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—If the Administrator makes a determination under subparagraph (A) or (C) of paragraph (3) with respect to a notice submitted under subsection (b)—

"(I) the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, as appropriate, shall prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the restrictions specified in the consent agreement or order that the Administrator determines are sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard; and

"(II) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, except in compliance with the restrictions specified in the consent agreement or order.

"(ii) LIKELY TO MEET STANDARD.—If the Administrator makes a determination under subparagraph (B) of paragraph (3) with respect to a chemical substance or significant new use for which a notice was submitted under subsection (b), at the end of the applicable period for review under paragraph (1), the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use.

"(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall—

"(i) take into consideration whether to promulgate a rule pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance, or of the chemical substance for a new use, that is not in compliance with the restrictions imposed by the consent agreement or order; and

"(ii)(I) initiate a rulemaking described in clause (i); or

"(II) publish a statement describing the reasons of the Administrator for not initiating a rulemaking.

"(C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include, as appropriate—

"(i) subject to section 18(g), a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator

"(ii) a requirement that manufacturers or processors of the chemical substance shall—

"(I) make and retain records of the processes used to manufacture or process, as applicable, the chemical substance; or

"(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, use, or disposal, as applicable, of the chemical substance, subject to section 4;

"(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

"(I) in general; or

"(II) for a particular use;

"(iv) a prohibition or other restriction of—

"(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

"(II) any method of commercial use of the chemical substance; or

"(III) any method of disposal of the chemical substance; or

"(v) a prohibition or other restriction on the manufacture, processing, or distribution in commerce of the chemical substance—

"(I) in general; or

"(II) for a particular use.

"(D) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(E) DEFINITION OF REQUIREMENT.—For purposes of this Act, the term 'requirement' as used in this section does not displace common law.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

"(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(C) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

"(D) on receipt of information the Administrator finds supports the determination under paragraph (3), shall promptly make the determination.";

(9) by striking subsections (e) through (g) and inserting the following:

"(e) Notice of Commencement.—

"(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—

"(A) the name of the manufacturer; and

"(B) the initial date of nonexempt commercial manufacture.

"(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

"(f) Further Evaluation.—The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—

"(1) a notice of commencement for a chemical substance under subsection (c); or

"(2) new information regarding the chemical substance.

"(g) Transparency.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, consent agreements, rules, and orders of the Administrator; and

"(2) all information submitted or issued under this section."; and

(10) in subsection (h)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking "(a) or";

(B) by striking paragraph (2);

(C) by redesignating paragraphs (3) through (6) as paragraphs (2) through (5), respectively;

(D) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking "subsections (a) and (b)" and inserting "subsection (b)";

(E) in paragraph (3) (as so redesignated)—

(i) in the first sentence, by striking "will not present an unreasonable risk of injury to health or the environment" and inserting "will meet the safety standard"; and

(ii) by striking the second sentence;

(F) in paragraph (4) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (b)"; and

(G) in paragraph (5) (as so redesignated), in the first sentence, by striking "paragraph (1) or (5)" and inserting "paragraph (1) or (4)".

SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections (g) and (h), respectively;

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) shall, as soon as practicable and not later than 6 months after the date on which a chemical substance is designated as a high-priority substance, define the scope of the safety assessment and safety determination to be conducted pursuant to this section, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that the Administrator expects to consider;

"(3) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(4) shall complete a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

"(5) shall promulgate a final rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; and

"(6) may extend any deadline under this subsection for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under paragraphs (4) and (5) and any deferral under subsection (c)(2) does not exceed 2 years.

"(b) Prior Actions.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination that was initiated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, prior to the effective date of the policies and procedures required to be established by the Administrator under section 3A or 4A.

"(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or rule solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure.

"(c) Safety Determinations.—

"(1) IN GENERAL.—Based on a review of the information available to the Administrator, including draft safety assessments submitted by interested persons, and subject to section 18, the Administrator shall determine that—

"(A) the relevant chemical substance meets the safety standard;

"(B) the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by rule under subsection (d)—

"(i) impose restrictions necessary to ensure that the chemical substance meets the safety standard under the conditions of use; or

"(ii) if the safety standard cannot be met with the application of restrictions, ban or phase out the chemical substance, as appropriate; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is necessary to make a safety assessment or safety determination for a high-priority substance, the Administrator—

"(A) shall provide an opportunity for interested persons to submit the additional information;

"(B) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

"(C) may defer, for a reasonable period consistent with the deadlines described in subsection (a), a safety assessment and safety determination until after receipt of the information; and

"(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety determination, shall make a determination under paragraph (1).

"(3) ESTABLISHMENT OF DEADLINE.—In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.

"(d) Rule.—

"(1) IMPLEMENTATION.—If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a rule establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

"(2) SCOPE.—The rule promulgated pursuant to this subsection—

"(A) may—

"(i) apply to mixtures containing the chemical substance, as appropriate; and

"(ii) exempt replacement parts for articles manufactured prior to the applicable compliance deadline; and

"(B) shall include dates by which compliance is mandatory, which—

"(i) shall be as soon as practicable; and

"(ii) as determined by the Administrator, may vary for different affected persons.

"(C) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(D) DEFINITION OF REQUIREMENT.—For the purposes of this Act, the term 'requirement' as used in this section does not displace common law.

"(3) RESTRICTIONS.—A restriction under paragraph (1) may include, as appropriate—

"(A) subject to section 18, a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator;

"(B) a requirement that manufacturers or processors of the chemical substance shall—

"(i) make and retain records of the processes used to manufacture or process the chemical substance;

"(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or

"(iii) monitor or conduct tests that are reasonably necessary to ensure compliance with the requirements of any rule under this subsection;

"(C) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

"(D) a requirement to ban or phase out, or any other rule regarding, the manufacture, processing, or distribution in commerce of the chemical substance for—

"(i) a particular use;

"(ii) a particular use at a concentration in excess of a level specified by the Administrator; or

"(iii) all uses;

"(E) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—

"(i) a particular use; or

"(ii) a particular use at a concentration in excess of a level specified by the Administrator;

"(F) a requirement to ban, phase out, or otherwise restrict any method of commercial use of the chemical substance;

"(G) a requirement to ban, phase out, or otherwise restrict any method of disposal of the chemical substance or any article containing the chemical substance; and

"(H) a requirement directing manufacturers or processors of the chemical substance to give notice of the Administrator's determination under subsection (c)(1)(B) to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

"(5) EXEMPTIONS.—

"(A) IN GENERAL.—The Administrator may exempt 1 or more uses of a chemical substance from any restriction in a rule promulgated under paragraph (1) if the Administrator determines that—

"(i) the rule cannot be complied with, without—

"(I) harming national security;

"(II) causing significant disruption in the national economy due to the lack of availability of a chemical substance; or

"(III) interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or

"(ii) the use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

"(B) EXEMPTION ANALYSIS.—In proposing a rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall make publicly available any analysis conducted under this paragraph to assess the need for the exemption.

"(C) STATEMENT REQUIRED.—In making final a rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall include a statement describing how the analysis considered under subparagraph (B) was taken into account.

"(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—In determining whether an exemption should be granted under this paragraph for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more technically and economically feasible alternatives to the chemical substance most likely to be used in place of the chemical substance under the conditions of use if the rule is promulgated.

"(E) CONDITIONS.—As part of a rule promulgated under paragraph (1), the Administrator shall include conditions in any exemption established under this paragraph, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption.

"(F) DURATION.—

"(i) IN GENERAL.—The Administrator shall establish, as part of a rule under paragraph (1) that contains an exemption under this paragraph, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis.

"(ii) AUTHORITY OF ADMINISTRATOR.—The Administrator, by rule, may extend, modify, or eliminate the exemption if the Administrator determines, on the basis of reasonably available information and after adequate public

justification, the exemption warrants extension or is no longer necessary.

"(iii) CONSIDERATIONS.—

"(I) IN GENERAL.—Subject to subclause (II), the Administrator shall issue exemptions and establish time periods by considering factors determined by the Administrator to be relevant to the goals of fostering innovation and the development of alternatives that meet the safety standard.

"(II) LIMITATION.—Any renewal of an exemption in the case of a rule requiring the ban or phase-out of a chemical substance shall not exceed 5 years.

"(e) Immediate Effect.—The Administrator may declare a proposed rule under subsection (d) to be effective on publication of the rule in the Federal Register and until the effective date of final action taken respecting the rule, if—

"(1) the Administrator determines that—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to the proposed rule or any combination of those activities is likely to result in an unreasonable risk of serious or widespread harm to health or the environment before the effective date; and

"(B) making the proposed rule so effective is necessary to protect the public interest; and

"(2) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under paragraph (1)(A), a court has granted relief in an action under section 7 with respect to that risk associated with the chemical substance or mixture.

"(f) Final Agency Action.—Under this section and subject to section 18—

"(1) a safety determination, and the associated safety assessment, for a chemical substance that the Administrator determines under subsection (c) meets the safety standard, shall be considered to be a final agency action, effective beginning on the date of issuance of the final safety determination; and

"(2) a final rule promulgated under subsection (d), and the associated safety assessment and safety determination that a chemical substance does not meet the safety standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule."; and

(4) in subsection (g) (as redesignated by paragraph (2))—

(A) by striking paragraph (4); and

(B) by redesignating paragraph (5) as paragraph (4).

SEC. 9. IMMINENT HAZARDS.

Section 7 of the Toxic Substances Control Act (15 U.S.C. 2606) is amended—

(1) by striking subsection (a) and inserting the following:

"(a) Civil Actions.—

"(1) IN GENERAL.—The Administrator may commence a civil action in an appropriate United States district court for—

"(A) seizure of an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture;

"(B) relief (as authorized by subsection (b)) against any person that manufactures, processes, distributes in commerce, uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture; or

"(C) both seizure described in subparagraph (A) and relief described in subparagraph (B).

"(2) RULE, ORDER, OR OTHER PROCEEDING.—A civil action may be commenced under this paragraph, notwithstanding—

"(A) the existence of—

"(i) a decision by the Administrator under section 4A, 5(d)(3), or 6(c)(1); or

"(ii) a rule, testing consent agreement, or order under section 4, 5(d)(4), 6(d), or 6(h); or

"(B) the pendency of any administrative or judicial proceeding under any provision of this Act.";

(2) in subsection (d), by striking "section 6(a)" and inserting "section 6(c)"; and

(3) in subsection (f), in the first sentence, by striking "and unreasonable".

SEC. 10. INFORMATION COLLECTION AND REPORTING.

Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amended—

(1) in subsection (a)—

(A) in paragraph (3)(A)(ii)(I)—

(i) by striking "5(b)(4)" and inserting "5";

(ii) by inserting "section 4 or" after "in effect under"; and

(iii) by striking "5(e)," and inserting "5(d)(4);"; and

(B) by adding at the end the following:

"(4) RULES.—

"(A) DEADLINE.—

"(i) IN GENERAL.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall promulgate rules requiring the maintenance of records and the reporting of information known or reasonably ascertainable by the person making the report, including rules requiring processors to report information, so that the

Administrator has the information necessary to carry out sections 4 and 6.

"(ii) MODIFICATION OF PRIOR RULES.—In carrying out this subparagraph, the Administrator may modify, as appropriate, rules promulgated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(B) CONTENTS.—The rules promulgated pursuant to subparagraph (A)—

"(i) may impose different reporting and recordkeeping requirements on manufacturers and processors; and

"(ii) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported.

"(C) ADMINISTRATION.—In implementing the reporting and recordkeeping requirements under this paragraph, the Administrator shall take measures—

"(i) to limit the potential for duplication in reporting requirements;

"(ii) to minimize the impact of the rules on small manufacturers and processors; and

"(iii) to apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.

"(5) GUIDANCE.—The Administrator shall develop guidance relating to the information required to be reported under the rules promulgated under this subsection.";

(2) in subsection (b), by adding at the end the following:

"(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 all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

"(I) cement, Portland, chemicals, CAS No. 65997–15–1;

"(II) cement, alumina, chemicals, CAS No. 65997–16–2;

"(III) glass, oxide, chemicals, CAS No. 65997–17–3;

"(IV) frits, chemicals, CAS No. 65997–18–4;

"(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

"(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature conventions, the Administrator shall—

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

"(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) RULES.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator, by rule, shall require manufacturers and processors to notify the Administrator, by not later than 180 days after the date of promulgation of the rule, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(ii) ACTIVE SUBSTANCES.—The Administrator shall, pursuant to paragraph (5)(A), designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—The rule promulgated by the Administrator pursuant to subparagraph (A) shall require—

"(i) the Administrator to maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

"(ii) a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

"(iii) the substantiation of those claims pursuant to section 14 and in

accordance with the review plan described in subparagraph (C).

"(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are notified pursuant to subparagraph (A) or identified as active substances under subsection (f)(1).

"(D) REQUIREMENTS OF REVIEW PLAN.—The review plan under subparagraph (C) shall—

"(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

"(ii) require the Administrator, in accordance with section 14—

"(I) to review each substantiation—

"(aa) submitted pursuant to clause (i) to determine if the claim warrants protection from disclosure; and

"(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

"(II) approve, modify, or deny each claim; and

"(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(iii) encourage manufacturers or processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

"(E) TIMELINE FOR COMPLETION OF REVIEWS.—

"(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years

after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

"(ii) CONSIDERATIONS.—

"(I) IN GENERAL.—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of applicable claims needing review and the available resources.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of reviews to be completed over the course of implementation of the plan.

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

"(A) IN GENERAL.—The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).

"(B) UPDATE.—The Administrator shall update the list of chemical substances designated as active substances as soon as practicable after the date of publication of the most recent data reported under—

"(i) part 711 of title 40, Code of Federal Regulations (or successor regulations); and

"(ii) the rules promulgated pursuant to subsection (a)(4).

"(C) CHANGE TO ACTIVE STATUS.—

"(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

"(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the inactive substance as confidential, the person shall—

"(I) in the notice submitted under clause (i), assert the claim; and

"(II) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

"(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

"(I) designate the applicable chemical substance as an active substance;

"(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific identity of the chemical substance and approve, modify, or deny the claim;

"(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of not less than 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines to be necessary.

"(D) CATEGORY STATUS.—The list of inactive substances shall not be considered to be a category for purposes of section 26(c).

"(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the rule required under this subsection, the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (or successor regulations), during the reporting period that most closely preceded the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as the interim list of active substances for the purposes of section 4A.

"(7) PUBLIC PARTICIPATION.—Subject to this subsection, the Administrator shall make available to the public—

"(A) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—

"(i) an active substance; or

"(ii) an inactive substance;

"(B) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received and approved by the Administrator pursuant to section 14; and

"(C) subject to section 14(g), the specific identity of any active substance for which—

"(i) no claim of protection against disclosure of the specific identity of the active substance pursuant to this subsection was received;

"(ii) a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or

"(iii) the time period for protection against disclosure of the specific identity of the active substance has expired.

"(8) LIMITATION.—No person may assert a new claim under this subsection for

protection from disclosure of a specific identity of any active or inactive chemical substance for which a notice is received under paragraph (4)(A)(i) or (5)(C)(i) that is not on the confidential portion of the list published under paragraph (1).

"(9) CERTIFICATION.—Under the rule promulgated under this subsection, manufacturers and processors shall be required—

"(A) to certify that each report the manufacturer or processor submits complies with the requirements of the rule, and that any confidentiality claims are true and correct; and

"(B) to retain a record supporting the certification for a period of 5 years beginning on the last day of the submission period.";

(3) in subsection (e)—

(A) by striking "Any person" and inserting the following:

"(1) IN GENERAL.—Any person"; and

(B) by adding at the end the following:

"(2) APPLICABILITY.—Any person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of harm to health and the environment."; and

(4) in subsection (f), by striking "For purposes of this section, the" and inserting the following: "In this section:

"(1) ACTIVE SUBSTANCE.—The term 'active substance' means a chemical substance—

"(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(B) that is added to the list published under subsection (b)(1) after that date of enactment; or

"(C) for which a notice is received under subsection (b)(5)(C).

"(2) INACTIVE SUBSTANCE.—The term 'inactive substance' means a chemical substance on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).

"(3) MANUFACTURE; PROCESS.—The".

SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.

Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the first sentence—

(i) by striking "presents or will present an unreasonable risk to health or the environment" and inserting "does not meet the safety standard"; and

(ii) by striking "such risk" the first place it appears and inserting "the risk posed

by the substance or mixture";

(B) in paragraph (2), in the matter following subparagraph (B), by striking "section 6 or 7" and inserting "section 6(d) or section 7"; and

(C) in paragraph (3), by striking "section 6 or 7" and inserting "section 6(d) or 7";

(2) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and inserting "Health and Human Services"; and

(3) by adding at the end the following:

"(e) Exposure Information.—If the Administrator obtains information related to exposures or releases of a chemical substance that may be prevented or reduced under another Federal law, including laws not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.".

SEC. 12. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA.

Section 10 of the Toxic Substances Control Act (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".

SEC. 13. EXPORTS.

Section 12 of the Toxic Substances Control Act (15 U.S.C. 2611) is amended—

(1) in subsection (a), by striking paragraph (2) and inserting the following:

"(2) EXCEPTION.—Paragraph (1) shall not apply to any chemical substance that the Administrator determines—

"(A) under section 5 is not likely to meet the safety standard; or

"(B) under section 6 does not meet the safety standard.

"(3) WAIVERS.—For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—

"(A) determine that paragraph (1) shall not apply to the mixture or article; or

"(B) establish a threshold concentration in a mixture or article at which paragraph (1) shall not apply.

"(4) TESTING.—The Administrator may require testing under section 4 of any chemical substance or mixture exempted from this Act under paragraph (1) for the purpose of determining whether the chemical substance or mixture meets the safety standard within the United States.";

(2) by striking subsection (b) and inserting the following:

"(b) Notice.—

"(1) IN GENERAL.—A person shall notify the Administrator that the person is exporting or

intends to export to a foreign country—

"(A) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 5 is not likely to meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(B) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 6 does not meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(C) a chemical substance for which the United States is obligated by treaty to provide export notification;

"(D) a chemical substance or mixture subject to a prohibition or other restriction pursuant to a rule, order, or consent agreement in effect under this Act; or

"(E) a chemical substance or mixture for which the submission of information is required under section 4.

"(2) RULES.—

"(A) IN GENERAL.—The Administrator shall promulgate rules to carry out paragraph (1).

"(B) CONTENTS.—The rules promulgated pursuant to subparagraph (A) shall—

"(i) include such exemptions as the Administrator determines to be appropriate, which may include exemptions identified under section 5(h); and

"(ii) indicate whether, or to what extent, the rules apply to articles containing a chemical substance or mixture described in paragraph (1).

"(3) NOTIFICATION.—The Administrator shall submit to the government of each country to which a chemical substance or mixture is exported—

"(A) for a chemical substance or mixture described in subparagraph (A), (B), or (D) of paragraph (1), a notice of the determination, rule, order, consent agreement, requirement, or designation;

"(B) for a chemical substance described in paragraph (1)(C), a notice that satisfies the obligation of the United States under the applicable treaty; and

"(C) for a chemical substance or mixture described in paragraph (1)(E), a notice of availability of the information on the chemical substance or mixture submitted to the Administrator."; and

(3) in subsection (c)—

(A) by striking paragraph (3); and

(B) by redesignating paragraphs (4) through (6) as paragraphs (3) through (5), respectively.

SEC. 14. IMPORTS.

Section 13 of the Toxic Substances Control Act (15 U.S.C. 2612) is amended to read as follows:

"SEC. 13. IMPORTS.

"(a) Refusal of Entry.—

"(1) IN GENERAL.—The Secretary of Homeland Security shall refuse entry into the customs territory of the United States (as defined in general note 2 to the Harmonized Tariff Schedule of the United States) any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry, if—

"(A) the Administrator—

"(i) has determined under section 6(c) that the chemical substance or mixture does not meet the safety standard; and

"(ii) has promulgated a rule pursuant to section 6(d) banning the chemical substance or mixture, as of the effective date of the rule;

"(B) the chemical substance—

"(i) is not included on the list under section 8(b)(1); and

"(ii) is not exempt from any requirement to be included on that list by this title or a rule promulgated by the Administrator pursuant to this title; or

"(C) the chemical substance, mixture, or any article containing the chemical substance or mixture is offered for entry in violation of—

"(i) a rule, consent agreement, or order in effect under this Act; or

"(ii) an order issued in a civil action brought under section 7 or title IV.

"(2) PROCEDURE.—

"(A) IN GENERAL.—Subject to subparagraph (B), if a chemical substance, mixture, or article containing a chemical substance or mixture is refused entry under paragraph (1), the Secretary of Homeland Security—

"(i) shall notify the consignee of the entry of the refusal;

"(ii) shall not release the chemical substance or mixture to the consignee; and

"(iii) shall cause the disposal or storage of the chemical substance or mixture under such rules as the Secretary may prescribe, if the chemical substance or mixture has not been exported by the consignee during the 90-day period beginning on the date of receipt of the notice of the refused entry.

"(B) EXCEPTION.—

"(i) IN GENERAL.—The Secretary of Homeland Security, pending a review by the Administrator, may release to the consignee the chemical substance or mixture if the consignee—

"(I) executes a bond for the amount of the full invoice of the chemical substance or mixture (as set forth in the customs entry); and

"(II) pays a duty on the chemical substance or mixture.

"(ii) ADMINISTRATION.—If a consignee fails to return a chemical substance or mixture released to that consignee under clause (i) for any cause to the custody of the Secretary of Homeland Security on demand, the consignee shall be liable to the United States for liquidated damages equal to the full amount of the bond executed under clause (i)(I).

"(C) STORAGE.—All charges for storage, cartage, and labor on or for the disposal of a chemical substance or mixture that is refused entry or released under this subsection shall be paid by the owner or consignee, and a default on that payment shall constitute a lien against any future entry made by the owner or consignee.

"(b) Certification.—

"(1) IN GENERAL.—A person offering a chemical substance or mixture subject to this Act for entry into the customs territory of the United States shall certify to the Secretary of Homeland Security that—

"(A) after reasonable inquiry and to the best knowledge and belief of the person, the chemical substance or mixture is in compliance with any applicable rule, consent agreement, or order under section 5 or 6; and

"(B) the chemical substance—

"(i) is included on the list under section 8(b)(1); or

"(ii) is exempt from any requirement to be included on that list by this title or a rule promulgated by the Administrator pursuant to this title.

"(2) ARTICLES.—

"(A) IN GENERAL.—The Administrator, by rule, may require certification under paragraph (1) for an article containing a chemical substance or mixture that is subject to rule under section 5 or 6.

"(B) REQUIREMENT.—The rule under subparagraph (A) shall identify, with reasonable specificity, the types of articles, including parts or components of articles, that will be subject to the certification requirement.

"(C) FACTORS FOR CONSIDERATION.—In determining the need for and content of a certification rule under this paragraph, the Administrator shall take into consideration—

"(i) the utility of the certification to enforcement of the applicable rule, consent agreement, or order under section 5 or 6;

"(ii) the contribution of imported articles to the potential risk presented by exposure to the chemical substance or mixture subject to rule under section 5 or 6;

"(iii) the impact on commerce and potential for the certification to impede or disrupt import of articles;

"(iv) the frequency or duration of the certification requirement; and

"(v) specification of the concentration of a chemical substance in an article that

would subject the article to the certification requirement.

"(3) REASONABLE INQUIRY.—

"(A) IN GENERAL.—For purposes of a certification under paragraph (1), reasonable inquiry shall include good faith reliance by an importer on—

"(i) a safety data sheet or similar declaration provided by a supplier that documents the specific identity of the chemical substance or the specific identities of all chemical substances in a mixture; or

"(ii) for chemical substances or mixtures claimed by the supplier as confidential, or not otherwise disclosed by the supplier, a certification by the supplier that the imported chemical substance or mixture satisfies the applicable certification requirements under paragraph (1).

"(B) ARTICLES.—For purposes of a certification under paragraph (2), reasonable inquiry shall include good faith reliance by an importer on a certification by the supplier that the imported article satisfies the applicable certification requirements in a rule promulgated pursuant to paragraph (2).

"(4) INFORMATION REGARDING IDENTITY.—For purposes of this subsection, the Administrator shall provide publicly accessible information regarding the identity of a chemical substance or mixture subject to rule under this Act that would be readily understood in import transactions.

"(c) Notice.—A person offering a chemical substance for entry into the customs territory of the United States shall notify the Secretary of Homeland Security if—

"(1) the chemical substance or chemical substance in a mixture is a high-priority substance;

"(2) the chemical substance or chemical substance in a mixture is 1 for which the United States is obligated to provide export notification by treaty; or

"(3) the chemical substance or chemical substance in a mixture—

"(A) is the subject of a safety assessment and safety determination conducted pursuant to section 6; and

"(B) has been found not to meet the safety standard.

"(d) Rules.—

"(1) IN GENERAL.—The Secretary of Homeland Security, after consultation with the Administrator, shall promulgate rules to carry out this section.

"(2) APPLICATION.—The rules under paragraph (1) may modify the application of any requirement of this section, as appropriate for the efficient and effective implementation of this Act.".

SEC. 15. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer and specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

"(7) Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if—

"(A) the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5; and

"(B) the claim—

"(i) is not subject to an exception under subsection (e); or

"(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (f)(2) or (g).

"(c) Information Not Protected From Disclosure.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

"(1) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

"(A) IN GENERAL.—Subject to subparagraph (B), subsection (a) does not prohibit the disclosure of—

"(i) any health and safety study that is submitted under this Act with respect to—

"(I) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

"(II) any chemical substance or mixture for which—

"(aa) testing is required under section 4; or

"(bb) a notification is required under section 5; or

"(ii) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in subclause (I) or (II) of clause (i).

"(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph authorizes the release of any information that discloses—

"(i) a process used in the manufacturing or processing of a chemical substance or mixture; or

"(ii) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

"(2) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(3) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

"(A) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

"(B) A safety assessment developed, or a safety determination made, under section 6.

"(C) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

"(D) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

"(4) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is otherwise eligible for protection under this section and contained in a submission of

information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

"(5) BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance—

"(A) any protection from disclosure provided under this section with respect to information relating to the chemical substance shall no longer apply; and

"(B) the Administrator promptly shall make the information public.

"(d) Requirements for Confidentiality Claims.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name shall—

"(i) conform with guidance prescribed by the Administrator under paragraph (3)(A); and

"(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are considered to be confidential; and

"(II) the disclosure of which would be likely to harm the competitive position of the person.

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for

protection from disclosure of information that is already publicly available.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in paragraphs (1) through (7) of subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the information that has been submitted is true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a) shall be disclosed if—

"(1) the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) the Administrator determines that disclosure is necessary to protect health or the environment;

"(4) the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, if—

"(A) 1 or more applicable agreements with the Administrator that conform with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; and

"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;

"(5) a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the

conditions that—

"(A) the statement of need and confidentiality agreement shall conform with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

"(9) the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION PROTECTED FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information that meets the requirements of subsection (d) for a period of 10 years, unless, prior to the expiration of the period—

"(i) an affected person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in subsection (g)(2).

"(B) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph (A), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph (A), a person reasserting the relevant claim shall submit to the Administrator a statement substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—

"(aa) review the request;

"(bb) make a determination regarding whether the information for which the request is made continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of not more than 10 years; or

"(BB) deny the claim.

"(C) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph (B), if the Administrator determines that the relevant statement under subparagraph (B)(ii)(I)—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection against disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating rules pursuant to section 6(d), subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d).

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection from disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) as necessary to comply with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(ii) if information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met; or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator on expiration of the period for appeal under subsection (g)(3), that has expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

"(B) DENIAL OR MODIFICATION.—

"(i) IN GENERAL.—Except as provided in subsections (c) and (f), the Administrator shall deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).

"(ii) REASONS FOR DENIAL OR MODIFICATION.—The Administrator shall provide to a person that has submitted a claim described in clause (i) a written statement of the reasons for the denial or modification of the claim.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection (b)(7), review all claims under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim under paragraph (1), the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

"(B) RELEASE OF INFORMATION.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

"(ii) EXCEPTIONS.—

"(I) IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

"(II) NO NOTIFICATION.—For information under paragraph (1), (2), (6), (7), or (9) of subsection (e), no prior notification shall be necessary.

"(3) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(4) ADMINISTRATION.—In carrying out this subsection, the Administrator shall use the procedures described in part 2 of title 40, Code of Federal Regulations (or successor regulations).

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information submitted to the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

"(2) PRIOR ACTIONS.—Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

SEC. 16. PROHIBITED ACTS.

Section 15 of the Toxic Substances Control Act (15 U.S.C. 2614) is amended by striking paragraph (1) and inserting the following:

"(1) fail or refuse to comply with—

"(A) any rule promulgated, consent agreement entered into, or order issued under section 4;

"(B) any requirement under section 5 or 6;

"(C) any rule promulgated, consent agreement entered into, or order issued under section 5 or 6; or

"(D) any requirement of, or any rule promulgated or order issued pursuant to title II;".

SEC. 17. PENALTIES.

Section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) is amended—

(1) in subsection (a)(1)—

(A) in the first sentence—

(i) by inserting "this Act or a rule or order promulgated or issued pursuant to this Act, including" after "a provision of"; and

(ii) by striking "$25,000" and inserting "$37,500"; and

(B) in the second sentence, by striking" violation of section 15 or 409" and inserting "violation of this Act"; and

(2) in subsection (b)—

(A) by striking "Any person who" and inserting the following:

"(1) IN GENERAL.—Any person that";

(B) by striking "section 15 or 409" and inserting "this Act";

(C) by striking "$25,000" and inserting "$50,000"; and

(D) by adding at the end the following:

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of this Act, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

"(B) ORGANIZATIONS.—An organization that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation.

"(3) KNOWLEDGE OF IMMINENT DANGER OR INJURY.—For purposes of determining whether a defendant knew that the violation placed another individual in imminent danger

of death or serious bodily injury—

"(A) the defendant shall be responsible only for actual awareness or actual belief possessed; and

"(B) knowledge possessed by an individual may not be attributed to the defendant.".

SEC. 18. STATE-FEDERAL RELATIONSHIP.

Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following:

"(a) In General.—

"(1) ESTABLISHMENT OR ENFORCEMENT.—Except as provided in subsections (c), (d), (e), (f), and (g), and subject to paragraph (2), no State or political subdivision of a State may establish or continue to enforce any of the following:

"(A) TESTING AND INFORMATION COLLECTION.—A statute or administrative action to require the development of information on a chemical substance or category of substances that is reasonably likely to produce the same information required under section 4, 5, or 6 in—

"(i) a rule promulgated by the Administrator;

"(ii) a testing consent agreement entered into by the Administrator; or

"(iii) an order issued by the Administrator.

"(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

"(i) found to meet the safety standard and consistent with the scope of the determination made under section 6; or

"(ii) found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

"(C) SIGNIFICANT NEW USE.—A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(2) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of State statutes and administrative actions applicable to specific substances shall not occur until the effective date of the applicable action described in paragraph (1) taken by the Administrator.

"(b) New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions.—Except as provided in subsections (c), (d), and (e), no State or political subdivision of a State may establish (after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) a statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority

substance designated under section 4A, as of the date on which the Administrator commences a safety assessment under section 6.

"(c) Scope of Preemption.—Federal preemption under subsections (a) and (b) of State statutes and administrative actions applicable to specific substances shall apply only to—

"(1) the chemical substances or category of substances subject to a rule, order, or consent agreement under section 4;

"(2) the uses or conditions of use of such substances that are identified by the Administrator as subject to review in a safety assessment and included in the scope of the safety determination made by the Administrator for the substance, or of any rule the Administrator promulgates pursuant to section 6(d); or

"(3) the uses of such substances that the Administrator has specified as significant new uses and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(d) Exceptions.—

"(1) IN GENERAL.—Subsections (a) and (b) shall not apply to a statute or administrative action of a State or a political subdivision of a State applicable to a specific chemical substance that—

"(A) is adopted under the authority of, or authorized to comply with, any other Federal law;

"(B) implements a reporting, monitoring, or other information collection obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, unless the action taken by the State or political subdivision of a State—

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii)(I) is already required by a decision by the Administrator under section 5 or 6;

"(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that are included in the scope of a safety determination pursuant to section 6 or the scope of a significant new use rule promulgated pursuant to section 5, but is inconsistent with the action of the Administrator; or

"(III) would cause a violation of the applicable action by the Administrator under section 5 or 6.

"(2) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—Nothing in this Act, nor any amendment made by this Act, nor any rule, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, safety determination, scientific assessment, or any protection for public

health or the environment that—

"(A) is adopted under the authority of, or authorized to comply with, any other Federal law;

"(B) implements a reporting, monitoring, or other information collection obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, unless the action taken by the State or political subdivision of a State—

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii)(I) is already required by a decision by the Administrator under section 5 or 6;

"(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that are included in the scope of a safety determination pursuant to section 6 or the scope of a significant new use rule promulgated pursuant to section 5, but is inconsistent with the action of the Administrator; or

"(III) would cause a violation of the applicable action by the Administrator under section 5 or 6.

"(3) APPLICABILITY TO CERTAIN RULES OR ORDERS.—Notwithstanding subsection (e)—

"(A) nothing in this section shall be construed as modifying the effect under this section, as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, of any rule or order promulgated or issued under this Act prior to that effective date; and

"(B) with respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 6 prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act with regards to manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance, this section (as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after that effective date, unless the latter rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under subsection (b) or (c) of section 4A or as an additional priority for safety assessment and safety determination under section 4A(d).

"(e) Preservation of Certain State Law.—

"(1) IN GENERAL.—Nothing in this Act, subject to subsection (g) of this section, shall—

"(A) be construed to preempt or otherwise affect any action taken before January 1, 2015, under the authority of a State law that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical

substance; or

"(B) be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003.

"(2) EFFECT OF SUBSECTION.—This subsection does not affect, modify, or alter the relationship between State and Federal law pursuant to any other Federal law.

"(f) State Waivers.—

"(1) IN GENERAL.—Upon application of a State or political subdivision of a State, the Administrator may—

"(A) by rule, exempt from subsection (a), under such conditions as may be prescribed in the rule, a statute or administrative action of that State or political subdivision of the State that relates to the effects of, or exposure to, a chemical substance under the conditions of use if the Administrator determines that—

"(i) compelling State or local conditions warrant granting the waiver to protect health or the environment;

"(ii) 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;

"(iii) 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

"(iv) based on the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is consistent with sound objective scientific practices, the weight of the evidence, and the best available science; or

"(B) 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—

"(i) the State has a compelling local interest that warrants granting the waiver to protect health or the environment;

"(ii) compliance with the proposed requirement of the State will not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(iii) compliance with the proposed requirement would not cause a violation of any applicable Federal law, rule, or order; and

"(iv) the proposed requirement is grounded in reasonable scientific concern.

"(2) APPROVAL OF A STATE WAIVER REQUEST.—The Administrator shall grant or deny a waiver application—

"(A) not later than 180 days after the date on which an application under paragraph (1)(A) is submitted; and

"(B) not later than 90 days after the date on which an application under paragraph (1)(B) is submitted.

"(3) NOTICE AND COMMENT.—The application of a State or political subdivision of the State shall be subject to public notice and comment.

"(4) FINAL AGENCY ACTION.—The decision of the Administrator on the application of a State or political subdivision of the State shall be—

"(A) considered to be a final agency action; and

"(B) subject to judicial review.

"(5) DURATION OF WAIVERS.—A waiver granted under paragraph (1)(B) shall remain in effect until the later of—

"(A) such time as the safety assessment and safety determination is completed; and

"(B) the date on which compliance with an applicable rule issued under section 6(d) is required.

"(6) JUDICIAL REVIEW OF WAIVERS.—Not later than 60 days after the date on which the Administrator makes a determination on an application of a State or political subdivision of the State under subparagraph (A) or (B) of paragraph (1), 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.

"(7) JUDICIAL REVIEW OF PRIORITIZATION SCREENING DECISION.—Not later than 60 days after the date on which the Administrator makes a decision on a recommendation made under section 4A(b)(4) to designate a chemical substance as a low priority, the Governor of a State or a State agency with responsibility for protecting health and the environment that submitted the recommendation under section 4A(a)(4)(A), as applicable, 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.

"(g) Savings.—

"(1) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF OR CRIMINAL CONDUCT.—

"(A) IN GENERAL.—Nothing in this Act, nor any amendment made by this Act, nor any safety standard, rule, requirement, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall be construed to preempt, displace, or supplant any state or Federal common law rights or any state or Federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.

"(B) CLARIFICATION OF NO PREEMPTION.—Notwithstanding any other provision of this Act, nothing in this Act, nor any amendments made by this Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any State law, maritime law, or Federal common law or statutory theory.

"(2) NO EFFECT ON PRIVATE REMEDIES.—

"(A) Nothing in this Act, nor any amendments made by this Act, nor any rules, regulations, requirements, safety assessments, safety determinations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.

"(B) This Act does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, safety assessments, scientific assessments, or orders issued pursuant to this Act.".

SEC. 19. JUDICIAL REVIEW.

Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking "section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting "section 4(a), 5(d), 6(c), 6(d), 6(g), or 8, or title II or IV"; and

(ii) in subparagraph (B), by striking "an order issued under subparagraph (A) or (B) of section 6(b)(1)" and inserting "an order issued under this title"; and

(B) in paragraph (2), in the first sentence, by striking "paragraph (1)(A)" and inserting "paragraph (1)"; and

(C) by striking paragraph (3); and

(2) in subsection (c)(1)(B)—

(A) in clause (i)—

(i) by striking "section 4(a), 5(b)(4), 6(a), or 6(e)" and inserting "section 4(a), 5(d), 6(d), or 6(g)"; and

(ii) by striking "evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;" and inserting "evidence (including any matter) in the rulemaking record, taken as a whole; and"; and

(B) by striking clauses (ii) and (iii) and the matter following clause (iii) and inserting the following:

"(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule, except as part of the rulemaking record, taken as a whole.".

SEC. 20. CITIZENS' PETITIONS.

Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an order under section 4 or 5(d)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "an order under section 4 or 5(d)"; and

(B) in paragraph (4), by striking subparagraph (B) and inserting the following:

"(B) DE NOVO PROCEEDING.—

"(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to promulgate a rule pursuant to section 4, 5, 6, or 8 or an order issued under section 4 or 5, the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.

"(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a rule or order under section 4, the information available to the Administrator is insufficient for the Administrator to perform an action described in section 4, 4A, 5, or 6(d);

"(bb) in the case of a petition to issue an order under section 5(d), there is a reasonable basis to conclude that the chemical substance is not likely to meet the safety standard;

"(cc) in the case of a petition to initiate a proceeding for the issuance of a rule under section 6(d), there is a reasonable basis to conclude that the chemical substance will not meet the safety standard; or

"(dd) in the case of a petition to initiate a proceeding for the issuance of a rule under section 8, there is a reasonable basis to conclude that the rule is necessary to protect health or the environment or ensure that the chemical substance meets the safety standard.

"(II) DEFERMENT.—The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

"(aa) the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act; and

"(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.".

SEC. 21. EMPLOYMENT EFFECTS.

Section 24(b)(2)(B)(ii) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by striking "section 6(c)(3)," and inserting "the applicable requirements of this Act;".

SEC. 22. STUDIES.

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.

SEC. 23. ADMINISTRATION.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) by striking subsection (b) and inserting the following:

"(b) Fees.—

"(1) IN GENERAL.—The Administrator shall establish, not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, by rule—

"(A) the payment of 1 or more reasonable fees as a condition of submitting a notice or requesting an exemption under section 5;

"(B) the payment of 1 or more reasonable fees by a manufacturer or processor that—

"(i) is required to submit a notice pursuant to the rule promulgated under section 8(b)(4)(A)(i) identifying a chemical substance as active;

"(ii) is required to submit a notice pursuant to section 8(b)(5)(B)(i) changing the status of a chemical substance from inactive to active;

"(iii) is required to report information pursuant to the rules promulgated under section 8(a)(4); and

"(iv) manufactures or processes a chemical substance subject to a safety assessment and safety determination pursuant to section 6.

"(2) UTILIZATION AND COLLECTION OF FEES.—The Administrator shall—

"(A) utilize the fees collected under paragraph (1) only to defray costs associated with the actions of the Administrator—

"(i) to collect, process, review, provide access to, and protect from disclosure (where appropriate) information on chemical substances under this Act;

"(ii) to review notices and make determinations for chemical substances under paragraphs (1) and (3) of section 5(d) and impose any necessary restrictions under section 5(d)(4);

"(iii) to make prioritization decisions under section 4A;

"(iv) to conduct and complete safety assessments and determinations under section 6; and

"(v) to conduct any necessary rulemaking pursuant to section 6(d);

"(B) insofar as possible, collect the fees described in paragraph (1) in advance of conducting any fee-supported activity;

"(C) deposit the fees in the Fund established by paragraph (4)(A); and

"(D) not collect excess fees or retain a significant amount of unused fees.

"(3) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—In setting fees under this section, the Administrator shall—

"(A) take into account the cost to the Administrator of conducting the activities described in paragraph (2);

"(B) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

"(C) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to defray approximately 25 percent of the costs of conducting the activities identified in paragraph (2)(A), not to exceed $18,000,000, not including fees under subparagraph (E) of this paragraph;

"(D) reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

"(E) for substances designated as additional priorities pursuant to section 4A(c), establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the safety assessment and safety determination under section 6;

"(F) 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 III of chapter 5 of title 5, United States Code, is applicable with respect to such meetings;

"(G) beginning with the fiscal year that is 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives, increase or decrease the fees established under paragraph (1) as necessary—

"(i) to ensure that funds deposited in the Fund are sufficient to conduct the activities identified in paragraph (2)(A) and the full costs of safety assessments and safety determinations pursuant to subparagraph (E); and

"(ii) to account for inflation;

"(H) adjust fees established under paragraph (1) as necessary to vary on account of differing circumstances, including reduced fees or waivers in appropriate circumstances, to reduce the burden on manufacturing or processing, remove barriers to innovation, or where the costs to the Administrator of collecting the fees exceed the fee revenue anticipated to be collected; and

"(I) if a notice submitted under section 5 is refused or subsequently withdrawn,

refund the fee or a portion of the fee if no substantial work was performed on the notice.

"(4) TSCA IMPLEMENTATION FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the 'TSCA Implementation Fund' (referred to in this subsection as the 'Fund'), consisting of—

"(i) such amounts as are deposited in the Fund under paragraph (2)(C); and

"(ii) any interest earned on the investment of amounts in the Fund; and

"(iii) any proceeds from the sale or redemption of investments held in the Fund.

"(B) CREDITING AND AVAILABILITY OF FEES.—

"(i) IN GENERAL.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation.

"(ii) REQUIREMENTS.—Fees collected under this section shall not—

"(I) be made available or obligated for any purpose other than to defray the costs of conducting the activities identified in paragraph (2)(A);

"(II) otherwise be available for any purpose other than implementation of this Act; and

"(III) so long as amounts in the Fund remain available, be subject to restrictions on expenditures applicable to the Federal government as a whole.

"(C) UNUSED FUNDS.—Amounts in the Fund not currently needed to carry out this subsection shall be—

"(i) maintained readily available or on deposit;

"(ii) invested in obligations of the United States or guaranteed by the United States; or

"(iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

"(D) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2015) of the Office of Pollution Prevention and Toxics of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for covered functions for fiscal year 2015 (excluding the amount of any fees appropriated for the fiscal year).

"(5) AUDITING.—

"(A) FINANCIAL STATEMENTS OF AGENCIES.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of an executive agency.

"(B) COMPONENTS.—The annual audit required under sections 3515(b) and 3521 of that title of the financial statements of activities under this subsection shall include an analysis of—

"(i) the fees collected under paragraph (1) and disbursed;

"(ii) compliance with the deadlines established in section 6 of this Act;

"(iii) the amounts budgeted, appropriated, collected from fees, and disbursed to meet the requirements of sections 4, 4A, 5, 6, 8, and 14, including the allocation of full time equivalent employees to each such section or activity; and

"(iv) the reasonableness of the allocation of the overhead associated with the conduct of the activities described in paragraph (2)(A).

"(C) INSPECTOR GENERAL.—The Inspector General of the Environmental Protection Agency shall—

"(i) conduct the annual audit required under this subsection; and

"(ii) report the findings and recommendations of the audit to the Administrator and to the appropriate committees of Congress.

"(6) TERMINATION.—The authority provided by this section shall terminate at the conclusion of the fiscal year that is 10 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, unless otherwise reauthorized or modified by Congress.";

(2) in subsection (e), by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services"; and

(3) adding at the end the following:

"(h) Prior Actions.—Nothing in this Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

SEC. 24. DEVELOPMENT AND EVALUATION OF TEST METHODS AND SUSTAINABLE CHEMISTRY.

Section 27 of the Toxic Substances Control Act (15 U.S.C. 2626) is amended—

(1) in subsection (a), in the first sentence by striking "Health, Education, and Welfare" and inserting "Health and Human Services"; and

(2) by adding at the end the following:

"(c) Sustainable Chemistry Program.—The President shall establish an interagency Sustainable Chemistry Program to promote and coordinate Federal sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities.

"(d) Program Activities.—The activities of the Program shall be designed to—

"(1) provide sustained support for sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training through—

"(A) coordination of sustainable chemistry research, development, demonstration, and technology transfer conducted at Federal laboratories and agencies; and

"(B) to the extent practicable, encouragement of consideration of sustainable chemistry in, as appropriate—

"(i) the conduct of Federal and State science and engineering research and development; and

"(ii) the solicitation and evaluation of applicable proposals for science and engineering research and development;

"(2) examine methods by which the Federal Government can create incentives for consideration and use of sustainable chemistry processes and products, including innovative financing mechanisms;

"(3) expand the education and training of undergraduate and graduate students and professional scientists and engineers, including through partnerships with industry, in sustainable chemistry science and engineering;

"(4) collect and disseminate information on sustainable chemistry research, development, and technology transfer including information on—

"(A) incentives and impediments to development, manufacturing, and commercialization;

"(B) accomplishments;

"(C) best practices; and

"(D) costs and benefits;

"(5) support (including through technical assistance, participation, financial support, or other forms of support) economic, legal, and other appropriate social science research to identify barriers to commercialization and methods to advance commercialization of sustainable chemistry.

"(e) Interagency Working Group.—

"(1) ESTABLISHMENT.—Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the President, in consultation with the Office of Science and Technology Policy, shall establish an Interagency Working Group that shall include representatives from the National Science Foundation, the National Institute of Standards and Technology, the Department of Energy, the Environmental Protection Agency, the Department of Agriculture, the Department of Defense, the National Institutes of Health, and any other agency that the President may designate to oversee the planning, management, and coordination of the Program.

"(2) GOVERNANCE.—The Director of the National Science Foundation and the Assistant Administrator for Research and Development of the Environmental Protection Agency, or their designees, shall serve as co-chairs of the Interagency Working Group.

"(3) RESPONSIBILITIES.—In overseeing the planning, management, and coordination of the Program, the Interagency Working Group shall—

"(A) establish goals and priorities for the Program, in consultation with the Advisory

Council;

"(B) provide for interagency coordination, including budget coordination, of activities under the Program;

"(C) meet not later than 90 days from its establishment and periodically thereafter; and

"(D) establish and consult with an Advisory Council on a regular basis.

"(4) MEMBERSHIP.—The Advisory Council members shall not be employees of the Federal Government and shall include a diverse representation of knowledgeable individuals from the private sector (including small- and medium-sized enterprises from across the value chain), academia, State and tribal governments, and nongovernmental organizations and others who are in a position to provide expertise.

"(f) Agency Budget Requests.—

"(1) IN GENERAL.—Each Federal agency and department participating in the Program shall, as part of its annual request for appropriations to the Office of Management and Budget, submit a report to the Office of Management and Budget that—

"(A) identifies the activities of the agency or department that contribute directly to the Program; and

"(B) states the portion of the agency or department's request for appropriations that is allocated to those activities.

"(2) ANNUAL BUDGET REQUEST TO CONGRESS.—The President shall include in the annual budget request to Congress a statement of the portion of the annual budget request for each agency or department that will be allocated to activities undertaken pursuant to the Program.

"(g) Report to Congress.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Interagency Working Group shall submit a report to the Committee on Science, Space, and Technology and Committee on Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works and the Committee on Commerce, Science, and Transportation of the Senate that shall include—

"(A) a summary of federally funded sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities;

"(B) a summary of the financial resources allocated to sustainable chemistry initiatives;

"(C) an analysis of the progress made toward achieving the goals and priorities of this Act, and recommendations for future program activities;

"(D) an assessment of the benefits of expanding existing, federally-supported regional innovation and manufacturing hubs to include sustainable chemistry and the value of directing the creation of 1 or more dedicated sustainable chemistry centers of excellence or hubs; and

"(E) an evaluation of steps taken and future strategies to avoid duplication of efforts, streamline interagency coordination, facilitate information sharing, and spread best practices between participating agencies in the Program.

"(2) SUBMISSION TO GAO.—The Interagency Working Group shall also submit the report described in paragraph (1) to the Government Accountability Office for consideration in future Congressional inquiries.".

SEC. 25. STATE PROGRAMS.

Section 28 of the Toxic Substances Control Act (15 U.S.C. 2627) is amended—

(1) in subsection (b)(1)—

(A) in subparagraphs (A) through (D), by striking the comma at the end of each subparagraph and inserting a semicolon; and

(B) in subparagraph (E), by striking ", and" and inserting "; and"; and

(2) by striking subsections (c) and (d).

SEC. 26. AUTHORIZATION OF APPROPRIATIONS.

Section 29 of the Toxic Substances Control Act (15 U.S.C. 2628) is repealed.

SEC. 27. ANNUAL REPORT.

Section 30 of the Toxic Substances Control Act (15 U.S.C. 2629) is amended by striking paragraph (2) and inserting the following:

"(2)(A) the number of notices received during each year under section 5; and

"(B) the number of the notices described in subparagraph (A) for chemical substances subject to a rule, testing consent agreement, or order under section 4;".

SEC. 28. EFFECTIVE DATE.

Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601 note; Public Law 94–469) is amended—

(1) by striking "Except as provided in section 4(f), this" and inserting the following:

"(a) In General.—This"; and

(2) by adding at the end the following:

"(b) Retroactive Applicability.—Nothing in this Act shall be interpreted to apply retroactively to any State, Federal, or maritime legal action commenced prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 3/16/2015 8:40:45 PM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]; Vaught, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c30920bcb6214a91b7e3c1e7810c63e1-Vaught, Laura]
Subject: Legal letter

March 16, 2015

The Honorable James Inhofe
Chairman
Committee on Environment & Public Works
410 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Barbara Boxer
Ranking Member
Committee on Environment & Public Works
456 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Inhofe and Ranking Member Boxer:

The undersigned are 25 law professors, legal scholars, and public interest lawyers from across the country who have years of collective experience in the fields of administrative, public health, and environmental law, with particular focus on state and federal toxics policy. We write to express serious reservations with a proposal before your committee to reform the Toxic Substances Control Act (TSCA), which essentially preserves the same inadequate "safety standard" used in current law. There is widespread agreement that TSCA is broken, and reform is due. The more important discussion is the discussion around why and how it is broken.

In order to truly reform TSCA, Congress must focus on the "safety standard." Since the passage of TSCA in 1976, the Environmental Protection Agency (EPA) has only been able to regulate or ban five chemicals under TSCA's section 6 authority to protect against unreasonable risk. To insure that chemicals pose no harm to the health and safety of the people and the environment, it is imperative that any reform legislation include a "reasonable certainty of no harm" health-protective safety standard — the same standard that EPA and FDA apply to chemicals in food and pesticides on produce, respectively.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act, a proposal to reform TSCA introduced March 10, 2015 (the Vitter-Udall Proposal), defines "safety standard" as a standard that "ensures, without taking into consideration cost or other non-risk factors, that no *unreasonable* risk of injury to health or the environment will result from exposure to a chemical substance under the conditions of use . . . " Frank R. Lautenberg Chemical Safety for the 21st Century Act, S. 697, 114th Cong. § 3(16) (2015) (emphasis added).

As interpreted by the courts, TSCA's current safety standard gives EPA the power to regulate "unreasonable risk" posed by a substance only if the severity and likelihood of injury from the substance are determined to be greater than the economic burden the regulation would cause industry and consumers. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1222 (5th Cir. 1991). TSCA's safety standard has thus been read to impose onerous cost-benefit analysis hurdles on the EPA before determining a chemical is unsafe. *E.g.*, John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 Colum. L. Rev. 261 (1991); John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 Ecology L.Q. 721 (2008); *see also* Noah M. Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 Vand. L. Rev. 1817 (2009).

Although the Vitter-Udall Proposal incorporates into its safety standard definition a prohibition against considering cost and non-risk factors, the definition remains ambiguous and — notably —completely contradictory to other sections of the Vitter-Udall Proposal.

The weakness of the prohibition on considering cost and non-risk factors raises **serious** concerns. By retaining the term "unreasonable risk," the Vitter-Udall Proposal's safety standard fails to send a clear signal that Congress intends to address the problems arising out of the *Corrosion Proof Fittings* decision. The Vitter-Udall Proposal defines what the safety standard is not, but it fails to define what the safety standard actually is. Because the Vitter-Udall Proposal's safety standard retains the term "unreasonable risk" but leaves the "unreasonable risk" undefined, courts would be likely to interpret Congress' intent, as it has been previously construed in case law, as still requiring a cost-benefit analysis (i.e., according to *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201). The ambiguity in this definition will likely result in costly and extensive litigation, delaying further EPA action to protect people and the environment from hazardous chemicals.

Preserving the term "unreasonable risk" also is deeply problematic from a public health perspective. It requires some balancing of risks to distinguish between those the public must live with and those worthy of regulation. Risks that the public may be compelled to live with may prove to be greater than those that are merely *de minimis*. Without a definition of "unreasonable risk," therefore, the Vitter-Udall Proposal is too ambiguous to

be an improvement on the existing statute and interpretive case law. Using a "reasonable certainty of no harm" health-protective safety standard would better protect the public health and eliminate any confusion as to whether EPA must weigh the health benefits of determining that a chemical is unsafe against the costs.

Furthermore, the Vitter-Udall Proposal, in its entirety, has not completely excluded the consideration of cost and non-risk factors when determining chemical harm. While the definition of "safety standard" seems to exclude consideration of costs and benefits, the Vitter-Udall Proposal's requirements regarding EPA's rulemaking analysis explicitly mandate consideration of costs (new Sec. 6(d)(4)(A)). The Vitter-Udall Proposal also explicitly requires a cost-benefit analysis for any exemption to a ban or phase-out (new Sec. 6(d)(5)(D)). Since the purpose of EPA rulemaking under the Vitter-Udall Proposal is to establish "restrictions necessary to ensure that [a] chemical substance meets the safety standard" (new Sec. 6(d)(1)), the contradiction between these sections and the definition of "safety standard" adds another layer of confusion to the Vitter-Udall Proposal.

Given the contradictions around consideration of costs and benefits throughout the Vitter-Udall Proposal and the ambiguity of the safety standard, it is deeply problematic from a public health perspective. To ensure that this Congress's TSCA reform efforts produce a statute that is better than the status quo, any legislative fix must use the truly health-protective safety standard, a "reasonable certainty of no harm."

We are available to provide substantive recommendations as needed.

Sincerely,

Note: Institutions listed for identification purposes only. The signators do not purport to represent the views of their institutions.

Nicholas A. Ashford, Ph.D., J.D.
Professor of Technology and Policy & Director, MIT Technology and Law Program
Massachusetts Institute of Technology

Hope Babcock
Professor of Law & Co-Director, Institute for Public Representation
Georgetown University Law Center

Alejandro E. Camacho
Professor of Law & Director, Center for Land, Environment, and Natural Resources
University of California, Irvine School of Law

David W. Case
Associate Professor of Law & Jessie D. Puckett, Jr. Lecturer
University of Mississippi School of Law

Thomas Cluderay
General Counsel
Environmental Working Group
Adjunct Professor of Law
Georgetown University Law Center

Carl Cranor
Distinguished Professor of Philosophy
University of California, Riverside

David M. Driesen
University Professor
Syracuse University College of Law

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Vermont Law School

Adam M. Finkel, Sc.D.
Senior Fellow & Executive Director, Penn Program on Regulation
University of Pennsylvania Law School
Clinical Professor of Environmental Health Sciences
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Steve C. Gold
Professor of Law & Judge Raymond J. Dearie Scholar
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Carmen G. Gonzalez
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Seattle University School of Law

Lisa Heinzerling
Justice William J. Brennan, Jr., Professor of Law
Georgetown University Law Center

Albert Lin
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UC Davis School of Law

Thomas O. McGarity
Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law
University of Texas at Austin School of Law

Joel A. Mintz
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University of Texas at Austin School of Law

Perry E. Wallace
Professor of Law
American University Washington College of Law

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 3/13/2015 4:23:07 PM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
Subject: Articles
Attachments: SCHF - Vitter-Udall Letter 3.8.15-final.pdf

The NGO's are concerned about this language.

> "(3) ARTICLES.—If the Administrator intends to prohibit or otherwise restrict an article on the basis of a chemical substance contained in that article, the Administrator shall have evidence of significant exposure to the chemical substance from such article.

This is my response.

> The Udall-Vitter bill does not in any way prevent or constrain EPA from restricting chemicals in imported products under Section 6. EPA can control such risks by placing restrictions on substances, mixtures or articles. And those restrictions could apply to manufacture, import, processing, use or disposal. EPA could also impose chemical or product-specific reporting requirements for imported products if that was deemed necessary.
>
> The bill provides statutory authority for EPA to require import certification for chemicals, mixtures and articles, the latter on a case-by case basis. This is similar to current regulatory authority, but the bill adds criteria to be used by EPA in imposing such requirements to ensure that feasibility, risk and burden are considered.
>
> Unlike for importers of chemicals and mixtures, the bill does not require importers of articles to provide notification for every high-priority chemical substance that might be in an article. This reflects the difference between articles and substances. Articles include highly complex products such as airplanes that comprise tens of thousands of parts each potentially containing hundreds of chemicals, where such notification is not practical.

EPA thoughts on this "articles" language? Does it do what the NGO letter states? (see below)

- Practical Limitations on Addressing Chemicals in Products

Consumers have come to increasingly understand the threat of toxic chemicals in consumer products, changing the marketplace. Several retailers and major brands have enacted their own restrictions on chemicals in the products they make and/or sell. This has been a primary driver of TSCA reform.

It is perplexing therefore, that the current draft, in a new provision, makes it harder for EPA to restrict an unsafe chemical in a consumer product. After EPA determined the chemical is unsafe, the EPA would have to jump through additional regulatory hoops to regulate the chemical in a product. There may be dozens of products that use a single chemical and this provision would require EPA to make a legal finding on each, substantially slowing down the agency's work in the area that most consumers would think is the primary point of reform. The new provision should be removed. Once EPA determines the chemical is unsafe, it should be able to address the presence of that chemical in whatever combination of products it deems necessary to protect public health.

Similarly, in the modern American economy most products are made overseas and imported. A system that purports to protect the public from toxic chemicals, especially in consumer products, must have a workable mechanism to address unsafe chemicals coming in from products manufactured overseas. The bill instead weakens EPA's ability to ensure that an imported product does not contain a restricted chemical. The importance of this issue was highlighted just last week, when 60 Minutes featured an investigative report of Lumber Liquidators bringing in formaldehyde treated wood at levels that violated California's standards but were certified as being compliant.

Safer Chemicals Healthy Families
www.saferchemicals.org

Dear Senators:

Our diverse coalition of public health, labor, environmental, and business organizations urges you to withhold your support for the pending legislation offered by Senators Vitter and Udall to reform the Toxic Substances Control Act.

In its current form, we must oppose this legislation because it continues to have serious flaws that undermine protection of public health. All of these flaws could readily be addressed by making a limited number of changes in the bill, and we continue to be ready to work with senators to get those changes. Senators Udall and Vitter have made improvements to their legislation over the past two years, and there is no good reason not to address the remaining concerns.

The most important problems include:

- Undue Restrictions on States' Ability to Protect Their Citizens

We generally concur with the analysis circulated by the California Attorney General stating that the bill still "eviscerates state authority." Our primary concern is the timing of preemption for chemicals named as "high priority" by EPA. Under the bill, states are blocked from taking action on a chemical at a point when EPA has merely identified the scope of a safety assessment. That is still years away from any action to protect the public. That gap in time creates a "regulatory void" where harm will go unaddressed, and it provides the potentially regulated company with every incentive to slow down or prolong the federal evaluation process. The appropriate time for preemption is at the effective date of EPA action.

Also, in a significant departure from other environmental and consumer protection laws, the bill bans states from enforcing restrictions that are *identical* to federal restrictions. State co-enforcement is often the primary mode of enforcement, and scholarly reviews of the subject show that it has not been abused, but is in fact, complementary to federal enforcement, and even vital. The ban appears to be nothing more than a naked attempt to limit enforcement under the new program.

We also agree with the Attorney General's analysis in regards to the waiver provision and inadequate protection for state air and water programs.

- The "Low Priority" Loophole

Under the bill chemicals must be separated into two tracks: High Priority or Low Priority. High Priority chemicals are reviewed against the safety standard, and if they flunk that

standard, the EPA is directed to impose appropriate risk management. Low Priority chemicals are not really reviewed at all. EPA makes a judgment as to whether the chemical is "likely to meet" the safety standard without conducting a new assessment. These chemicals are then treated as safe for any and all uses.

Needless to say, a low priority designation will be highly coveted by any chemical company, resulting in enormous pressure on the agency to stretch the murky concept of "likely to meet" as far as possible. Yet this is the one major decision in the bill that the public cannot challenge in court. The omission is conspicuous and an invitation to abuse.

- Practical Limitations on Addressing Chemicals in Products

Consumers have come to increasingly understand the threat of toxic chemicals in consumer products, changing the marketplace. Several retailers and major brands have enacted their own restrictions on chemicals in the products they make and/or sell. This has been a primary driver of TSCA reform.

It is perplexing therefore, that the current draft, in a new provision, makes it harder for EPA to restrict an unsafe chemical in a consumer product. After EPA determined the chemical is unsafe, the EPA would have to jump through additional regulatory hoops to regulate the chemical in a product. There may be dozens of products that use a single chemical and this provision would require EPA to make a legal finding on each, substantially slowing down the agency's work in the area that most consumers would think is the primary point of reform. The new provision should be removed. Once EPA determines the chemical is unsafe, it should be able to address the presence of that chemical in whatever combination of products it deems necessary to protect public health.

Similarly, in the modern American economy most products are made overseas and imported. A system that purports to protect the public from toxic chemicals, especially in consumer products, must have a workable mechanism to address unsafe chemicals coming in from products manufactured overseas. The bill instead weakens EPA's ability to ensure that an imported product does not contain a restricted chemical. The importance of this issue was highlighted just last week, when 60 Minutes featured an investigative report of Lumber Liquidators bringing in formaldehyde treated wood at levels that violated California's standards but were certified as being compliant.

In general, the public health community has moved considerably on a large number of issues in this debate to find a point of accommodation with regulated industry. These remaining issues get at the core question of whether the program will do more harm than good.

Sincerely,

Andy Igrejas
Safer Chemicals, Healthy Families

David Goldston
Natural Resources Defense Council

Mark Mitchell, MD
National Medical Association

Elena Rios, MD
National Hispanic Medical Association

Maureen Swanson
Learning Disabilities Association

Tiernan Sittenfeld
League of Conservation Voters

Jeanne Rizzo, President & CEO
Breast Cancer Fund

Ted Schettler, MD
Science and Environmental Health Network

Mike Belliveau
Environmental Health Strategy Center

Kathleen Schuler
Healthy Legacy Minnesota

Laurie Valeriano
Washington Toxics Coalition

Michael Green, Executive Director
Center for Environmental Health

Kathleen A. Curtis, LPN
Clean and Healthy New York

Harold A. Schaitberger, General President
International Association of Fire Fighters

Holly Hart, Legislative Director and Assistant to the President
United Steelworkers

Katie Huffling, RN, CNM
Alliance of Nurses for Healthy Environments

Pamela Miller, Executive Director
Alaska Community Action on Toxics

Bob Wendelgass, President and CEO
Clean Water Action

Alexis Blizman, JD, Policy Director
Ecology Center

Rebecca Meuninck, Campaign Director
Michigan Network for Children's Environmental Health

Sarah Doll
SAFER States

John Rumpler, Senior Attorney
Environment America

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 3/6/2015 8:02:05 PM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]; Kaiser, Sven-Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac78d3704ba94edbbd0da970921271ff-SKAISER]
Subject: Need immediate assistance...
Attachments: EPA TA.9_3_14 draft of CSIA_rev9_4_14.docx

When we met with EPA technical assistance, you demonstrated that there was inconsistency with the use of "injury" and "harm". You represented that "injury" is in current TSCA.

As a result, we conformed our legislation to be "injury".

Can you give us a quick response on what you believe "injury" to mean?

The term applies to health and the environment.

EPA comment on page 1.
"The bill uses "injury" numerous times, as does existing TSCA. Should be consistent, or have a reason for using injury in some places and harm in others."

Safety Standard from bill:

> "(16) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of injury to health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of injury to—
>
> "(A) the general population; or
>
> "(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

These comments are provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency or the administration on the bill, the draft language and comments.

Senate Legislative Counsel
Draft Copy of O:\ARP\ARP14174.XML

Title: To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Chemical Safety Improvement Act".

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(a) of the Toxic Substances Control Act (15 U.S.C. 2601(a)) is amended—

(1) in paragraph (2)—

(A) by striking "injury" and inserting "harm"; and

(B) by striking "and" at the end;

(2) by redesignating paragraph (3) as paragraph (4); and

(3) by inserting after paragraph (2) the following:

"(3) reform of this Act in accordance with the amendments made by the Chemical Safety Improvement Act—

"(A) shall be administered in a manner that—

"(i) protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and

"(ii) ensures that appropriate information on chemical substances and mixtures is available to public health officials and first responders in the event of an emergency; and

"(B) shall not displace or supplant common law rights of action or remedies for civil relief; and".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) by redesignating paragraphs (7), (8), (9), (10) , (11), (12), (13), and (14) as paragraphs (9), (10), (11), (13), (14), (19), (20), and (21), respectively;

(2) by inserting after paragraph (6) the following:

"(7) INFORMATION.—The term 'information' means any qualitative, quantitative, or descriptive facts, data, analysis, or assessment related to chemical hazards, use, or exposure

Commented [A1]: This retains the mandatory economic and social considerations of 2(c) for "any action." The bill is now clear that some actions (eg, safety determinations, and probably prioritization decisions) have no economic component, so this provision seems overbroad.

Commented [A2]: The bill uses "injury" numerous times, as does existing TSCA. Should be consistent, or have a reason for using injury in some places and harm in others.

Commented [A3]: 1.This appears under "Findings" (subsection (a)), but (3) provides implementation direction, not findings. 2. Consider simply providing that "This Act shall. . . ." Over time, the distinction between CSIA portions and earlier portions will be obscure, and CSIA largely replaces Title I in any event.

Commented [A4]: This definition is too narrow for the entire statute. Under this, commercial information cannot be CBI under section 14, because it is not information at all. There may be additional places in the bill and TSCA where "information" is also used more broadly.

These comments are provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency or the administration on the bill, the draft language and comments.

(including the nature and extent of exposure to a chemical substance), including from health and safety studies.

"(8) INTENDED OR REASONABLY ANTICIPATED CONDITIONS OF USE.—The term 'intended or reasonably anticipated conditions of use' means the circumstances the Administrator determines are those under which a chemical substance is intended, reasonably known, or reasonably anticipated to be manufactured, processed, distributed in commerce, used, and disposed of.";

Commented [A5]: What does "reasonably known" mean?

Commented [A6]: Should probably be "or".

(3) by inserting after paragraph (11) (as so redesignated) the following:

"(12) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.—The term 'potentially exposed or susceptible population' means 1 or more groups—

"(A) of individuals within the general population who may be—

"(i) differentially exposed to chemical substances under the intended or reasonably anticipated conditions of use; or

"(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

"(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; and

(4) by inserting after paragraph (14) (as so redesignated) the following:

"(15) PUBLICLY AVAILABLE.—

"(A) IN GENERAL.—The term 'publicly available', with respect to information, means information that is—

"(i) generally accessible and available to the general public; or

"(ii) in the public domain.

"(B) INCLUSIONS.—The term 'publicly available', with respect to information, includes information that has been published in periodicals, books, print, an electronic format, or other media available for general distribution to any member of the public.

"(16) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the intended or reasonably anticipated conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.

"(17) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the intended or reasonably anticipated conditions of use.

"(18) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance under the intended or reasonably anticipated conditions of use, including no unreasonable risk of harm to—

Commented [A7]: TSCA Title I generally uses "health", not "human health", although there is some of both. It would be most consistent with the portions of Title I being retained to use just "health".

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"(A) the general population; or

"(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

The Toxic Substances Control Act is amended by inserting after section 3 (15 U.S.C. 2602) the following:

"SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

"(a) Definition of Guidance.—In this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.

"(b) Deadline.—Not later than 2 years after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.

Commented [A8]: Are policies and procedures something other than guidance? It appears from (a) that only significant guidance need be subject to notice and comment; does the same limitation apply to the obligation for policies and procedures?

"(c) Use of Science.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance on the use of science in making decisions under sections 4, 4A, 5, and 6.

"(2) GOAL.—A goal of the policies and procedures described in paragraph (1) shall be to make the basis of decisions clear to the public.

Commented [A9]: How about guidance? This section is inconsistent on the use of these three terms.

"(3) REQUIREMENTS.—The policies, procedures, and guidance issued under this section shall describe the manner in which the Administrator shall ensure that —

Commented [A10]: Among other things, EPA has a duty to establish "procedures. . . [to] describe how the Administrator will ensure that. . . decisions made by the Administrator. . . are based on. . . procedures. . . employed in a manner consistent with the best available science." This is a fairly convoluted set of commands.

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;

Commented [A11]: This seems to mixing concepts of WoE with systematic review, which would be one of the procedures, processes or methods by which the Agency typically ensures that assumptions/methods are clearly and completely described and documented, i.e. (ii) above

"(B) to the extent practicable and if appropriate, the use of peer review, standardized

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test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.

Commented [A12]: How do guidelines and policies relate to policies, procedures and guidance?

"(e) Review.—Not later than 5 years after the date of enactment of this section, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(1) review the adequacy of any policies, procedures, and guidance developed under this section, including animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this Act; and

"(2) after providing public notice and an opportunity for comment, revise the policies, procedures, and guidance if necessary to reflect new scientific developments or understandings.

"(f) Sources of Information.—In making any decision with respect to a chemical substance under section 4, 4A, 5, or 6, the Administrator shall take into consideration information relating to the hazards and exposures of a chemical substance under the intended or reasonably anticipated conditions of use that is reasonably available to the Administrator, including information that is—

Commented [A13]: This seems potentially too broad. Eg, per 4A, EPA can apparently identify a substance as high priority based on the potential for either high hazard or high exposure. This provision seems to suggest that EPA must, eg, conduct an active search for exposure information before designating a chemical as high priority even for a high hazard chemical.

"(1) submitted to the Administrator pursuant to any regulation, consent agreement, order, or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act, by—

Commented [A14]: Throughout, leg counsel changed "rule" to "regulation". Existing TSCA uses "rule" (eg, in the judicial review provisions in section 19, and in retained portions of section 5), and it will be confusing to to have both terms used. Suggest sticking with "rule".

"(A) manufacturers or processors of a substance;

"(B) the public;

"(C) other Federal departments or agencies; or

"(D) the Governor of a State or a State agency with responsibility for protecting health or the environment;

"(2) submitted to a governmental entity in any jurisdiction pursuant to a governmental requirement relating to the protection of human health or the environment; or

"(3) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible by the Administrator.

"(g) Testing of Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator shall establish policies and procedures for the testing of chemical substances or mixtures under section 4.

"(2) GOAL.—A goal of the policies and procedures established under paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) CONTENTS.—The policies and procedures established under paragraph (1) shall—

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential;

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations;

"(C) require the Administrator to consult with the Director of the National Institute for Occupational Safety and Health prior to prescribing epidemiologic studies of employees; and

"(D) prior to adopting a requirement for testing using vertebrate animals, require the Administrator to take into consideration, as appropriate and to the extent practicable, reasonably available—

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

"(iii) high-throughput screening methods and the prediction models of those methods; and

"(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.

"(4) TIERED TESTING.—

"(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.

"(B) SCREENING-LEVEL TESTS.—

"(i) IN GENERAL.—The screening-level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.

Commented [A15]: 1.In ordinary usage, guidance cannot impose requirements. Guidance that does so would likely be viewed as a final, reviewable agency action. 2. This is one of many places in the bill where it might make more sense for the bill to impose the requirement on EPA, rather than to instruct EPA to impose the requirement on itself. There seems to be no exercise of discretion here.

Commented [A16]: Same comment re imposing requirements through guidance.

Commented [A17]: Vertebrate animal?

Commented [A18]: Note that paragraph 4 imposes direct requirements on EPA, and so is a little out of place in this section on policies, procedures and guidance.

Commented [A19]: (A) says EPA can employ tests or assessments. This suggests that screening level tests are required. Terminology should be consistent throughout this paragraph.

Commented [A20]: Are these something other than tests or assessments?

"(ii) USE.—Screening-level tests shall be used—

"(I) to screen chemical substances or mixtures for potential adverse effects; and

"(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.

"(C) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for safety assessments or safety determinations, the Administrator may require more advanced tests for potential human health or environmental effects or exposure potential.

"(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

"(h) Safety Assessments and Safety Determinations.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(A) IN GENERAL.—The Administrator shall establish, by regulation, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

"(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

"(C) MINIMUM REQUIREMENTS.—At a minimum, the policies and procedures under this paragraph shall—

"(i) describe—

"(I) the manner in which the Administrator will identify informational needs and seek that information from the public;

"(II) the information (including draft safety assessments) that may be submitted by interested individuals or entities, including States; and

"(III) the criteria by which that information will be evaluated;

Commented [A21]: These are not the only purposes of testing identified in section 4. Is there a reason these are singled out here?

Commented [A22]: Should this phrase be dropped? Section 4 specifies the allowable purposes for testing; why paraphrase here?

Commented [A23]: Note that paragraph 1 imposes direct requirements on EPA, and so is a little out of place in this section on policies, procedures and guidance.

Commented [A24]: Is there some reason these policies and procedures are established by regulation, in contrast to the other policies, procedures and guidance in this section? 3A(b) imposes a notice and comment requirement on guidance, so rulemaking isn't necessary to ensure that.

Commented [A25]: It is doubtful that EPA can limit the information that may be submitted.

Commented [A26]: Which information? The info submitted by interested individuals and entities?

"(ii) require the Administrator—

"(I)(aa) to identify the hazards, exposures, intended or reasonably anticipated conditions of use, and potentially exposed and susceptible populations that the Administrator expects to consider in a safety assessment;

"(bb) to explain the basis for those identifications; and

"(cc) to accept comments regarding the identifications; and

"(II)(aa) to identify the items described in subclause (I) that the Administrator has considered in the final safety assessment; and

"(bb) to explain the basis for the consideration of those items;

"(iii) describe the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the intended or reasonably anticipated conditions of use will be considered, and explain the basis for that consideration in the final safety assessment;

"(iv) require that each safety assessment and safety determination shall include—

"(I) a description of the weight of the scientific evidence of risk; and

"(II) a summary of the information regarding the impact on human health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies; and

"(v) establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination.

"(i) Publicly Available Information.—Subject to section 14, the Administrator shall—

"(1) make publicly available a nontechnical summary, and the final version, of each safety assessment and safety determination;

"(2) provide public notice and an opportunity for comment on each proposed safety assessment and safety determination; and

"(3) make public in a final safety assessment and safety determination—

"(A) the list of studies considered by the Administrator in carrying out the safety assessment or safety determination; and

"(B) the list of policies, procedures, and guidance that were followed in carrying out the safety assessment or safety determination.

"(j) Consultation With Science Advisory Committee on Chemicals.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section,

Commented [A27]: Same comment as above re whether it makes more sense for the bill to impose these requirements directly.

Commented [A28]: How will EPA identify these in advance of the safety assessment itself? Does this require EPA to generate an identification document prior to conducting the safety assessment? And, per cc, is a separate notice and comment process required on this identification?

Commented [A29]: Again, must this description occur before the assessment itself?

Commented [A30]: How can the policy and procedure document itself explain the basis for the consideration of exposure in a final safety assessment?

Commented [A31]: Same comments as above re whether it makes more sense for the bill to impose these requirements directly.

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the Administrator shall establish an advisory committee, to be known as the 'Science Advisory Committee on Chemicals' (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, on the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, industry, and other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(5) RELATIONSHIP TO OTHER LAW.—All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).".

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking subsections (a), (b), (c), (d), and (g);

(2) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively;

Commented [A32]: It may be confusing and distracting to retain the interagency testing committee, established by 4(e). Its purpose – to advise EPA on testing priority – is arguably obsolete, given the new general FACA created in 3A and the clearer role of testing as it relates to section 6 in the bill, compared to TSCA. Sec 4(e) has a set of criteria for the ITC to consider, which may not align with priorities as established by the bill.

(3) in subsection (f) (as so redesignated)—

(A) by striking "rule" each place it appears and inserting "regulation, testing consent agreement, or order";

(B) by striking "under subsection (a)" each place it appears and inserting "under this subsection"; and

(C) in paragraph (1)(B), in the last sentence, by striking "rulemaking";

(4) in subsection (g) (as so redesignated)—

(A) in the first sentence, by striking "from cancer, gene mutations, or birth defects"; and

(B) by striking the last sentence; and

(5) by inserting before subsection (f) (as so redesignated) the following:

"(a) Development of New Information on Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section if the

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Administrator determines that the information is necessary—

"(A) to perform a safety assessment or safety determination under section 6;

"(B) to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4);

"(C) pursuant to section 12(a)(4); or

"(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

"(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.

"(B) PROHIBITION.—Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.

"(C) LIMITATION.—The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

"(3) FORM.—Subject to section 3A(f), the Administrator may require the development of test data and information described in paragraph (1) or (2) by—

"(A) promulgating a regulation;

"(B) entering into a testing consent agreement; or

"(C) issuing an order.

"(4) CONTENTS.—

"(A) IN GENERAL.—A regulation, testing consent agreement, or order issued under this subsection shall include—

"(i) identification of the chemical substance or mixture for which testing is required;

"(ii) identification of the persons required to conduct the testing;

"(iii) test protocols and methodologies for the development of test data and information for the chemical substance or mixture, including specific reference to reliable nonanimal test procedures; and

"(iv) specification of the period within which individuals and entities required to conduct the testing shall submit to the Administrator the information developed in accordance with the procedures described in clause (iii).

"(B) CONSIDERATIONS.—In determining the procedures and period to be required under subparagraph (A), the Administrator shall take into consideration—

"(i) the relative costs of the various test protocols and methodologies that may

Commented [A33]: 1.If reference to the testing subsection of 3A is intended, that should be 3A(g). 2. 3A has nothing to say about the form of testing requirements and does not instruct EPA to develop guidance along these lines; does it make sense to reference it here? What's intended?

Commented [A34]: Here and anywhere else it appears, data should be stricken, since information subsumes data.

Commented [A35]: Same comment re data. This needs a global search.

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be required; and

"(ii) the reasonably foreseeable availability of facilities and personnel required to perform the testing.

"(b) Statement of Need.—

"(1) IN GENERAL.—In promulgating a regulation, entering into a testing consent agreement, or issuing an order for the development of additional information (including information on exposure or exposure potential) pursuant to this section, the Administrator shall—

"(A) identify the need intended to be met by the regulation, agreement, or order;

"(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of vertebrate animals.

"(2) EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an order is warranted instead of promulgating a regulation or entering into a testing consent agreement.

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a description of—

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

"(ii) the extent to which the Administrator has obtained or attempted to obtain the information through voluntary submissions; and

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

Commented [A36]: Vertebrate animals?

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"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

"(I) animal-based studies; and

"(II) emerging methods and models; and

"(B) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

Commented [A37]: Vertebrate animal tests?

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) after providing an opportunity for public comment, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information used in safety assessments and safety determinations under section 6 that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) beginning on the date that is 5 years after the date of enactment of the Chemical Safety Improvement Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation; and

"(C) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any safety assessment or safety determination under section 6.

Commented [A38]: Presumably this means "in any testing for purposes of conducting any safety assessment. . . ." EPA would not use animals in the assessments and determinations themselves.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

Commented [A39]: The title of (c) uses "vertebrates". This title uses "animal". The text uses "vertebrate animals" and "animals". Should be consistent.

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(d) Testing Requirements.—

"(1) IN GENERAL.—The Administrator may require the development of information by—

"(A) manufacturers and processors of the chemical substance or mixture; and

"(B) persons that begin to manufacture or process the chemical substance or mixture—

"(i) after the effective date of the regulation, testing consent agreement, or order; but

"(ii) subject to paragraph (3), before the period ending on the date that is 180 days after the end of the period described in this section.

"(2) DESIGNATION.—The Administrator may permit 2 or more persons identified in subparagraph (A) or (B) of paragraph (1) to designate 1 of the persons or a qualified third party—

"(A) to develop the information; and

"(B) to submit the information on behalf of the persons making the designation.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—A person otherwise subject to a regulation, testing consent agreement, or order under this section may submit to the Administrator an application for an exemption on the basis that the information is being developed by a person designated under paragraph (2).

"(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

"(i) IN GENERAL.—If the Administrator accepts an application submitted under subparagraph (A), the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as agreed to between the applicant and the designee.

"(ii) ARBITRATION.—If the applicant and a person designated under paragraph (2) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.

"(C) TERMINATION.—If, after granting an exemption under this paragraph, the Administrator determines that a person covered by the exemption has failed to comply with the regulation, testing consent agreement, or order, the Administrator shall—

Commented [A40]: Should probably be promulgation date, to avoid possible gap in coverage, if this is supposed to pick up where (1)(A) leaves off.

Commented [A41]: What period described in this section? Even if that were clear, it's hard to see how this makes sense. And why is ii in particular subject to para 3?

Commented [A42]: Why doesn't the bill directly require this, rather than having EPA require it? And why have EPA direct private parties to comply with their own agreements?

Commented [A43]: This doesn't make sense – termination should be triggered by failure of the designee to comply, not failure of an exempted person. This error was introduced by leg counsel changes.

"(i) by order, terminate the exemption; and

"(ii) notify in writing each person that received an exemption of the requirements with respect to which the exemption was granted.

"(e) Transparency.—Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders and all information submitted under this section.".

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the third sentence by striking "section 4(e)" and inserting "section 4(f)".

SEC. 6. PRIORITIZATION SCREENING.

The Toxic Substances Control Act is amended by inserting after section 4 (15 U.S.C. 2603) the following:

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) Establishment and List of Substances.—

Commented [A44]: Establishment of substances? What does it mean to establish a substance?

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish, by regulation, a risk-based screening process and criteria for identifying existing chemical substances that are—

"(A) a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances'); and

"(B) a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').

"(2) INITIAL LIST OF HIGH-PRIORITY SUBSTANCES.—

"(A) IN GENERAL.—Before the date of promulgation of the regulation under paragraph (1) and not later than 180 days after the date of enactment of this section, the Administrator—

"(i) shall take into consideration and publish an initial list of high-priority substances; and

Commented [A45]: What does it mean to take into consideration a list that doesn't exist yet?

"(ii) pursuant to section 6(b)(2), may initiate or continue safety assessments and safety determinations for those chemical substances.

Commented [A46]: This should be dropped. The bill already requires safety assessments and determinations for high priority chemicals, and the requirement is imposed by 6(a), not 6(b)(2), so the citation is confusing.

"(B) REQUIREMENTS.—The initial list of high-priority substances shall contain at least 10 chemical substances.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator shall take into consideration active substances, as determined under section 8,

Commented [A47]: It doesn't make sense for EPA to take into consideration active substances when promulgating the process rule, which is what paragraph 1 requires. This was a leg counsel change.

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which may include chemical substances on the interim list of active substances established under that section.

"(ii) INACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator may take into consideration inactive substances, as determined under section 8, that the Administrator determines—

"(I)(aa) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) have the potential for high hazard and widespread exposure; or

"(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) with respect to which there exists the potential for residual high hazards or widespread exposures not otherwise addressed by the regulatory or other action.

"(iii) REPOPULATION.—

"(I) IN GENERAL.—On the completion of a safety determination under section 6 for a chemical substance, the Administrator shall remove the chemical substance from the list of high-priority substances established under this subsection.

"(II) ADDITIONS.—The Administrator shall add at least 1 chemical substance to the list of high-priority substances for each chemical substance removed from the list of high-priority substances established under this subsection, until a safety assessment and safety determination is completed for all high-priority substances.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) not later than 180 days after the effective date of the final regulation under paragraph (1), begin the prioritization screening process; and

"(II) make every effort to complete the prioritization screening of all active substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a regulation, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical substance as a high-priority substance or low-priority substance.

"(iii) CONSIDERATION.—

"(I) IN GENERAL.—The Administrator shall screen substances taking into consideration the ability of the Administrator to schedule and complete

Commented [A48]: Same comment.

Commented [A49]: The use of "or" here and "and" in (I)(bb) leads to the odd result that the bar for prioritizing banned substances is lower than the bar for non-banned substances.

Commented [A50]: This 1-for-1 scheme, which is the forcing mechanism in this section, accounts for removal of substances via completion of safety determinations, but not for removal via re-prioritizing from high to low per (b)(8). This creates the possibility that the priority list could shrink below 10 substances.

Commented [A51]: This seems inconsistent with the requirement to establish the initial high priority list before the regulation is done. More generally, why not even start prioritizing until 180 days after the effective date (which presumably will be some time after the promulgation date)?

safety assessments and safety determinations under section 6 in a timely manner.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.

"(C) SCREENING OF CATEGORIES OF SUBSTANCES.—The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate safety assessments and safety determinations.

Commented [A52]: EPA can already do this (or anything else) by category under sec 26(c). Specifically providing for this here will call the breadth of that section into question.

"(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—Not less frequently than once each year, the Administrator shall publish a list of chemical substances that—

"(i) are being considered in the prioritization screening process and the status of the chemical substances in the prioritization process, including those chemical substances for which prioritization decisions have been deferred; and

"(ii) are designated as high-priority substances or low-priority substances, including the bases for such designations.

"(4) CRITERIA.—The criteria described in paragraph (1) shall account for—

"(A) the recommendation of the Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances appropriate for prioritization screening;

"(B) the hazard and exposure potential of the chemical substance (or category of substances), including specific scientific classifications and designations by authoritative governmental entities;

"(C) the intended or reasonably anticipated conditions of use or significant changes in the conditions of use of the chemical substance;

Commented [A53]: Wouldn't intended or reasonably anticipated uses cover significant changes in uses?

"(D) evidence and indicators of exposure potential to humans or the environment from the chemical substance, including potentially exposed or susceptible populations;

"(E) the volume of a chemical substance manufactured or processed;

"(F) whether the volume of a chemical substance as reported under a regulation promulgated pursuant to section 8(a) has significantly increased or decreased during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance;

Commented [A54]: This provision was redrafted by leg counsel and now does not make sense.

"(G) the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

"(H) the extent of Federal or State regulation of the chemical substance or the extent

of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a low-priority substance.

"(b) Prioritization Screening Process and Decisions.—

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall include a requirement that the Administrator shall—

"(A) identify the chemical substances being considered for prioritization;

"(B) request interested persons to supply information regarding the chemical substances being considered;

"(C) apply the criteria identified in subsection (a)(4); and

"(D) subject to paragraph (5) and using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.

"(2) INTEGRATION OF INFORMATION.—The prioritization screening decision regarding a chemical substance shall integrate any hazard and exposure information relating to the chemical substance that is available to the Administrator.

"(3) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(A) shall identify as a high-priority substance a chemical substance that, relative to other chemical substances, the Administrator determines has the potential for high hazard and widespread exposure;

"(B) may identify as a high-priority substance a chemical substance that, relative to other chemical substances, the Administrator determines has the potential for high hazard or widespread exposure; and

"(C) may identify as a high-priority substance an inactive substance, as determined under subsection (a)(3)(A)(ii) and section 8(b), that the Administrator determines warrants a safety assessment and safety determination under section 6.

"(4) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that the chemical substance is likely to meet the applicable safety standard.

"(5) DEFERRING A DECISION.—If the Administrator determines that additional information is required to establish the priority of a chemical substance under this section, the Administrator may defer the prioritization screening decision for a reasonable period—

"(A) to allow for the submission of additional information by an interested person and for the Administrator to evaluate the additional information; or

"(B) to require the development of information pursuant to a regulation, testing consent agreement, or order issued under section 4(a)(2).

Commented [A55]: Does it make sense that state regulation is a factor in designating a substance as low priority, which will preempt further state regulation?

Commented [A56]: Consider whether this would this be better imposed directly by the bill.

Commented [A57]: Does this mean EPA must apply all of the criteria in every prioritization decision? (b)(3) provides that EPA can designate a chemical high priority based on potential for high hazard or widespread exposure, whereas this provision suggests a much more involved analysis.

Commented [A58]: Similar comment to the previous one. The requirement to integrate any hazard and exposure information creates tension with the authority to prioritize based on either.

Commented [A59]: "Applicable" should be dropped. There's only one safety standard.

Commented [A60]: In general, this section does not provide for deadlines to be deferred. The only deadline is under the expedited screening process, in (c). Is EPA intended to have authority to defer that?

Commented [A61]: Changed from "needed" by leg counsel. "Needed" was better, as "required" could suggest a legal requirement.

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"(6) DEADLINES FOR SUBMISSION OF INFORMATION.—If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of the information.

"(7) NOTICE AND COMMENT.—The Administrator shall—

"(A) publish the proposed decisions made under paragraphs (3), (4), and (5) and the basis for the decisions; and

"(B) provide an opportunity for public comment.

Commented [A62]: Does it really make sense to require notice and comment on "deferral" of a prioritization decision, given that there are no deadlines (except in (c))? The forcing mechanism for this section is the 1-for-1 repopulation requirement, rather than deadlines for individual prioritization decisions.

"(8) REVISION BASED ON NEW INFORMATION.—

"(A) IN GENERAL.—At any time, and at the discretion of the Administrator, the Administrator may revise the designation of a chemical substance as a high-priority substance or a low-priority substance based on new information made available to the Administrator after the date of the determination under paragraph (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.

"(9) REVIEW.—Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Administrator shall—

"(A) review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and

"(B) if necessary, modify the prioritization screening process.

"(10) EFFECT.—Subject to section 18, a designation by the Administrator under this section with respect to a chemical substance shall not affect—

"(A) the manufacture, processing, distribution, use, or disposal of the chemical substance; or

Commented [A63]: Should use "distribution in commerce" throughout the bill --- it's a defined term. Should do a global search for this.

"(B) the regulation of those activities.

"(c) Expedited Prioritization Screening.—

"(1) IN GENERAL.—Not later than 180 days after the date on which the Administrator receives from the Governor of a State or a State agency with responsibility for protecting health and the environment a recommendation and relevant information justifying that an active substance be identified as a high-priority substance or a low-priority substance, the Administrator shall make a prioritization screening decision for the active substance.

Commented [A64]: When does the 180-day clock start running? From date of receipt of any submission, or from date of receipt of a submission that EPA concludes contains "relevant information justifying" a priority designation?

"(2) LIMITATION.—The Governor of a State or a State agency with responsibility for protecting health and the environment may annually recommend not more than 2 chemical substances for prioritization screening under paragraph (1).

"(3) RECOMMENDATION.—Notwithstanding subsection (b)(8), a recommendation by the

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Governor of a State or a State agency with responsibility for protecting health and the environment with respect to a chemical substance that has been previously prioritized shall not be required to be based on new information.

Commented [A65]: Ideally, the bill should also provide that EPA can grant such a petition; (b)(8) restricts EPA's authority to re-prioritize, not the content of petitions.

"(4) NOTICE AND COMMENT.—The public shall be provided notice and an opportunity to comment regarding the recommendations submitted under this subsection.

"(5) EXPLANATION OF REASONS.—The Administrator shall—

"(A) make available to the Governor or State agency, as applicable, and to the public a brief explanation of the reasons for—

"(i) identifying a chemical substance recommended by the Governor or State agency for prioritization screening as a high-priority substance or a low-priority substance; or

"(ii) deferring a prioritization screening decision; and

Commented [A66]: Per above comments, does this indicate that EPA can defer beyond the 180-day deadline created by this subsection?

"(B) identify the information relied on in making that identification.

"(d) Treatment.—Except as provided in section 18(e)(6)(B), an action by the Administrator under this section shall not be—

"(1) considered to be a final agency action; or

"(2) subject to judicial review.".

SEC. 7. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.";

(2) by striking subsection (b);

(3) by redesignating subsection (a) as subsection (b);

(4) by redesignating subsection (i) as subsection (a) and moving the subsection so as to appear at the beginning of the section;

(5) in subsection (b) (as so redesignated)—

(A) in the subsection heading, by striking "In General" and inserting "Notices"; and

(B) in paragraph (1), in the matter following subparagraph (B)—

(i) by striking "subsection (d)" and inserting "subsection (b)"; and

(ii) by striking "and such person complies with any applicable requirement of

subsection (b)";

(6) by redesignating subsections (c) and (d) as subsection (d) and (c), respectively, and moving subsection (c) (as so redesigned) so as appear after subsection (b) (as redesignated by paragraph (3));

(7) in subsection (c) (as so redesignated)—

(A) by striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—The notice required by subsection (a) shall include, with respect to a chemical substance—

"(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

"(B) information regarding intended or reasonably anticipated conditions of use and reasonably anticipated exposures.";

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking "or of data under subsection (b)";

(ii) in subparagraph (A), by adding "and" after the semicolon at the end;

(iii) in subparagraph (B), by striking "; and" and inserting a period; and

(iv) by striking subparagraph (C); and

(C) in paragraph (3), by striking "subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "subsection (b) and for which the notification period prescribed by subsection (b) or (d)";

(8) by striking subsection (d) (as redesignated by paragraph (6)) and inserting the following:

"(d) Review of Notice.—

"(1) INITIAL REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall—

"(i) conduct an initial review of the notice;

"(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

"(iii) make any necessary determination under paragraph (3).

"(B) EXTENSION.—Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.

Commented [A67]: Note that this reference to EPA regulations, including successor regulation, provides no statutory content. What was the reason for replacing existing TSCA 5(d)(1)?

Commented [A68]: All known or reasonably ascertainable information? As written, this provides a very minimal requirement (apparently any information) for a key element of new chemical review.

Commented [A69]: In addition, the reference to (a) in this matter must be changed to (b).

Commented [A70]: Should be changed to "a determination". A determination will always be necessary.

"(2) INFORMATION SOURCES.—In evaluating a notice under paragraph (1), the Administrator shall take into consideration—

"(A) any relevant information identified in subsection (c)(1); and

"(B) any other relevant additional information available to the Administrator.

"(3) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), and based on the information described in paragraph (2), the Administrator shall determine that—

"(A) the relevant chemical substance or significant new use is not likely to meet the safety standard, in which case the Administrator shall take appropriate action under paragraph (5);

"(B) the relevant chemical substance or significant new use is likely to meet the safety standard, in which case the Administrator shall allow the review period to expire without additional restrictions; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (5).

"(4) RESTRICTIONS.—

"(A) IN GENERAL.—If the Administrator makes a determination under subparagraph (A) or (C) of paragraph (3) with respect to a notice submitted under subsection (b), the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, as appropriate, shall prohibit or restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the restrictions specified in the consent agreement or order that the Administrator determines are sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard.

"(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall—

"(i) take into consideration whether to promulgate a regulation pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance, or of the chemical substance for a new use, that is not in compliance with the restrictions imposed by the consent agreement or order; and

"(ii)(I) initiate a rulemaking described in clause (i); or

"(II) publish a statement describing the reasons of the Administrator for not initiating a rulemaking.

"(C) INCLUSIONS.—A prohibition or restriction under subparagraph (A) may include, as appropriate—

Commented [A71]: Should be (4)

Commented [A72]: This is confusing – a prohibition is a restriction.

Commented [A73]: "consider" would make more sense – this was a leg counsel change..

Commented [A74]: This phrase doesn't make sense – the preceding litany already covers new uses.

Commented [A75]: "consistent with" would probably be better, since the order does not impose obligations on anyone other than the submitter.

Commented [A76]: The downside of enacting a lengthy and specific list of inclusions – which TSCA 5(e) does not have – is that some authority will be missed. The current list has some issues, as identified below. Also, this list differs somewhat from the list of restrictions EPA can impose under 6(d), which could create confusion. If the intent is to give EPA authority to impose such restrictions as are reasonably necessary, it would be simpler to just say that.

Commented [A77]: Same comment about prohibition and restriction. Sections 5 and 6 should be scrubbed for consist use of "restriction" as encompassing all measures, including prohibition, ban and phaseout.

"(i) a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal~~, or any combination of those~~ activities, with the form and content of the warnings and instructions to be prescribed by the Administrator;

Commented [A78]: No authority to prescribe warnings/instructions for manufacture and processing?

"(ii) a requirement that manufacturers and processors of the chemical substance shall—

Commented [A79]: Does the requirement have to apply to both?

"(I) make and retain records of the processes used to manufacture or process, as applicable, the chemical substance; or

"(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, use, or disposal, as applicable, of the chemical substance, subject to section 4;

"(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

"(I) in general; or

"(II) for a particular use;

"(iv) a prohibition or other regulation of—

"(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

Commented [A80]: This is subsumed by (v).

"(II) any method of commercial use of the chemical substance; or

"(III) any method of disposal of the chemical substance; or

"(v) a prohibition or other appropriate restriction on the manufacture, processing, or distribution in commerce of the chemical substance—

Commented [A81]: Doesn't (v) subsume (iii)? If use and disposal were added to (v), it seems like it would subsume all the other "inclusions".

Commented [A82]: Why not "other regulation of", as in iv?

"(I) in general; or

"(II) for a particular use.

"(D) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or restriction under this subsection to address workplace exposures.

Commented [A83]: This required consultation may add to the difficulty of issuing the order or consent agreement by the end of the notice period.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

"(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional

information;

"(C) may promulgate a regulation, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

"(D) on receipt of information the Administrator finds supports the determination under paragraph (3), shall promptly make the determination.

"(6) REGULATION PENDING DEVELOPMENT OF INFORMATION.—Subject to paragraph (4)(B), the Administrator may permit manufacture for commercial purposes of a chemical substance to commence pending receipt of the additional information, subject to compliance with any restrictions under paragraph (4) determined by the Administrator to be sufficient to ensure that the chemical substance is likely to meet the safety standard.

"(7) COMMENCEMENT OF MANUFACTURE.—Subject to paragraphs (4), (5), and (6), at the end of the applicable period for review under paragraph (1), the submitter of a notice under subsection (a) may commence manufacture for commercial purposes of a chemical substance or a chemical substance for a significant new use.";

(9) by striking subsections (e) through (g) and inserting the following:

"(e) Notice of Commencement.—

"(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer or processor that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer or processor shall submit to the Administrator a notice of commencement that identifies—

"(A) the name of the manufacturer or processor; and

"(B) the initial date of nonexempt commercial manufacture.

"(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

"(f) Further Evaluation.—The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—

"(1) a notice of commencement for a chemical substance under subsection (c); or

"(2) new information regarding the chemical substance.

"(g) Transparency.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, consent agreements, regulations, and orders of the Administrator; and

"(2) all information submitted or issued under this section.";

(10) in subsection (h)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking "(a) or";

Commented [A84]: This basis for testing is not included in 4(a). It should be added.

Commented [A85]: Not clear what this adds.

Commented [A86]: This suggests that manufacture would otherwise be barred, whereas (7) suggests that manufacture can commence at the end of the notification period unless EPA prevents it.

Commented [A87]: How about processing, in the case of a SNUN?

Commented [A88]: Now about processing, in the case of a SNUN?

Commented [A89]: References to processor and processing should be stricken in this subsection. It's a holdover from when this subsection provided for NOCs for SNUNs.

Commented [A90]: (f) is unnecessary, since EPA has authority to do this under 4A, and it could create arguments as to the scope of the 4A authority.

Commented [A91]: Should add "under this section". Also, this provision suggests that notices are "of the Administrator".

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(B) by striking paragraph (2);

(C) by redesignating paragraphs (3) through (6) as paragraphs (2) through (5), respectively;

(D) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking "subsections (a) and (b)" and inserting "subsection (b)";

(E) in paragraph (3) (as so redesignated)—

(i) in the first sentence, by striking "will not present an unreasonable risk of injury to health or the environment" and inserting "will meet the safety standard"; and

(ii) by striking the second sentence;

(F) in paragraph (4) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (b)"; and

(G) in paragraph (5) (as so redesignated), in the first sentence, by striking "paragraph (1) or (5)" and inserting "paragraph (1) or (4),"; and

(11) by adding at the end the following:

"(i) Prior Actions.—Nothing in this section requires the Administrator to modify or withdraw any regulation or order promulgated pursuant to this section before the date of enactment of the Chemical Safety Improvement Act.".

SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections (h) and (i), respectively;

Commented [A92]: There doesn't seem to be a (g).

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(3) shall complete a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

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"(4) shall promulgate a final regulation pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; and

"(5) may extend any deadline under this subsection for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under paragraphs (3) and (4) and any deferral under subsection (c)(2) does not exceed 2 years.

"(b) Prior Actions.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination that was initiated before the date of enactment of the Chemical Safety Improvement Act, prior to the effective date of the policies and procedures required to be established by the Administrator under section 3A or 4A.

"(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or regulation solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of a completed assessment, determination, or regulation shall not be determined based on the content of such a policy or procedure.

"(c) Safety Determinations.—

"(1) IN GENERAL.—Based on a review of the information available to the Administrator, including draft safety assessments submitted by interested persons, the Administrator shall determine that—

"(A) the relevant chemical substance meets the safety standard;

"(B) the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by regulation under subsection (d)—

"(i) impose restrictions necessary to ensure that the chemical substance meets the safety standard under the intended or reasonably anticipated conditions of use; or

"(ii) if the safety standard cannot be met with the application of restrictions, ban or phase out the chemical substance, as appropriate; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action

Commented [A93]: "any necessary" would be better, since there won't always be a need.

Commented [A94]: Also need to refer to paragraph 5.

Commented [A95]: "including any deferral" would be more accurate, since a deferral is a form of extension.

Commented [A96]: Per comments in 3A and 4A, should be consistent re use of policies, procedures, guidance, and other such terms.

Commented [A97]: This should be dropped – it's covered by the definition of the safety standard, and its inclusion in some specific places will cause confusion.

Commented [A98]: This is confusing, because bans and phaseouts are forms of restriction – they are included among the "restrictions" enumerated in (d)(3).

under paragraph (2).

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is necessary to make a safety assessment or safety determination for a high-priority substance, the Administrator—

"(A) shall provide an opportunity for interested persons to submit the additional information;

"(B) may promulgate a regulation, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

"(C) may defer, for a reasonable period consistent with the deadlines described in subsection (a), a safety assessment and safety determination until after receipt of the information; and

"(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety determination, shall make a determination under paragraph (1).

"(3) ESTABLISHMENT OF DEADLINE.—In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.

"(d) Regulation.—

"(1) IMPLEMENTATION.—If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a regulation establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

"(2) SCOPE.—The regulation promulgated pursuant to this subsection—

"(A) may—

"(i) apply to mixtures containing the chemical substance, as appropriate; and

"(ii) exempt replacement parts for articles manufactured prior to the applicable compliance deadline; and

"(B) shall include dates by which compliance is mandatory, which—

"(i) shall be as soon as practicable; and

"(ii) as determined by the Administrator, may vary for different affected persons.

"(C) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or restriction under this subsection to address workplace exposures.

Commented [A99]: This clause does not follow grammatically from the chapeau.

"(3) RESTRICTIONS.—A restriction under paragraph (1) may include, as appropriate—

Commented [A100]: As with section 5, there are downsides to trying to enumerate all of the conditions EPA can impose, the main one being that something may be omitted.

"(A) a requirement that a chemical substance shall be marked with, or accompanied

by, clear and adequate warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the warnings and instructions to be prescribed by the Administrator;

"(B) a requirement that manufacturers and processors of the chemical substance shall—

"(i) make and retain records of the processes used to manufacture or process the chemical substance;

"(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or

"(iii) monitor or conduct tests that are reasonably necessary to ensure compliance with the requirements of any regulation under this subsection;

"(C) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

"(D) a requirement to ban or phase out, or any other regulation regarding, the manufacture, processing, or distribution in commerce of the chemical substance for—

"(i) a particular use;

"(ii) a particular use at a concentration in excess of a level specified by the Administrator; or

"(iii) all uses;

"(E) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—

"(i) a particular use; or

"(ii) a particular use at a concentration in excess of a level specified by the Administrator;

"(F) a requirement to restrict, ban, or phase out, or any other regulation of, any method of commercial use of the chemical substance;

"(G) a requirement to restrict, ban, or phase out, or any other regulation of, any method of disposal of the chemical substance or any article containing the chemical substance; and

"(H) a requirement directing manufacturers or processors of the chemical substance to give notice of unreasonable risks of harm to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a regulation under paragraph (1), the Administrator shall take

Commented [A101]: No authority to impose warning/instructions for manufacture and processing?

Commented [A102]: Should this be "or"?

Commented [A103]: This test authority is not included in 4(a); it should be added.

Commented [A104]: Doesn't D subsume C and E, and couldn't it subsume everything if use and disposal were added?

Commented [A105]: Throughout the bill (and existing TSCA), consider whether to change unreasonable risk to a reference to the safety standard. It is clear that the safety standard does not consider nonrisk factors; it's less clear that unreasonable risk operates the same way.

into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a regulation under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a regulation under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

"(5) EXEMPTIONS.—

"(A) IN GENERAL.—The Administrator may exempt 1 or more uses of a chemical substance from any restriction in a regulation promulgated under paragraph (1) if the Administrator determines that—

Commented [A106]: Does this mean that the exemption has to be part of the rulemaking under (1)? Or does "in a regulation promulgated under paragraph (1)" just modify "any restriction"? If the latter, must EPA do rulemaking to create an exemption, or can it be done by order?

"(i) the regulation cannot be complied with, without—

"(I) harming national security;

"(II) causing significant disruption in the national economy due to the lack of availability of a chemical substance; or

"(III) interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or

"(ii) the use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to human health, the environment, or public safety.

"(B) EXEMPTION ANALYSIS.—In proposing a regulation under paragraph (1) that includes an exemption under this paragraph, the Administrator shall make publicly available any analysis conducted under this paragraph to assess the need for the exemption.

Commented [A107]: B, C, E, and F impose requirements if the exemption is part of the rulemaking under paragraph 1, but not otherwise. Is the intent that EPA can create an exemption only in the control rule under paragraph 1?

"(C) STATEMENT REQUIRED.—In making final a regulation under paragraph (1) that includes an exemption under this paragraph, the Administrator shall include a statement describing how the analysis considered under subparagraph (B) was taken into account.

"(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—In determining whether an exemption should be granted under this paragraph for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the

These comments are provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency or the administration on the bill, the draft language and comments.

extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more technically and economically feasible alternatives to the chemical substance most likely to be used in place of the chemical substance under the intended or reasonably anticipated conditions of use if the regulation is promulgated.

"(E) CONDITIONS.—As part of a regulation promulgated under paragraph (1), the Administrator shall include conditions in any exemption established under this paragraph, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect human health and the environment while achieving the purposes of the exemption.

"(F) DURATION.—

"(i) IN GENERAL.—The Administrator shall establish, as part of a regulation under paragraph (1) that contains an exemption under this paragraph, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis.

"(ii) AUTHORITY OF ADMINISTRATOR.—The Administrator, by regulation, may extend, modify, or eliminate the exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or is no longer necessary.

"(iii) CONSIDERATIONS.—

"(I) IN GENERAL.—Subject to subclause (II), the Administrator shall issue exemptions and establish time periods by considering factors determined by the Administrator to be relevant to the goals of fostering innovation and the development of alternatives that meet the safety standard.

"(II) LIMITATION.—Any renewal of an exemption in the case of a regulation requiring the ban or phase-out of a chemical substance shall not exceed 5 years.

"(e) Immediate Effect.—The Administrator may declare a proposed regulation under subsection (d) to be effective on publication of the regulation in the Federal Register and until the effective date of final action taken respecting the regulation, if—

"(1) the Administrator determines that—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to the proposed regulation or any combination of those activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before the effective date; and

"(B) making the proposed regulation so effective is necessary to protect the public interest; and

Commented [A108]: It is very difficult to follow what D is instructing EPA to do.

Commented [A109]: This is confusing, because presumably this is what EPA is trying to do by requiring compliance with the safety standard, which an exemption would waive at lleast in part. Could say: "necessary to protect health and the environment to the extent practicable while achieving the purposes. . . ."

Commented [A110]: EPA has authority to do this anyway, and this provision if anything might be argued to constrain that authority by adding hurdles.

Commented [A111]: Why have a time limit on renewals only? And why only for bans and phaseouts?

These comments are provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency or the administration on the bill, the draft language and comments.

"(2) in the case of a proposed regulation to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under paragraph (1)(A), a court has granted relief in an action under section 7 with respect to that risk associated with the chemical substance or mixture.

"(f) Final Agency Action.—Under this section—

"(1) a safety determination, and the associated safety assessment, for a chemical substance that the Administrator determines under subsection (c) meets the safety standard, shall be considered to be a final agency action, effective beginning on the date of issuance of the final safety determination; and

"(2) a final regulation promulgated under subsection (d), and the associated safety assessment and safety determination that a chemical substance does not meet the safety standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final regulation.";

(4) in subsection (h) (as redesignated by paragraph (2))—

(A) by striking paragraph (4); and

(B) by redesignating paragraph (5) as paragraph (4); and

(5) by adding at the end the following:

"(j) Prior Actions.—Nothing in this section requires the Administrator to modify or withdraw any regulation or order promulgated pursuant to this section, as in effect on the day before the date of enactment of the Chemical Safety Improvement Act.".

SEC. 9. IMMINENT HAZARDS.

Section 7 of the Toxic Substances Control Act (15 U.S.C. 2606) is amended—

(1) by striking subsection (a) and inserting the following:

"(a) Civil Actions.—

"(1) IN GENERAL.—The Administrator may commence a civil action in an appropriate United States district court for—

"(A) seizure of an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture;

"(B) relief (as authorized by subsection (b)) against any person that manufactures, processes, distributes in commerce, uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture; or

"(C) both seizure described in subparagraph (A) and relief described in subparagraph (B).

"(2) REGULATION, ORDER, OR OTHER PROCEEDING.—A civil action may be commenced under this paragraph, notwithstanding—

"(A) the existence of—

"(i) a decision by the Administrator under section 4A, 5(d)(3), or 6(c)(1); or

"(ii) a regulation, testing consent agreement, or order under section 4, 5(d)(4), 6(d), or 6(h); or

"(B) the pendency of any administrative or judicial proceeding under any provision of this Act.";

(2) in subsection (d), by striking "section 6(a)" and inserting "section 6(c)"; and

(3) in subsection (f), in the first sentence, by striking "and unreasonable".

SEC. 10. INFORMATION COLLECTION AND REPORTING.

Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amended—

(1) in subsection (a)—

(A) in paragraph (3)(A)(ii)(I)—

(i) by striking "5(b)(4)" and inserting "5";

(ii) by inserting "section 4 or" after "in effect under"; and

(iii) by striking "5(e)," and inserting "5(d)(4);"; and

(B) by adding at the end the following:

"(4) REGULATIONS.—

"(A) DEADLINE.—

"(i) IN GENERAL.—Not later than 2 years after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall promulgate regulations requiring the maintenance of records and the reporting of information known or reasonably ascertainable by the person making the report, including regulations requiring processors to report information, so that the Administrator has the information necessary to carry out sections 4 and 6.

"(ii) MODIFICATION OF PRIOR REGULATIONS.—In carrying out this subparagraph, the Administrator may modify, as appropriate, regulations promulgated before the date of enactment of the Chemical Safety Improvement Act.

"(B) CONTENTS.—The regulations promulgated pursuant to subparagraph (A)—

"(i) may impose different reporting requirements on manufacturers and processors;

"(ii) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported; and

"(iii) shall apply only in cases in which the Administrator determines that the

Commented [A112]: 1.Reference to rule or order under Title IV is missing; it's in current section 7. 2. It seems preferable to refer to any actions under section 4, 4A, 5, or 6. The current text seems to capture all the relevant actions under the revised title I, but section 7 does not currently refer to individual subsections, and there's a risk that something has been omitted.

Commented [A113]: This does not allow EPA to require maintenance of records by processors, as EPA can require for manufacturers. Was that intentional?

Commented [A114]: The relationship between this new authority and the (a)(1) authority is not clear. Is (a)(4) the exclusive authority for information related to sections 4 and 6, and (a)(1) to be used for other purposes?

Commented [A115]: EPA has this authority anyway, so this provision doesn't do anything.

Commented [A116]: It's not clear what this means. Is the intent to limit the persons to whom a rule would apply, and if so how does this differ from (C)(iii), below? Is the intent to limit EPA's authority to issue such rules at all? To limit the information that EPA can require (which might be suggested by the fact it's under "Contents")? Also, this references only submission of reports; does it not apply to maintenance of records.

1 submission of reports would assist in the effective implementation of this Act.

2 "(C) ADMINISTRATION.—In implementing this paragraph, the Administrator shall
3 take measures—

4 "(i) to limit the potential for duplication in reporting requirements;

5 "(ii) to minimize the impact of the regulations on small manufacturers and
6 processors; and

7 "(iii) to apply any reporting obligations to those persons likely to have
8 information relevant to the effective implementation of this title.

9 "(5) GUIDANCE.—The Administrator shall develop guidance relating to the information
10 required to be reported under the regulations promulgated under this subsection.";

11 (2) in subsection (b), by adding at the end the following:

12 "(3) NOMENCLATURE.—

13 "(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

14 "(i) maintain the use of Class 2 nomenclature in use on the date of enactment of
15 the Chemical Safety Improvement Act;

16 "(ii) maintain the use of the Soap and Detergent Association Nomenclature
17 System, published in March 1978 by the Administrator in section 1 of addendum
18 III of the document entitled 'Candidate List of Chemical Substances', and further
19 described in the appendix A of volume I of the 1985 edition of the Toxic
20 Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–
21 85–002a); and

22 "(iii) treat all components of categories that are considered to be statutory
23 mixtures under this Act as being included on the list published under paragraph
24 (1) under the Chemical Abstracts Service numbers for the respective categories,
25 including, without limitation—

26 "(I) cement, Portland, chemicals, CAS No. 65997–15–1;

27 "(II) cement, alumina, chemicals, CAS No. 65997–16–2;

28 "(III) glass, oxide, chemicals, CAS No. 65997–17–3;

29 "(IV) frits, chemicals, CAS No. 65997–18–4;

30 "(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

31 "(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

32 "(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

33 "(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature
34 conventions, the Administrator shall—

35 "(I) maintain the nomenclature conventions for substances; and

Commented [A117]: The Act, or sections 4 and 6, per the scope of (i)?

Commented [A118]: This title, or sections 4 and 6?

Commented [A119]: The content of this provision has been eliminated over various drafts; consider whether it makes sense to drop it.

Commented [A120]: This and the following provisions in (3) apparently require that these systems and conventions be maintained forever. Is that the intent?

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

"(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) REGULATIONS.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, the Administrator, by regulation, shall require manufacturers and processors to notify the Administrator, by not later than 180 days after the date of promulgation of the regulation, 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 Chemical Safety Improvement Act.

Commented [A121]: Consider whether it makes more sense for the bill to require this directly. There does not seem to be any room for discretion here.

"(ii) ACTIVE SUBSTANCES.—The Administrator shall, pursuant to paragraph (5)(A), designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—The regulation promulgated by the Administrator pursuant to subparagraph (A) shall require—

Commented [A122]: Again, why does the bill not require this directly?

"(i) the Administrator to maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

"(ii) a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

"(iii) the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C).

"(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a regulation that establishes a plan to review all claims

to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are notified pursuant to subparagraph (A) or identified as active substances under subsection (f)(1).

"(D) REQUIREMENTS OF REVIEW PLAN.—The review plan under subparagraph (C) shall—

Commented [A123]: Why doesn't the bill just directly impose the requirements and encouragement referenced in D? There does not appear to be any room for discretion.

"(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

"(ii) require the Administrator, in accordance with section 14—

"(I) to review each substantiation—

"(aa) submitted pursuant to clause (i) to determine if the claim warrants protection from disclosure; and

"(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

"(II) approve, modify, or deny each claim; and

"(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

Commented [A124]: Even if the person requests a shorter period?

"(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(iii) encourage manufacturers or processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

"(E) TIMELINE FOR COMPLETION OF REVIEWS.—

"(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

Commented [A125]: This provision reinforces the comment on (C) above that the Plan should pertain only to pre-existing claims. EPA could not complete review if the Plan covered new claims.

"(ii) CONSIDERATIONS.—

"(I) IN GENERAL.—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of applicable claims needing review and the available resources.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of reviews to be completed over the course of implementation of the plan.

"(F) LIMITATION.—The specific identity of any chemical substance that is not on the confidential portion of the list published under paragraph (1) or subsequently added to the confidential portion of the list pursuant to section 14 shall not be eligible for protection from disclosure.

"(G) CERTIFICATION.—The regulation under this subsection shall require a manufacturer or processor—

"(i) to certify the accuracy of each report of the manufacturer or processor carried out under the regulation; and

"(ii) to retain a record supporting that certification for a period of 5 years beginning on the last day of the submission period.

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

"(A) IN GENERAL.—The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).

"(B) UPDATE.—The Administrator shall update the list of chemical substances designated as active substances as soon as practicable after the date of publication of the most recent data reported under—

"(i) part 711 of title 40, Code of Federal Regulations (or successor regulations); and

"(ii) the regulations promulgated pursuant to subsection (a)(4).

"(C) CHANGE TO ACTIVE STATUS.—

"(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

"(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—

"(I) IN GENERAL.—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

Commented [A126]: "applicable" doesn't make sense.

Commented [A127]: This paragraph is unnecessary and potentially confusing; under section 14, a public chem. id could not be CBI – it's already disclosed.

Commented [A128]: Literally, this would preclude CBI treatment for chemicals that aren't on the inventory at all. Presumably that's not the intent.

Commented [A129]: If this paragraph is retained, the highlighted language should be dropped. The inventory is an ongoing list, so "subsequently added" chemicals are already covered by the first phrase in this sentence.

Commented [A130]: Why doesn't the bill require this directly?

Commented [A131]: B makes no sense. Any chemical reported under CDR must already be an active substance, so there should be no occasion to update the list.

Commented [A132]: Most recent as of when? Is this intended to be a one-time obligation or recurring?

1 disclosure of the specific identity of the inactive substance as confidential,
2 the person shall—

3 "(aa) in the notice submitted under clause (i), assert the claim; and

4 "(bb) by not later than 30 days after providing the notice under clause
5 (i), substantiate the claim.

6 "(II) LIMITATION.—The specific identity of any inactive substance that is
7 not on the confidential portion of the list published under paragraph (1) or
8 subsequently added to the confidential portion of the list pursuant to section
9 14 shall not be eligible for protection from disclosure.

10 "(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the
11 Administrator shall—

12 "(I) designate the applicable chemical substance as an active substance;

13 "(II) pursuant to section 14, promptly review any claim and associated
14 substantiation submitted pursuant to clause (ii) for protection against
15 disclosure of the specific identity of the chemical substance and approve,
16 modify, or deny the claim;

17 "(III) except as provided in this section and section 14, protect from
18 disclosure the specific identity of the chemical substance for which the
19 Administrator approves a claim under subclause (II) for a period of not less
20 than 10 years, unless, prior to the expiration of the period—

21 "(aa) the person notifies the Administrator that the person is
22 withdrawing the confidentiality claim, in which case the Administrator
23 shall promptly make the information available to the public; or

24 "(bb) the Administrator otherwise becomes aware that the need for
25 protection from disclosure can no longer be substantiated, in which case
26 the Administrator shall take the actions described in section 14(g)(2);
27 and

28 "(IV) pursuant to section 4A, review the priority of the chemical substance
29 as the Administrator determines to be necessary.

30 "(D) CATEGORY STATUS.—The list of inactive substances shall not be considered to
31 be a category for purposes of section 26(c).

32 "(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the regulation
33 required under this subsection, the Administrator shall designate the chemical substances
34 reported under part 711 of title 40, Code of Federal Regulations (or successor regulations),
35 during the reporting period that most closely preceded the date of enactment of the
36 Chemical Safety Improvement Act, as the initial list of active substances for the purposes of
37 section 4A.

38 "(7) PUBLIC PARTICIPATION.—Subject to this subsection, the Administrator shall make

Commented [A133]: This phrase should be dropped if the subclause is retained.

Commented [A134]: This subclause is unnecessary, for the reason stated in the comment on (4)(F), and for the additional reason that it duplicates (4)(F).

Commented [A135]: Not consistent with other provisions, which specify 10 years.

Commented [A136]: Should be interim.

Commented [A137]: This paragraph is largely unnecessary and confusing. The only thing is seems to add is an obligation to make public the accession number, etc., for chemicals on the confidential portion of the inventory. We suggest just saying that, if that's the goal

available to the public—

"(A) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—

"(i) an active substance; or

"(ii) an inactive substance;

"(B) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received and approved by the Administrator pursuant to section 14; and

"(C) subject to section 14(g), the specific identity of any active substance for which—

"(i) no claim of protection against disclosure of the specific identity of the active substance pursuant to this subsection was received;

"(ii) a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or

"(iii) the time period for protection against disclosure of the specific identity of the active substance has expired.";

(3) in subsection (e)—

(A) by striking "Any person" and inserting the following:

"(1) IN GENERAL.—Any person"; and

(B) by adding at the end the following:

"(2) APPLICABILITY.—Any person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of injury to human health and the environment."; and

(4) in subsection (f), by striking "For purposes of this section, the" and inserting the following: "In this section:

"(1) ACTIVE SUBSTANCE.—The term 'active substance' means a chemical substance—

"(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Chemical Safety Improvement Act;

"(B) that is added to the list published under subsection (b)(1) after that date of enactment; or

"(C) for which a notice is received under subsection (b)(5)(C).

"(2) INACTIVE SUBSTANCE.—The term 'inactive substance' means a chemical substance

Commented [A138]: If the specific id is on the nonconfidential portion of the list, it's already public; what is added by instructing EPA to make it available?

Commented [A139]: This means that if the claim is among the 75% that EPA is not required to review, EPA is not required to make this information public. This should just refer to chemicals on the confidential portion of the inventory; let section 14 take care of itself.

Commented [A140]: (C)Is subsumed by (A).

Commented [A141]: This provision doesn't accomplish anything (other than possibly confuse 8(e) for the reason stated below); any person may already submit such information, without the need for statutory permission.

Commented [A142]: Note that manufacturers, processors and distributors are already *required* by 8(e) to submit such information; it might be confusing to have a broader requirement allowing them (and others) to submit it.

Commented [A143]: Note that, under these definitions, active substances can never become inactive (although inactive substances can become active). A substance that meets the terms of the definition of active substance on the day of enactment will always meet those terms, and never meet the terms of the inactive substance definition.

on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).

"(3) MANUFACTURE; PROCESS.—The".

SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.

Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the first sentence—

(i) by striking "presents or will present an unreasonable risk to health or the environment" and inserting "does not meet the safety standard"; and

(ii) by striking "such risk" the first place it appears and inserting "the risk posed by the substance or mixture";

(B) in paragraph (2), in the matter following subparagraph (B), by striking "section 6 or 7" and inserting "section 6(d) or section 7"; and

(C) in paragraph (3), by striking "section 6 or 7" and inserting "section 6(d) or 7"; and

(2) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

Commented [A144]: Consider whether 9(a), even as amended by the draft bill, remains a good fit for the amended TSCA. Current TSCA was intended as a "gap filler", hence the requirement to defer to other agencies with adequate authority to regulate unreasonable risks. If CSIA is envisioned as the principal statute to regulate chemical risks, then section 9(a) does not seem like a good fit. Among other things, 9(a) would allow another agency to overrule EPA's conclusion that a chemical does not meet the safety standard, creating the potential for inconsistent regulation of chemicals. In any event, if it is retained, edits should be made to the mandatory rulemaking schedule in 6(a), since the absolute deadlines there are inconsistent with 9(a)'s deferral to other agencies.

SEC. 12. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA.

Section 10 of the Toxic Substances Control Act (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".

SEC. 13. EXPORTS.

Section 12 of the Toxic Substances Control Act (15 U.S.C. 2611) is amended—

(1) in subsection (a), by striking paragraph (2) and inserting the following:

"(2) EXCEPTION.—Paragraph (1) shall not apply to any chemical substance that the Administrator determines—

"(A) under section 5 is not likely to meet the safety standard; or

"(B) under section 6 does not meet the safety standard.

"(3) WAIVERS.—For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—

"(A) determine that paragraph (1) shall not apply to the mixture or article; or

Commented [A145]: As revised, this exception largely guts the rule, in (1), that TSCA does not apply to chemicals that are manufactured solely for export. For the most part, EPA would not regulate a chemical at all under CSIA unless it is found unlikely to or not to meet the safety standard; by the terms of (2), that would void the export exemption. The current draft language changes the concept of current section 12, which is that TSCA does not regulate risks unless they are presented within the United States.

Commented [A146]: This doesn't seem like the right word to capture the content of the paragraph, which seems to concern whether mixtures and articles are covered by the exception in 2.

"(B) establish a threshold concentration in a mixture or article at which paragraph (1) shall not apply.

"(4) TESTING.—The Administrator may require testing under section 4 of any chemical substance or mixture exempted from this Act under paragraph (1) for the purpose of determining whether the chemical substance or mixture presents an unreasonable risk of harm to human health within the United States or to the environment of the United States.";

(2) by striking subsection (b) and inserting the following:

"(b) Notice.—

"(1) IN GENERAL.—A person shall notify the Administrator that the person is exporting or intends to export to a foreign country—

"(A) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 5 is not likely to meet the safety standard and for which a prohibition or restriction has been proposed or established under that section;

"(B) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 6 does not meet the safety standard and for which a prohibition or restriction has been proposed or established under that section;

"(C) a chemical substance for which the United States is obligated by treaty to provide export notification;

"(D) a chemical substance or mixture subject to a prohibition or restriction pursuant to a regulation, order, or consent agreement in effect under this Act; or

"(E) a chemical substance or mixture for which the submission of information is required under section 4.

"(2) REGULATIONS.—

"(A) IN GENERAL.—The Administrator shall promulgate regulations to carry out paragraph (1).

"(B) CONTENTS.—The regulations promulgated pursuant to subparagraph (A) shall—

"(i) include such exemptions as the Administrator determines to be appropriate, which may include exemptions identified under section 5(h); and

"(ii) indicate whether, or to what extent, the regulations apply to articles containing a chemical substance or mixture described in paragraph (1).

"(3) NOTIFICATION.—The Administrator shall submit to the government of each country to which a chemical substance or mixture is exported—

"(A) for a chemical substance or mixture described in subparagraph (A), (B), or (D) of paragraph (1), a notice of the determination, regulation, order, consent agreement, requirement, or designation;

Commented [A147]: Applying the unreasonable risk standard makes sense under current TSCA, since this is the test for determining whether to regulate the exported chemical, but it does not seem to make sense here.

Commented [A148]: TSCA requires notification of chemicals subject to section 7 judicial actions; this paragraph does not. Is that intentional?

Commented [A149]: This should be deleted, since the mixture containing the chemical substance is captured by the reference to the chemical substance.

Commented [A150]: Consider dropping this phrase. The logic of notification is that the US should notify a foreign country of the import to that country of chemicals for which the US has identified concerns; whether EPA has yet regulated does not seem very relevant. (If this is retained, "prohibition" and "restriction" should not be distinguished.)

Commented [A151]: Same comment re mixture

Commented [A152]: Same comment as above re this phrase.

Commented [A153]: This subsumes most of A and B as they are currently drafted. This appears to add only judicial section 7 orders (but, per above comment, it does not add section 7 actions).

Commented [A154]: A, B and D don't seem to involve designations.

"(B) for a chemical substance described in paragraph (1)(C), a notice that satisfies the obligation of the United States under the applicable treaty; and

"(C) for a chemical substance or mixture described in paragraph (1)(E), a notice of availability of the information on the chemical substance or mixture submitted to the Administrator."; and

(3) in subsection (c)—

(A) by striking paragraph (3); and

(B) by redesignating paragraphs (4) through (6) as paragraphs (3) through (5), respectively.

SEC. 14. IMPORTS.

Section 13 of the Toxic Substances Control Act (15 U.S.C. 2612) is amended to read as follows:

"SEC. 13. IMPORTS.

"(a) Refusal of Entry.—

"(1) IN GENERAL.—The Secretary of Homeland Security shall refuse entry into the customs territory of the United States (as defined in general note 2 to the Harmonized Tariff Schedule of the United States) any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry, if—

"(A) the Administrator—

"(i) has determined under section 6(c) that the chemical substance or mixture does not meet the safety standard; and

"(ii) has promulgated a regulation pursuant to section 6(d) banning the chemical substance or mixture, as of the effective date of the regulation;

"(B) the chemical substance—

"(i) is not included on the list under section 8(b)(1); and

"(ii) is not exempt from any requirement to be included on that list by this title or a regulation promulgated by the Administrator pursuant to this title; or

"(C) the chemical substance, mixture, or any article containing the chemical substance or mixture is offered for entry in violation of—

"(i) a regulation, consent agreement, or order in effect under this Act; or

"(ii) an order issued in a civil action brought under section 7 or title IV.

"(2) PROCEDURE.—

"(A) IN GENERAL.—Subject to subparagraph (B), if a chemical substance, mixture, or article containing a chemical substance or mixture is refused entry under paragraph

Commented [A155]: 13(a) could be greatly simplified by simply saying that DHS shall refuse entry of "any chemical substancel, mixture, or article containing a chemical substance or mixture offered for such entry if the entry would violate this Act or any regulation ["rule" would be better], consent agreement or order in effect under this Act." The intent seems to be to prevent unlawful import, and a simpler formulation will do that without the complications of trying to summarize complex requirements.

Commented [A156]: A is subsumed by C and should be dropped.

Commented [A157]: Mixtures are not subject to safety determinations.

Commented [A158]: Isn't ii subsumed by i? It seems like a section 7 judicial order would be an order in effect under this Act. Also, Title IV does not create a specific judicial action, so it's not clear what the reference to Title IV covers. If ii is included, it will suggest that judicial orders under section 7 are not orders under the Act, which will suggest that section 7 orders are not included in the export provisions of 12(b)(1)D).

Commented [A159]: In contract to TSCA, nothing in 13(a) as drafted bars import of PCBs on the grounds that import violates the statutory PCB ban (although the import would be barred by virtue of EPA regulations codifying the ban).

These comments are provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency or the administration on the bill, the draft language and comments.

(1), the Secretary of Homeland Security—

"(i) shall notify the consignee of the entry of the refusal;

"(ii) shall not release the chemical substance or mixture to the consignee; and

"(iii) shall cause the disposal or storage of the chemical substance or mixture under such regulations as the Secretary may prescribe, if the chemical substance or mixture has not been exported by the consignee during the 90-day period beginning on the date of receipt of the notice of the refused entry.

"(B) EXCEPTION.—

"(i) IN GENERAL.—The Secretary of Homeland Security, pending a review by the Administrator, may release to the consignee the chemical substance or mixture if the consignee—

"(I) executes a bond for the amount of the full invoice of the chemical substance or mixture (as set forth in the customs entry); and

"(II) pays a duty on the chemical substance or mixture.

"(ii) ADMINISTRATION.—If a consignee fails to return a chemical substance or mixture released to that consignee under clause (i) for any cause to the custody of the Secretary of Homeland Security on demand, the consignee shall be liable to the United States for liquidated damages equal to the full amount of the bond executed under clause (i)(I).

"(C) STORAGE.—All charges for storage, cartage, and labor on or for the disposal of a chemical substance or mixture that is refused entry or released under this subsection shall be paid by the owner or consignee, and a default on that payment shall constitute a lien against any future entry made by the owner or consignee.

"(b) Certification.—

"(1) IN GENERAL.—A person offering a chemical substance or mixture subject to this Act for entry into the customs territory of the United States shall certify to the Secretary of Homeland Security that—

Commented [A160]: Should drop this – all chemical substances and mixtures are subject to TSCA. The jurisdictional exclusions are built right into the definition of "chemical substance."

"(A) after reasonable inquiry and to the best knowledge and belief of the person, the chemical substance or mixture is in compliance with any applicable regulation, consent agreement, or order under section 5 or 6; and

Commented [A161]: Note that this does not require certification of compliance with section 7 judicial orders or Title IV. Is there a reason the scope of the certification requirement is not the same as the scope of the refusal-of-entry requirements?

"(B) the chemical substance—

"(i) is included on the list under section 8(b)(1); or

"(ii) is exempt from any requirement to be included on that list by this title or a regulation promulgated by the Administrator pursuant to this title.

Commented [A162]: Should be "the requirement".

"(2) ARTICLES.—

"(A) IN GENERAL.—The Administrator, by regulation, may require certification

1 under paragraph (1) for an article containing a chemical substance or mixture that is
2 subject to regulation under section 5 or 6.

3 "(B) REQUIREMENT.—The regulation under subparagraph (A) shall identify, with
4 reasonable specificity, the types of articles, including parts or components of articles,
5 that will be subject to the certification requirement.

6 "(C) FACTORS FOR CONSIDERATION.—In determining the need for and content of a
7 certification regulation under this paragraph, the Administrator shall take into
8 consideration—

9 "(i) the utility of the certification to enforcement of the applicable regulation,
10 consent agreement, or order under section 5 or 6;

11 "(ii) the contribution of imported articles to the potential risk presented by
12 exposure to the chemical substance or mixture subject to regulation under section
13 5 or 6;

14 "(iii) the impact on commerce and potential for the certification to impede or
15 disrupt import of articles;

16 "(iv) the frequency or duration of the certification requirement; and

17 "(v) specification of the concentration of a chemical substance in an article that
18 would subject the article to the certification requirement.

19 "(3) REASONABLE INQUIRY.—

20 "(A) IN GENERAL.—For purposes of a certification under paragraph (1), reasonable
21 inquiry shall include good faith reliance by an importer on—

22 "(i) a safety data sheet or similar declaration provided by a supplier that
23 documents the specific identity of the chemical substance or the specific identities
24 of all chemical substances in a mixture; or

25 "(ii) for chemical substances or mixtures claimed by the supplier as
26 confidential, or not otherwise disclosed by the supplier, a certification by the
27 supplier that the imported chemical substance or mixture satisfies the applicable
28 certification requirements under paragraph (1).

29 "(B) ARTICLES.—For purposes of a certification under paragraph (2), reasonable
30 inquiry shall include good faith reliance by an importer on a certification by the
31 supplier that the imported article satisfies the applicable certification requirements in a
32 regulation promulgated pursuant to paragraph (2).

33 "(4) INFORMATION REGARDING IDENTITY.—For purposes of this subsection, the
34 Administrator shall provide publicly accessible information regarding the identity of a
35 chemical substance or mixture subject to regulation under this Act that would be readily
36 understood in import transactions.

37 "(c) Notice.—A person offering a chemical substance for entry into the customs territory of

Commented [A163]: Why use this formulation here rather than the "regulation, consent agreement, or order" formulation used elsewhere in this section? This could suggest that only regulations are covered. (This is another reason to use "rule" rather than, as leg counsel prefers, "regulation" in the bill, so that generic reference to "regulation" is not construed as being limited to legislative rules.)

Commented [A164]: This provides no authority to require certification for articles containing chemicals that are not on the inventory. Is that intentional?

Commented [A165]: Technically the certification is under paragraph (1), even for articles.

Commented [A166]: The intent of this seems to be to ensure that importers have fair notice of chem ids. If so, what does this add to general fair notice caselaw? And how would the information needed to understand chem id in import transaction differ from the information needed in other contexts?

the United States shall notify the Secretary of Homeland Security if—

"(1) the chemical substance or chemical substance in a mixture is a high-priority substance;

"(2) the chemical substance or chemical substance in a mixture is 1 for which the United States is obligated to provide export notification by treaty; or

"(3) the chemical substance or chemical substance in a mixture—

"(A) is the subject of a safety assessment and safety determination conducted pursuant to section 6; and

"(B) has been found not to meet the safety standard.

"(d) Regulations.—

"(1) IN GENERAL.—The Secretary of Homeland Security, after consultation with the Administrator, shall promulgate regulations to carry out this section.

"(2) APPLICATION.—The regulations under paragraph (1) may modify the application of any requirement of this section, as appropriate for the efficient and effective implementation of this Act.".

SEC. 15. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsection (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

Commented [A167]: This phrase should be stricken. Reference to the chemical substance captures the substance in a mixture, and this phrase could suggest otherwise.

Commented [A168]: Same comment.

Commented [A169]: 3 is subsumed by 1 – every chemical that has had a safety assessment and determination will be a high priority substance.

Commented [A170]: The current TSCA wording is: "pursuant to subsection (a) of section 552 of Title 5 by reason of subsection (b)(4) of such section". We understand that the intent was to mirror that language.

Commented [A171]: This proviso applies only to the (b) information, not to other CBI. Is that intentional? (It's not clear this provision is necessary at all. CBI prevents disclosure only by EPA. Is the intent to ensure that EPA obey court requirements or that other parties obey court requirements? If that letter, this provision is unnecessary and may suggest a broader reach of 14(a) than is warranted by its terms)

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer and specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

"(7) Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if—

"(A) the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5; and

"(B) the claim has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (e), (f)(2), or (g).

"(c) Information Not Protected From Disclosure.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

"(1) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

"(A) IN GENERAL.—Subject to subparagraph (B), subsection (a) does not prohibit the disclosure of—

"(i) any health and safety study that is submitted under this Act with respect to—

"(I) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

"(II) any chemical substance or mixture for which—

"(aa) testing is required under section 4; or

"(bb) a notification is required under section 5; or

"(ii) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in subclause (I) or (II) of clause (i).

"(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph authorizes the release of any information that discloses—

"(i) a process used in the manufacturing or processing of a chemical substance or mixture; or

"(ii) in the case of a mixture, the portion of the mixture comprised by any

Commented [A172]: When will the Administrator make this determination? Isn't the point of (b) to identify information that is protected without the need for a finding? If EPA makes the finding described here, then this information would be protected without the need for the presumption.

Commented [A173]: What if the chemical is subject to a section 5 exemption? Or what if the claimant has not yet submitted a section 5 notice?

Commented [A174]: This should be true of all CBI claims, not just chem id claims, and stating here could call that into question. Also, the reference to (e) in here is wrong, since (e) does not pertain to whether information is CBI – this is a recurring issue in this section.

chemical substance in the mixture.

"(2) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(3) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

"(A) For information submitted after the date of enactment of the Chemical Safety Improvement Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

"(B) A safety assessment developed, or a safety determination made, under section 6.

"(C) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

"(D) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

"(4) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is otherwise eligible for protection under this section and contained in a submission of information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

"(5) LIMITATION.—Except as provided in paragraph (1)(B), the specific identity of any chemical substance that is not on the confidential portion of the list published under section 8(b)(1) or subsequently added to the confidential portion of the list pursuant to this section shall not be eligible for protection from disclosure.

"(6) BAN OR PHASE-OUT.—If the Administrator promulgates a regulation pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance—

"(A) any protection from disclosure provided under this section with respect to information relating to the chemical substance shall no longer apply; and

"(B) the Administrator promptly shall make the information public.

"(d) Requirements for Confidentiality Claims.—

Commented [A175]: This paragraph (2) should be moved to the end of (c) and made applicable to both the (1) and (3) information. .

Commented [A176]: (1)(A) would be clearer.

Commented [A177]: Should be consistent with the wording in (c)(1).

Commented [A178]: (A) should be dropped. Meeting the requirements of D is a prerequisite for ANY CBI, and it's confusing to specify that for chemi id.

Commented [A179]: This appears to modify all that follows and apply to eg consumer uses of a chemical substance. Is that intentional?

Commented [A180]: This is a confusing provision, in part because it is based on the idea of protectable information appearing in "a submission described in this subsection". This subsection does not really describe "submissions"; it describes information elements that are not protectable, so this provision is not necessary. If retained, it would be clearer to say: Any information that is eligible for protection under this section and is submitted along with information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d)." The final phrase does not seem necessary.

Commented [A181]: This subclause is confusing. Literally read, it prevents CBI treatment for chemicals that are not on the inventory at all. If the intent is merely to refer to chemicals whose specific id's appear on the non-confidential portion of the inventory, the provision is unnecessary because those id's won't qualify as CBI anyway.

Commented [A182]: This doesn't make sense. If the specific chem id is publicly listed on the inventory, it can't be CBI, even if it meets the (1)(B) criteria.

Commented [A183]: This phrase should be dropped; the inventory is a "living" list, there is no need to say that references to it include chemicals added over time.

Commented [A184]: Looks like this should be a subclause of (3). Also note that the sweep of this paragraph is very broad – eg, customer lists pertaining to a chemical would no longer be CBI if the chemical is banned or phased out.

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such regulations 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 chemical identity;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law in connection with 1 or more uses subject to this Act;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the conditions that—

"(i) the generic name shall—

"(I) conform with guidance prescribed by the Administrator under paragraph (3)(A); and

"(II) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(aa) that are considered to be confidential; and

"(bb) the disclosure of which would be likely to harm the competitive position of the person.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in paragraphs (1) through (7) of subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the regulations promulgated and guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

Commented [A185]: This should presumably refer to information generally, since (d)(1) is not speciffic to chem id

Commented [A186]: The effect of this language is obscure.

Commented [A187]: There is no (ii).

Commented [A188]: Per comments on 3A, requiring conformance to guidance will likely render the guidance final agency action.

Commented [A189]: Drop parentheses around A.

Commented [A190]: This formulation is different from the formulation in (1)(B)(iii). The latter seems more consistent with CBI caselaw.

Commented [A191]: This should be dropped, since it encompasses all of (b).

Commented [A192]: Same comment as above re requiring conformance with guidance.

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the information that has been submitted is true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a) shall be disclosed if—

"(1) the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of human health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) the Administrator determines that disclosure is necessary to protect human health or the environment;

"(4) the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, if—

"(A) 1 or more applicable agreements with the Administrator that conform with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; and

"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;

"(5) a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement shall conform with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

Commented [A193]: This is out of place under (d), since it does not pertain to requirements of claims.

Commented [A194]: "The information" seems to literally refer to the content of the submission that is subject to the CBI claim. Presumably the intent is narrower: to require certification that the given basis for the CBI claim is true and correct.

Commented [A195]: Same comment as above re requiring conformance with guidance.

Commented [A196]: It's odd that notification is handled here for this provision, but in (g) for all other provisions of (e).

Commented [A197]: Same comment about requiring conformance with guidance.

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

Commented [A198]: Per (g)(2), EPA has no obligation to notify the submitter of a release under (6). How will the submitter know to request this?

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

Commented [A199]: It's not clear how this post-disclosure requirement will work. What happens if the terms of the statement and agreement cannot be worked out? Or if the recipient doctor, nurse, etc, does not agree to provide the statement and agreement? That might create a question as to whether the information could be shared with a patient.

"(7) the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee;

"(9) the information is publicly available; or

"(10) the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION PROTECTED FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information that meets the requirements of subsection (d) for a period of 10 years, unless, prior to the expiration of the period—

"(i) an affected person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in subsection (g)(2).

"(B) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph (A), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph (A), a person reasserting the relevant claim shall submit to the Administrator a statement substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—

"(aa) review the request;

"(bb) make a determination regarding whether the information for which the request is made continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of not more than 10 years; or

"(BB) deny the claim.

Commented [A200]: This should be dropped. If deals with whether information is CBI and is out of place in (e), which is about release of CBI. Also, publicly available information can't be CBI.

Commented [A201]: Need to add reference to (a), which contains the substantive CBI standard.

Commented [A202]: Per earlier comment, consider whether it makes sense to impose a fixed 10-year period, which will apply even if the submitter doesn't need or request that much time.

Commented [A203]: The person that asserted the claim, consistent with wording in (B)(i)? What other affected person could submit this notification?

Commented [A204]: It would be clearer to say that "the information no longer qualifies for confidential treatment under subsection (a)", or something like that. "Substantiated" has a particular meaning in this section.

Commented [A205]: This appears to require review and determination on every claim for extension. In contrast, (g) does not require review and determination for (b) information, and allows EPA to act on as little as 25% of other claims. Is that intentional?

Commented [A206]: If EPA receives the statement after it is submitted, EPA action could come after the expiration of the claim. Would probably be better if the deadline for this obligation were the date of expiration.

Commented [A207]: Is this intentional or a holdover?

"(C) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph (B), if the Administrator determines that the relevant statement under subparagraph (B)(ii)(I)—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection against disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Chemical Safety Improvement Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

Commented [A208]: Should drop this. Subsec (a) already describes the scope of this section and uses different words. Dropping will require minor rewording later in setence.

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating regulations pursuant to section 6(d), subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d).

Commented [A209]: This is true of I through iii as well and should be dropped. It is clear without this that iv authorizes only the imposition of a substantiation requirement, not disclosure. (If retained, the reference should be to (a), not (d).)

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection from disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Chemical Safety Improvement Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

Commented [A210]: Should be dropped, per above comment.

"(i) as necessary to comply with a request for information received by the Administrator under section 552 of title 5, United States Code;

Commented [A211]: FOIA does not literally impose a requirement on EPA to require substantiation.

"(ii) if information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met; or

Commented [A212]: Missing words. Also, 552(b)(4) supplies a standard; it does not exactly impose requirements.

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under

subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator on expiration of the period for appeal under subsection (g)(3), that has expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

"(B) DENIAL OR MODIFICATION.—

"(i) IN GENERAL.—Except as provided in subsections (c) and (f), the Administrator shall deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).

Commented [A213]: (3) seems out of place under (f).

Commented [A214]: This proviso does not seem to be included in other release provisions, which could create issues. Seems best to let (g)(3) function on its own.

Commented [A215]: This appears to exempt (b) information from the review provisions under (f), but per comments above, (f) does not read that way.

Commented [A216]: (f) does not seem to provide any grounds for exception from this provision.

Commented [A217]: 1. This should not be limited to chem id – it is a general provision. 2. This subclause is unnecessary; it's already true that EPA must approve a claim if it meet the requirements of (a) and (d). 3. A refers to claims and requests, and B(i) refers only to claims; seems like they should be consistent.

Commented [A218]: Should be "or".

"(ii) REASONS FOR DENIAL OR MODIFICATION.—The Administrator shall provide to a person that has submitted a claim ~~described in clause (i) a written statement~~ of the reasons for the denial or modification of the claim.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection (b)(7), review all claims under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim under paragraph (1), the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

"(B) RELEASE OF INFORMATION.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

"(ii) EXCEPTIONS.—

"(I) IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to human health or the environment, in which case no prior notification shall be necessary.

"(II) NO NOTIFICATION.—For information under paragraph (1), (2), (6), (7), (9), or (10) of subsection (e), no prior notification shall be necessary.

"(3) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released, the person may bring an action to restrain disclosure of the information in—

Commented [A219]: Or request?

Commented [A220]: This should be dropped. (e) does not involve denial or modification of claims.

Commented [A221]: Seems like this should be dropped. (f) does not appear to provide exceptions to the provisions of (g)(2), and in fact refers to the procedures in (g)(2) as applicable.

Commented [A222]: Or request?

Commented [A223]: Consider whether this carries over from TSCA an outdated form of notification.

Commented [A224]: (ii) is out of place. It deals with notification of release under (e) of information that IS CBI; it does not involve denial or modification of CBI claims. So these provisions are not "exceptions" to (g)(2)(B)(i).

Commented [A225]: Paragraph (e)(5) is not addressed in B. (And per above comment, (e)(4) for some reason is addressed in (4) rather than here.)

Commented [A226]: Due to confusion about scope in paras 1 and 2, it's not clear if 3 applies only denials and modifications, or also to releases under (e).

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(4) ADMINISTRATION.—In carrying out this subsection, the Administrator shall use the procedures described in part 2 of title 40, Code of Federal Regulations (or successor regulations).

Commented [A227]: 1.These are not EPA's only CBI regulations – eg, EPA has some CDR-specific CBI regulations in Part 711. Could just refer to applicable procedures in title 40. 2. This provision has no effect, since it just says that EPA will follow whatever rules it has in place.

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information submitted to the Administrator under this Act before the date of enactment of the Chemical Safety Improvement Act; or

Commented [A228]: Should be consistent with the language in (a).

"(B) to impose substantiation or resubstantiation requirements under this Act that

are more extensive than those required under this section.

"(2) PRIOR ACTIONS.—Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such regulations applicable to those claims as the Administrator may promulgate after the date of enactment of the Chemical Safety Improvement Act.".

Commented [A229]: 1.Despite the title, this paragraph seems to pertain to post-CSIA actions. 2. This seems inconsistent with (i)(1).

SEC. 16. PROHIBITED ACTS.

Section 15 of the Toxic Substances Control Act (15 U.S.C. 2614) is amended by striking paragraph (1) and inserting the following:

"(1) fail or refuse to comply with—

"(A) any regulation promulgated, consent agreement entered into, or order issued under section 4;

"(B) any requirement under section 5 or 6;

"(C) any regulation promulgated, consent agreement entered into, or order issued under section 5 or 6; or

"(D) any requirement of, or any regulation promulgated or order issued pursuant to title II;".

SEC. 17. PENALTIES.

Section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) is amended—

(1) in subsection (a)(1)—

(A) in the first sentence—

(i) by inserting "this Act or a regulation or order promulgated or issued pursuant to this Act, including" after "a provision of"; and

(ii) by striking "$25,000" and inserting "$37,500"; and

(B) in the second sentence, by striking" violation of section 15 or 409" and inserting "violation of this Act"; and

(2) in subsection (b)—

(A) by striking "Any person who" and inserting the following:

"(1) IN GENERAL.—Any person that";

(B) by striking "section 15 or 409" and inserting "this Act";

(C) by striking "$25,000" and inserting "$50,000"; and

(D) by adding at the end the following:

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

Commented [A230]: The addition of this text to section 16 renders most of section 15 unnecessary. Currently, section 15 circumscribes the violations of TSCA that are "prohibited acts", and section 16 establishes penalties for those prohibited acts. If section 16 is expanded to subject to penalties any violation of the Act or any requirements thereunder, then 15(1), (3) and (4) have no function.

But 15(2) would still have a function, since it makes unlawful activity that would otherwise not be unlawful.

Also, if section 16 is expanded in this way, section 17 should probably be expanded too.

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of this Act, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

"(B) ORGANIZATIONS AND ENTITIES.—An [organization or entity] that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation. [Client note: The other laws that have this provision (CAA, CWA, RCRA, etc.) read as follows: 'Any person committing such violation which is an organization ... .' The intent is to distinguish between individuals and organizations – do we need 'entity' here then?]

Commented [A231]: Is it clear that "entity" refers exclusively to an organization, not a natural person?

"(3) KNOWLEDGE OF IMMINENT DANGER OR INJURY.—For purposes of determining whether a defendant knew that the violation placed another individual in imminent danger of death or serious bodily injury—

Commented [A232]: Why "another individual" here but "an individual" above?

"(A) the defendant shall be responsible only for actual awareness or actual belief possessed; and

"(B) knowledge possessed by another individual may not be attributed to the defendant.".

SEC. 18. PREEMPTION.

Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amended to read as follows:

"SEC. 18. PREEMPTION.

"(a) In General.—

"(1) ESTABLISHMENT OR ENFORCEMENT.—Except as provided in subsections (c) and (d), no State or political subdivision of a State may establish or continue to enforce a law or administrative action—

Commented [A233]: This had previously said "a statute". The change is substantive, since it would create a stronger argument that state common law can be preempted.

"(A) relating to the development of information regarding a chemical substance or category of chemical substances that is reasonably likely to produce the same information as is required under section 4, 5, or 6 in—

"(i) a regulation promulgated by the Administrator;

"(ii) a testing consent agreement entered into by the Administrator; or

"(iii) an order issued by the Administrator;

"(B) to prohibit or restrict the manufacture, processing, distribution in commerce, or use of a chemical substance—

"(i) for a chemical substance found to meet the safety standard and consistent with the scope of the safety determination made under section 6; or

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"(ii) for a chemical substance found not to meet the safety standard, after the effective date of the regulation promulgated pursuant to section 6(d) for the chemical substance, consistent with the scope of the relevant safety determination made by the Administrator; or

"(C) requiring the notification of a use of a chemical substance—

"(i) that the Administrator has specified as a significant new use; and

"(ii) for which the Administrator has required notification pursuant to a regulation promulgated pursuant to section 5.

"(2) EFFECTIVE DATE FOR CERTAIN PREEMPTION.—For purposes of this subsection, Federal preemption of State laws and administrative actions applicable to specific chemical substances—

"(A) shall be consistent with the scope of the determination made by the Administrator; and

"(B) shall not take effect until the date on which, as applicable—

"(i) the Administrator determines that the chemical substance meets the safety standard; or

"(ii) compliance with the applicable regulation promulgated pursuant to section 6(d) is required.

"(b) New Laws and Administrative Actions.—Except as provided in subsections (c) and (d), no State or political subdivision of a State may establish, after the date of enactment of the Chemical Safety Improvement Act, any law or administrative action that prohibits or restricts the manufacture, processing, distribution in commerce, or use of a chemical substance that—

"(1) is a high-priority substance identified under section 4A, as of the date on which the Administrator commences a safety assessment under section 6; or

"(2) is a low-priority substance identified under section 4A, as of the date on which the Administrator designates the substance as a low-priority substance.

"(c) Exceptions.—

"(1) IN GENERAL.—Subsections (a) and (b) shall not apply to a requirement, prohibition, or restriction of a State or a political subdivision of a State that—

"(A) is adopted pursuant to any other provision of Federal law;

"(B) implements a reporting, monitoring, or information collection requirement not otherwise required—

"(i) by the Administrator under this Act; or

"(ii) under any other provision of Federal law; or

"(C) is adopted pursuant to a law of the State or political subdivision of the State relating to water quality, air quality, or waste treatment or disposal that—

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"(i) does not impose a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii) is not otherwise required or inconsistent with an action by the Administrator under section 5 or 6.

"(2) NO PREEMPTION.—Nothing in this Act (including any regulation, requirement, standard of performance, safety determination, or scientific assessment implemented under this Act) affects the right of a State or a political subdivision of a State to adopt or enforce any regulation, requirement, standard of performance, safety determination, scientific assessment, or provision for protection for public health or the environment that—

"(A) is adopted or authorized to comply with any other provision of Federal law;

"(B) implements a reporting, monitoring, or information collection requirement not otherwise required—

"(i) by the Administrator under this Act; or

"(ii) under any other provision of Federal law; or

"(C) is adopted pursuant to a law of the State or political subdivision of the State relating to water quality, air quality, or waste treatment or disposal that—

"(i) does not impose a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii) is not otherwise required or inconsistent with an action by the Administrator under section 5 or 6.

"(3) EXISTING REGULATIONS AND ORDERS.—Nothing in this section—

"(A) requires the Administrator to modify or withdraw any regulation or order under section 5 or 6; or

"(B) modifies the effect of this section, as in effect on the day before the date of enactment of the Chemical Safety Improvement Act, on any regulation or order promulgated or issued pursuant to this Act before that date of enactment.

"(d) Preservation of Certain State Law.—Nothing in this section preempts or otherwise affects any warning requirement relating to consumer products or substances that is established pursuant to a State law that was in effect on August 31, 2003, unless a regulation, consent agreement, or order is issued under section 6 imposing a warning requirement, which shall preempt a chemical-specific State warning requirement consistent with the scope of a determination of the Administrator under section 6.

"(e) State Waivers.—

"(1) IN GENERAL.—On receipt of an application of a State or political subdivision of a State, the Administrator may provide a waiver from the requirements of subsections (a) and (b)(1) regarding a law or administrative action of the State or political subdivision relating to the effects or exposure to any chemical substance under the intended or reasonably

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anticipated conditions of use, if—

"(A)(i) the State or political subdivision determines that waiting until the end of the period specified in the established schedule and deadline for the completion of a full safety assessment and safety determination established under section 4A is not practicable; and

Commented [A234]: Should be section 6.

"(ii) the Administrator determines that—

"(I) compelling State or local conditions warrant granting the waiver to protect human health or the environment;

"(II) compliance with the proposed requirement of the State or political subdivision will not unduly burden interstate and foreign commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(III) compliance with the proposed requirement of the State or political subdivision would not cause a violation of any applicable Federal law, regulation, or order; and

"(IV) in the judgment of the Administrator, the proposed requirement of the State or political subdivision is consistent with sound objective scientific practices, the weight of the evidence, and the best available science;

"(B)(i) the Administrator determines that a safety assessment or safety determination has been unreasonably delayed; and

"(ii) the State certifies that—

"(I) the State has a compelling local interest to protect human health or the environment;

"(II) compliance with the proposed requirement of the State will not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(III) compliance with the proposed requirement would not cause a violation of any applicable Federal law, regulation, or order; and

"(IV) the proposed requirement is grounded in reasonable scientific concern; or

"(C)(i) the State has entered into a contract with the National Academy of Sciences to assess the hazard, use and exposure, and risk of a chemical substance;

"(ii) the report complies with the requirements of the Federal Advisory Committee Act (5 U.S.C. App.); and

"(iii) based on the best available evidence described in the report of the National Academy of Sciences, the State establishes a requirement relating to the effects of or exposure to a chemical substance.

"(2) APPROVAL OF REQUEST.—The Administrator shall determine whether to grant or

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1 deny a waiver application under paragraph (1) by not later than, as applicable—

2 "(A) 180 days after the date on which an application under paragraph (1)(A) is
3 submitted; or

4 "(B) 90 days after the date on which an application under paragraph (1)(B) is
5 submitted.

6 "(3) NOTICE AND COMMENT.—The application of a State or political subdivision of a
7 State shall be subject to public notice and comment.

8 "(4) FINAL AGENCY ACTION.—A determination of the Administrator regarding the
9 application of a State or political subdivision shall be—

10 "(A) considered to be a final agency action; and

11 "(B) subject to judicial review.

12 "(5) DURATION OF WAIVERS.—A waiver granted under—

13 "(A) paragraph (1)(A) shall remain in effect unless the waiver is found to be in
14 conflict with a completed safety assessment and safety determination; and

15 "(B) subparagraph (B) or (C) of paragraph (1) shall remain in effect until such time
16 as the applicable safety assessment and safety determination are completed.

17 "(6) JUDICIAL REVIEW.—

18 "(A) IN GENERAL.—Not later than 60 days after the date on which the Administrator
19 makes a determination regarding an application of a State or political subdivision
20 under paragraph (1), any person may file a petition for judicial review in the United
21 States Court of Appeals for the District of Columbia Circuit, which shall have
22 exclusive jurisdiction over the determination.

23 "(B) JUDICIAL REVIEW OF PRIORITIZATION SCREENING DECISION.—Not later than 60
24 days after the date on which the Administrator makes a decision on a recommendation
25 made under section 4A(c) to designate a chemical substance as a low priority, the
26 Governor of a State or a State agency with responsibility for protecting health and the
27 environment that submitted the recommendation, as applicable, may file a petition for
28 judicial review in the United States Court of Appeals for the District of Columbia
29 Circuit, which shall have exclusive jurisdiction over the determination.

30 "(7) SAVINGS PROVISION.—

31 "(A) IN GENERAL.—Nothing in this Act (including any regulation, requirement,
32 standard of performance, safety determination, or scientific assessment implemented
33 under this Act) preempts, displaces, or supplants any Federal or State—

34 "(i) common law right; or

35 "(ii) law that creates—

36 "(I) a remedy for civil relief, including for civil damage; or

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"(II) a penalty for a criminal conduct.

"(B) CLARIFICATION.—Notwithstanding any other provision of this Act, nothing in this Act preempts or precludes 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 Federal, State, maritime, or common law or statutory theory.

"(C) NO EFFECT ON PRIVATE REMEDIES.—Nothing in this Act (including any regulation, requirement, standard of performance, safety determination, or scientific assessment implemented under this Act)—

"(i) is dispositive in any civil action in favor of any plaintiff or defendant; or

"(ii) affects the authority of any court to make a determination in an adjudicatory proceeding under applicable Federal or State law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, safety assessments, scientific assessments, or orders issued pursuant to this Act.".

SEC. 19. JUDICIAL REVIEW.

Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking "section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting "section 4(a), 5(d)(4), 6(d), or 8"; and

(ii) in subparagraph (B), by striking "an order issued under subparagraph (A) or (B) of section 6(b)(1)" and inserting ["a regulation promulgated pursuant to section 6(d)"]; and

(B) in paragraph (2), in the first sentence, by striking "paragraph (1)(A)" and inserting "paragraph (1)"; and

(C) by striking paragraph (3); and

(2) in subsection (c)(1)—

(A) in subparagraph (B)—

(i) in clause (i)—

(I) by striking "section 4(a), 5(b)(4), 6(a), or 6(e)" and inserting "section 4(a), 5(d)(4), or 6(d)"; and

(II) by striking "evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;" and inserting "evidence (including any matter) in the rulemaking record, taken as a whole; and"; and

Commented [A235]: Several things have dropped in this substitution of citations: significant new use rules; PCB rules; and any rules under Title II or IV. In addition, there are significant new actions under this bill that would probably make sense to have reviewed under section 19: eg, positive safety determinations, new chemical determinations under 5(d)(3), maybe denials of section 18 Governor petitions.

Commented [A236]: This bracketed insert is wrong; section 6(d) rules are covered above. Consider, though, whether some orders to be issued under this bill should be subject to these judicial review provisions – eg, test orders, section 5 orders.

Commented [A237]: Should be stricken. There are no 5d4 rules.

Commented [A238]: Reference to PCB rules has been dropped. Reference should be to 6g or h, depending on final codification.

Commented [A239]: This is an imprecise relocation of language from a stricken provision of section 19. Suggest deleting it – it's unnecessary.

(ii) by striking clauses (ii) and (iii) and the matter following clause (iii) and inserting the following:

"(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 regulation, except as part of the rulemaking record, taken as a whole."; and

[(B) by striking subparagraph (C).]

SEC. 20. CITIZENS' PETITIONS.

Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an order under section 4 or 5(d)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "an order under section 4 or 5(d)"; and

(B) in paragraph (4), by striking subparagraph (B) and inserting the following:

"(B) DE NOVO PROCEEDING.—

"(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to promulgate a regulation pursuant to section 4, 5(d), 6(b), 6(c), 6(d), or 8 or an order issued under section 4 or 5(d), the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.

"(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a regulation or order under section 4, the information available to the Administrator is insufficient for the Administrator to perform an action described in section 4 or 6(d);

"(bb) in the case of a petition to issue an order under section 5(d), there is a reasonable basis to conclude that the chemical substance is not likely to meet the safety standard;

"(cc) in the case of a petition to initiate a proceeding for the issuance of a regulation under section 6(d), there is a reasonable basis to conclude that the chemical substance will not meet the safety standard; or

Commented [A240]: Why enumerate the specific subsections here, when (a)(1) and (b)(1) just list the sections?

Commented [A241]: This doesn't make sense – it's not the standard for a section 4 rule or order. In particular, the reference to an action under section 4 makes no sense, and the 6(d) reference is too narrow.

Commented [A242]: Sec 5(d) orders do not seem to be a good candidate for citizen petition. Section 5 creates EPA duties to decide whether new chemicals are likely to meet the safety standard and to issue orders under 5(d) for chemicals that are not likely to meet the standard. I seems like a citizen's recourse would be a mandatory duty suit under section 20 or an unreasonable delay suit, not a citizen petition under section 21. Also, the PMN review period does not provide enough time for a citizen petition to be effective.

Commented [A243]: Similar comment. Section 6 imposes mandatory schedules for issuing control rules, which can be enforced by citizens under section 20.

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"(dd) in the case of a petition to initiate a proceeding for the issuance of a regulation under section 8, there is a reasonable basis to conclude that the regulation is necessary to protect human health or the environment from an unreasonable risk of harm to human health or the environment.

"(II) DEFERMENT.—The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

"(aa) the extent of the risk to human health or the environment alleged by the petitioner is less than the extent of risks to human health or the environment with respect to which the Administrator is taking action under this Act; and

"(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.".

SEC. 21. EMPLOYMENT EFFECTS.

Section 24(b)(2)(B)(ii) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by striking "section 6(c)(3)," and inserting "the applicable requirements of this Act;".

SEC. 22. STUDIES.

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.

SEC. 23. ADMINISTRATION.

Section 26(e) of the Toxic Substances Control Act (15 U.S.C. 2625(e)) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".

SEC. 24. DEVELOPMENT AND EVALUATION OF TEST METHODS.

Section 27(a) of the Toxic Substances Control Act (15 U.S.C. 2626(a)) is amended in the first sentence by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

SEC. 25. STATE PROGRAMS.

Section 28 of the Toxic Substances Control Act (15 U.S.C. 2627) is amended—

(1) in subsection (b)(1)—

(A) in subparagraphs (A) through (D), by striking the comma at the end of each subparagraph and inserting a semicolon; and

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(B) in subparagraph (E), by striking “, and” and inserting “; and”; and

(2) by striking subsections (c) and (d).

SEC. 26. AUTHORIZATION OF APPROPRIATIONS.

Section 29 of the Toxic Substances Control Act (15 U.S.C. 2628) is repealed.

SEC. 27. ANNUAL REPORT.

Section 30 of the Toxic Substances Control Act (15 U.S.C. 2629) is amended by striking paragraph (2) and inserting the following:

“(2)(A) the number of notices received during each year under section 5; and

“(B) the number of the notices described in subparagraph (A) for chemical substances subject to a regulation, testing consent agreement, or order under section 4;”.

SEC. 28. EFFECTIVE DATE.

Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601 note; Public Law 94–469) is amended by striking “Except as provided in section 4(f), this” and inserting “This”.

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 3/5/2015 2:59:11 PM
To: Kaiser, Sven-Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac78d3704ba94edbbd0da970921271ff-SKAISER]
CC: Vaught, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c30920bcb6214a91b7e3c1e7810c63e1-Vaught, Laura]; Distefano, Nichole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31d32a3a3a9e4591b5fdfc3eb96e8b78-Distefano,]; Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]; Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]
Subject: FRL21
Attachments: Frank R. Lautenberg Chemical Safety for the 21st Century Act.pdf

This draft was shared with the Ranking Member of EPW yesterday as a part of the March 18th Hearing scope.

This will be the topic of the discussion at that hearing.

A few changes to the previous draft you saw:

- Judicial Review for Low Priority designations (by States, within 60 days)
- Carve-out for Prop 65
- Increase in through-put of chemicals
  - EPA Shall have a minimum of 10 High-priority and 10 low-priority by the end of the first year
  - A minimum of 20 high-priority and 20 low-priority by the end of the third year
  - A minimum of 25 high-priority and 25 low-priority by the end of the fifth year
- There are some other additional changes, but those are the biggest

114TH CONGRESS
1ST SESSION

S. _____

To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. UDALL (for himself and Mr. VITTER) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act".

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(c) of the Toxic Substances Control Act (15 U.S.C. 2601(c)) is amended—

(1) by striking "It is the intent" and inserting the following:

"(1) ADMINISTRATION.—It is the intent";

(2) in paragraph (1) (as so redesignated), by inserting ", as provided under this Act" before the period at the end; and

(3) by adding at the following:

"(2) REFORM.—It is the intent of Congress that reform of this Act in accordance with the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act—

"(A) shall be administered in a manner that—

"(i) protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and

"(ii) ensures that appropriate information on chemical substances and mixtures is available to public health officials and first responders in the event of an emergency; and

"(B) shall not displace or supplant common law rights of action or remedies for civil relief.".

1 **SEC. 3. DEFINITIONS.**

2 Section 3 of the Toxic Substances Control Act (15
3 U.S.C. 2602) is amended—

4 (1) by redesignating paragraphs (4), (5), (6),
5 (7), (8), (9), (10), (11), (12), (13), and (14) as
6 paragraphs (5), (6), (7), (8), (9), (10), (12), (13),
7 (17), (18), and (19), respectively;

8 (2) by inserting after paragraph (3) the fol-
9 lowing:

10 "(4) CONDITIONS OF USE.—The term 'condi-
11 tions of use' means the intended, known, or reason-
12 ably foreseeable circumstances the Administrator de-
13 termines a chemical substance is manufactured,
14 processed, distributed in commerce, used, or dis-
15 posed of.";

16 (3) by inserting after paragraph (10) (as so re-
17 designated) the following:

18 "(11) POTENTIALLY EXPOSED OR SUSCEPTIBLE
19 POPULATION.—The term 'potentially exposed or sus-
20 ceptible population' means 1 or more groups—

21 "(A) of individuals within the general pop-
22 ulation who may be—

23 "(i) differentially exposed to chemical
24 substances under the conditions of use; or

"(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

"(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; and

(4) by inserting after paragraph (13) (as so redesignated) the following:

"(14) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.

"(15) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the conditions of use.

"(16) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of injury to health or the environment will result from exposure to a chem-

ical substance under the conditions of use, including no unreasonable risk of injury to—

"(A) the general population; or

"(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

The Toxic Substances Control Act is amended by inserting after section 3 (15 U.S.C. 2602) the following:

"SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

"(a) DEFINITION OF GUIDANCE.—In this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.

"(b) DEADLINE.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.

"(c) USE OF SCIENCE.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance on the use

of science in making decisions under sections 4, 4A, 5, and 6.

"(2) GOAL.—A goal of the policies and procedures described in paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) REQUIREMENTS.—The policies, procedures, and guidance issued under this section shall describe the manner in which the Administrator shall ensure that —

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;

"(B) to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

1 "(d) EXISTING EPA POLICIES, PROCEDURES, AND
2 GUIDANCE.—The policies, procedures, and guidance de-
3 scribed in subsection (b) shall incorporate, as appropriate,
4 existing relevant hazard, exposure, and risk assessment
5 guidelines and methodologies, data evaluation and quality
6 criteria, testing methodologies, and other relevant guide-
7 lines and policies of the Environmental Protection Agency.
8 "(e) REVIEW.—Not later than 5 years after the date
9 of enactment of this section, and not less frequently than
10 once every 5 years thereafter, the Administrator shall—
11 "(1) review the adequacy of any policies, proce-
12 dures, and guidance developed under this section, in-
13 cluding animal, nonanimal, and epidemiological test
14 methods and procedures for assessing and deter-
15 mining risk under this Act; and
16 "(2) after providing public notice and an oppor-
17 tunity for comment, revise the policies, procedures,
18 and guidance if necessary to reflect new scientific
19 developments or understandings.
20 "(f) SOURCES OF INFORMATION.—In making any de-
21 cision with respect to a chemical substance under section
22 4, 4A, 5, or 6, the Administrator shall take into consider-
23 ation information relating to the hazards and exposures
24 of a chemical substance under the conditions of use that

1 is reasonably available to the Administrator, including in-
2 formation that is—
3 "(1) submitted to the Administrator pursuant
4 to any rule, consent agreement, order, or other re-
5 quirement of this Act, or on a voluntary basis, in-
6 cluding pursuant to any request made under this
7 Act, by—
8 "(A) manufacturers or processors of a sub-
9 stance;
10 "(B) the public;
11 "(C) other Federal departments or agen-
12 cies; or
13 "(D) the Governor of a State or a State
14 agency with responsibility for protecting health
15 or the environment;
16 "(2) submitted to a governmental entity in any
17 jurisdiction pursuant to a governmental requirement
18 relating to the protection of health or the environ-
19 ment; or
20 "(3) identified through an active search by the
21 Administrator of information sources that are pub-
22 licly available or otherwise accessible by the Admin-
23 istrator.
24 "(g) TESTING OF CHEMICAL SUBSTANCES AND MIX-
25 TURES.—

1 "(1) IN GENERAL.—The Administrator shall es-
2 tablish policies and procedures for the testing of
3 chemical substances or mixtures under section 4.
4 "(2) GOAL.—A goal of the policies and proce-
5 dures established under paragraph (1) shall be to
6 make the basis of decisions clear to the public.
7 "(3) CONTENTS.—The policies and procedures
8 established under paragraph (1) shall—
9 "(A) address how and when the exposure
10 level or exposure potential of a chemical sub-
11 stance would factor into decisions to require
12 new testing, subject to the condition that the
13 Administrator shall not interpret the lack of ex-
14 posure information as a lack of exposure or ex-
15 posure potential;
16 "(B) describe the manner in which the Ad-
17 ministrator will determine that additional infor-
18 mation is necessary to carry out this Act, in-
19 cluding information relating to potentially ex-
20 posed or susceptible populations;
21 "(C) require the Administrator to consult
22 with the Director of the National Institute for
23 Occupational Safety and Health prior to pre-
24 scribing epidemiologic studies of employees; and

"(D) prior to adopting a requirement for testing using vertebrate animals, require the Administrator to take into consideration, as appropriate and to the extent practicable, reasonably available—

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

"(iii) high-throughput screening methods and the prediction models of those methods; and

"(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.

"(4) TIERED TESTING.—

"(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.

"(B) SCREENING-LEVEL TESTS.—

"(i) IN GENERAL.—The screening-level tests required for a chemical sub-

1 stance or mixture may include tests for
2 hazard (which may include in silico, in
3 vitro, and in vivo tests), environmental and
4 biological fate and transport, and measure-
5 ments or modeling of exposure or exposure
6 potential, as appropriate.
7 "(ii) USE.—Screening-level tests shall
8 be used—
9 "(I) to screen chemical sub-
10 stances or mixtures for potential ad-
11 verse effects; and
12 "(II) to inform a decision of the
13 Administrator regarding whether
14 more complex or targeted additional
15 testing is necessary.
16 "(C) ADDITIONAL TESTING.—If the Ad-
17 ministrator determines under subparagraph (B)
18 that additional testing is necessary to provide
19 more definitive information for safety assess-
20 ments or safety determinations, the Adminis-
21 trator may require more advanced tests for po-
22 tential health or environmental effects or expo-
23 sure potential.
24 "(D) ADVANCED TESTING WITHOUT
25 SCREENING.—The Administrator may require

more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

"(h) SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(C) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall identify the substances subject to safety assessments and safety determinations to be completed that year.

1 "(2) POLICIES AND PROCEDURES FOR SAFETY
2 ASSESSMENTS AND SAFETY DETERMINATIONS.—
3 "(A) IN GENERAL.—The Administrator
4 shall establish, by rule, policies and procedures
5 regarding the manner in which the Adminis-
6 trator shall carry out section 6.
7 "(B) GOAL.—A goal of the policies and
8 procedures under this paragraph shall be to
9 make the basis of decisions of the Adminis-
10 trator clear to the public.
11 "(C) MINIMUM REQUIREMENTS.—At a
12 minimum, the policies and procedures under
13 this paragraph shall—
14 "(i) describe—
15 "(I) the manner in which the Ad-
16 ministrator will identify informational
17 needs and seek that information from
18 the public;
19 "(II) the information (including
20 draft safety assessments) that may be
21 submitted by interested individuals or
22 entities, including States; and
23 "(III) the criteria by which that
24 information will be evaluated;
25 "(ii) require the Administrator—

1 "(I)(aa) to define the scope of
2 the safety assessment and safety de-
3 termination to be conducted under
4 section 6, including the hazards, expo-
5 sures, conditions of use, and poten-
6 tially exposed and susceptible popu-
7 lations that the Administrator expects
8 to consider in a safety assessment;
9 "(bb) to explain the basis for the
10 scope of the safety assessment and
11 safety determination; and
12 "(cc) to accept comments regard-
13 ing the scope of the safety assessment
14 and safety determination; and
15 "(II)(aa) to identify the items de-
16 scribed in subclause (I) that the Ad-
17 ministrator has considered in the final
18 safety assessment; and
19 "(bb) to explain the basis for the
20 consideration of those items;
21 "(iii) describe the manner in which
22 aggregate exposures, or significant subsets
23 of exposures, to a chemical substance
24 under the conditions of use will be consid-

1 ered, and explain the basis for that consid-
2 eration in the final safety assessment;
3 "(iv) require that each safety assess-
4 ment and safety determination shall in-
5 clude—
6 "(I) a description of the weight
7 of the scientific evidence of risk; and
8 "(II) a summary of the informa-
9 tion regarding the impact on health
10 and the environment of the chemical
11 substance that was used to make the
12 assessment or determination, includ-
13 ing, as available, mechanistic, animal
14 toxicity, and epidemiology studies;
15 "(v) establish a timely and trans-
16 parent process for evaluating whether new
17 information submitted or obtained after
18 the date of a final safety assessment or
19 safety determination warrants reconsider-
20 ation of the safety assessment or safety de-
21 termination; and
22 "(vi) when relevant information is
23 provided or otherwise made available to the
24 Administrator, shall consider the extent of