1 Federal regulation under other Federal
2 laws.
3 "(D) GUIDANCE.—
4 "(i) IN GENERAL.—Not later than 1
5 year after the date of enactment of the
6 Frank R. Lautenberg Chemical Safety for
7 the 21st Century Act, the Administrator
8 shall develop guidance to assist interested
9 persons in developing draft safety assess-
10 ments and other information for submis-
11 sion to the Administrator, which may be
12 considered at the discretion of the Admin-
13 istrator.
14 "(ii) REQUIREMENT.—The guidance
15 shall, at a minimum, address the quality of
16 the information submitted and the process
17 to be followed in developing a draft assess-
18 ment for consideration by the Adminis-
19 trator.
20 "(3) ARTICLES.—If the Administrator intends
21 to prohibit or otherwise restrict an article on the
22 basis of a chemical substance contained in that arti-
23 cle, the Administrator shall have evidence of signifi-
24 cant exposure to the chemical substance from such
25 article.

1 "(i) PUBLICLY AVAILABLE INFORMATION.—Subject
2 to section 14, the Administrator shall—
3 "(1) make publicly available a nontechnical
4 summary, and the final version, of each safety as-
5 sessment and safety determination;
6 "(2) provide public notice and an opportunity
7 for comment on each proposed safety assessment
8 and safety determination; and
9 "(3) make public in a final safety assessment
10 and safety determination—
11 "(A) the list of studies considered by the
12 Administrator in carrying out the safety assess-
13 ment or safety determination; and
14 "(B) the list of policies, procedures, and
15 guidance that were followed in carrying out the
16 safety assessment or safety determination.
17 "(j) CONSULTATION WITH SCIENCE ADVISORY COM-
18 MITTEE ON CHEMICALS.—
19 "(1) ESTABLISHMENT.—Not later than 1 year
20 after the date of enactment of this section, the Ad-
21 ministrator shall establish an advisory committee, to
22 be known as the 'Science Advisory Committee on
23 Chemicals' (referred to in this subsection as the
24 'Committee').

1 "(2) PURPOSE.—The purpose of the Committee
2 shall be to provide independent advice and expert
3 consultation, on the request of the Administrator,
4 with respect to the scientific and technical aspects of
5 issues relating to the implementation of this title.
6 "(3) COMPOSITION.—The Committee shall be
7 composed of representatives of such science, govern-
8 ment, labor, public health, public interest, animal
9 protection, industry, and other groups as the Admin-
10 istrator determines to be advisable, including, at a
11 minimum, representatives that have specific sci-
12 entific expertise in the relationship of chemical expo-
13 sures to women, children, and other potentially ex-
14 posed or susceptible populations.
15 "(4) SCHEDULE.—The Administrator shall con-
16 vene the Committee in accordance with such sched-
17 ule as the Administrator determines to be appro-
18 priate, but not less frequently than once every 2
19 years.
20 "(5) RELATIONSHIP TO OTHER LAW.—All pro-
21 ceedings and meetings of the Committee shall be
22 subject to the Federal Advisory Committee Act (5
23 U.S.C. App.).".

1 **SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.**

2 (a) IN GENERAL.—Section 4 of the Toxic Substances
3 Control Act (15 U.S.C. 2603) is amended—

4 (1) by striking subsections (a), (b), (c), (d), and
5 (g);

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

8 (3) in subsection (f) (as so redesignated)—

9 (A) by striking "rule" each place it ap-
10 pears and inserting "rule, testing consent
11 agreement, or order";

12 (B) by striking "under subsection (a)"
13 each place it appears and inserting "under this
14 subsection"; and

15 (C) in paragraph (1)(B), in the last sen-
16 tence, by striking "rulemaking";

17 (4) in subsection (g) (as so redesignated)—

18 (A) in the first sentence, by striking "from
19 cancer, gene mutations, or birth defects"; and

20 (B) by striking the last sentence; and

21 (5) by inserting before subsection (f) (as so re-
22 designated) the following:

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

25 "(1) IN GENERAL.—The Administrator may re-
26 quire the development of new information relating to

1 a chemical substance or mixture in accordance with
2 this section if the Administrator determines that the
3 information is necessary—
4 "(A) to review a notice under section 5(d)
5 or to perform a safety assessment or safety de-
6 termination under section 6;
7 "(B) to implement a requirement imposed
8 in a consent agreement or order issued under
9 section 5(d)(4) or under a rule promulgated
10 under section 6(d)(3);
11 "(C) pursuant to section 12(a)(4); or
12 "(D) at the request of the implementing
13 authority under another Federal law, to meet
14 the regulatory testing needs of that authority.
15 "(2) LIMITED TESTING FOR PRIORITIZATION
16 PURPOSES.—
17 "(A) IN GENERAL.—Except as provided in
18 subparagraph (B), the Administrator may re-
19 quire the development of new information for
20 the purposes of section 4A.
21 "(B) PROHIBITION.—Testing required
22 under subparagraph (A) shall not be required
23 for the purpose of establishing or implementing
24 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 mix-

1 ture, including specific reference to reliable
2 nonanimal test procedures; and
3 "(iv) specification of the period within
4 which individuals and entities required to
5 conduct the testing shall submit to the Ad-
6 ministrator the information developed in
7 accordance with the procedures described
8 in clause (iii).
9 "(B) CONSIDERATIONS.—In determining
10 the procedures and period to be required under
11 subparagraph (A), the Administrator shall take
12 into consideration—
13 "(i) the relative costs of the various
14 test protocols and methodologies that may
15 be required; and
16 "(ii) the reasonably foreseeable avail-
17 ability of facilities and personnel required
18 to perform the testing.
19 "(b) STATEMENT OF NEED.—
20 "(1) IN GENERAL.—In promulgating a rule, en-
21 tering into a testing consent agreement, or issuing
22 an order for the development of additional informa-
23 tion (including information on exposure or exposure
24 potential) pursuant to this section, the Adminis-
25 trator 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 reli-

able 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

1 vertebrate animals under this section, the Adminis-
2 trator may adapt or waive the requirement, if the
3 Administrator determines that—
4 "(A) there is sufficient evidence from sev-
5 eral independent sources of information to sup-
6 port a conclusion that a chemical substance or
7 mixture has, or does not have, a particular
8 property if the information from each individual
9 source alone is insufficient to support the con-
10 clusion;
11 "(B) as a result of 1 or more physical or
12 chemical properties of the chemical substance
13 or mixture or other toxicokinetic consider-
14 ations—
15 "(i) the substance cannot be absorbed;
16 or
17 "(ii) testing for a specific endpoint is
18 technically not practicable to conduct; or
19 "(C) a chemical substance or mixture can-
20 not be tested in vertebrate animals at con-
21 centrations that do not result in significant
22 pain or distress, because of physical or chemical
23 properties of the chemical substance or mixture,
24 such as a potential to cause severe corrosion or
25 severe irritation to the tissues of the animal.

1 "(d) TESTING REQUIREMENTS.—
2 "(1) IN GENERAL.—The Administrator may re-
3 quire the development of information by—
4 "(A) manufacturers and processors of the
5 chemical substance or mixture; and
6 "(B) persons that begin to manufacture or
7 process the chemical substance or mixture—
8 "(i) after the effective date of the
9 rule, testing consent agreement, or order;
10 but
11 "(ii) subject to paragraph (3), before
12 the period ending on the date that is 180
13 days after the end of the period described
14 in this section.
15 "(2) DESIGNATION.—The Administrator may
16 permit 2 or more persons identified in subparagraph
17 (A) or (B) of paragraph (1) to designate 1 of the
18 persons or a qualified third party—
19 "(A) to develop the information; and
20 "(B) to submit the information on behalf
21 of the persons making the designation.
22 "(3) EXEMPTIONS.—
23 "(A) IN GENERAL.—A person otherwise
24 subject to a rule, testing consent agreement, or
25 order under this section may submit to the Ad-

1 ministrator an application for an exemption on
2 the basis that the information is being devel-
3 oped by a person designated under paragraph
4 (2).
5 "(B) FAIR AND EQUITABLE REIMBURSE-
6 MENT TO DESIGNEE.—
7 "(i) IN GENERAL.—If the Adminis-
8 trator accepts an application submitted
9 under subparagraph (A), the Adminis-
10 trator shall direct the applicant to provide
11 to the person designated under paragraph
12 (2) fair and equitable reimbursement, as
13 agreed to between the applicant and the
14 designee.
15 "(ii) ARBITRATION.—If the applicant
16 and a person designated under paragraph
17 (2) cannot reach agreement on the amount
18 of fair and equitable reimbursement, the
19 amount shall be determined by arbitration.
20 "(C) TERMINATION.—If, after granting an
21 exemption under this paragraph, the Adminis-
22 trator determines that a person covered by the
23 exemption has failed to comply with the rule,
24 testing consent agreement, or order, the Admin-
25 istrator 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

1 substances identified by the Administrator
2 in the October, 2014 TSCA Work Plan
3 and subsequent updates, and at least 10
4 low-priority substances.
5 "(ii) SUBSEQUENTLY IDENTIFIED
6 SUBSTANCES.—Insofar as possible, at least
7 50 percent of all substances subsequently
8 identified by the Administrator as high-pri-
9 ority substances shall be drawn from the
10 list of chemical substances identified by the
11 Administrator in the October, 2014 TSCA
12 Work Plan and subsequent updates, until
13 all Work Plan chemicals have been des-
14 ignated under this subsection.
15 "(C) ADDITIONAL CHEMICAL REVIEWS.—
16 The Administrator shall—
17 "(i) 3 years after the date of enact-
18 ment of the Frank R. Lautenberg Chem-
19 ical Safety for the 21st Century Act, add
20 additional high-priority substances suffi-
21 cient to ensure that at least a total of 20
22 high-priority substances have undergone or
23 are undergoing the process established in
24 section 6(a), and additional low-priority
25 substances sufficient to ensure that at

1 least a total of 20 low-priority substances
2 have been designated; and
3 "(ii) as soon as practicable and not
4 later than 5 years after the date of enact-
5 ment of the Frank R. Lautenberg Chem-
6 ical Safety for the 21st Century Act, add
7 additional high-priority substances suffi-
8 cient to ensure that at least a total of 25
9 high-priority substances have undergone or
10 are undergoing the process established in
11 section 6(a), and additional low-priority
12 substances sufficient to ensure that at
13 least a total of 25 low-priority substances
14 have been designated.
15 "(3) IMPLEMENTATION.—
16 "(A) CONSIDERATION OF ACTIVE AND IN-
17 ACTIVE SUBSTANCES.—
18 "(i) ACTIVE SUBSTANCES.—In car-
19 rying out paragraph (1), the Administrator
20 shall take into consideration active sub-
21 stances, as determined under section 8,
22 which may include chemical substances on
23 the interim list of active substances estab-
24 lished 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 re-

1 move the chemical substance from the
2 list of high-priority substances estab-
3 lished under this subsection.
4 "(II) ADDITIONS.—The Adminis-
5 trator shall add at least 1 chemical
6 substance to the list of high-priority
7 substances for each chemical sub-
8 stance removed from the list of high-
9 priority substances established under
10 this subsection, until a safety assess-
11 ment and safety determination is com-
12 pleted for all high-priority substances.
13 "(III) LOW-PRIORITY SUB-
14 STANCES.—If a low-priority substance
15 is subsequently designated as a high-
16 priority substance, the Administrator
17 shall remove that substance from the
18 list of low-priority substances.
19 "(B) TIMELY COMPLETION OF
20 PRIORITIZATION SCREENING PROCESS.—
21 "(i) IN GENERAL.—The Administrator
22 shall—
23 "(I) not later than 180 days
24 after the effective date of the final

1 rule under paragraph (1), begin the
2 prioritization screening process; and
3 "(II) make every effort to com-
4 plete the designation of all active sub-
5 stances as high-priority substances or
6 low-priority substances in a timely
7 manner.
8 "(ii) DECISIONS ON SUBSTANCES SUB-
9 JECT TO TESTING FOR PRIORITIZATION
10 PURPOSES.—Not later than 90 days after
11 the date of receipt of information regard-
12 ing a chemical substance complying with a
13 rule, testing consent agreement, or order
14 issued under section 4(a)(2), the Adminis-
15 trator shall designate the chemical sub-
16 stance as a high-priority substance or low-
17 priority substance.
18 "(iii) CONSIDERATION.—
19 "(I) IN GENERAL.—The Admin-
20 istrator shall screen substances and
21 designate high-priority substances
22 taking into consideration the ability of
23 the Administrator to schedule and
24 complete safety assessments and safe-

1 ty determinations under section 6 in a
2 timely manner.
3 "(II) ANNUAL GOAL.—The Ad-
4 ministrator shall publish an annual
5 goal for the number of chemical sub-
6 stances to be subject to the
7 prioritization screening process.
8 "(C) SCREENING OF CATEGORIES OF SUB-
9 STANCES.—The Administrator may screen cat-
10 egories of chemical substances to ensure an effi-
11 cient prioritization screening process to allow
12 for timely and adequate designations of high-
13 priority substances and low-priority substances
14 and safety assessments and safety determina-
15 tions for high-priority substances.
16 "(D) PUBLICATION OF LIST OF CHEMICAL
17 SUBSTANCES.—Not less frequently than once
18 each year, the Administrator shall publish a list
19 of chemical substances that—
20 "(i) are being considered in the
21 prioritization screening process and the
22 status of the chemical substances in the
23 prioritization process, including those
24 chemical substances for which

1 prioritization decisions have been deferred;
2 and
3 "(ii) are designated as high-priority
4 substances or low-priority substances, in-
5 cluding the bases for such designations.
6 "(4) CRITERIA.—The criteria described in para-
7 graph (1) shall account for—
8 "(A) the recommendation of the Governor
9 of a State or a State agency with responsibility
10 for protecting health or the environment from
11 chemical substances appropriate for
12 prioritization screening;
13 "(B) the hazard and exposure potential of
14 the chemical substance (or category of sub-
15 stances), including specific scientific classifica-
16 tions and designations by authoritative govern-
17 mental entities;
18 "(C) the conditions of use or significant
19 changes in the conditions of use of the chemical
20 substance;
21 "(D) evidence and indicators of exposure
22 potential to humans or the environment from
23 the chemical substance, including potentially ex-
24 posed 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

1 factor in designating a chemical substance to be
2 a low-priority substance.
3 "(b) PRIORITIZATION SCREENING PROCESS AND DE-
4 CISIONS.—
5 "(1) IN GENERAL.—The prioritization screening
6 process developed under subsection (a) shall include
7 a requirement that the Administrator shall—
8 "(A) identify the chemical substances
9 being considered for prioritization;
10 "(B) request interested persons to supply
11 information regarding the chemical substances
12 being considered;
13 "(C) apply the criteria identified in sub-
14 section (a)(4); and
15 "(D) subject to paragraph (5) and using
16 the information available to the Administrator
17 at the time of the decision, identify a chemical
18 substance as a high-priority substance or a low-
19 priority substance.
20 "(2) INTEGRATION OF INFORMATION.—The
21 prioritization screening decision regarding a chem-
22 ical substance shall integrate any hazard and expo-
23 sure information relating to the chemical substance
24 that is available to the Administrator.

1 "(3) IDENTIFICATION OF HIGH-PRIORITY SUB-
2 STANCES.—The Administrator—
3 "(A) shall identify as a high-priority sub-
4 stance a chemical substance that, relative to
5 other chemical substances, the Administrator
6 determines has the potential for high hazard
7 and widespread exposure;
8 "(B) may identify as a high-priority sub-
9 stance a chemical substance that, relative to
10 other chemical substances, the Administrator
11 determines has the potential for high hazard or
12 widespread exposure; and
13 "(C) may identify as a high-priority sub-
14 stance an inactive substance, as determined
15 under subsection (a)(3)(A)(ii) and section 8(b),
16 that the Administrator determines warrants a
17 safety assessment and safety determination
18 under section 6.
19 "(4) IDENTIFICATION OF LOW-PRIORITY SUB-
20 STANCES.—The Administrator shall identify as a
21 low-priority substance a chemical substance that the
22 Administrator concludes has information sufficient
23 to establish that the chemical substance is likely to
24 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,

1 processing, distribution in commerce, or use of
2 a chemical substance that the Administrator
3 has not as designated a high-priority substance,
4 the Governor or State agency with responsi-
5 bility for implementing the statute or adminis-
6 trative action shall notify the Administrator.
7 "(B) REQUESTS FOR INFORMATION.—Fol-
8 lowing receipt of a notification provided under
9 subparagraph (A), the Administrator may re-
10 quest any available information from the Gov-
11 ernor or the State agency with respect to—
12 "(i) scientific evidence related to the
13 hazards, exposures and risks of the chem-
14 ical substance under the conditions of use
15 which the statute or administrative action
16 is intended to address;
17 "(ii) any State or local conditions
18 which warranted the statute or administra-
19 tive action;
20 "(iii) the statutory or administrative
21 authority on which the action is based; and
22 "(iv) any other available information
23 relevant to the prohibition or other restric-
24 tion, including information on any alter-

1 natives considered and their hazards, expo-
2 sures, and risks.
3 "(C) PRIORITIZATION SCREENING.—The
4 Administrator shall conduct a prioritization
5 screening under this subsection for all sub-
6 stances that—
7 "(i) are the subject of notifications re-
8 ceived under subparagraph (A); and
9 "(ii) the Administrator determines—
10 "(I) are likely to have significant
11 health or environmental impacts;
12 "(II) are likely to have signifi-
13 cant impact on interstate commerce;
14 or
15 "(III) have been subject to a pro-
16 hibition or other restriction under a
17 statute or administrative action in 2
18 or more States.
19 "(D) AVAILABILITY TO PUBLIC.—Subject
20 to section 14 and any applicable State law re-
21 garding the protection of confidential informa-
22 tion provided to the State or to the Adminis-
23 trator, the Administrator shall make informa-
24 tion received from a Governor or State agency
25 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 "(1) IN GENERAL.—The prioritization screening
2 process developed under subsection (a) shall—
3 "(A) include a process by which a manu-
4 facturer or processor of an active chemical sub-
5 stance that has not been designated a high-pri-
6 ority substance, or that has not been subject to
7 or is not in the process of a prioritization
8 screening by the Administrator, may request
9 that the Administrator designate the substance
10 for a safety assessment and safety determina-
11 tion, subject to the payment of fees pursuant to
12 section 26(b)(3)(E); and
13 "(B) provide guidance to submitters on the
14 information to be provided in such requests,
15 and specify the criteria the Administrator shall
16 use to determine whether or not to grant such
17 a request, which shall include whether the sub-
18 stance is subject to restrictions imposed by stat-
19 utes enacted or administrative actions taken by
20 1 or more States on the manufacture, proc-
21 essing, distribution in commerce, or use of the
22 substance.
23 "(2) PREFERENCE.—Subject to paragraph (3),
24 in deciding whether to grant requests under this
25 subsection the Administrator shall give a preference

1 to requests concerning substances for which the Ad-
2 ministrator determines that restrictions imposed by
3 1 or more States have the potential to have a signifi-
4 cant impact on interstate commerce or health or the
5 environment.

6 "(3) LIMITATIONS.—In considering whether to
7 grant a request submitted under paragraph (1), the
8 Administrator shall ensure that—

9 "(A) not more than 15 percent of the total
10 number of substances designated to undergo
11 safety assessments and safety determinations
12 under this section are substances designated
13 under the process and criteria pursuant to
14 paragraph (1); and

15 "(B) the resources allocated to conducting
16 safety assessments and safety determinations
17 for additional priorities designated under this
18 subsection are proportionate to the number of
19 such substances relative to the total number of
20 substances designated to undergo safety assess-
21 ments and safety determinations under this sec-
22 tion.

23 "(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).".

1 **SEC. 7. NEW CHEMICALS AND SIGNIFICANT NEW USES.**

2 Section 5 of the Toxic Substances Control Act (15
3 U.S.C. 2604) is amended—

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

6 **"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.";**

7 (2) by striking subsection (b);

8 (3) by redesignating subsection (a) as sub-
9 section (b);

10 (4) by redesignating subsection (i) as subsection
11 (a) and moving the subsection so as to appear at the
12 beginning of the section;

13 (5) in subsection (b) (as so redesignated)—

14 (A) in the subsection heading, by striking
15 "IN GENERAL" and inserting "NOTICES"; and

16 (B) in paragraph (1), in the matter fol-
17 lowing subparagraph (B)—

18 (i) by striking "subsection (d)" and
19 inserting "subsection (b)"; and

20 (ii) by striking "and such person com-
21 plies with any applicable requirement of
22 subsection (b)";

23 (6) by redesignating subsections (c) and (d) as
24 subsection (d) and (c), respectively, and moving sub-
25 section (c) (as so redesigned) so as appear after sub-
26 section (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 no-

1 tification period prescribed by subsection (b) or
2 (d)";
3 (8) by striking subsection (d) (as redesignated
4 by paragraph (6)) and inserting the following:
5 "(d) REVIEW OF NOTICE.—
6 "(1) INITIAL REVIEW.—
7 "(A) IN GENERAL.—Subject to subpara-
8 graph (B), not later than 90 days after the date
9 of receipt of a notice submitted under sub-
10 section (b), the Administrator shall—
11 "(i) conduct an initial review of the
12 notice;
13 "(ii) as needed, develop a profile of
14 the relevant chemical substance and the
15 potential for exposure to humans and the
16 environment; and
17 "(iii) make any necessary determina-
18 tion under paragraph (3).
19 "(B) EXTENSION.—Except as provided in
20 paragraph (5), the Administrator may extend
21 the period described in subparagraph (A) for
22 good cause for 1 or more periods, the total of
23 which shall be not more than 90 days.

1 "(2) INFORMATION SOURCES.—In evaluating a
2 notice under paragraph (1), the Administrator shall
3 take into consideration—
4 "(A) any relevant information identified in
5 subsection (c)(1); and
6 "(B) any other relevant additional infor-
7 mation available to the Administrator.
8 "(3) DETERMINATIONS.—Before the end of the
9 applicable period for review under paragraph (1),
10 based on the information described in paragraph (2),
11 and subject to section 18, the Administrator shall
12 determine that—
13 "(A) the relevant chemical substance or
14 significant new use is not likely to meet the
15 safety standard, in which case the Adminis-
16 trator shall take appropriate action under para-
17 graph (4);
18 "(B) the relevant chemical substance or
19 significant new use is likely to meet the safety
20 standard, in which case the Administrator shall
21 allow the review period to expire without addi-
22 tional restrictions; or
23 "(C) additional information is necessary in
24 order to make a determination under subpara-
25 graph (A) or (B), in which case the Adminis-

1 trator shall take appropriate action under para-
2 graph (5).
3 "(4) RESTRICTIONS.—
4 "(A) DETERMINATION BY ADMINIS-
5 TRATOR.—
6 "(i) IN GENERAL.—If the Adminis-
7 trator makes a determination under sub-
8 paragraph (A) or (C) of paragraph (3)
9 with respect to a notice submitted under
10 subsection (b)—
11 "(I) the Administrator, before
12 the end of the applicable period for re-
13 view under paragraph (1) and by con-
14 sent agreement or order, as appro-
15 priate, shall prohibit or otherwise re-
16 strict the manufacture, processing,
17 use, distribution in commerce, or dis-
18 posal (as applicable) of the chemical
19 substance, or of the chemical sub-
20 stance for a significant new use, with-
21 out compliance with the restrictions
22 specified in the consent agreement or
23 order that the Administrator deter-
24 mines are sufficient to ensure that the
25 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, 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 con-

1 tent of the minimum warnings and instruc-
2 tions to be prescribed by the Administrator
3 "(ii) a requirement that manufactur-
4 ers or processors of the chemical substance
5 shall—
6 "(I) make and retain records of
7 the processes used to manufacture or
8 process, as applicable, the chemical
9 substance; or
10 "(II) monitor or conduct such
11 additional tests as are reasonably nec-
12 essary to address potential risks from
13 the manufacture, processing, distribu-
14 tion in commerce, use, or disposal, as
15 applicable, of the chemical substance,
16 subject to section 4;
17 "(iii) a restriction on the quantity of
18 the chemical substance that may be manu-
19 factured, processed, or distributed in com-
20 merce—
21 "(I) in general; or
22 "(II) for a particular use;
23 "(iv) a prohibition or other restriction
24 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

1 nonexempt commercial manufacture of a chemical
2 substance, the manufacturer shall submit to the Ad-
3 ministrator a notice of commencement that identi-
4 fies—
5 "(A) the name of the manufacturer; and
6 "(B) the initial date of nonexempt com-
7 mercial manufacture.
8 "(2) WITHDRAWAL.—A manufacturer or proc-
9 essor that has submitted a notice under subsection
10 (b), but that has not commenced nonexempt com-
11 mercial manufacture or processing of the chemical
12 substance, may withdraw the notice.
13 "(f) FURTHER EVALUATION.—The Administrator
14 may review a chemical substance under section 4A at any
15 time after the Administrator receives—
16 "(1) a notice of commencement for a chemical
17 substance under subsection (c); or
18 "(2) new information regarding the chemical
19 substance.
20 "(g) TRANSPARENCY.—Subject to section 14, the Ad-
21 ministrator shall make available to the public—
22 "(1) all notices, determinations, consent agree-
23 ments, rules, and orders of the Administrator; and
24 "(2) all information submitted or issued under
25 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)".

1 **SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINA-**
2 **TIONS.**
3 Section 6 of the Toxic Substances Control Act (15
4 U.S.C. 2605) is amended—
5 (1) by striking the section designation and
6 heading and inserting the following:
7 **"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINA-**
8 **TIONS.";**
9 (2) by redesignating subsections (e) and (f) as
10 subsections (g) and (h), respectively;
11 (3) by striking subsections (a) through (d) and
12 inserting the following:
13 "(a) IN GENERAL.—The Administrator—
14 "(1) shall conduct a safety assessment and
15 make a safety determination of each high-priority
16 substance in accordance with subsections (b) and
17 (c);
18 "(2) shall, as soon as practicable and not later
19 than 6 months after the date on which a chemical
20 substance is designated as a high-priority substance,
21 define the scope of the safety assessment and safety
22 determination to be conducted pursuant to this sec-
23 tion, including the hazards, exposures, conditions of
24 use, and potentially exposed or susceptible popu-
25 lations 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 be-

1 fore the date of enactment of the Frank R.
2 Lautenberg Chemical Safety for the 21st Cen-
3 tury Act, prior to the effective date of the poli-
4 cies and procedures required to be established
5 by the Administrator under section 3A or 4A.
6 "(B) INTEGRATION OF PRIOR POLICIES
7 AND PROCEDURES.—As policies and procedures
8 under section 3A and 4A are established, to the
9 maximum extent practicable, the Administrator
10 shall integrate the policies and procedures into
11 ongoing safety assessments and safety deter-
12 minations.
13 "(2) ACTIONS COMPLETED PRIOR TO COMPLE-
14 TION OF POLICIES AND PROCEDURES.—Nothing in
15 this Act requires the Administrator to revise or with-
16 draw a completed safety assessment, safety deter-
17 mination, or rule solely because the action was com-
18 pleted prior to the completion of a policy or proce-
19 dure established under section 3A or 4A, and the va-
20 lidity of a completed assessment, determination, or
21 rule shall not be determined based on the content of
22 such a policy or procedure.
23 "(c) SAFETY DETERMINATIONS.—
24 "(1) IN GENERAL.—Based on a review of the
25 information available to the Administrator, including

1 draft safety assessments submitted by interested
2 persons, and subject to section 18, the Adminis-
3 trator shall determine that—
4 "(A) the relevant chemical substance meets
5 the safety standard;
6 "(B) the relevant chemical substance does
7 not meet the safety standard, in which case the
8 Administrator shall, by rule under subsection
9 (d)—
10 "(i) impose restrictions necessary to
11 ensure that the chemical substance meets
12 the safety standard under the intended or
13 reasonably anticipated conditions of use; or
14 "(ii) if the safety standard cannot be
15 met with the application of restrictions,
16 ban or phase out the chemical substance,
17 as appropriate; or
18 "(C) additional information is necessary in
19 order to make a determination under subpara-
20 graph (A) or (B), in which case the Adminis-
21 trator shall take appropriate action under para-
22 graph (2).
23 "(2) ADDITIONAL INFORMATION.—If the Ad-
24 ministrator determines that additional information is
25 necessary to make a safety assessment or safety de-

1 termination for a high-priority substance, the Ad-
2 ministrator—
3 "(A) shall provide an opportunity for inter-
4 ested persons to submit the additional informa-
5 tion;
6 "(B) may promulgate a rule, enter into a
7 testing consent agreement, or issue an order
8 under section 4 to require the development of
9 the information;
10 "(C) may defer, for a reasonable period
11 consistent with the deadlines described in sub-
12 section (a), a safety assessment and safety de-
13 termination until after receipt of the informa-
14 tion; and
15 "(D) consistent with the deadlines de-
16 scribed in subsection (a), on receipt of informa-
17 tion the Administrator finds supports the safety
18 assessment and safety determination, shall
19 make a determination under paragraph (1).
20 "(3) ESTABLISHMENT OF DEADLINE.—In re-
21 questing the development or submission of informa-
22 tion under this section, the Administrator shall es-
23 tablish a deadline for the submission of the informa-
24 tion.
25 "(d) RULE.—

1 "(1) IMPLEMENTATION.—If the Administrator
2 makes a determination under subsection (c)(1)(B)
3 with respect to a chemical substance, the Adminis-
4 trator shall promulgate a rule establishing restric-
5 tions necessary to ensure that the chemical sub-
6 stance meets the safety standard.
7 "(2) SCOPE.—The rule promulgated pursuant
8 to this subsection—
9 "(A) may—
10 "(i) apply to mixtures containing the
11 chemical substance, as appropriate; and
12 "(ii) exempt replacement parts for ar-
13 ticles manufactured prior to the applicable
14 compliance deadline; and
15 "(B) shall include dates by which compli-
16 ance is mandatory, which—
17 "(i) shall be as soon as practicable;
18 and
19 "(ii) as determined by the Adminis-
20 trator, may vary for different affected per-
21 sons.
22 "(C) WORKPLACE EXPOSURES.—The Ad-
23 ministrator shall consult with the Assistant Sec-
24 retary of Labor for Occupational Safety and
25 Health before adopting any prohibition or other

1 restriction under this subsection to address
2 workplace exposures.
3 "(D) DEFINITION OF REQUIREMENT.—For
4 the purposes of this Act, the term 'requirement'
5 as used in this section does not displace com-
6 mon law.
7 "(3) RESTRICTIONS.—A restriction under para-
8 graph (1) may include, as appropriate—
9 "(A) subject to section 18, a requirement
10 that a chemical substance shall be marked with,
11 or accompanied by, clear and adequate min-
12 imum warnings and instructions with respect to
13 use, distribution in commerce, or disposal, or
14 any combination of those activities, with the
15 form and content of the minimum warnings and
16 instructions to be prescribed by the Adminis-
17 trator;
18 "(B) a requirement that manufacturers or
19 processors of the chemical substance shall—
20 "(i) make and retain records of the
21 processes used to manufacture or process
22 the chemical substance;
23 "(ii) describe and apply the relevant
24 quality control procedures followed in the

1 manufacturing or processing of the sub-
2 stance; or
3 "(iii) monitor or conduct tests that
4 are reasonably necessary to ensure compli-
5 ance with the requirements of any rule
6 under this subsection;
7 "(C) a restriction on the quantity of the
8 chemical substance that may be manufactured,
9 processed, or distributed in commerce;
10 "(D) a requirement to ban or phase out, or
11 any other rule regarding, the manufacture,
12 processing, or distribution in commerce of the
13 chemical substance for—
14 "(i) a particular use;
15 "(ii) a particular use at a concentra-
16 tion in excess of a level specified by the
17 Administrator; or
18 "(iii) all uses;
19 "(E) a restriction on the quantity of the
20 chemical substance that may be manufactured,
21 processed, or distributed in commerce for—
22 "(i) a particular use; or
23 "(ii) a particular use at a concentra-
24 tion in excess of a level specified by the
25 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

1 more primary alternative regulatory actions
2 considered by the Administrator.
3 "(B) ALTERNATIVES.—As part of the
4 analysis, the Administrator shall review any 1
5 or more technically and economically feasible al-
6 ternatives to the chemical substance that the
7 Administrator determines are relevant to the
8 rulemaking.
9 "(C) PUBLIC AVAILABILITY.—In proposing
10 a rule under paragraph (1), the Administrator
11 shall make publicly available any analysis con-
12 ducted under this paragraph.
13 "(D) STATEMENT REQUIRED.—In making
14 final a rule under paragraph (1), the Adminis-
15 trator shall include a statement describing how
16 the analysis considered under subparagraph (A)
17 was taken into account.
18 "(5) EXEMPTIONS.—
19 "(A) IN GENERAL.—The Administrator
20 may exempt 1 or more uses of a chemical sub-
21 stance from any restriction in a rule promul-
22 gated under paragraph (1) if the Administrator
23 determines that—
24 "(i) the rule cannot be complied with,
25 without—

1 "(I) harming national security;
2 "(II) causing significant disrup-
3 tion in the national economy due to
4 the lack of availability of a chemical
5 substance; or
6 "(III) interfering with a critical
7 or essential use for which no tech-
8 nically and economically feasible safer
9 alternative is available, taking into
10 consideration hazard and exposure; or
11 "(ii) the use of the chemical sub-
12 stance, as compared to reasonably available
13 alternatives, provides a substantial benefit
14 to health, the environment, or public safe-
15 ty.
16 "(B) EXEMPTION ANALYSIS.—In pro-
17 posing a rule under paragraph (1) that includes
18 an exemption under this paragraph, the Admin-
19 istrator shall make publicly available any anal-
20 ysis conducted under this paragraph to assess
21 the need for the exemption.
22 "(C) STATEMENT REQUIRED.—In making
23 final a rule under paragraph (1) that includes
24 an exemption under this paragraph, the Admin-
25 istrator shall include a statement describing

1 how the analysis considered under subpara-
2 graph (B) was taken into account.
3 "(D) ANALYSIS IN CASE OF BAN OR
4 PHASE-OUT.—In determining whether an ex-
5 emption should be granted under this para-
6 graph for a chemical substance for which a ban
7 or phase-out is proposed, the Administrator
8 shall take into consideration, to the extent prac-
9 ticable based on reasonably available informa-
10 tion, the quantifiable and nonquantifiable costs
11 and benefits of the 1 or more technically and
12 economically feasible alternatives to the chem-
13 ical substance most likely to be used in place of
14 the chemical substance under the conditions of
15 use if the rule is promulgated.
16 "(E) CONDITIONS.—As part of a rule pro-
17 mulgated under paragraph (1), the Adminis-
18 trator shall include conditions in any exemption
19 established under this paragraph, including rea-
20 sonable recordkeeping, monitoring, and report-
21 ing requirements, to the extent that the Admin-
22 istrator determines the conditions are necessary
23 to protect health and the environment while
24 achieving the purposes of the exemption.
25 "(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.

1 "(II) LIMITATION.—Any renewal
2 of an exemption in the case of a rule
3 requiring the ban or phase-out of a
4 chemical substance shall not exceed 5
5 years.
6 "(e) IMMEDIATE EFFECT.—The Administrator may
7 declare a proposed rule under subsection (d) to be effective
8 on publication of the rule in the Federal Register and until
9 the effective date of final action taken respecting the rule,
10 if—
11 "(1) the Administrator determines that—
12 "(A) the manufacture, processing, distribu-
13 tion in commerce, use, or disposal of the chem-
14 ical substance or mixture subject to the pro-
15 posed rule or any combination of those activi-
16 ties is likely to result in an unreasonable risk
17 of serious or widespread injury to health or the
18 environment before the effective date; and
19 "(B) making the proposed rule so effective
20 is necessary to protect the public interest; and
21 "(2) in the case of a proposed rule to prohibit
22 the manufacture, processing, or distribution of a
23 chemical substance or mixture because of the risk
24 determined under paragraph (1)(A), a court has
25 granted relief in an action under section 7 with re-

1 spect to that risk associated with the chemical sub-
2 stance or mixture.
3 "(f) FINAL AGENCY ACTION.—Under this section
4 and subject to section 18—
5 "(1) a safety determination, and the associated
6 safety assessment, for a chemical substance that the
7 Administrator determines under subsection (c) meets
8 the safety standard, shall be considered to be a final
9 agency action, effective beginning on the date of
10 issuance of the final safety determination; and
11 "(2) a final rule promulgated under subsection
12 (d), and the associated safety assessment and safety
13 determination that a chemical substance does not
14 meet the safety standard, shall be considered to be
15 a final agency action, effective beginning on the date
16 of promulgation of the final rule."; and
17 (4) in subsection (g) (as redesignated by para-
18 graph (2))—
19 (A) by striking paragraph (4); and
20 (B) by redesignating paragraph (5) as
21 paragraph (4).
22 **SEC. 9. IMMINENT HAZARDS.**
23 Section 7 of the Toxic Substances Control Act (15
24 U.S.C. 2606) is amended—

1 (1) by striking subsection (a) and inserting the
2 following:
3 "(a) CIVIL ACTIONS.—
4 "(1) IN GENERAL.—The Administrator may
5 commence a civil action in an appropriate United
6 States district court for—
7 "(A) seizure of an imminently hazardous
8 chemical substance or mixture or any article
9 containing the chemical substance or mixture;
10 "(B) relief (as authorized by subsection
11 (b)) against any person that manufactures,
12 processes, distributes in commerce, uses, or dis-
13 poses of, an imminently hazardous chemical
14 substance or mixture or any article containing
15 the chemical substance or mixture; or
16 "(C) both seizure described in subpara-
17 graph (A) and relief described in subparagraph
18 (B).
19 "(2) RULE, ORDER, OR OTHER PROCEEDING.—
20 A civil action may be commenced under this para-
21 graph, notwithstanding—
22 "(A) the existence of—
23 "(i) a decision by the Administrator
24 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.—

1 "(i) IN GENERAL.—Not later than 2
2 years after the date of enactment of the
3 Frank R. Lautenberg Chemical Safety for
4 the 21st Century Act, the Administrator
5 shall promulgate rules requiring the main-
6 tenance of records and the reporting of in-
7 formation known or reasonably ascertain-
8 able by the person making the report, in-
9 cluding rules requiring processors to report
10 information, so that the Administrator has
11 the information necessary to carry out sec-
12 tions 4 and 6.
13 "(ii) MODIFICATION OF PRIOR
14 RULES.—In carrying out this subpara-
15 graph, the Administrator may modify, as
16 appropriate, rules promulgated before the
17 date of enactment of the Frank R. Lauten-
18 berg Chemical Safety for the 21st Century
19 Act.
20 "(B) CONTENTS.—The rules promulgated
21 pursuant to subparagraph (A)—
22 "(i) may impose different reporting
23 and recordkeeping requirements on manu-
24 facturers 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

1 processed for a nonexempt commercial pur-
2 pose during the 10-year period ending on
3 the day before the date of enactment of the
4 Frank R. Lautenberg Chemical Safety for
5 the 21st Century Act.
6 "(ii) ACTIVE SUBSTANCES.—The Ad-
7 ministrator shall, pursuant to paragraph
8 (5)(A), designate chemical substances for
9 which notices are received under clause (i)
10 to be active substances on the list pub-
11 lished under paragraph (1).
12 "(B) CONFIDENTIAL CHEMICAL SUB-
13 STANCES.—The rule promulgated by the Ad-
14 ministrator pursuant to subparagraph (A) shall
15 require—
16 "(i) the Administrator to maintain the
17 list under paragraph (1), which shall in-
18 clude a confidential portion and a noncon-
19 fidential portion consistent with this sec-
20 tion and section 14;
21 "(ii) a manufacturer or processor that
22 is submitting a notice pursuant to sub-
23 paragraph (A) for a chemical substance on
24 the confidential portion of the list pub-
25 lished under paragraph (1) to indicate in

1 the notice whether the manufacturer or
2 processor seeks to maintain any existing
3 claim for protection against disclosure of
4 the specific identity of the substance as
5 confidential pursuant to section 14; and
6 "(iii) the substantiation of those
7 claims pursuant to section 14 and in ac-
8 cordance with the review plan described in
9 subparagraph (C).
10 "(C) REVIEW PLAN.—Not later than 1
11 year after the date on which the Administrator
12 compiles the initial list of active substances pur-
13 suant to subparagraph (A), the Administrator
14 shall promulgate a rule that establishes a plan
15 to review all claims to protect the specific iden-
16 tities of chemical substances on the confidential
17 portion of the list published under paragraph
18 (1) that are notified pursuant to subparagraph
19 (A) or identified as active substances under
20 subsection (f)(1).
21 "(D) REQUIREMENTS OF REVIEW PLAN.—
22 The review plan under subparagraph (C)
23 shall—
24 "(i) require, at the time requested by
25 the Administrator, all manufacturers or

1 processors asserting claims under subpara-
2 graph (B) to substantiate the claim unless
3 the manufacturer or processor has sub-
4 stantiated the claim in a submission made
5 to the Administrator during the 5-year pe-
6 riod ending on the date of the request by
7 the Administrator;
8 "(ii) require the Administrator, in ac-
9 cordance with section 14—
10 "(I) to review each substan-
11 tiation—
12 "(aa) submitted pursuant to
13 clause (i) to determine if the
14 claim warrants protection from
15 disclosure; and
16 "(bb) submitted previously
17 by a manufacturer or processor
18 and relied on in lieu of the sub-
19 stantiation required pursuant to
20 clause (i), if the substantiation
21 has not been previously reviewed
22 by the Administrator, to deter-
23 mine if the claim warrants pro-
24 tection from disclosure;

1 "(II) approve, modify, or deny
2 each claim; and
3 "(III) except as provided in this
4 section and section 14, protect from
5 disclosure information for which the
6 Administrator approves such a claim
7 for a period of 10 years, unless, prior
8 to the expiration of the period—
9 "(aa) the person notifies the
10 Administrator that the person is
11 withdrawing the confidentiality
12 claim, in which case the Adminis-
13 trator shall promptly make the
14 information available to the pub-
15 lic; or
16 "(bb) the Administrator oth-
17 erwise becomes aware that the
18 need for protection from disclo-
19 sure can no longer be substan-
20 tiated, in which case the Admin-
21 istrator shall take the actions de-
22 scribed in section 14(g)(2); and
23 "(iii) encourage manufacturers or
24 processors that have previously made
25 claims to protect the specific identities of

1 chemical substances identified as inactive
2 pursuant to subsection (f)(2) to review and
3 either withdraw or substantiate the claims.
4 "(E) TIMELINE FOR COMPLETION OF RE-
5 VIEWS.—
6 "(i) IN GENERAL.—The Administrator
7 shall implement the review plan so as to
8 complete reviews of all claims specified in
9 subparagraph (C) not later than 5 years
10 after the date on which the Administrator
11 compiles the initial list of active substances
12 pursuant to subparagraph (A).
13 "(ii) CONSIDERATIONS.—
14 "(I) IN GENERAL.—The Admin-
15 istrator may extend the deadline for
16 completion of the reviews for not more
17 than 2 additional years, after an ade-
18 quate public justification, if the Ad-
19 ministrator determines that the exten-
20 sion is necessary based on the number
21 of applicable claims needing review
22 and the available resources.
23 "(II) ANNUAL GOAL.—The Ad-
24 ministrator shall publish an annual
25 goal for the number of reviews to be

1 completed over the course of imple-
2 mentation of the plan.
3 "(5) ACTIVE AND INACTIVE SUBSTANCES.—
4 "(A) IN GENERAL.—The Administrator
5 shall maintain and keep current designations of
6 active substances and inactive substances on
7 the list published under paragraph (1).
8 "(B) UPDATE.—The Administrator shall
9 update the list of chemical substances des-
10 ignated as active substances as soon as prac-
11 ticable after the date of publication of the most
12 recent data reported under—
13 "(i) part 711 of title 40, Code of Fed-
14 eral Regulations (or successor regulations);
15 and
16 "(ii) the rules promulgated pursuant
17 to subsection (a)(4).
18 "(C) CHANGE TO ACTIVE STATUS.—
19 "(i) IN GENERAL.—Any person that
20 intends to manufacture or process for a
21 nonexempt commercial purpose a chemical
22 substance that is designated as an inactive
23 substance shall notify the Administrator
24 before the date on which the inactive sub-
25 stance 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 iden-

1 tity of the chemical substance and ap-
2 prove, modify, or deny the claim;
3 "(III) except as provided in this
4 section and section 14, protect from
5 disclosure the specific identity of the
6 chemical substance for which the Ad-
7 ministrator approves a claim under
8 subclause (II) for a period of not less
9 than 10 years, unless, prior to the ex-
10 piration of the period—
11 "(aa) the person notifies the
12 Administrator that the person is
13 withdrawing the confidentiality
14 claim, in which case the Adminis-
15 trator shall promptly make the
16 information available to the pub-
17 lic; or
18 "(bb) the Administrator oth-
19 erwise becomes aware that the
20 need for protection from disclo-
21 sure can no longer be substan-
22 tiated, in which case the Admin-
23 istrator shall take the actions de-
24 scribed in section 14(g)(2); and

1 "(IV) pursuant to section 4A, re-
2 view the priority of the chemical sub-
3 stance as the Administrator deter-
4 mines to be necessary.
5 "(D) CATEGORY STATUS.—The list of in-
6 active substances shall not be considered to be
7 a category for purposes of section 26(c).
8 "(6) INTERIM LIST OF ACTIVE SUBSTANCES.—
9 Prior to the promulgation of the rule required under
10 this subsection, the Administrator shall designate
11 the chemical substances reported under part 711 of
12 title 40, Code of Federal Regulations (or successor
13 regulations), during the reporting period that most
14 closely preceded the date of enactment of the Frank
15 R. Lautenberg Chemical Safety for the 21st Century
16 Act, as the interim list of active substances for the
17 purposes of section 4A.
18 "(7) PUBLIC PARTICIPATION.—Subject to this
19 subsection, the Administrator shall make available to
20 the public—
21 "(A) the specific identity of each chemical
22 substance on the nonconfidential portion of the
23 list published under paragraph (1) that the Ad-
24 ministrator has designated as—
25 "(i) an active substance; or

1 "(ii) an inactive substance;
2 "(B) the accession number, generic name,
3 and, if applicable, premanufacture notice case
4 number for each chemical substance on the con-
5 fidential portion of the list published under
6 paragraph (1) for which a claim of confiden-
7 tiality was received and approved by the Admin-
8 istrator pursuant to section 14; and
9 "(C) subject to section 14(g), the specific
10 identity of any active substance for which—
11 "(i) no claim of protection against dis-
12 closure of the specific identity of the active
13 substance pursuant to this subsection was
14 received;
15 "(ii) a claim for protection against
16 disclosure of the specific identity of the ac-
17 tive substance has been denied by the Ad-
18 ministrator; or
19 "(iii) the time period for protection
20 against disclosure of the specific identity of
21 the active substance has expired.
22 "(8) LIMITATION.—No person may assert a
23 new claim under this subsection for protection from
24 disclosure of a specific identity of any active or inac-
25 tive chemical substance for which a notice is received

1 under paragraph (4)(A)(i) or (5)(C)(i) that is not on
2 the confidential portion of the list published under
3 paragraph (1).
4 "(9) CERTIFICATION.—Under the rule promul-
5 gated under this subsection, manufacturers and
6 processors shall be required—
7 "(A) to certify that each report the manu-
8 facturer or processor submits complies with the
9 requirements of the rule, and that any confiden-
10 tiality claims are true and correct; and
11 "(B) to retain a record supporting the cer-
12 tification for a period of 5 years beginning on
13 the last day of the submission period.";
14 (3) in subsection (e)—
15 (A) by striking "Any person" and inserting
16 the following:
17 "(1) IN GENERAL.—Any person"; and
18 (B) by adding at the end the following:
19 "(2) APPLICABILITY.—Any person may submit
20 to the Administrator information reasonably sup-
21 porting the conclusion that a chemical substance or
22 mixture presents, will present, or does not present a
23 substantial risk of injury to health and the environ-
24 ment."; 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

1 such information available to the relevant Federal agency
2 or office of the Environmental Protection Agency.".

3 **SEC. 12. RESEARCH, DEVELOPMENT, COLLECTION, DIS-**
4 **SEMINATION, AND UTILIZATION OF DATA.**

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

9 **SEC. 13. EXPORTS.**

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

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

14 "(2) EXCEPTION.—Paragraph (1) shall not
15 apply to any chemical substance that the Adminis-
16 trator determines—

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

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

21 "(3) WAIVERS.—For a mixture or article con-
22 taining a chemical substance described in paragraph
23 (2), the Administrator may—

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

1 "(B) establish a threshold concentration in
2 a mixture or article at which paragraph (1)
3 shall not apply.
4 "(4) TESTING.—The Administrator may re-
5 quire testing under section 4 of any chemical sub-
6 stance or mixture exempted from this Act under
7 paragraph (1) for the purpose of determining wheth-
8 er the chemical substance or mixture meets the safe-
9 ty standard within the United States.";
10 (2) by striking subsection (b) and inserting the
11 following:
12 "(b) NOTICE.—
13 "(1) IN GENERAL.—A person shall notify the
14 Administrator that the person is exporting or in-
15 tends to export to a foreign country—
16 "(A) a chemical substance or a mixture
17 containing a chemical substance that the Ad-
18 ministrator has determined under section 5 is
19 not likely to meet the safety standard and for
20 which a prohibition or other restriction has
21 been proposed or established under that section;
22 "(B) a chemical substance or a mixture
23 containing a chemical substance that the Ad-
24 ministrator has determined under section 6
25 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

1 a chemical substance or mixture described
2 in paragraph (1).
3 "(3) NOTIFICATION.—The Administrator shall
4 submit to the government of each country to which
5 a chemical substance or mixture is exported—
6 "(A) for a chemical substance or mixture
7 described in subparagraph (A), (B), or (D) of
8 paragraph (1), a notice of the determination,
9 rule, order, consent agreement, requirement, or
10 designation;
11 "(B) for a chemical substance described in
12 paragraph (1)(C), a notice that satisfies the ob-
13 ligation of the United States under the applica-
14 ble treaty; and
15 "(C) for a chemical substance or mixture
16 described in paragraph (1)(E), a notice of avail-
17 ability of the information on the chemical sub-
18 stance or mixture submitted to the Adminis-
19 trator."; and
20 (3) in subsection (c)—
21 (A) by striking paragraph (3); and
22 (B) by redesignating paragraphs (4)
23 through (6) as paragraphs (3) through (5), re-
24 spectively.

1 **SEC. 14. IMPORTS.**

2 Section 13 of the Toxic Substances Control Act (15
3 U.S.C. 2612) is amended to read as follows:

4 **"SEC. 13. IMPORTS.**

5 "(a) REFUSAL OF ENTRY.—

6 "(1) IN GENERAL.—The Secretary of Homeland
7 Security shall refuse entry into the customs territory
8 of the United States (as defined in general note 2
9 to the Harmonized Tariff Schedule of the United
10 States) any chemical substance, mixture, or article
11 containing a chemical substance or mixture offered
12 for such entry, if—

13 "(A) the Administrator—

14 "(i) has determined under section 6(c)
15 that the chemical substance or mixture
16 does not meet the safety standard; and

17 "(ii) has promulgated a rule pursuant
18 to section 6(d) banning the chemical sub-
19 stance or mixture, as of the effective date
20 of the rule;

21 "(B) the chemical substance—

22 "(i) is not included on the list under
23 section 8(b)(1); and

24 "(ii) is not exempt from any require-
25 ment to be included on that list by this

1 title or a rule promulgated by the Adminis-
2 trator pursuant to this title; or
3 "(C) the chemical substance, mixture, or
4 any article containing the chemical substance or
5 mixture is offered for entry in violation of—
6 "(i) a rule, consent agreement, or
7 order in effect under this Act; or
8 "(ii) an order issued in a civil action
9 brought under section 7 or title IV.
10 "(2) PROCEDURE.—
11 "(A) IN GENERAL.—Subject to subpara-
12 graph (B), if a chemical substance, mixture, or
13 article containing a chemical substance or mix-
14 ture is refused entry under paragraph (1), the
15 Secretary of Homeland Security—
16 "(i) shall notify the consignee of the
17 entry of the refusal;
18 "(ii) shall not release the chemical
19 substance or mixture to the consignee; and
20 "(iii) shall cause the disposal or stor-
21 age of the chemical substance or mixture
22 under such rules as the Secretary may pre-
23 scribe, if the chemical substance or mix-
24 ture has not been exported by the con-
25 signee during the 90-day period beginning

1 on the date of receipt of the notice of the
2 refused entry.
3 "(B) EXCEPTION.—
4 "(i) IN GENERAL.—The Secretary of
5 Homeland Security, pending a review by
6 the Administrator, may release to the con-
7 signee the chemical substance or mixture if
8 the consignee—
9 "(I) executes a bond for the
10 amount of the full invoice of the
11 chemical substance or mixture (as set
12 forth in the customs entry); and
13 "(II) pays a duty on the chemical
14 substance or mixture.
15 "(ii) ADMINISTRATION.—If a con-
16 signee fails to return a chemical substance
17 or mixture released to that consignee
18 under clause (i) for any cause to the cus-
19 tody of the Secretary of Homeland Secu-
20 rity on demand, the consignee shall be lia-
21 ble to the United States for liquidated
22 damages equal to the full amount of the
23 bond executed under clause (i)(I).
24 "(C) STORAGE.—All charges for storage,
25 cartage, and labor on or for the disposal of a

1 chemical substance or mixture that is refused
2 entry or released under this subsection shall be
3 paid by the owner or consignee, and a default
4 on that payment shall constitute a lien against
5 any future entry made by the owner or con-
6 signee.
7 "(b) CERTIFICATION.—
8 "(1) IN GENERAL.—A person offering a chem-
9 ical substance or mixture subject to this Act for
10 entry into the customs territory of the United States
11 shall certify to the Secretary of Homeland Security
12 that—
13 "(A) after reasonable inquiry and to the
14 best knowledge and belief of the person, the
15 chemical substance or mixture is in compliance
16 with any applicable rule, consent agreement, or
17 order under section 5 or 6; and
18 "(B) the chemical substance—
19 "(i) is included on the list under sec-
20 tion 8(b)(1); or
21 "(ii) is exempt from any requirement
22 to be included on that list by this title or
23 a rule promulgated by the Administrator
24 pursuant to this title.
25 "(2) ARTICLES.—

1 "(A) IN GENERAL.—The Administrator, by
2 rule, may require certification under paragraph
3 (1) for an article containing a chemical sub-
4 stance or mixture that is subject to rule under
5 section 5 or 6.
6 "(B) REQUIREMENT.—The rule under sub-
7 paragraph (A) shall identify, with reasonable
8 specificity, the types of articles, including parts
9 or components of articles, that will be subject to
10 the certification requirement.
11 "(C) FACTORS FOR CONSIDERATION.—In
12 determining the need for and content of a cer-
13 tification rule under this paragraph, the Admin-
14 istrator shall take into consideration—
15 "(i) the utility of the certification to
16 enforcement of the applicable rule, consent
17 agreement, or order under section 5 or 6;
18 "(ii) the contribution of imported arti-
19 cles to the potential risk presented by ex-
20 posure to the chemical substance or mix-
21 ture subject to rule under section 5 or 6;
22 "(iii) the impact on commerce and po-
23 tential for the certification to impede or
24 disrupt import of articles;

1 "(iv) the frequency or duration of the
2 certification requirement; and
3 "(v) specification of the concentration
4 of a chemical substance in an article that
5 would subject the article to the certifi-
6 cation requirement.
7 "(3) REASONABLE INQUIRY.—
8 "(A) IN GENERAL.—For purposes of a cer-
9 tification under paragraph (1), reasonable in-
10 quiry shall include good faith reliance by an im-
11 porter on—
12 "(i) a safety data sheet or similar dec-
13 laration provided by a supplier that docu-
14 ments the specific identity of the chemical
15 substance or the specific identities of all
16 chemical substances in a mixture; or
17 "(ii) for chemical substances or mix-
18 tures claimed by the supplier as confiden-
19 tial, or not otherwise disclosed by the sup-
20 plier, a certification by the supplier that
21 the imported chemical substance or mix-
22 ture satisfies the applicable certification re-
23 quirements under paragraph (1).
24 "(B) ARTICLES.—For purposes of a cer-
25 tification under paragraph (2), reasonable in-

1 quiry shall include good faith reliance by an im-
2 porter on a certification by the supplier that the
3 imported article satisfies the applicable certifi-
4 cation requirements in a rule promulgated pur-
5 suant to paragraph (2).
6 "(4) INFORMATION REGARDING IDENTITY.—
7 For purposes of this subsection, the Administrator
8 shall provide publicly accessible information regard-
9 ing the identity of a chemical substance or mixture
10 subject to rule under this Act that would be readily
11 understood in import transactions.
12 "(c) NOTICE.—A person offering a chemical sub-
13 stance for entry into the customs territory of the United
14 States shall notify the Secretary of Homeland Security
15 if—
16 "(1) the chemical substance or chemical sub-
17 stance in a mixture is a high-priority substance;
18 "(2) the chemical substance or chemical sub-
19 stance in a mixture is 1 for which the United States
20 is obligated to provide export notification by treaty;
21 or
22 "(3) the chemical substance or chemical sub-
23 stance 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

1 "(2) for which the requirements of subsection
2 (d) are met.
3 "(b) INFORMATION GENERALLY PROTECTED FROM
4 DISCLOSURE.—The following information specific to, and
5 submitted by, a manufacturer, processor, or distributor
6 that meets the requirements of subsections (a) and (d)
7 shall be presumed to be protected from disclosure, subject
8 to the condition that nothing in this Act prohibits the dis-
9 closure of any such information through discovery, sub-
10 poena, other court order, or any other judicial process oth-
11 erwise allowed under applicable Federal or State law:
12 "(1) Specific information describing the proc-
13 esses used in manufacture or processing of a chem-
14 ical substance, mixture, or article.
15 "(2) Marketing and sales information.
16 "(3) Information identifying a supplier or cus-
17 tomer.
18 "(4) Details of the full composition of a mixture
19 and the respective percentages of constituents.
20 "(5) Specific information regarding the use,
21 function, or application of a chemical substance or
22 mixture in a process, mixture, or product.
23 "(6) Specific production or import volumes of
24 the manufacturer and specific aggregated volumes
25 across manufacturers, if the Administrator deter-

1 mines that disclosure of the specific aggregated vol-
2 umes would reveal confidential information.
3 "(7) Except as otherwise provided in this sec-
4 tion, the specific identity of a chemical substance
5 prior to the date on which the chemical substance is
6 first offered for commercial distribution, including
7 the chemical name, molecular formula, Chemical Ab-
8 stracts Service number, and other information that
9 would identify a specific chemical substance, if—
10 "(A) the specific identity was claimed as
11 confidential information at the time it was sub-
12 mitted in a notice under section 5; and
13 "(B) the claim—
14 "(i) is not subject to an exception
15 under subsection (e); or
16 "(ii) has not subsequently been with-
17 drawn or found by the Administrator not
18 to warrant protection as confidential infor-
19 mation under subsection (f)(2) or (g).
20 "(c) INFORMATION NOT PROTECTED FROM DISCLO-
21 SURE.—Notwithstanding subsections (a) and (b), the fol-
22 lowing information shall not be protected from disclosure:
23 "(1) INFORMATION FROM HEALTH AND SAFETY
24 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).

1 "(B) A safety assessment developed, or a
2 safety determination made, under section 6.
3 "(C) Any general information describing
4 the manufacturing volumes, expressed as spe-
5 cific aggregated volumes or, if the Adminis-
6 trator determines that disclosure of specific ag-
7 gregated volumes would reveal confidential in-
8 formation, expressed in ranges.
9 "(D) A general description of a process
10 used in the manufacture or processing and in-
11 dustrial, commercial, or consumer functions and
12 uses of a chemical substance, mixture, or article
13 containing a chemical substance or mixture, in-
14 cluding information specific to an industry or
15 industry sector that customarily would be
16 shared with the general public or within an in-
17 dustry or industry sector.
18 "(4) MIXED CONFIDENTIAL AND NONCON-
19 FIDENTIAL INFORMATION .—Any information that is
20 otherwise eligible for protection under this section
21 and contained in a submission of information de-
22 scribed in this subsection shall be protected from
23 disclosure, if the submitter complies with subsection
24 (d), subject to the condition that information in the

1 submission that is not eligible for protection against
2 disclosure shall be disclosed.
3 "(5) BAN OR PHASE-OUT.—If the Adminis-
4 trator promulgates a rule pursuant to section 6(d)
5 that establishes a ban or phase-out of the manufac-
6 ture, processing, or distribution in commerce of a
7 chemical substance—
8 "(A) any protection from disclosure pro-
9 vided under this section with respect to infor-
10 mation relating to the chemical substance shall
11 no longer apply; and
12 "(B) the Administrator promptly shall
13 make the information public.
14 "(d) REQUIREMENTS FOR CONFIDENTIALITY
15 CLAIMS.—
16 "(1) ASSERTION OF CLAIMS.—
17 "(A) IN GENERAL.—A person seeking to
18 protect any information submitted under this
19 Act from disclosure (including information de-
20 scribed in subsection (b)) shall assert to the Ad-
21 ministrator a claim for protection concurrent
22 with submission of the information, in accord-
23 ance with such rules regarding a claim for pro-
24 tection from disclosure as the Administrator

1 has promulgated or may promulgate pursuant
2 to this title.
3 "(B) INCLUSION.—An assertion of a claim
4 under subparagraph (A) shall include a state-
5 ment that the person has—
6 "(i) taken reasonable measures to pro-
7 tect the confidentiality of the information;
8 "(ii) determined that the information
9 is not required to be disclosed or otherwise
10 made available to the public under any
11 other Federal law;
12 "(iii) a reasonable basis to conclude
13 that disclosure of the information is likely
14 to cause substantial harm to the competi-
15 tive position of the person; and
16 "(iv) a reasonable basis to believe that
17 the information is not readily discoverable
18 through reverse engineering.
19 "(C) SPECIFIC CHEMICAL IDENTITY.—In
20 the case of a claim under subparagraph (A) for
21 protection against disclosure of a specific chem-
22 ical identity, the claim shall include a struc-
23 turally descriptive generic name for the chem-
24 ical substance that the Administrator may dis-

1 close to the public, subject to the condition that
2 the generic name shall—
3 "(i) conform with guidance prescribed
4 by the Administrator under paragraph
5 (3)(A); and
6 "(ii) describe the chemical structure
7 of the substance as specifically as prac-
8 ticable while protecting those features of
9 the chemical structure—
10 "(I) that are considered to be
11 confidential; and
12 "(II) the disclosure of which
13 would be likely to harm the competi-
14 tive position of the person.
15 "(D) PUBLIC INFORMATION.—No person
16 may assert a claim under this section for pro-
17 tection from disclosure of information that is al-
18 ready publicly available.
19 "(2) ADDITIONAL REQUIREMENTS FOR CON-
20 FIDENTIALITY CLAIMS.—Except for information de-
21 scribed in paragraphs (1) through (7) of subsection
22 (b), a person asserting a claim to protect informa-
23 tion from disclosure under this Act shall substan-
24 tiate the claim, in accordance with the rules promul-
25 gated and guidance issued by the Administrator.

1 "(3) GUIDANCE.—The Administrator shall de-
2 velop guidance regarding—
3 "(A) the determination of structurally de-
4 scriptive generic names, in the case of claims
5 for the protection against disclosure of specific
6 chemical identity; and
7 "(B) the content and form of the state-
8 ments of need and agreements required under
9 paragraphs (4), (5), and (6) of subsection (e).
10 "(4) CERTIFICATION.—An authorized official of
11 a person described in paragraph (1)(A) shall certify
12 that the information that has been submitted is true
13 and correct.
14 "(e) EXCEPTIONS TO PROTECTION FROM DISCLO-
15 SURE.—Information described in subsection (a) shall be
16 disclosed if—
17 "(1) the information is to be disclosed to an of-
18 ficer or employee of the United States in connection
19 with the official duties of the officer or employee—
20 "(A) under any law for the protection of
21 health or the environment; or
22 "(B) for a specific law enforcement pur-
23 pose;

1 "(2) the information is to be disclosed to a con-
2 tractor of the United States and employees of that
3 contractor—
4 "(A) if, in the opinion of the Adminis-
5 trator, the disclosure is necessary for the satis-
6 factory performance by the contractor of a con-
7 tract with the United States for the perform-
8 ance of work in connection with this Act; and
9 "(B) subject to such conditions as the Ad-
10 ministrator may specify;
11 "(3) the Administrator determines that disclo-
12 sure is necessary to protect health or the environ-
13 ment;
14 "(4) the information is to be disclosed to a
15 State or political subdivision of a State, on written
16 request, for the purpose of development, administra-
17 tion, or enforcement of a law, if—
18 "(A) 1 or more applicable agreements with
19 the Administrator that conform with the guid-
20 ance issued under subsection (d)(3)(B) ensure
21 that the recipient will take appropriate meas-
22 ures, and has adequate authority, to maintain
23 the confidentiality of the information in accord-
24 ance with procedures comparable to the proce-

1 dures used by the Administrator to safeguard
2 the information; and
3 "(B) the Administrator notifies the person
4 that submitted the information that the infor-
5 mation has been disclosed to the State or polit-
6 ical subdivision of a State;
7 "(5) a health or environmental professional em-
8 ployed by a Federal or State agency or a treating
9 physician or nurse in a nonemergency situation pro-
10 vides a written statement of need and agrees to sign
11 a written confidentiality agreement with the Admin-
12 istrator, subject to the conditions that—
13 "(A) the statement of need and confiden-
14 tiality agreement shall conform with the guid-
15 ance issued under subsection (d)(3)(B);
16 "(B) the written statement of need shall be
17 a statement that the person has a reasonable
18 basis to suspect that—
19 "(i) the information is necessary for,
20 or will assist in—
21 "(I) the diagnosis or treatment of
22 1 or more individuals; or
23 "(II) responding to an environ-
24 mental release or exposure; and

1 "(ii) 1 or more individuals being diag-
2 nosed or treated have been exposed to the
3 chemical substance concerned, or an envi-
4 ronmental release or exposure has oc-
5 curred; and
6 "(C) the confidentiality agreement shall
7 provide that the person will not use the infor-
8 mation for any purpose other than the health or
9 environmental needs asserted in the statement
10 of need, except as otherwise may be authorized
11 by the terms of the agreement or by the person
12 submitting the information to the Adminis-
13 trator, except that nothing in this Act prohibits
14 the disclosure of any such information through
15 discovery, subpoena, other court order, or any
16 other judicial process otherwise allowed under
17 applicable Federal or State law;
18 "(6) in the event of an emergency, a treating
19 physician, nurse, agent of a poison control center,
20 public health or environmental official of a State or
21 political subdivision of a State, or first responder
22 (including any individual duly authorized by a Fed-
23 eral agency, State, or political subdivision of a State
24 who is trained in urgent medical care or other emer-
25 gency procedures, including a police officer, fire-

1 fighter, or emergency medical technician) requests
2 the information, subject to the conditions that—
3 "(A) the treating physician, nurse, agent,
4 public health or environmental official of a
5 State or a political subdivision of a State, or
6 first responder shall have a reasonable basis to
7 suspect that—
8 "(i) a medical or public health or en-
9 vironmental emergency exists;
10 "(ii) the information is necessary for,
11 or will assist in, emergency or first-aid di-
12 agnosis or treatment; or
13 "(iii) 1 or more individuals being di-
14 agnosed or treated have likely been ex-
15 posed to the chemical substance concerned,
16 or a serious environmental release of or ex-
17 posure to the chemical substance con-
18 cerned has occurred;
19 "(B) if requested by the person submitting
20 the information to the Administrator, the treat-
21 ing physician, nurse, agent, public health or en-
22 vironmental official of a State or a political sub-
23 division of a State, or first responder shall, as
24 described in paragraph (5)—

1 "(i) provide a written statement of
2 need; and
3 "(ii) agree to sign a confidentiality
4 agreement; and
5 "(C) the written confidentiality agreement
6 or statement of need shall be submitted as soon
7 as practicable, but not necessarily before the in-
8 formation is disclosed;
9 "(7) the Administrator determines that disclo-
10 sure is relevant in a proceeding under this Act, sub-
11 ject to the condition that the disclosure shall be
12 made in such a manner as to preserve confidentiality
13 to the maximum extent practicable without impair-
14 ing the proceeding;
15 "(8) the information is to be disclosed, on writ-
16 ten request of any duly authorized congressional
17 committee, to that committee; or
18 "(9) the information is required to be disclosed
19 or otherwise made public under any other provision
20 of Federal law.
21 "(f) DURATION OF PROTECTION FROM DISCLO-
22 SURE.—
23 "(1) IN GENERAL.—
24 "(A) INFORMATION PROTECTED FROM DIS-
25 CLOSURE.—Subject to paragraph (2), the Ad-

1 ministrator shall protect from disclosure infor-
2 mation that meets the requirements of sub-
3 section (d) for a period of 10 years, unless,
4 prior to the expiration of the period—
5 "(i) an affected person notifies the
6 Administrator that the person is with-
7 drawing the confidentiality claim, in which
8 case the Administrator shall promptly
9 make the information available to the pub-
10 lic; or
11 "(ii) the Administrator otherwise be-
12 comes aware that the need for protection
13 from disclosure can no longer be substan-
14 tiated, in which case the Administrator
15 shall take the actions described in sub-
16 section (g)(2).
17 "(B) EXTENSIONS.—
18 "(i) IN GENERAL.—Not later than the
19 date that is 60 days before the expiration
20 of the period described in subparagraph
21 (A), the Administrator shall provide to the
22 person that asserted the claim a notice of
23 the impending expiration of the period.
24 "(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.

1 "(C) NO LIMIT ON NUMBER OF EXTEN-
2 SIONS.—There shall be no limit on the number
3 of extensions granted under subparagraph (B),
4 if the Administrator determines that the rel-
5 evant statement under subparagraph
6 (B)(ii)(I)—
7 "(i) establishes the need to extend the
8 period; and
9 "(ii) meets the requirements estab-
10 lished by the Administrator.
11 "(2) REVIEW AND RESUBSTANTIATION.—
12 "(A) DISCRETION OF ADMINISTRATOR.—
13 The Administrator may review, at any time, a
14 claim for protection against disclosure under
15 subsection (a) for information submitted to the
16 Administrator regarding a chemical substance
17 and require any person that has claimed protec-
18 tion for that information, whether before, on, or
19 after the date of enactment of the Frank R.
20 Lautenberg Chemical Safety for the 21st Cen-
21 tury Act, to withdraw or reassert and substan-
22 tiate or resubstantiate the claim in accordance
23 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

1 chemical substance and require any person that
2 has claimed protection for that information,
3 whether before, on, or after the date of enact-
4 ment of the Frank R. Lautenberg Chemical
5 Safety for the 21st Century Act, to withdraw or
6 reassert and substantiate or resubstantiate the
7 claim in accordance with this section—
8 "(i) as necessary to comply with a re-
9 quest for information received by the Ad-
10 ministrator under section 552 of title 5,
11 United States Code;
12 "(ii) if information available to the
13 Administrator provides a basis that the re-
14 quirements of section 552(b)(4) of title 5,
15 United States Code, are no longer met; or
16 "(iii) for any substance for which the
17 Administrator has made a determination
18 under section 6(c)(1)(B).
19 "(C) ACTION BY RECIPIENT.—If the Ad-
20 ministrator makes a request under subpara-
21 graph (A) or (B), the recipient of the request
22 shall—
23 "(i) reassert and substantiate or re-
24 substantiate the claim; or
25 "(ii) withdraw the claim.

1 "(D) PERIOD OF PROTECTION.—Protec-
2 tion from disclosure of information subject to a
3 claim that is reviewed and approved by the Ad-
4 ministrator under this paragraph shall be ex-
5 tended for a period of 10 years from the date
6 of approval, subject to any subsequent request
7 by the Administrator under this paragraph.
8 "(3) UNIQUE IDENTIFIER.—The Administrator
9 shall—
10 "(A)(i) develop a system to assign a
11 unique identifier to each specific chemical iden-
12 tity for which the Administrator approves a re-
13 quest for protection from disclosure, other than
14 a specific chemical identity or structurally de-
15 scriptive generic term; and
16 "(ii) apply that identifier consistently to all
17 information relevant to the applicable chemical
18 substance;
19 "(B) annually publish and update a list of
20 chemical substances, referred to by unique iden-
21 tifier, for which claims to protect the specific
22 chemical identity from disclosure have been ap-
23 proved, including the expiration date for each
24 such claim;

1 "(C) ensure that any nonconfidential infor-
2 mation received by the Administrator with re-
3 spect to such a chemical substance during the
4 period of protection from disclosure—
5 "(i) is made public; and
6 "(ii) identifies the chemical substance
7 using the unique identifier; and
8 "(D) for each claim for protection of spe-
9 cific chemical identity that has been denied by
10 the Administrator on expiration of the period
11 for appeal under subsection (g)(3), that has ex-
12 pired, or that has been withdrawn by the sub-
13 mitter, provide public access to the specific
14 chemical identity clearly linked to all noncon-
15 fidential information received by the Adminis-
16 trator with respect to the chemical substance.
17 "(g) DUTIES OF ADMINISTRATOR.—
18 "(1) DETERMINATION.—
19 "(A) IN GENERAL.—Except as provided in
20 subsection (b), the Administrator shall, subject
21 to subparagraph (C), not later than 90 days
22 after the receipt of a claim under subsection
23 (d), and not later than 30 days after the receipt
24 of a request for extension of a claim under sub-

1 section (f), review and approve, modify, or deny
2 the claim or request.
3 "(B) DENIAL OR MODIFICATION.—
4 "(i) IN GENERAL.—Except as pro-
5 vided in subsections (c) and (f), the Ad-
6 ministrator shall deny a claim to protect a
7 chemical identity from disclosure only if
8 the person that has submitted the claim
9 fails to meet the requirements of sub-
10 sections (a) and (d).
11 "(ii) REASONS FOR DENIAL OR MODI-
12 FICATION.—The Administrator shall pro-
13 vide to a person that has submitted a
14 claim described in clause (i) a written
15 statement of the reasons for the denial or
16 modification of the claim.
17 "(C) SUBSETS.—The Administrator
18 shall—
19 "(i) except for claims described in
20 subsection (b)(7), review all claims under
21 this section for the protection against dis-
22 closure of the specific identity of a chem-
23 ical substance; and

1 "(ii) review a representative subset,
2 comprising at least 25 percent, of all other
3 claims for protection against disclosure.
4 "(D) EFFECT OF FAILURE TO ACT.—The
5 failure of the Administrator to make a decision
6 regarding a claim for protection against disclo-
7 sure or extension under this section shall not be
8 the basis for denial or elimination of a claim for
9 protection against disclosure.
10 "(2) NOTIFICATION.—
11 "(A) IN GENERAL.—Except as provided in
12 subparagraph (B) and subsections (c), (e), and
13 (f), if the Administrator denies or modifies a
14 claim under paragraph (1), the Administrator
15 shall notify, in writing and by certified mail, the
16 person that submitted the claim of the intent of
17 the Administrator to release the information.
18 "(B) RELEASE OF INFORMATION.—
19 "(i) IN GENERAL.—Except as pro-
20 vided in clause (ii), the Administrator shall
21 not release information under this sub-
22 section until the date that is 30 days after
23 the date on which the person that sub-
24 mitted the request receives notification
25 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

1 may bring an action to restrain disclosure of
2 the information in—
3 "(i) the United States district court of
4 the district in which the complainant re-
5 sides or has the principal place of business;
6 or
7 "(ii) the United States District Court
8 for the District of Columbia.
9 "(B) NO DISCLOSURE.—The Adminis-
10 trator shall not disclose any information that is
11 the subject of an appeal under this section be-
12 fore the date on which the applicable court
13 rules on an action under subparagraph (A).
14 "(4) ADMINISTRATION.—In carrying out this
15 subsection, the Administrator shall use the proce-
16 dures described in part 2 of title 40, Code of Fed-
17 eral Regulations (or successor regulations).
18 "(h) CRIMINAL PENALTY FOR WRONGFUL DISCLO-
19 SURE.—
20 "(1) OFFICERS AND EMPLOYEES OF UNITED
21 STATES.—
22 "(A) IN GENERAL.—Subject to paragraph
23 (2), a current or former officer or employee of
24 the United States described in subparagraph
25 (B) shall be guilty of a misdemeanor and fined

1 under title 18, United States Code, or impris-
2 oned for not more than 1 year, or both.
3 "(B) DESCRIPTION.—A current or former
4 officer or employee of the United States re-
5 ferred to in subparagraph (A) is a current or
6 former officer or employee of the United States
7 who—
8 "(i) by virtue of that employment or
9 official position has obtained possession of,
10 or has access to, material the disclosure of
11 which is prohibited by subsection (a); and
12 "(ii) knowing that disclosure of that
13 material is prohibited by subsection (a),
14 willfully discloses the material in any man-
15 ner to any person not entitled to receive
16 that material.
17 "(2) OTHER LAWS.—Section 1905 of title 18,
18 United States Code, shall not apply with respect to
19 the publishing, divulging, disclosure, making known
20 of, or making available, information reported or oth-
21 erwise obtained under this Act.
22 "(3) CONTRACTORS.—For purposes of this sub-
23 section, any contractor of the United States that is
24 provided information in accordance with subsection
25 (e)(2), including any employee of that contractor,

1 shall be considered to be an employee of the United
2 States.
3 "(i) APPLICABILITY.—
4 "(1) IN GENERAL.—Except as otherwise pro-
5 vided in this section, section 8, or any other applica-
6 ble Federal law, the Administrator shall have no au-
7 thority—
8 "(A) to require the substantiation or re-
9 substantiation of a claim for the protection
10 from disclosure of information submitted to the
11 Administrator under this Act before the date of
12 enactment of the Frank R. Lautenberg Chem-
13 ical Safety for the 21st Century Act; or
14 "(B) to impose substantiation or re-
15 substantiation requirements under this Act that
16 are more extensive than those required under
17 this section.
18 "(2) PRIOR ACTIONS.—Nothing in this Act pre-
19 vents the Administrator from reviewing, requiring
20 substantiation or resubstantiation for, or approving,
21 modifying or denying any claim for the protection
22 from disclosure of information before the effective
23 date of such rules applicable to those claims as the
24 Administrator may promulgate after the date of en-

1 actment of the Frank R. Lautenberg Chemical Safe-
2 ty for the 21st Century Act.''.

3 **SEC. 16. PROHIBITED ACTS.**

4 Section 15 of the Toxic Substances Control Act (15
5 U.S.C. 2614) is amended by striking paragraph (1) and
6 inserting the following:

7 ''(1) fail or refuse to comply with—
8 ''(A) any rule promulgated, consent agree-
9 ment entered into, or order issued under section
10 4;
11 ''(B) any requirement under section 5 or 6;
12 ''(C) any rule promulgated, consent agree-
13 ment entered into, or order issued under section
14 5 or 6; or
15 ''(D) any requirement of, or any rule pro-
16 mulgated or order issued pursuant to title II;''.

17 **SEC. 17. PENALTIES.**

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

20 (1) in subsection (a)(1)—
21 (A) in the first sentence—
22 (i) by inserting ''this Act or a rule or
23 order promulgated or issued pursuant to
24 this Act, including'' after ''a provision of'';
25 and

1 (ii) by striking "$25,000" and insert-
2 ing "$37,500"; and
3 (B) in the second sentence, by striking"
4 violation of section 15 or 409" and inserting
5 "violation of this Act"; and
6 (2) in subsection (b)—
7 (A) by striking "Any person who" and in-
8 serting the following:
9 "(1) IN GENERAL.—Any person that";
10 (B) by striking "section 15 or 409" and
11 inserting "this Act";
12 (C) by striking "$25,000" and inserting
13 "$50,000"; and
14 (D) by adding at the end the following:
15 "(2) IMMINENT DANGER OF DEATH OR SERIOUS
16 BODILY INJURY.—
17 "(A) IN GENERAL.—Any person that
18 knowingly or willfully violates any provision of
19 this Act, and that knows at the time of the vio-
20 lation that the violation places an individual in
21 imminent danger of death or serious bodily in-
22 jury, shall be subject on conviction to a fine of
23 not more than $250,000, or imprisonment for
24 not more than 15 years, or both.

1 "(B) ORGANIZATIONS.—An organization
2 that commits a violation described in subpara-
3 graph (A) shall be subject on conviction to a
4 fine of not more than $1,000,000 for each vio-
5 lation.
6 "(3) KNOWLEDGE OF IMMINENT DANGER OR
7 INJURY.—For purposes of determining whether a
8 defendant knew that the violation placed another in-
9 dividual in imminent danger of death or serious bod-
10 ily injury—
11 "(A) the defendant shall be responsible
12 only for actual awareness or actual belief pos-
13 sessed; and
14 "(B) knowledge possessed by an individual
15 may not be attributed to the defendant.".
16 **SEC. 18. STATE-FEDERAL RELATIONSHIP.**
17 Section 18 of the Toxic Substances Control Act (15
18 U.S.C. 2617) is amended by striking subsections (a) and
19 (b) and inserting the following:
20 "(a) IN GENERAL.—
21 "(1) ESTABLISHMENT OR ENFORCEMENT.—Ex-
22 cept as provided in subsections (c), (d), and (e) and
23 subject to paragraph (2), no State or political sub-
24 division of a State may establish or continue to en-
25 force 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 sub-

1 stance, consistent with the scope of the de-
2 termination made by the Administrator.
3 "(C) SIGNIFICANT NEW USE.—A statute or
4 administrative action requiring the notification
5 of a use of a chemical substance that the Ad-
6 ministrator has specified as a significant new
7 use and for which the Administrator has re-
8 quired notification pursuant to a rule promul-
9 gated under section 5.
10 "(2) EFFECTIVE DATE OF PREEMPTION.—
11 Under this subsection, Federal preemption of State
12 statutes and administrative actions applicable to spe-
13 cific substances shall not occur until the effective
14 date of the applicable action described in paragraph
15 (1) taken by the Administrator.
16 "(b) NEW STATUTES OR ADMINISTRATIVE ACTIONS
17 CREATING PROHIBITIONS OR OTHER RESTRICTIONS.—
18 Except as provided in subsections (c), (d), and (e), no
19 State or political subdivision of a State may establish
20 (after the date of enactment of the Frank R. Lautenberg
21 Chemical Safety for the 21st Century Act) a statute or
22 administrative action prohibiting or restricting the manu-
23 facture, processing, distribution in commerce or use of a
24 chemical substance that is a high-priority substance des-
25 ignated under section 4A, as of the date on which the Ad-

1 ministrator commences a safety assessment under section
2 6.
3 "(c) SCOPE OF PREEMPTION.—Federal preemption
4 under subsections (a) and (b) of State statutes and admin-
5 istrative actions applicable to specific substances shall
6 apply only to—
7 "(1) the chemical substances or category of
8 substances subject to a rule, order, or consent agree-
9 ment under section 4;
10 "(2) the uses or conditions of use of such sub-
11 stances that are identified by the Administrator as
12 subject to review in a safety assessment and in-
13 cluded in the scope of the safety determination made
14 by the Administrator for the substance, or of any
15 rule the Administrator promulgates pursuant to sec-
16 tion 6(d); or
17 "(3) the uses of such substances that the Ad-
18 ministrator has specified as significant new uses and
19 for which the Administrator has required notifica-
20 tion pursuant to a rule promulgated under section 5.
21 "(d) EXCEPTIONS.—
22 "(1) IN GENERAL.—Subsections (a) and (b)
23 shall not apply to a statute or administrative action
24 of a State or a political subdivision of a State appli-
25 cable to a specific chemical substance that—

1 "(A) is adopted under the authority of, or
2 authorized to comply with, any other Federal
3 law;
4 "(B) implements a reporting, monitoring,
5 or other information collection obligation for
6 the chemical substance not otherwise required
7 by the Administrator under this Act or required
8 under any other Federal law; or
9 "(C) is adopted pursuant to authority
10 under a law of the State or political subdivision
11 of the State related to water quality, air qual-
12 ity, or waste treatment or disposal, unless the
13 action taken by the State or political subdivi-
14 sion of a State—
15 "(i) imposes a restriction on the man-
16 ufacture, processing, distribution in com-
17 merce, or use of a chemical substance; and
18 "(ii)(I) is already required by a deci-
19 sion by the Administrator under section 5
20 or 6;
21 "(II) is taken to address a health or
22 environmental concern that applies to the
23 uses or conditions of use that are included
24 in the scope of a safety determination pur-
25 suant to section 6 or the scope of a signifi-

1 cant new use rule promulgated pursuant to
2 section 5, but is inconsistent with the ac-
3 tion of the Administrator; or
4 "(III) would cause a violation of the
5 applicable action by the Administrator
6 under section 5 or 6.
7 "(2) NO PREEMPTION OF STATE STATUTES
8 AND ADMINISTRATIVE ACTIONS.—Nothing in this
9 Act, nor any amendment made by this Act, nor any
10 rule, standard of performance, safety determination,
11 or scientific assessment implemented pursuant to
12 this Act, shall affect the right of a State or a polit-
13 ical subdivision of a State to adopt or enforce any
14 rule, standard of performance, safety determination,
15 scientific assessment, or any protection for public
16 health or the environment that—
17 "(A) is adopted under the authority of, or
18 authorized to comply with, any other Federal
19 law;
20 "(B) implements a reporting, monitoring,
21 or other information collection obligation for
22 the chemical substance not otherwise required
23 by the Administrator under this Act or required
24 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)—

1 "(A) nothing in this section shall be con-
2 strued as modifying the effect under this sec-
3 tion, as in effect on the day before the effective
4 date of the Frank R. Lautenberg Chemical
5 Safety for the 21st Century Act, of any rule or
6 order promulgated or issued under this Act
7 prior to that effective date; and
8 "(B) with respect to a chemical substance
9 or mixture for which any rule or order was pro-
10 mulgated or issued under section 6 prior to the
11 effective date of the Frank R. Lautenberg
12 Chemical Safety for the 21st Century Act with
13 regards to manufacturing, processing, distribu-
14 tion in commerce, use, or disposal of a chemical
15 substance, this section (as in effect on the day
16 before the effective date of the Frank R. Lau-
17 tenberg Chemical Safety for the 21st Century
18 Act) shall govern the preemptive effect of any
19 rule or order that is promulgated or issued re-
20 specting such chemical substance or mixture
21 under section 6 of this Act after that effective
22 date, unless the latter rule or order is with re-
23 spect to a chemical substance or mixture con-
24 taining a chemical substance and follows a des-
25 ignation of that chemical substance as a high-

1 priority substance under subsection (b) or (c) of
2 section 4A or as an additional priority for safe-
3 ty assessment and safety determination under
4 section 4A(d).
5 "(e) PRESERVATION OF CERTAIN STATE LAW.—
6 "(1) IN GENERAL.—Nothing in this Act, sub-
7 ject to subsection (f)(8) of this section, shall—
8 "(A) be construed to preempt or otherwise
9 affect any action taken before January 1, 2015,
10 under the authority of a State law that pro-
11 hibits or otherwise restricts manufacturing,
12 processing, distribution in commerce, use, or
13 disposal of a chemical substance; or
14 "(B) be construed to preempt or otherwise
15 affect any action taken pursuant to a State law
16 that was in effect on August 31, 2003.
17 "(2) EFFECT OF SUBSECTION.—This sub-
18 section does not affect, modify, or alter the relation-
19 ship between State and Federal law pursuant to any
20 other Federal law.
21 "(f) STATE WAIVERS.—
22 "(1) IN GENERAL.—Upon application of a State
23 or political subdivision of a State, the Administrator
24 may—

1 "(A) by rule, exempt from subsection (a),
2 under such conditions as may be prescribed in
3 the rule, a statute or administrative action of
4 that State or political subdivision of the State
5 that relates to the effects of, or exposure to, a
6 chemical substance under the conditions of use
7 if the Administrator determines that—
8 "(i) compelling State or local condi-
9 tions warrant granting the waiver to pro-
10 tect health or the environment;
11 "(ii) compliance with the proposed re-
12 quirement of the State or political subdivi-
13 sion of the State would not unduly burden
14 interstate commerce in the manufacture,
15 processing, distribution in commerce, or
16 use of a chemical substance;
17 "(iii) compliance with the proposed re-
18 quirement of the State or political subdivi-
19 sion of the State would not cause a viola-
20 tion of any applicable Federal law, rule, or
21 order; and
22 "(iv) based on the judgment of the
23 Administrator, the proposed requirement
24 of the State or political subdivision of the
25 State is consistent with sound objective sci-

1 entific practices, the weight of the evi-
2 dence, and the best available science; or
3 "(B) exempt from subsection (b) a statute
4 or administrative action of a State or political
5 subdivision of a State that relates to the effects
6 of exposure to a chemical substance under the
7 conditions of use if the Administrator deter-
8 mines that—
9 "(i) the State has a compelling local
10 interest that warrants granting the waiver
11 to protect health or the environment;
12 "(ii) compliance with the proposed re-
13 quirement of the State will not unduly bur-
14 den interstate commerce in the manufac-
15 ture, processing, distribution in commerce,
16 or use of a chemical substance;
17 "(iii) compliance with the proposed re-
18 quirement would not cause a violation of
19 any applicable Federal law, rule, or order;
20 and
21 "(iv) the proposed requirement is
22 grounded in reasonable scientific concern.
23 "(2) APPROVAL OF A STATE WAIVER RE-
24 QUEST.—The Administrator shall grant or deny a
25 waiver application—

1 "(A) not later than 180 days after the date
2 on which an application under paragraph (1)(A)
3 is submitted; and
4 "(B) not later than 90 days after the date
5 on which an application under paragraph
6 (1)(B) is submitted.
7 "(3) NOTICE AND COMMENT.—The application
8 of a State or political subdivision of the State shall
9 be subject to public notice and comment.
10 "(4) FINAL AGENCY ACTION.—The decision of
11 the Administrator on the application of a State or
12 political subdivision of the State shall be—
13 "(A) considered to be a final agency ac-
14 tion; and
15 "(B) subject to judicial review.
16 "(5) DURATION OF WAIVERS.—A waiver grant-
17 ed under paragraph (1)(B) shall remain in effect
18 until the later of—
19 "(A) such time as the safety assessment
20 and safety determination is completed; and
21 "(B) the date on which compliance with an
22 applicable rule issued under section 6(d) is re-
23 quired.
24 "(6) JUDICIAL REVIEW OF WAIVERS.—Not later
25 than 60 days after the date on which the Adminis-

1 trator makes a determination on an application of a
2 State or political subdivision of the State under sub-
3 paragraph (A) or (B) of paragraph (1), any person
4 may file a petition for judicial review in the United
5 States Court of Appeals for the District of Columbia
6 Circuit, which shall have exclusive jurisdiction over
7 the determination.

8 "(7) JUDICIAL REVIEW OF PRIORITIZATION
9 SCREENING DECISION.—Not later than 60 days after
10 the date on which the Administrator makes a deci-
11 sion on a recommendation made under section
12 4A(b)(4) to designate a chemical substance as a low
13 priority, the Governor of a State or a State agency
14 with responsibility for protecting health and the en-
15 vironment that submitted the recommendation under
16 section 4A(a)(4)(A), as applicable, may file a peti-
17 tion for judicial review in the United States Court
18 of Appeals for the District of Columbia Circuit,
19 which shall have exclusive jurisdiction over the deter-
20 mination.

21 "(8) SAVINGS.—

22 "(A) NO PREEMPTION OF COMMON LAW
23 OR STATUTORY CAUSES OF ACTION FOR CIVIL
24 RELIEF OR CRIMINAL CONDUCT.—

1 "(i) IN GENERAL.—Nothing in this
2 Act, nor any amendment made by this Act,
3 nor any safety standard, rule, requirement,
4 standard of performance, safety determina-
5 tion, or scientific assessment implemented
6 pursuant to this Act, shall be construed to
7 preempt, displace, or supplant any state or
8 Federal common law rights or any state or
9 Federal statute creating a remedy for civil
10 relief, including those for civil damage, or
11 a penalty for a criminal conduct.
12 "(ii) CLARIFICATION OF NO PREEMP-
13 TION.—Notwithstanding any other provi-
14 sion of this Act, nothing in this Act, nor
15 any amendments made by this Act, shall
16 preempt or preclude any cause of action
17 for personal injury, wrongful death, prop-
18 erty damage, or other injury based on neg-
19 ligence, strict liability, products liability,
20 failure to warn, or any other legal theory
21 of liability under any State, maritime, or
22 Federal common law or statutory theory.
23 "(B) NO EFFECT ON PRIVATE REM-
24 EDIES.—

"(i) 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.

"(ii) 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)—

(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), 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

1 (ii) by striking clauses (ii) and (iii)
2 and the matter following clause (iii) and
3 inserting the following:
4 "(ii) the court may not review the
5 contents and adequacy of any statement of
6 basis and purpose required by section
7 553(c) of title 5, United States Code, to be
8 incorporated in the rule, except as part of
9 the rulemaking record, taken as a whole.";
10 and
11 [(B) by striking subparagraph (C).]
12 **SEC. 20. CITIZENS' PETITIONS.**
13 Section 21 of the Toxic Substances Control Act (15
14 U.S.C. 2620) is amended—
15 (1) in subsection (a), by striking "an order
16 under section 5(e) or 6(b)(2)" and inserting "an
17 order under section 4 or 5(d)"; and
18 (2) in subsection (b)—
19 (A) in paragraph (1), by striking "an
20 order under section 5(e), 6(b)(1)(A), or
21 6(b)(1)(B)" and inserting "an order under sec-
22 tion 4 or 5(d)"; and
23 (B) in paragraph (4), by striking subpara-
24 graph (B) and inserting the following:
25 "(B) DE NOVO PROCEEDING.—

1 "(i) IN GENERAL.—In an action
2 under subparagraph (A) to initiate a pro-
3 ceeding to promulgate a rule pursuant to
4 section 4, 5, 6, or 8 or an order issued
5 under section 4 or 5, the petitioner shall be
6 provided an opportunity to have the peti-
7 tion considered by the court in a de novo
8 proceeding.
9 "(ii) DEMONSTRATION.—
10 "(I) IN GENERAL.—The court in
11 a de novo proceeding under this sub-
12 paragraph shall order the Adminis-
13 trator to initiate the action requested
14 by the petitioner if the petitioner dem-
15 onstrates to the satisfaction of the
16 court by a preponderance of the evi-
17 dence that—
18 "(aa) in the case of a peti-
19 tion to initiate a proceeding for
20 the issuance of a rule or order
21 under section 4, the information
22 available to the Administrator is
23 insufficient for the Administrator
24 to perform an action described in
25 section 4, 4A, 5, or 6(d);

1 "(bb) in the case of a peti-
2 tion to issue an order under sec-
3 tion 5(d), there is a reasonable
4 basis to conclude that the chem-
5 ical substance is not likely to
6 meet the safety standard;
7 "(cc) in the case of a peti-
8 tion to initiate a proceeding for
9 the issuance of a rule under sec-
10 tion 6(d), there is a reasonable
11 basis to conclude that the chem-
12 ical substance will not meet the
13 safety standard; or
14 "(dd) in the case of a peti-
15 tion to initiate a proceeding for
16 the issuance of a rule under sec-
17 tion 8, there is a reasonable basis
18 to conclude that the rule is nec-
19 essary to protect health or the
20 environment or ensure that the
21 chemical substance meets the
22 safety standard.
23 "(II) DEFERMENT.—The court
24 in a de novo proceeding under this
25 subparagraph may permit the Admin-

1 istrator to defer initiating the action
2 requested by the petitioner until such
3 time as the court prescribes, if the
4 court finds that—
5 "(aa) the extent of the risk
6 to health or the environment al-
7 leged by the petitioner is less
8 than the extent of risks to health
9 or the environment with respect
10 to which the Administrator is
11 taking action under this Act; and
12 "(bb) there are insufficient
13 resources available to the Admin-
14 istrator to take the action re-
15 quested by the petitioner.".

16 **SEC. 21. EMPLOYMENT EFFECTS.**

17 Section 24(b)(2)(B)(ii) of the Toxic Substances Con-
18 trol Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by
19 striking "section 6(c)(3)," and inserting "the applicable
20 requirements of this Act;".

21 **SEC. 22. STUDIES.**

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

1 **SEC. 23. ADMINISTRATION.**

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

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

6 "(b) FEES.—

7 "(1) IN GENERAL.—The Administrator shall es-
8 tablish, not later than 1 year after the date of enact-
9 ment of the Frank R. Lautenberg Chemical Safety
10 for the 21st Century Act, by rule—

11 "(A) the payment of 1 or more reasonable
12 fees as a condition of submitting a notice or re-
13 questing an exemption under section 5;

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

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

20 "(ii) is required to submit a notice
21 pursuant to section 8(b)(5)(B)(i) changing
22 the status of a chemical substance from in-
23 active to active;

24 "(iii) is required to report information
25 pursuant to the rules promulgated under
26 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);

1 "(B) insofar as possible, collect the fees
2 described in paragraph (1) in advance of con-
3 ducting any fee-supported activity;
4 "(C) deposit the fees in the Fund estab-
5 lished by paragraph (4)(A); and
6 "(D) not collect excess fees or retain a sig-
7 nificant amount of unused fees.
8 "(3) AMOUNT AND ADJUSTMENT OF FEES; RE-
9 FUNDS.—In setting fees under this section, the Ad-
10 ministrator shall—
11 "(A) take into account the cost to the Ad-
12 ministrator of conducting the activities de-
13 scribed in paragraph (2);
14 "(B) prescribe lower fees for small busi-
15 ness concerns, after consultation with the Ad-
16 ministrator of the Small Business Administra-
17 tion;
18 "(C) set the fees established under para-
19 graph (1) at levels such that the fees will, in
20 aggregate, provide a sustainable source of funds
21 to defray approximately 25 percent of the costs
22 of conducting the activities identified in para-
23 graph (2)(A), not to exceed $18,000,000, not
24 including fees under subparagraph (E) of this
25 paragraph;

1 "(D) reflect an appropriate balance in the
2 assessment of fees between manufacturers and
3 processors, and allow the payment of fees by
4 consortia of manufacturers or processors;
5 "(E) for substances designated as addi-
6 tional priorities pursuant to section 4A(c), es-
7 tablish the fee at a level sufficient to defray the
8 full costs to the Administrator of conducting
9 the safety assessment and safety determination
10 under section 6;
11 "(F) prior to the establishment or amend-
12 ment of any fees under paragraph (1), consult
13 and meet with parties potentially subject to the
14 fees or their representatives, subject to the con-
15 dition that no obligation under the Federal Ad-
16 visory Committee Act (5 U.S.C. App.) or sub-
17 chapter III of chapter 5 of title 5, United
18 States Code, is applicable with respect to such
19 meetings;
20 "(G) beginning with the fiscal year that is
21 3 years after the date of enactment of the
22 Frank R. Lautenberg Chemical Safety for the
23 21st Century Act, and every 3 years thereafter,
24 after consultation with parties potentially sub-
25 ject to the fees and their representatives, in-

1 crease or decrease the fees established under
2 paragraph (1) as necessary—
3 "(i) to ensure that funds deposited in
4 the Fund are sufficient to conduct the ac-
5 tivities identified in paragraph (2)(A) and
6 the full costs of safety assessments and
7 safety determinations pursuant to subpara-
8 graph (E); and
9 "(ii) to account for inflation;
10 "(H) adjust fees established under para-
11 graph (1) as necessary to vary on account of
12 differing circumstances, including reduced fees
13 or waivers in appropriate circumstances, to re-
14 duce the burden on manufacturing or proc-
15 essing, remove barriers to innovation, or where
16 the costs to the Administrator of collecting the
17 fees exceed the fee revenue anticipated to be
18 collected; and
19 "(I) if a notice submitted under section 5
20 is refused or subsequently withdrawn, refund
21 the fee or a portion of the fee if no substantial
22 work was performed on the notice.
23 "(4) TSCA IMPLEMENTATION FUND.—
24 "(A) ESTABLISHMENT.—There is estab-
25 lished in the Treasury of the United States a

1 fund, to be known as the 'TSCA Implementa-
2 tion Fund' (referred to in this subsection as the
3 'Fund'), consisting of—
4 "(i) such amounts as are deposited in
5 the Fund under paragraph (2)(C); and
6 "(ii) any interest earned on the in-
7 vestment of amounts in the Fund; and
8 "(iii) any proceeds from the sale or
9 redemption of investments held in the
10 Fund.
11 "(B) CREDITING AND AVAILABILITY OF
12 FEES.—
13 "(i) IN GENERAL.—Fees authorized
14 under this section shall be collected and
15 available for obligation only to the extent
16 and in the amount provided in advance in
17 appropriations Acts, and shall be available
18 without fiscal year limitation.
19 "(ii) REQUIREMENTS.—Fees collected
20 under this section shall not—
21 "(I) be made available or obli-
22 gated for any purpose other than to
23 defray the costs of conducting the ac-
24 tivities identified in paragraph (2)(A);

1 "(II) otherwise be available for
2 any purpose other than implementa-
3 tion of this Act; and
4 "(III) so long as amounts in the
5 Fund remain available, be subject to
6 restrictions on expenditures applicable
7 to the Federal government as a whole.
8 "(C) UNUSED FUNDS.—Amounts in the
9 Fund not currently needed to carry out this
10 subsection shall be—
11 "(i) maintained readily available or on
12 deposit;
13 "(ii) invested in obligations of the
14 United States or guaranteed by the United
15 States; or
16 "(iii) invested in obligations, partici-
17 pations, or other instruments that are law-
18 ful investments for fiduciary, trust, or pub-
19 lic funds.
20 "(D) MINIMUM AMOUNT OF APPROPRIA-
21 TIONS.—Fees may not be assessed for a fiscal
22 year under this section unless the amount of
23 appropriations for salaries, contracts, and ex-
24 penses for the functions (as in existence in fis-
25 cal year 2015) of the Office of Pollution Pre-

1 vention and Toxics of the Environmental Pro-
2 tection Agency for the fiscal year (excluding the
3 amount of any fees appropriated for the fiscal
4 year) are equal to or greater than the amount
5 of appropriations for covered functions for fiscal
6 year 2015 (excluding the amount of any fees
7 appropriated for the fiscal year).
8 "(5) AUDITING.—
9 "(A) FINANCIAL STATEMENTS OF AGEN-
10 CIES.—For the purpose of section 3515(c) of
11 title 31, United States Code, the Fund shall be
12 considered a component of an executive agency.
13 "(B) COMPONENTS.—The annual audit re-
14 quired under sections 3515(b) and 3521 of that
15 title of the financial statements of activities
16 under this subsection shall include an analysis
17 of—
18 "(i) the fees collected under para-
19 graph (1) and disbursed;
20 "(ii) compliance with the deadlines es-
21 tablished in section 6 of this Act;
22 "(iii) the amounts budgeted, appro-
23 priated, collected from fees, and disbursed
24 to meet the requirements of sections 4, 4A,
25 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 requires the Administrator to modify or withdraw 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—

1 "(A) incentives and impediments to devel-
2 opment, manufacturing, and commercialization;
3 "(B) accomplishments;
4 "(C) best practices; and
5 "(D) costs and benefits;
6 "(5) support (including through technical as-
7 sistance, participation, financial support, or other
8 forms of support) economic, legal, and other appro-
9 priate social science research to identify barriers to
10 commercialization and methods to advance commer-
11 cialization of sustainable chemistry.
12 "(e) INTERAGENCY WORKING GROUP.—
13 "(1) ESTABLISHMENT.—Not later than 180
14 days after the date of enactment of the Frank R.
15 Lautenberg Chemical Safety for the 21st Century
16 Act, the President, in consultation with the Office of
17 Science and Technology Policy, shall establish an
18 Interagency Working Group that shall include rep-
19 resentatives from the National Science Foundation,
20 the National Institute of Standards and Technology,
21 the Department of Energy, the Environmental Pro-
22 tection Agency, the Department of Agriculture, the
23 Department of Defense, the National Institutes of
24 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

1 (including small- and medium-sized enterprises from
2 across the value chain), academia, State and tribal
3 governments, and nongovernmental organizations
4 and others who are in a position to provide exper-
5 tise.
6 "(f) AGENCY BUDGET REQUESTS.—
7 "(1) IN GENERAL.—Each Federal agency and
8 department participating in the Program shall, as
9 part of its annual request for appropriations to the
10 Office of Management and Budget, submit a report
11 to the Office of Management and Budget that—
12 "(A) identifies the activities of the agency
13 or department that contribute directly to the
14 Program; and
15 "(B) states the portion of the agency or
16 department's request for appropriations that is
17 allocated to those activities.
18 "(2) ANNUAL BUDGET REQUEST TO CON-
19 GRESS.—The President shall include in the annual
20 budget request to Congress a statement of the por-
21 tion of the annual budget request for each agency or
22 department that will be allocated to activities under-
23 taken pursuant to the Program.
24 "(g) REPORT TO CONGRESS.—

1 "(1) IN GENERAL.—Not later than 2 years
2 after the date of enactment of the Frank R. Lauten-
3 berg Chemical Safety for the 21st Century Act, the
4 Interagency Working Group shall submit a report to
5 the Committee on Science, Space, and Technology
6 and Committee on Energy and Commerce of the
7 House of Representatives and the Committee on En-
8 vironment and Public Works and the Committee on
9 Commerce, Science, and Transportation of the Sen-
10 ate that shall include—
11 "(A) a summary of federally funded sus-
12 tainable chemistry research, development, dem-
13 onstration, technology transfer, commercializa-
14 tion, education, and training activities;
15 "(B) a summary of the financial resources
16 allocated to sustainable chemistry initiatives;
17 "(C) an analysis of the progress made to-
18 ward achieving the goals and priorities of this
19 Act, and recommendations for future program
20 activities;
21 "(D) an assessment of the benefits of ex-
22 panding existing, federally-supported regional
23 innovation and manufacturing hubs to include
24 sustainable chemistry and the value of directing

1 the creation of 1 or more dedicated sustainable
2 chemistry centers of excellence or hubs; and
3 "(E) an evaluation of steps taken and fu-
4 ture strategies to avoid duplication of efforts,
5 streamline interagency coordination, facilitate
6 information sharing, and spread best practices
7 between participating agencies in the Program.
8 "(2) SUBMISSION TO GAO.—The Interagency
9 Working Group shall also submit the report de-
10 scribed in paragraph (1) to the Government Ac-
11 countability Office for consideration in future Con-
12 gressional inquiries.".

13 **SEC. 25. STATE PROGRAMS.**

14 Section 28 of the Toxic Substances Control Act (15
15 U.S.C. 2627) is amended—
16 (1) in subsection (b)(1)—
17 (A) in subparagraphs (A) through (D), by
18 striking the comma at the end of each subpara-
19 graph and inserting a semicolon; and
20 (B) in subparagraph (E), by striking ",
21 and" and inserting "; and"; and
22 (2) by striking subsections (c) and (d).

23 **SEC. 26. AUTHORIZATION OF APPROPRIATIONS.**

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

1 **SEC. 27. ANNUAL REPORT.**

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

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

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

11 **SEC. 28. EFFECTIVE DATE.**

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

14 (1) by striking "Except as provided in section
15 4(f), this" and inserting the following:
16 "(a) IN GENERAL.—This"; and

17 (2) by adding at the end the following:

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

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 5/15/2015 2:39:45 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: Joint Letter on S. 697 from NCSL and ECOS
Attachments: S697_NCSL_ECOS_Letter.pdf

FYI...

From: Melanie Condon [mailto:melanie.condon@ncsl.org]
Sent: Friday, May 15, 2015 10:37 AM
To: Black, Jonathan (Tom Udall)
Cc: Alexandra Dapolito Dunn; Susan Frederick; Carolyn Hanson
Subject: Joint Letter on S. 697 from NCSL and ECOS

Jonathan,

Please see attached for the joint NCSL/ECOS letter that was just sent to Senators Inhofe and Boxer. Please let us know if you have any questions. Thank you for your continued outreach on this issue to the states, we look forward to continuing to work with you.

Melanie Condon
Policy Specialist, Natural Resources & Infrastructure Committee
National Conference of State Legislatures
444 North Capital St. NW - Ste. 515, Washington, DC 20001
202-624-3597 (o) | 202-549-7688 (c)
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Strong States, Strong Nation

NATIONAL CONFERENCE
of STATE LEGISLATURES
The Forum for America's Ideas

ECOS

May 15, 2015

The Honorable James Inhofe
Chairman
Environment and Public Works Committee
United States Senate
205 Russell Senate Office Building
Washington D.C., 20510

The Honorable Barbara Boxer
Ranking Member
Environment and Public Works Committee
United States Senate
112 Hart Senate Office Building
Washington D.C., 20510

Dear Chairman Inhofe and Senator Boxer,

On behalf of the National Conference of State Legislatures (NCSL) and the Environmental Council of the States (ECOS), we are encouraged by the Committee's efforts towards a bipartisan compromise to reform the Toxic Substances Control Act (TSCA). We acknowledge that serious reform is needed to update this antiquated statute so that the federal government and states, as partners, have the necessary tools to better evaluate and regulate chemicals.

A reformed TSCA should shift from the current process whereby EPA has to show that there is substantial evidence of an unreasonable risk, before taking risk reduction actions, to one where manufacturers must provide adequate evidence that the chemicals they manufacturer may be used safely in commerce.

While no compromise is perfect, NCSL and ECOS support efforts by the Committee members to acknowledge and preserve state laws and regulations of harmful chemicals in the absence of federal action on toxic chemical regulation. We do, however, urge the Senate to go further, as preemption language with potentially harmful consequences still remains in the bill. States have traditionally acted more quickly to address state and regional problems than the federal government in identifying and successfully regulating toxic chemicals. We would support language that allows states to regulate a particular chemical in the absence of an EPA final determination.

NCSL and ECOS are grateful for the strides that have been taken in the latest iteration of S. 697 and feel that continued dialogue with the states is critical going forward. We appreciate modifications to Sec. 17 of the new bill that would allow states to co-enforce the federal requirements, as we have long been proponents of working together with the federal government

to administer environmental laws. We acknowledge and appreciate that language added to the bill was designed to make it easier for states to qualify for waivers than what was previously proposed; however, the waiver language remains complicated and creates uncertainty. States are willing to offer specific suggestions for streamlining.

Additionally, we approve of the language that ensures persistent and bioaccumulative chemicals are given preference when setting the initial list of high-priority chemicals.

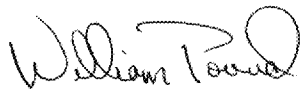
Resource Issues

We realize that many states have neither the staff nor resources to be able to sufficiently protect their citizens from harmful chemicals, so they look to the federal government for assistance, including funding for state and tribal assistance grants. NCSL and ECOS are in favor of a strong federal regulatory system for those states with limited resources, if that system is adequately funded and has the means necessary to do the job intended by the legislation. An additional concern raised by the bill is that EPA will not have the requisite funding needed to carry out its testing and enforcement responsibilities under S. 697.

Therefore, we urge the Senators to ensure that TSCA reform legislation contains an actual appropriation so that EPA has enough financial resources available to test high-priority chemicals before taking that ability away from states. Furthermore, we urge Senators to fund state grant programs, authorized under section 28 of TSCA, in recognition of the enhanced state-federal relationship. A competitive grant program will provide states with the resources to more fully partner with the EPA in regulating chemicals.

Again, NCSL and ECOS appreciate the strides taken in S. 697 thus far. We offer our assistance in drafting language changes that respect state authority as the bill moves forward. We stand ready to work with both houses of Congress to achieve meaningful TSCA reform. Please contact NCSL staff, Melanie Condon (Melanie.condon@ncsl.org) and Susan Parnas Frederick (susan.frederick@ncsl.org) and ECOS staff Carolyn Hanson (Chanson@ecos.org) with any questions.

Sincerely,



William T. Pound
Executive Director
National Conference of State Legislatures

Alexandra Dapolito Dunn
Executive Director
Environmental Council of the States

Attached:

NCSL Federal Chemical Policy Reform Policy Directive
NCSL Federalism Policy Directive
ECOS Resolution 10-8, Reforming the Toxic Substances Control Act

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 5/15/2015 2:00:26 PM
To: Vaught, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c30920bcb6214a91b7e3c1e7810c63e1-Vaught, Laura]; 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]
CC: Karakitsos, Dimitri (EPW) [Dimitri_Karakitsos@epw.senate.gov]; Deveny, Adrian (Merkley) [Adrian_Deveny@merkley.senate.gov]; Enderle, Emily (Whitehouse) [Emily_Enderle@whitehouse.senate.gov]; Zipkin, Adam (Booker) [Adam_Zipkin@booker.senate.gov]; Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: EPA T.A. Follow-up
Attachments: S. 697 as reported out 4-28-15 plus TA.DOCX; Udall-Vitter Draft P and T redline 20150211 -- February Comments.docx

Team EPA:

Dimitri and I had sat down with you to review some technical assistance on drafting and clarity/intent back before the bill was introduced.

During that time of intense negotiation, we were unable to incorporate a number of EPA T.A. suggestions because it was too frantic.

We would like to try to address as many of them as possible, now, though.

Please find attached:

1. February EPA T.A. document that **you** provided to us (showing comments and some redlines)
2. S.697 as reported out of the EPW committee, plus **NEW REDLINES** that attempt to incorporate the EPA T.A. from February.

Request:

Can you review the #2 document (S.697 as reported)?

- Please comment on the proposed fixes
  - Do they address EPA T.A. suggestions?
  - If not, can you explain why not?

None of these technical corrections have been agreed to by the cc'd parties. We will want to sit down with you and review them before doing so. We will then probably need to vet them through stakeholders.

Timing:

Please let me know how long you think it might take.

Best case scenario would be to meet and discuss Friday, May 22nd.

If that's too quick a turn-around, I will be out of town over the recess, but others may be available to meet the week of May 25th.

Purpose: In the nature of a substitute.

S. 697

To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE INTENDED TO BE PROPOSED BY _____

Viz:

Strike all after the enacting clause and insert the following:

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.—This Act, including ~~It is the intent of Congress that~~ reforms ~~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 under which the Administrator determines a chemical substance is or may be 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 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.".

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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.~~

"(a~~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.

"(b~~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 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 policies, procedures, and guidance, as appropriate and consistent with this Act~~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 Act~~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 Act~~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 carrying out ~~making any decision with respect to a chemical substance under~~ sections 4, 4A, 5, and~~or~~ 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.—In establishing ~~T~~the policies and procedures ~~established~~ under paragraph (1), the Administrator 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) consult, as appropriate, ~~require the Administrator to consult~~ with the Director of the National Institute for Occupational Safety and Health with respect ~~prior~~ to any requirements to conduct ~~prescribing~~ epidemiologic studies of employees; and

"(D) with respect to any ~~prior to making a~~ request or ~~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.

"(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.—In establishing ~~At a minimum,~~ the policies and procedures under this paragraph, the Administrator shall, at a minimum—

"(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 submitted by interested individuals or entities will be evaluated;

"(ii) require that each draft and final safety assessment and safety determination of the Administrator include a description of—

"(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 of the chemical substance, and potentially exposed and susceptible populations that the Administrator ~~expects to~~ has considered in a safety assessment; and

"(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;~~

"(II~~iii~~) ~~describe~~ the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the conditions of use were ~~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—~~

"(III) ~~a description of~~ the weight of the scientific evidence of risk; and

"(IV~~I~~) ~~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;

"(iii~~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

"(iv~~i~~) 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. 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), (e), and (g);

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(2) by redesignating subsection~~s (e) and~~ (f) as subsection~~s (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)—~~

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

~~(ii) in subparagraph (B), in the last sentence, by striking "rulemaking";~~

(3~~4~~) in subsection (g) (as so redesignated)—

(A) in the first sentence—

(i) by striking "from cancer, gene mutations, or birth defects"; and

(ii) by inserting ", without taking into account cost or other nonrisk factors" before the period at the end; and

(B) by striking the last sentence; and

(4~~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(g~~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 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.

"(5) The Administrator shall consider the recommendations of other federal agencies respecting the chemical substances and mixtures to which the Administrator should give priority consideration under this section.

"(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

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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 no ~~a~~ person has complied ~~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.

"(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.".

(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) Prioritization Screening Process ~~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~~ consider~~ation~~ 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 th~~ose~~ high-priority substances identified under section 6(b).

"(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 implementing the prioritization screening process under ~~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 implementing the prioritization screening process under ~~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 chemical ~~high-priority~~ substances not designated as a low priority.

"(III) ~~LOW-PRIORITY SUBSTANCES~~REPRIORTIZATION.—

"(aa) 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.

"(bb) If a high-priority substance is subsequently designated as a low-priority substance, the Administrator shall remove that substance from the list of high-priority substances.

Commented [Z1]: Revised based on TA to clarify.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

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

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

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

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical 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.—The Administrator shall keep current and publish and provide an opportunity for public comment on a list of chemical substances ~~that—~~

"(i) that are being considered in the prioritization screening process and the status of the chemical substances in the prioritization process~~, including those chemical substances~~

"(ii) for which prioritization decisions have been postponed pursuant to

subsection (b)(5), including the basis for such postponements~~deferred~~; and

"(iii) that 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 pursuant to ~~under~~ a rule promulgated under ~~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.—In implementing ~~T~~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~~ REASONABLY AVAILABLE INFORMATION.—The prioritization screening decision regarding a chemical substance shall ~~integrate~~ consider any hazard and exposure information relating to the chemical substance that is reasonably 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~~ POSTPONING A DECISION.—If the Administrator determines that additional information is needed ~~required~~ to establish the priority of a chemical substance under this section, the Administrator may ~~defer~~ postpone a ~~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.~~

"(~~7~~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.

"(8~~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.

"(9~~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.

"(10~~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 rule promulgated under subsection (a) ~~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 (including the criteria identified in subsection (a)(4)) that 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.—Chemical substances for which ~~R~~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 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 identified under subsection (a)(2)(B).

"(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), 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. 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";

(B) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking "subsection (h)" and inserting "paragraph (3) and subsection (h)"; and

(ii) in the matter following subparagraph (B)—

(I) by striking "subsection (d)" and inserting "subsection (c)"; and

(II) by striking "and such person complies with any applicable requirement of subsection (b)"; and

(C) by adding at the end the following:

"(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 paragraph (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.";

(6) by redesignating subsections (c) and (d) as subsections (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 (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.";

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by replacing "subsection (a)" with "subsection (b)";

(ii) by striking "or of data under subsection (b)";

(iii) in subparagraph (A), by adding "and" after the semicolon at the end;

(iv~~ii~~) 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 a~~ny 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~~ consider~~ation~~ 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 does not conform to ~~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 Administrator 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.~~

"(E~~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.";

(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 submitted under this section or made by ~~of~~ the Administrator under this section; and

"(2) all information submitted or issued under this section."; and

(10) in subsection (h)—

(A) in paragraph (1)—

(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 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 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 this subsection, including ~~paragraphs (4) and (5) and~~ 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 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, 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, 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 other 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~~ otherwise restrict ~~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, 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 restrictions included in the rule under paragraph (1) 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 ~~(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~~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 ~~technically and economically feasible~~ 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 ~~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 to the extent practicable 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~~ 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 or otherwise restrict 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).

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 title 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(c)"; 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 ~~requiring~~ processors ~~to report information~~, so that the Administrator has the information necessary to carry out this title~~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.

"(C) The requirements of this paragraph shall be subject to section 3A(e).

"(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).

"(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 ~~T~~the rule ~~promulgated~~ established ~~by the Administrator~~ pursuant to subparagraph (A), the Administrator 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) 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) requirethe 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.—Under ~~T~~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) ~~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).~~

"(B~~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 paragraph 4(A)~~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 INFORMATION~~PARTICIPATION~~.—Subject to this subsection, the ~~Administrator~~ following information shall be made ~~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) a claim for protection against disclosure of the specific identity of the active chemical substance was not asserted, as required by this subsection or section 14(d) or (f)~~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 rules promulgated under this subsection, manufacturers and processors shall be required—

"(A) to certify that each notice or substantiation ~~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~~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"; and

(iii) by striking "has reason to believe" and inserting "has a reasonable basis to conclude";

(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) by redesignating paragraph (3) as paragraph (5);

(D~~C~~) in paragraph (5~~3~~) (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) 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 does not—

"(A) respond within the time frame specified by the Administrator; or

"(B) make the determination, issue the order, or initiate action under the law (or laws) administered by such Agency to protect against the risk identified by the Administrator,

the Administrator shall initiate action under section 6(d) or 7 with respect to such risk.

"(4) This subsection shall not be construed to relieve the Administrator of any

obligation to take action under section 6(d) or 7 to address risks from the manufacture, processing, distribution in commerce, use, or disposal or a chemical substance or mixture, or any combination of such activities, that are not identified in a report issued by the Administrator under paragraph (1).”; and

(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 within the U.S.; or

“(B) under section 6 does not meet the safety standard within the U.S..

“(3) ~~WAIVERS~~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 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—

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"(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; 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), ~~or~~ (D), or (F) of paragraph (1), a notice of the determination, rule, order, consent agreement, action or relief, or 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. 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) ~~and s~~Specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

"(8~~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.—

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

"(A~~1~~) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

"(i~~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).

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

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

"(II~~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.~~

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

"(i~~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).

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

"(iii~~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.

"(iv~~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.

"(24) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is ~~otherwise~~ eligible for protection under this section and is submitted with ~~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.

"(35) 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 ~~conform with~~ guidance issued ~~prescribed~~ by the Administrator under paragraph (3)(A) of this subsection; 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 ~~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 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 ~~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 are consistent ~~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 are consistent ~~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 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).

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"(B~~A~~) INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION~~ED 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 ~~an~~ affected person that asserted the claim 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~~ information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any ~~the~~ action~~s~~ required under ~~described in~~ subsection (g)(2).

"(C~~B~~) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph (B~~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 (B~~A~~), a person reasserting the relevant claim shall submit to the Administrator a request for extension ~~statement~~ 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)~~that is 30 days after the date of receipt of a statement under subclause (I)~~, 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 ~~information~~ for which the request was submitted ~~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 or request.

"(C) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph (C~~B~~), if the Administrator determines that the request ~~relevant statement~~ under subparagraph (C~~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 of information 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 determine whether the information qualifies for an exemption from disclosure in connection with a request for information received by the Administrator ~~comply with a request for information received by the Administrator~~ under section 552 of title 5, United States Code;

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"(ii) if ~~information available to~~ the Administrator ~~provides~~ has a reasonable basis to believe that the information does not qualify for an exemption from disclosure under ~~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~~ 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 ~~D~~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.—~~If ~~T~~the Administrator denies or modifies a claim or request under subparagraph (A), the Administrator shall provide to ~~a~~ the person that ~~has~~ submitted ~~a~~ the claim or request ~~described in clause (i)~~ 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)(7), 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 or request of the intent of the Administrator to release the information.

"(B) RELEASE OF INFORMATION.—

~~"(i) IN GENERAL.—~~Except as provided in subparagraph (C)~~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).

"(C) EXCEPTIONS.—

"(i) 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 human health or the environment, in which case no prior notification shall be necessary.

"(ii) For information under paragraph (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) For information under paragraph (1), (2), (7), (9), or (10) of subsection (e), no notification shall be necessary.

"(iv) No notification shall be required for the disclosure of information for which a notice under subsection (f)(1)(C)(i) was received and for which no request was received by the Administrator on or before the date of expiration of the period for which protection from disclosure applies.

~~"(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)(3~~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, in section 8, or under 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 ~~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 A~~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,~~—~~

~~(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";~~

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

(C~~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 section 15 or 409~~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. 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 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 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 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, or 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 a State would ~~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) 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. 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), by inserting "(1)(A) Except as otherwise provided in this Chapter";

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(ii) 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 "all rules under this Chapter~~section 4(a), 5(d), 6(c), 6(d), 6(g), or 8, or title II or IV~~"; and

(iii) in subparagraph (B), by inserting "(B) Except as otherwise provided in this Chapter";

(iv) 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~~

(B~~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(b)~~(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. 19. 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 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 is needed for a

purpose identified in section 4(a)~~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. 20. 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. 21. STUDIES.

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

SEC. 22. 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~~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) take into account the cost to the Administrator of conducting the activities described in paragraph (2);~~

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

"(B~~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 (D~~E~~) of this paragraph;

"(C~~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;

"(D~~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;

"(E~~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;

"(F~~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 pursuant to subparagraph (E), 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 (D~~E~~); and

"(ii) to account for inflation;

"(G~~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

"(H~~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. 23. 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. 24. 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. 25. AUTHORIZATION OF APPROPRIATIONS.

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

SEC. 26. 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. 27. 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.".

WORKING DRAFT P February 5, 2015

WORKING DRAFT P and T February 11, 2015

Reflecting changes to the September, 2014 draft

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~~ subsection(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:~~ in subsection (c)—

(A) by designating the existing paragraph as paragraph (1);

(B) by inserting at the end of paragraph (1) as so designated, "as provided under this Act."; and

(C) by inserting at the end of paragraph (1) (as so designated), the following:

"(2~~3~~) Rreform 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—

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Commented [GB1]: Should consistently use "harm" or "injury" throughout TSCA.

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Commented [GB2]: Seems like the better verb would be "implementation". Also, even if the word is changed, this provision raises the question whether the portions of existing TSCA that are retained should not be administered to protect children, etc., and whether they displace common law rights. Eg, do section 7 actions displace common law rights?

(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 the manufacture, processing, distribution in commerce, use or disposal of chemical substances or to chemical hazards, use, or exposure (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 intended, known or reasonably foreseeable circumstances under which 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~~ or disposed of. ~~The term does not include intentional misuse for non-commercial purposes.~~";

(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.

Commented [GB3]: It's awkward that chemical hazards, etc., is already covered by the new added phrase "manufacture", etc, since hazard, use and exposure information is part of information relating to manufacture, ect. Most obviously, "use" is listed twice. Might be most straightforward to end the definition after "assessment".

Commented [GB4]: Reasonably foreseeable circumstances under which a chemical substance "is" manufactured, etc., does not really make sense.

Commented [GB5]: This could be very broad. Is any "off label" use not included, even if it's widely practiced?

"(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—

"(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.

Commented [GB6]: Why not define "policies, procedures and guidance"? That is the phrase used in this section. If this purpose of this is to limit the notice and comment obligation imposed in (b), it leaves open the question whether even insignificant policies and procedures require notice and comment.

"(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.

"(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 —

Commented [SI_7]: This is an example of a guidance that appears to create requirements – it seems to require guidance that requires use of best available science, weight of evidence, etc.

"(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 policies, procedures and guidance, as appropriate, and consistent with this Act. ~~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 carrying out~~making any decision with respect to a chemical substance under~~ sections 4, 4A, 5, ~~or~~ 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 ~~intended or reasonably anticipated~~ conditions of use that is reasonably available to the Administrator, including information that is—

"(1) submitted to the Administrator pursuant to any ~~regulation~~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 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.—In establishing t~~T~~he policies and procedures ~~established~~ under paragraph (1) the Administrator 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~~ consult, as appropriate,~~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—~~

Commented [SI_8]: Doesn't make sense – says EPA must consult NIOSH prior to requiring epi studies in establishing the policies procedures and guidance.

Commented [SI_9]: This appears to require imposition of requirements through guidance. Also, as with previous comment, this seems to impose a requirement on individual EPA actions, but the overall context here is what EPA must do in establishing the guidance.

~~"(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.

"(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 ~~regulation~~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.—In establishing ~~At a minimum,~~ the policies and procedures under this paragraph the Administrator shall, at a minimum—

"(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 submitted by interested individuals or organizations will be evaluated;

"(ii) require that each draft and final safety assessment and safety determination of the Administrator include a description of~~the Administrator—~~

"(I)(aa) ~~to identify~~ the hazards, exposures, ~~intended or reasonably anticipated~~ conditions of use of the chemical substance, and potentially exposed and susceptible populations that the Administrator has considered~~expects to consider in a safety assessment~~; and

"(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;~~

"(II~~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~~were considered, and ~~explain~~ the basis for that consideration ~~in the final safety assessment~~;

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

"(III) ~~a description of~~ the weight of the scientific evidence of risk; and

"(IV~~I~~) ~~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

"(iii~~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.

"(D) GUIDANCE.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Chemical Safety Improvement 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.

Commented [SI_10]: Why is this "Guidance" treated as separate from the "policies, procedures and guidance" required under A, rather than as a specific type of policy, procedure and guidance required? Does "guidance" here have a different meaning than it does in "policies, procedures and guidance" used elsewhere?

"(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, 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), (e) 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 "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";~~

(3~~4~~) in subsection (g) (as so designated)—

(A) in the first sentence, by striking "from cancer, gene mutations, or birth defects"; and

(B) by striking the last sentence; and

(4~~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(g~~f~~), the Administrator may require the development of ~~test data and~~ information described in paragraph (1) or (2) by—

"(A) promulgating a ~~regulation~~rule;

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

"(C) issuing an order.

"(4) CONTENTS.—

"(A) IN GENERAL.—A ~~regulation~~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

Commented [SI_11]: Would be better to add "any" before "reliable", to account for situations where there are none.

Commented [SI_12]: There remains tension in the bill as to whether the goal is to reduce all animal testing or only vertebrate animal testing.

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; and

"(iii) the recommendations of other federal agencies respecting the chemical substances and mixtures to which the Administrator should give priority consideration under this section.

Commented [SI_13]: If the idea is to require EPA to consider recommendations of other agencies re testing priority, this doesn't do it. As placed under (B), this relates to how the Administrator carries out (A), which pertains only to the content of individual test rules and orders, not to which chemicals get tested.

"(b) Statement of Need.—

"(1) IN GENERAL.—In promulgating a ~~regulation~~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 ~~regulation~~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.

Commented [SI_14]: Again, ideally should reconcile "animals" and "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~~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;

Commented [SI_15]: Vertebrate animals, consistent with the subsection heading and intro text to the paragraph? We haven't flagged every instance of this discrepancy.

"(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 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 testing for the purposes of conducting a safety assessment or safety determination under section 6.

"(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 ~~regulation~~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~~the rule, testing consent agreement or order issued under paragraph (4)(A).

"(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~~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

Commented [SI_16]: Why is (i) not subject to (3)?

Commented [SI_17]: This citation should be to 4(a)(4)(A), because otherwise it could be misconstrued as a reference to 4(d)(4)(A), since we're now in subsection 4(d).

Commented [SI_18]: This still doesn't make sense. "The period ending on the date. . ." doesn't have any beginning, so how can the manufacture commence before that period? What is actually envisioned here?

Administrator determines that ~~a person covered by the exemption has failed to comply~~no person has complied with the ~~regulation~~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 that may be 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 a purpose described in section 4(a), the Administrator may require more advanced tests for potential human health or environmental effects or exposure potential.

Commented [SI_19]: Shouldn't this say "for such purpose", linking back to 4(a), rather than adding a new description of the purposes of testing under 4(a)?

"(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.".

(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~~ Prioritization Screening Process 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 regulation~~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 ~~regulation~~ rule under paragraph (1) and not later than 180 days after the date of enactment of this section, the Administrator—

"(i) shall ~~take into~~ consider~~ation~~ and publish an initial list of high-priority substances **and low-priority substances**; and

"(ii) pursuant to section 6(b)~~(2)~~, may initiate or continue safety assessments and safety determinations for those ~~chemical~~ **high-priority** substances.

"(B) REQUIREMENTS.—The initial list of ~~high-priority~~ chemical substances shall contain at least 10 ~~chemical~~ **high-priority substances and at least 10 low-priority** substances.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In ~~carrying out~~implementing the prioritization screening process under paragraph (1), the Administrator shall ~~take into~~ consider~~ation~~ 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~~implementing the prioritization screening process under 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.—

Commented [SI_20]: Add "by" back in

Commented [SI_21]: Does this mean that criteria established under other provision of the bill should not be explicit?

Commented [SI_22]: "May" is wrong. EPA must initiate safety assessments and determinations on high priority substances, and that is pursuant to 6(a), not 6(b).

"(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~~ chemical substances not designated as low-priority.

"(III) ~~LOW-PRIORITY SUBSTANCES~~REPRIORITIZATION.—

"(aa) 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.

"(bb) If a high-priority substance is subsequently designated as a low-priority substance, the Administrator shall remove that substance from the list of high-priority substances.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

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

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

"(II) make every effort to complete the ~~prioritization screening~~ **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 ~~regulation~~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 and provide an opportunity for public comment on a list of chemical substances ~~that—~~

"(i) that are being considered in the prioritization screening process and the status of the chemical substances in the prioritization process~~, including those chemical substances~~;

"(ii) for which prioritization decisions have been ~~deferred~~postponed pursuant to subsection (b)(5), including the basis for such postponements; and

"(iii) that 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;

"(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 pursuant to a rule promulgated under ~~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~~;

"(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.

Commented [SI_23]: This appears to suggest that existing regulation would militate in favor of a low priority designation. Is that what's intended? If so, it seems in tension with (b)(8), which seems to suggest that state regulation would militate in favor of a high priority designation. Overall, the bill is not clear which way existing regulation cuts.

"(b) Prioritization Screening Process and Decisions.—

"(1) IN GENERAL.—In implementing t~~T~~he 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~~REASONABLY AVAILABLE INFORMATION.—The prioritization screening decision regarding a chemical substance shall ~~integrate~~consider any hazard and exposure information relating to the chemical substance that is reasonably 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~~POSTPONING A DECISION.—If the Administrator determines that additional information is ~~required~~ needed to establish the priority of a chemical substance under this section, the Administrator may ~~defer~~postpone a ~~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~~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.~~

"(7~~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.

"(8~~9~~) **OTHER INFORMATION RELEVANT TO PRIORITIZATION.—**

"(A) IN GENERAL.—If, after the date of enactment of the Chemical Safety Improvement Act, a State enacts a statute or takes an administrative action to ~~restrict or~~ 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 ~~intended~~ 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 ~~or prohibition~~, 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 ~~restriction or 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 subject a State to section 15.

Commented [SI_24]: What does this mean? It's probably not a big deal, but it could suggest that states are not otherwise subject to section 15, or be taken as providing some relief to a state under section15.

"(9~~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.

~~"(10)~~**"(10~~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) Expedited Prioritization ~~Screening.—~~ **Screening Requested by States.—**

"(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~~ **a** substance be ~~identified~~ **designated under paragraph (3) or (4) of subsection (b)** as a high-priority substance or a low-priority substance, the Administrator shall make a prioritization screening decision for the ~~active~~ substance.

"(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)(7~~8~~), a recommendation by the 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.

"(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~~ postponing the~~a~~ ~~prioritization screening~~ prioritization screening decision on the chemical substance pursuant to section (b)(5); and

"(B) identify the information relied on in making that identification.

"(d) ~~Treatment.—Except as provided in section 18(e)(6)(B), an~~ **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

Commented [SI_25]: It would probably be better to require development of a separate screening process here, rather than describe it as part of the process under (a). The screening process under (a) is described as a risk-based process for identifying high and low priority chemicals, but the apparent intent of this subsection is to develop a process to identify substances for safety assessments and determinations even thought they are not high priority and do not necessarily have potential for high hazard or high exposure.

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(h) 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).

Commented [SI_26]: Would be clearer if this said: "Chemical substances for which requests have been granted under this subsection"

"(e) Treatment.—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) known or reasonably ascertainable information regarding ~~intended or reasonably anticipated~~ conditions of use and reasonably anticipated exposures.";

Commented [SI_27]: Consider adding "all" before "known", if that's the intent.

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by replacing "subsection (a)" with "subsection (b)";

(ii) by striking "or of data under subsection (b)";

(iii) in subparagraph (A), by adding "and" after the semicolon at the end;

(iv~~ii~~) in subparagraph (B), by striking "; and" and inserting a period; and

(~~i~~v) 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 a~~ny 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), 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 (4~~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 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.

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

"(i) ~~take into~~ consider~~ation~~ whether to promulgate a ~~regulation~~ 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 does not conform to~~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) 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;

"(ii) a requirement that manufacturers or~~and~~ 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 ~~regulation~~ 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 ~~appropriate~~ 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~~before adopting any prohibition or restriction under this subsection to address workplace exposures.]

"(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~~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.

"(6) ~~REGULATION~~ RESTRICTIONS PENDING DEVELOPMENT OF INFORMATION.—Subject to paragraph (4)(B), the Administrator may permit manufacture for commercial purposes of a chemical substance, or manufacture or processing of a chemical substance for a significant new use, 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 or significant new use is likely to meet the safety standard.

Commented [SI_28]: This provision seems unnecessary in light of (d)(4) and has terms (eg, "permit") that seem confusing.

"(7) COMMENCEMENT OF MANUFACTURE OR PROCESSING.—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 manufacture or processing of 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~~rules, and orders submitted under this section or made by ~~of~~ the Administrator under this section; 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";

(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

Commented [SI_29]: Note that (7) (and section 5 generally) does not bar manufacture or processing in the face of a negative safety finding unless EPA has gotten the order under (4) in place by the end of the review period.

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

~~(H) 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 (g~~h~~) and (h~~i~~), 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) 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;

"(4) shall promulgate any necessary final ~~regulation~~ rule 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)~~ this subsection, including ~~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.

Commented [SI_30]: Should be "policies, procedures and guidance", throughout the bill.

"(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~~ 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 ~~regulation~~ 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, 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~~ rule 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 other 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 ~~regulation~~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) ~~Regulation~~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 ~~regulation~~ rule establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

"(2) SCOPE.—

"(A) The ~~regulation~~ rule promulgated pursuant to this subsection—

"(i~~A~~) may—

"(I~~i~~) apply to mixtures containing the chemical substance, as appropriate; and

"(II~~ii~~) exempt replacement parts for articles manufactured prior to the applicable compliance deadline; and

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

"(I~~i~~) shall be as soon as practicable; and

"(II~~ii~~) as determined by the Administrator, may vary for different affected persons.

"(B~~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.

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

"(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~~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 ~~regulation~~ 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~~ otherwise ~~regulation~~ restrict ~~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~~otherwise restrict ~~of,~~ any method of commercial use of the chemical substance;

"(G) a requirement to ~~restrict,~~ ban, ~~or~~ phase out, or otherwise restrict ~~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 the Administrator's determination under subsection (c)(1)(B) ~~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~~ 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 ~~regulation~~ rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a ~~regulation~~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 by rule or order exempt 1 or more uses of a chemical substance from any restriction in a ~~regulation~~ rule promulgated under paragraph (1) if the Administrator determines that—

"(i) the ~~regulation~~ 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 human health, the environment, or public safety.

"(B) EXEMPTION ANALYSIS.—In proposing a ~~regulation~~ 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.

Commented [SI_31]: Although the addition of "or order" in (5)(A) partially addresses our earlier comment, (B) through (F) still create confusion. (B) through (F) apply only when EPA creates an exemption as part of the rulemaking under (1) – ie, the initial rulemaking establishing the restrictions for the chemical. They do not apply if EPA creates an exemption by order, or if EPA creates an exemption through a separate rulemaking after the rulemaking under (1) (assuming the intent is that EPA can do that). Was that the intent? It seems odd that the applicability of all these extensive analyses and limitations depends on the timing of when the exemption is created. This structure will create an argument that EPA can create exemptions only in the initial rulemaking under (1), at least when EPA acts by rule.

"(C) STATEMENT REQUIRED.—In making final a ~~regulation~~ 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 the Administrator determines to be technically and economically feasible and most likely to be used in place of the chemical substance under the ~~intended or reasonably anticipated~~ conditions of use if the ~~regulation~~ rule is promulgated.

Commented [SI_32]: The rule establishing the exemption? The rule establishing the restrictions? It's hard to follow what (D) requires.

"(E) CONDITIONS.—As part of a ~~regulation~~ 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 human health and the environment to the extent practicable while achieving the purposes of the exemption.

"(F) DURATION.—

"(i) IN GENERAL.—The Administrator shall establish, as part of a ~~regulation~~ 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 ~~regulation~~rule, may extend, modify, or eliminate an~~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.

Commented [SI_33]: We have to do this by rule even if the exemption was created by order?

"(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~~ 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 ~~regulation~~ rule under subsection (d) to be effective on publication of the ~~regulation~~ rule in the Federal Register and until the effective date of final action taken respecting the ~~regulation~~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 ~~regulation~~ rule or any combination of those activities is likely to result in ~~an unreasonable risk of~~ serious or widespread ~~injury~~ harm to health or the environment before the effective date; and

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

"(2) in the case of a proposed ~~regulation~~ rule to prohibit or otherwise restrict 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.

Commented [SI_34]: This should be dropped. The point of (2) is to specify additional requirements to make a prohibition immediately effective.

"(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~~ 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 ~~regulation~~rule.";

(4) in subsection (~~g~~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~~RULE, ORDER, OR OTHER PROCEEDING.—A civil action may be commenced under this paragraph, notwithstanding—

"(A) the existence of—

~~"(i)~~ a decision, rule, consent agreement, or order by the Administrator under sections 4, 4A, 5~~(d)(3)~~, ~~or 6(c)(1)~~ or Title IV; 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~~RULES.—

"(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~~ rules requiring the maintenance of records and the reporting of additional 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~~this title.

"(ii) MODIFICATION OF PRIOR ~~REGULATIONS~~RULES.—In carrying out this subparagraph, the Administrator may modify, as appropriate, ~~regulations~~ rules promulgated before the date of enactment of the Chemical Safety Improvement Act.

"(B) CONTENTS.—The ~~regulations~~ 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.~~; and~~

~~"(iii) shall apply only in cases in which the Administrator determines that the submission of reports would assist in the effective implementation of this Act.~~

"(C) ADMINISTRATION.—In implementing the recordkeeping and reporting 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 ~~regulations~~ 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 regulations 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) subject to section 3A(e), maintain the use of Class 2 nomenclature in use on the date of enactment of the Chemical Safety Improvement 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—

Commented [SI_35]: This text is surplussage.

Commented [SI_36]: If this is intended to give EPA authority to modify the conventions codified in the paragraph, it doesn't do that because: 1. 3A(e) gives EPA authority only to review policies and procedures developed under 3A, not to change statutory requirements in other sections; and 2. This proviso applies only to (i), not (ii) and (iii).

"(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) REGULATIONS.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, the Administrator, by ~~regulation~~rule, shall require manufacturers and processors to notify the Administrator, by not later than 180 days after the date of promulgation of the ~~regulation,~~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 Chemical Safety Improvement 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).

"(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 t~~T~~he ~~regulation~~ rule ~~promulgated by the Administrator~~established pursuant to subparagraph (A) the Administrator 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) 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 ~~regulation~~ 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.—Under t~~T~~he 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) ~~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);

Commented [SI_37]: Seems like it would be clearer to instead say: "that are asserted under subparagraph (B)".

Commented [SI_38]: Inclusion of active substances identified under (f)(1) doesn't make sense here. It appears that the intent of the Plan is to ensure review of all *pre-existing* claims. There are separate provisions in the bill to address review of new claims or claims pertaining the inactive substances that become active. (C) should presumably be limited to claims under (B).

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.

"(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~~ rule 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~~rule; 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).~~

"(B~~C~~) CHANGE TO ACTIVE STATUS.—

Commented [SI_39]: This deadline reinforces the comment on (C), above, that the plan should be limited to pre-existing claims. How can EPA meet this deadline as to claims asserted in the future in new PMN submissions?

Commented [SI_40]: 1)Per conversations, at the very least this should be changed to avoid the result that identities of new chemicals cannot be CBI (because they are not on the confidential inventory). And if the intent is to address *how* CBI claims over the link between Chem ID and other data are asserted (i.e., not by masking the Chem ID itself) this needs to be phrased differently. That would not be a restriction on what can be claimed as CBI but rather a restriction on the manner in which a CBI claim can be asserted. These comments apply wherever similar language is used in the bill.

Commented [SI_41]: This is confusing. This subsection (b) requires two rules: the A rule for active/inactive, and the C rule establishing a review plan. Which is intended?

Commented [SI_42]: This is also confusing. Neither of these rules requires reports. Was G intended to apply to the (a)(4) rule, which is in a different subsection?

"(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 disclosure of the specific identity of the inactive substance as confidential, the person shall—

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

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

"(II) LIMITATION.—The specific identity of any inactive 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.

Commented [SI_43]: Same comment as above.

"(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 ~~regulation~~

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 Chemical Safety Improvement Act, as the ~~initial~~ interim list of active substances for the purposes of section 4A.

"(7) PUBLIC ~~PARTICIPATION~~INFORMATION.—Subject to this subsection, the ~~Administrator shall make~~following information shall be made 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) except as provided in subparagraph (C), 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~~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~~ harm 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

Commented [SI_44]: The (b)(4) rule?

Commented [SI_45]: This should be stricken, since the reference here is to the previous reports under the exiting rule.

Commented [SI_46]: This suggests that something in (C) allows the withholding even of accession number, etc., for confidential chemicals.

Commented [SI_47]: Consider rewording as: "a claim for protection against disclosure of the specific identity of the active chemical substance was not asserted as required by this subsection or section 14." The issue with the current wording is that not all CBI chem. id claims will be received under this subsection; claims for new chemicals will be asserted and received under section 14.

Commented [SI_48]: This is a good example of where the un-reconciled use of "harm" and "injury" will cause problems. TSCA 8(e) (retained here as 8(e)(1)) uses "injury"; the new 8(e)(2) would use "harm".

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"; and

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

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~~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

Commented [SI_49]: Note that an active substance can never become inactive, so EPA will never to able to "reset" the inventory.

Commented [SI_50]: At a minimum, Section 6 obligations to act should be relieved, to the extent that Section 9 forbids EPA to act.

In light of Section 6 deadlines, it would also be helpful to clarify:

(1) That the option to make a referral doesn't open up until *after* the EPA makes its own safety determination.

(2) That EPA is free to proceed with the 6(d) risk management process if the other federal agency is not timely and appropriately responsive.

Commented [SI_51]: This is a very significant change to current TSCA. TSCA generally exempts exported chemicals from otherwise applicable TSCA regulations, unless the exported chemical will present unreasonable risk *in the US*. The logic of section 12 is that TSCA is designed to protect US citizens, and it requires EPA to give notice of export of chemicals of concern so that foreign governments can protect their citizens. As revised, this would regulate exported chemicals any time an adverse section 5 or section 6 finding is made for the chemical as a whole (not for the exported fraction). This could suggest that EPA must consider risks beyond the US when regulating under section 5 and 6. It also largely eliminates the effect of 12(a)(1), since almost all chemicals that are regulated and potentially subject to the 12(a)(1) exemption will fall into the class of chemicals that are subject to this 12(a)(2) exception.

"(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~~meets the safety standard 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 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 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; or

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

"(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)

Commented [SI_52]: This paragraph is surplussage given the revisions to 12(a)(2). The purpose of this test authority in TSCA is so EPA can determine whether an exported chemical will present unreasonable risk in the US. The revised 12(a)(2) would except any chemicals for which adverse safety findings have been made under section 5 or 6; those sections already contain adequate authority to require testing.

Commented [SI_53]: Per discussion, this significantly changes the logic of 12(b). Current 12(b) is designed to give notice to foreign governments of export of chemicals of concern. Under that logic, it's not clear why notice would not be given until EPA actually establishes the prohibition or other restriction.

Commented [SI_54]: Should be deleted, consistent with change to (A).

Commented [SI_55]: Same comment above.

Commented [SI_56]: There is no accounting for the new subparagraph (F).

of paragraph (1), a notice of the determination, regulation, order, consent agreement, or 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 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~~ the 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)~~ this title or a ~~regulation~~rule, consent agreement, or order in effect under this chapter~~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,

Commented [T57]: Flag for discussion. TA A155 suggests a simplification to refuse entry ti any chemical substance or mixture that violates the Act or any rule. Seems to be generally acceptable although it is not clear where TSCA explicitly bans the import of a substance not on the Inventory, which suggests (B) should be retained.

Commented [SI_58]: Agree the simplification would be cleanest, but have added specific comments in case that's not done.

Commented [SI_59]: Should add "of" before "any".

Commented [SI_60]: Mixtures are not subject to safety determations.

Commented [SI_61]: Should be deleted.

Commented [SI_62]: This should be "rule", right?

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 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—

"(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~~rule, consent agreement, or order under section 5, ~~or~~ 6, 7 or title IV; and

"(B) the chemical substance—

"(i) is included on the list under section 8(b)(1); or

"(ii) is exempt from ~~any~~the requirement to be included on that list by this title or a ~~regulation~~ rule promulgated by the Administrator pursuant to this title.

"(2) ARTICLES.—

"(A) IN GENERAL.—The Administrator, by ~~regulation~~rule, may require certification under paragraph (1) for an article containing a chemical substance or mixture that is subject to regulation under section 5 or 6.

Commented [SI_63]: Why not use the formulation used elsewhere: "rule, consent decree or order"?

"(B) REQUIREMENT.—The ~~regulation~~ 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 regulation under this paragraph, the Administrator shall take into consideration—

"(i) the utility of the certification to enforcement of the applicable regulation, 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 regulation 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 regulation 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 regulation 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) 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.

"(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~~

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

"(8~~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 (e), (f)(2), or (g).

Commented [SI_64]: 1.This is true of all claimed CBI, including all the other items in (b). Why specify this for chem. id only? 2. The inclusion of reference to (e) here is confusing, since (e) addresses whether CBI must be released, whereas this section addresses what is and is not CBI. The inclusion of (e) could be taken as saying that if EPA could hand out the information on a limited basis to people with a need-to-know under 14(e), then it furthermore can't be CBI at all, and it has to be made public to anyone who asks for it

"(c) Information Not Protected From Disclosure.—

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

"(A1) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

"(iA) 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).

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

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

"(IIii) 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.

"(B3) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

"(iA) 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).

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

"(iii~~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.

"(iv~~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.

"(2~~4~~) MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is ~~otherwise~~ eligible for protection under this section and is submitted with ~~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.

"(3~~5~~) LIMITATION.—~~Except as provided in paragraph (1)(B), T~~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.

"(4~~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) except for information protected from disclosure under subsection (b), any protection from disclosure provided under this section with respect to information relating to the chemical substance shall no longer apply;

"(B) for information protected from disclosure under subsection (b), and subject to subsection (g), the Administrator shall determine what of that information should remain protected from disclosure; and

"(C~~B~~) the Administrator promptly shall make public the information described in subparagraph (A), and the information described in subparagraph (B) that the Administrator has determined is not to be protected from disclosure~~public~~.

"(5) 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)(A)(i) that is not described in paragraph (1)(A)(ii), 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

Commented [SI_65]: This is true of all CBI; this suggests otherwise.

Commented [SI_66]: Same issues as above on this language. Plus this is not a full sentence.

Commented [SI_67]: This should probably say "subject to disclosure under this subsection". The purpose if this provision – at least in current TSCA -- is that the FOIA trade secrets protections cannot be invoked to shield information affirmatively made subject to disclosure in (c).

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~~information;

"(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~~I~~) conform with guidance prescribed by the Administrator under paragraph (3)(A) of this subsection; and

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

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

"(II~~bb~~) the disclosure of which would be likely to cause substantial harm to 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

"(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

Commented [SI_68]: Another example of where guidance is used in an apparently binding way.

Commented [SI_69]: Another example of where guidance is used in an apparently binding way.

(2) are~~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~~

Commented [SI_70]: Again, binding guidance.

~~"(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);

Commented [SI_71]: Again, binding guidance.

"(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;

"(9) the information is publicly available; or

Commented [SI_72]: We continue to think this is out of place, as it is a basis to reject a CBI claim, not a basis to disclose CBI.

"(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 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~~A~~) INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION~~ED FROM DISCLOSURE~~.—Subject to paragraph (2), the Administrator shall protect from disclosure information, other than information described in subection (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) ~~an affected~~the person that asserted the claim 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~~ information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any ~~the~~ actions ~~described in~~ required under subsection (g)(2).

"(C~~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.

Commented [SI_73]: Should be B.

"(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 request for extension ~~statement~~ substantiating, in accordance with subsection (d)(2), the need to extend the period.

Commented [SI_74]: B

"(II) ACTION BY ADMINISTRATOR.—Not later than the date of expiration of the period described in subparagraph (B)~~that is 30 days after the date of receipt of a statement under subclause (I)~~, the Administrator shall, in accordance with subsection (g)(1)(C)—

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

"(bb) make a determination regarding whether the claim ~~information~~

for which the ~~request is made~~request was submitted 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 or request.

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

"(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).~~

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection of information 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—

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

"(ii) ~~if information available to~~ if the Administrator ~~provides~~ has a reasonable a basis to believe that the information does not qualify for an exemption from disclosure under ~~requirements of~~ section 552(b)(4) of title 5, United States Code,

Commented [SI_75]: Should retain the stricken language but modified to say something like: "in connection with a request for information received by the Administrator". Otherwise, this provision will suggest that the standard for disclosure is section 552, not section 14. The point of our earlier comment re that language was not to delete reference to a FOIA request, but to drop the concept of "comply".

~~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~~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.

Commented [SI_76]: Need to insert "or" before "expired".

"(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 D~~D~~ENIAL 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.—~~TIf the Administrator denies or modifies a claim or request under subparagraph (A), the Administrator shall provide to ~~a~~the person that ~~has~~ submitted ~~a~~the claim or request ~~described in clause (i)~~ a written statement of the reasons for the denial or modification of the claim.

Commented [SI_77]: Should add "or request".

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection (b)(7), review all claims and 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), or intends to release information pursuant to subsection (e), the Administrator shall notify, in writing and by certified mail, the person that submitted the claim or request of the intent of the Administrator to release the information.

"(B) RELEASE OF INFORMATION.—

~~"(i) IN GENERAL.—~~Except as provided ~~in clause (ii)~~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) 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 human health or the environment, in which case no prior notification shall be necessary.

"(ii) For information under paragraph (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) For information under paragraph (1), (2), (7), (9), or (10) of subsection (e), no notification shall be necessary.

"(iv) No notification shall be required for the disclosure of information for which a notice under subsection (f)(1)(C)(i) was received and for which no request was received by the Administrator on or before the date of expiration of the period for which protection from disclosure applies.

~~"(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—

"(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, in section 8, or under 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~~ reported to or otherwise obtained by the Administrator under this Act before the date of enactment of the Chemical Safety Improvement Act; or

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

"(2) PRIOR-INITIATED 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 [SI_78]: To avoid confusion with the issue of pre-CSIA claims (previous paragraph), suggest the following title:

ACTION PRIOR TO PROMULGATION OF REGULATIONS

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";~~

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

(C~~D~~) by adding at the end the following:

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

"(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~~harm, 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.

"(3) KNOWLEDGE OF IMMINENT DANGER OR ~~INJURY~~HARM.—For purposes of determining whether a defendant knew that the violation placed another individual in imminent danger of death or serious bodily ~~injury~~harm—

"(A) the defendant shall be responsible only for actual awareness or actual belief possessed; and

"(B) knowledge possessed by an~~other~~ individual may not be attributed to the defendant.".

Commented [SI_79]: This should probably refer to "sections 2614 and 2689 of this Act", in conformance with the rest of section 16.

SEC. 18. ~~PREEMPTION~~ 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) and (d) **and subject to paragraphs (2) and (3)**, no State or political subdivision of a State may establish or continue to enforce [any of the following:~~[Legis. Counsel note: this phrase and the colon have been inserted here and in subsection (b) to comply with formatting conventions regarding the use below of provisions with headers.]]~~

"(A) TESTING AND INFORMATION COLLECTION.—A statute or administrative action to require ~~for~~ 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) ~~for a substance~~ found to meet the safety standard and consistent with the scope of the determination made under section 6; ~~[or]~~

"(ii) ~~for a substance~~ 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 FOR~~ **SCOPE OF** CERTAIN PREEMPTION.—Under this subsection, Federal preemption **provided under paragraph (1)(B)** of State statutes and administrative actions applicable to specific substances shall ~~be consistent with the scope of the~~ **apply only to the uses or conditions of use of such substances that are included in the scope of the safety** determination made by the Administrator ~~and~~ **for the substance, and of any rule the Administrator promulgates pursuant to section 6(d).**

"(3) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of State statutes and administrative actions applicable to specific substances shall not occur until the ~~date of the Administrator's determination that the substance meets the safety standard or until the date on which compliance with the rule issued under section 6(d) is required.~~ **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) and (d), no State or political subdivision of a State may establish (after the date of enactment of the Chemical Safety Improvement Act) **a**~~[any of the following:]~~

~~"(1) High priority.—A~~ statute or administrative action prohibiting or otherwise restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance ~~identified~~ **designated** under section 4A, as of the date on which the Administrator commences a safety assessment under section 6.

~~"(2) Low priority.—A statute or administrative action prohibiting or restricting the~~

Commented [SI_80]: Or political subdivision, consistent with (a)(1)?

Commented [SI_81]: Shouldn't this be dropped? "Conditions of use" is used throughout.

Commented [SI_82]: Or political subdivision?

Commented [SI_83]: Note that this preemption is not delimited by the scope of the conditions of use EPA may have based its prioritization decision on or is assessing. Per earlier discussions, it's not clear if that was the intent (although the current formulation might make sense, since the scope may not clear at those junctures).

~~manufacture, processing, distribution in commerce or use of a chemical substance that is a low-priority substance identified under section 4A, as of the date on which the Administrator designates the substance as a low priority.~~

"(c) Exceptions.—

"(1) ~~[IN GENERAL]. SUBSECTIONS~~ **IN GENERAL.—Subsections** (a) and (b) shall not apply to a ~~requirement, prohibition, or restriction~~ **statute or administrative action** of a State or a political subdivision of a State ~~that —[Legis. Counsel note: Generic header was added here and in paragraph (3) to ensure consistency with paragraph (2), which was given a header in client specs]~~ **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 ~~requirement~~ **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 ~~that—~~**, unless that action taken by the State or political subdivision of a State—**

~~"(i) does not impose~~**"(i) imposes** a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii) ~~is not otherwise required by or inconsistent with an~~ **(I) is already required by an action by the Administrator under section 5 or 6;**

"(II) is taken to address a human health or environmental concern that applies to the uses or conditions of use that are included in the scope of~~is taken to address the same specific human health or environmental concern as an action taken~~ the safety determination made **by the Administrator** for the substance, and any rule the Administrator promulgates pursuant to section 6(d), or the scope of a significant new use rule the Administrator promulgates pursuant to section 5, ~~under section 5 or 6 but~~ 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 regulation, ~~requirement,~~ 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 regulation, ~~requirement,~~ 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 ~~requirement~~ **obligation for the chemical substance** not otherwise required by the

Commented [SI_84]: This does not capture most federally authorized state requirements – eg, under the Clean Water Act and RCRA – because they are not authorized "to comply with" federal law.

Commented [SI_85]: Should probably be dropped.

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Commented [SI_86]: What does this mean? If a state seeks to regulate to protect water quality from a chemical that EPA has found safe, would that regulation be considered inconsistent with the EPA action? If so, then this seems likely to swallow the exception.

Commented [SI_87]: (2) seems like a slightly different version of (1). It seems like one of them should be deleted (and (2) seems like the best candidate for deletion, since the broader drafting could suggest that EPA actions under CSIA can have preemptive effect beyond that specified in 18 (a) and (b)).

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 ~~that does not impose~~**, unless the~~at~~ 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 is not otherwise required by or inconsistent with an~~ **; and**

"(ii)(I) is already required by an action by the Administrator under section 5 or 6;

"(II) is taken to address a human health or environmental concern that applies to the uses or conditions of use that are included in the scope of the safety determination~~is taken to address the same specific human health or environmental concern as an action taken~~ made **by the Administrator** for the substance, and any rule the Administrator promulgates pursuant to section 6(d), or the scope of a significant new use rule the Administrator promulgates pursuant to section 5, ~~under section 5 or 6 but~~ 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 (d)—[~~RULE OF CONSTRUCTION~~]—~~NOTHING CONSTRUCTION.—N~~

"(A) nothing in this section shall be construed as ~~requiring the Administrator to modify or withdraw, any rule or order under section 5 or 6 of this Act, or as~~ modifying the effect under ~~of~~ this section, as in effect immediately ~~enacted~~ prior to [insert the effective date of the Chemical Safety Improvement Act], of ~~on~~ any rule or order promulgated or issued under this Act prior to [insert the effective date of the Chemical Safety Improvement Act]; and

"(B) with respect to a chemical substance or mixture for which for which any rule or order was promulgated or issued under section 6 prior to [insert the effective date of the Chemical Safety Improvement Act], this section as enacted prior to [insert the effective date of the Chemical Safety Improvement 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 [insert the effective date of the Chemical Safety Improvement Act], unless such rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under section 4A(b) or (c) or as an additional priority for safety assessment and safety determination under section 4A(d).

"(d) Preservation of Certain State Law.—Nothing in this section shall be construed to preempt or otherwise affect any ~~warning requirement relating to consumer products or substances that is statute or administrative~~ **action** taken before January 1, 2015, under the authority of a State law, **that prohibits or otherwise restricts chemical manufacturing, processing, distribution in commerce,** ~~or~~ **use** or disposal of a chemical substance. This subsection does not affect the

Commented [SI_88]: Should be changed to "as in effect immediately".

Commented [T89]: Flag for discussion. It is not clear which reference to "rule or order" (line 11-12 or line 14-15) this applies to.

Commented [SI_90]: Per discussions, the reference is to the second rule or order.

Commented [SI_91]: Or political subdivision?

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relationship between state and federal law pursuant to any other federal law. established pursuant to State law that was in effect on August 31, 2003, unless a rule, consent agreement, or order is promulgated under section 6 imposing a warning requirement, which shall preempt a chemical specific State warning requirement consistent with the scope of the Administrator's determination under section 6. January 1, 2015.

"(e) State Waivers.—

"(1) IN GENERAL.—Upon application of a State or political subdivision of a State, the Administrator may provide a waiver **may—**

"(A) by rule, exempt from subsection (a) and subsection (b)(1), regarding**, 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 any**, a** chemical substance under the intended or reasonably anticipated conditions of use **if** if—

"(A)(i) the State or political subdivision of the State determines it cannot wait until the end of the period specified in the established schedule and deadline for the completion of a full safety assessment and determination established under section 3A; and

"(ii) the Administrator determines that—

"(I)**"(i)** compelling State or local conditions warrant granting the waiver to protect human health or the environment;

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

"(III)**"(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)**"(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)(i) the Administrator finds a safety assessment or determination has been unreasonably delayed; and

"(ii) the State certifies that—**"(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** intended or reasonably intended **conditions of use if the Administrator determines that—**

"(I)**"(i)** the State has a compelling local interest **that warrants granting the waiver** to protect human health or the environment;

"(II)**"(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;

Commented [SI_92]: In general, the wording of A and B should be conformed, except where there is reason for it to be different. For example, is a B waiver not granted by rule, in contrast to A?

Commented [SI_93]: (A) says "effects of, or exposure to,".

Commented [SI_94]: Or political subdivision? Scrub for this throughout Why is the wording different from (A)?

Commented [SI_95]: Would, per A?

Commented [SI_96]: No consideration of foreign commerce here, as in (A)?

~~"(III)~~**"(iii)** compliance with the proposed requirement would not cause a violation of any applicable Federal law, rule, or order; and

~~"(IV)~~**"(iv)** the proposed requirement is grounded in reasonable scientific concern~~; or~~

~~"(C)(i) the State has contracted 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 Amendments of 1997; 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 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** ~~waiver—~~

~~"(A)~~ granted under paragraph **(1)(B)**~~(1)(A) shall remain in effect unless the waiver is found to be in conflict with a completed safety assessment and determination; and~~

~~"(B) granted under [subparagraph (B) or (C) of paragraph (2)]~~ shall remain in effect until **the later of**~~—~~

"(A) such time as the safety assessment and determination is completed**; and**~~.~~

~~"(6) Judicial review.—~~**"(B) the date on which compliance with an applicable rule issued under section 6(d) is required.**

~~"(A) In general.—Not~~**"(6) JUDICIAL REVIEW.—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.

~~"(B) 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(c) to designate a chemical substance as a low priority, the Governor of a State or a State~~

Commented [SI_97]: If the intent (as we understand it) is that (b) preemption applies only so long as the substance remains high priority, so that it is replaced by (a) preemption once a positive safety determination is completed or a control rule becomes effective, then this paragraph is unnecessary – the waiver becomes moot, because the preemptive effect of (b) has terminated.

Commented [SI_98]: If this paragraph is retained and the intent here is to say the waiver remains in effect until a positive safety determination or, in case of a negative safety determination, until the effective date of the rule, this doesn't say that.

Commented [SI_99]: It would be best to incorporate waiver decisions into section 19 and delete this pargraph.

~~agency with responsibility for protecting health and the environment that submitted the recommendation, 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.~~

"(7) SAVINGS.—

"(A) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF OR CRIMINAL CONDUCT.—Nothing in this Act, nor any amendment made by this Act, nor any regulation, 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 in 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, maritime, or Federal common law or statutory theory.

"(C) NO EFFECT ON PRIVATE REMEDIES.—

"(i) 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.

"(ii) 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)~~(4)~~, 6(c), 6(d), 6(g), or 8 of this title, or title II or IV of this chapter"; 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" 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

Commented [SI_100]: This seems to say the same things several different ways, and to be internally inconsistent at points.

Commented [SI_101]: There are no rules under 5(d) or 6(c). Section 5(d) merely alludes to rules under 5(b). Section 6(c) merely alludes to rules under 4(a).

Commented [SI_102]: Not currently included: Significant new use rules under 5(b)(2); procedural rules for safety determinations under 3A(h)(2); procedural rules for prioritization under 4A(a)(1); new chemical exemption rules under 5(h); rules regarding import certification for articles under 13(b); State preemption waiver rules under 18(e); Fee rules under 26(b). Consistent with (ii), consider just referencing all rules under this title to avoid missing anything. You could add "Except as otherwise provided in this Chapter" to the beginning, to ensure that nothing unintended is swept in.

Commented [SI_103]: Per previous comment, consider adding "Except as otherwise provided in this Chapter".

Commented [SI_104]: This change probably should not be made. It is not necessitated by any other changes to this section.

(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) 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

(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~~ rule 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~~ 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);

Commented [SI_105]: There are no rules under 5(d). Section 5(d) merely alludes to rules under 5(b).

Commented [SI_106]: Should be "rule".

Commented [SI_107]: Delete "issued"

Commented [SI_108]: (d) should be retained.

Commented [SI_109]: This makes no sense as drafted. Could say instead: "the information is needed for a purpose identified in section 4(a)". Note that, even with this corrected formulation, this would be an expansion of current section 21 as to testing. Current section 4 is a mandatory authority once the requisite findings are made, and current section 21 requires EPA to initiate a test rule if the section 4 triggers are met. CSIA section 21 is discretionary, and it arguably would make more sense to drop section 4 from section 21 entirely.

"(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~~ 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 ~~regulation~~ rule under section 8, there is a reasonable basis to conclude that the regulation is necessary to protect human health or the environment or ensure that the chemical substance meets the safety standard. ~~from an unreasonable risk of harm to human health or the~~ environment.

Commented [SI_110]: This is not that different of a standard from what would trigger a high priority designation, and yet it could be the basis for any person to obtain a court order forcing EPA to proceed directly to the development of a 6(d) rule, skipping entirely over the prioritization process and any safety determination. It is also unclear whether there would be any preemption under 18(b) under this pathway.

"(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~~ **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 Chemical Safety Improvement 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~~s~~ a notice pursuant to the rule promulgated under section 8(b)(4) identifying a chemical substance as active;

"(ii) is required to submit~~s~~ a notice pursuant to section 8(b)(5)(E)(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 designated by the Administrator as a high-priority substance pursuant to section 4A(b).

"(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 section 5(d)(1) and (3)~~c)(3)~~ and impose any~~d~~ necessary restrictions under section 5(d)(4)~~c)(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) take into account the cost to the Administrator of conducting the activities described in paragraph (2);~~

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

"(B~~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 a portion of the costs of conducting the activities identified in ~~that~~ paragraph 2(A), not to exceed [__] percent of the cost of conducting the activities described in paragraph (2)(A);

"(C~~D~~) establish appropriate criteria for manufacturers or processors that

Commented [SI_111]: This should be "or"

Commented [SI_112]: This should also refer to substances designated for safety assessments and determinations per 4A(d), since, as drafted, those substances are not high priority substances.

results in a proportionate assessment of fees;

"(D~~E~~) for substances designated as additional priorities pursuant to section 4A(d), 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;

"(E~~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, ~~shall accrue~~is applicable with respect to such meetings;

"(F~~G~~) beginning with the fiscal year that is 3 years after the date of enactment of the Chemical Safety Improvement 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 ~~and not more than reasonably necessary to defray the portion of the costs specified in subparagraph (C) of conductingto conduct~~ the activities identified in paragraph (2~~1~~)(A) and the full costs of safety assessments and determinations pursuant to subparagraph (D~~E~~); and

"(ii) to account for inflation~~; and~~

~~"(iii) to minimize, to the maximum extent practicable, shortfalls in or an accumulation of unused amounts in the Fund established by paragraph (4)(A);~~

"(G~~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

"(H~~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.

Commented [SI_113]: If intent is to have these consultations not be subject to FACA or subchapter III, should say that.

Commented [SI_114]: garbled

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"(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)~~1~~);

"(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 ~~paragraph~~ 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 ~~allocation of costs~~ associated with the conduct of the activities described in paragraph (2)(A~~1~~).

"(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 [10/15] years after the date of enactment of the Chemical Safety Improvement Act, unless otherwise reauthorized or modified by Congress."; and

(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 section requires the Administrator to modify or withdraw any ~~regulation~~rule or order promulgated or issued pursuant to this ~~section~~Act before the date of enactment of the Chemical Safety Improvement Act.".

Commented [SI_115]: This should say Act or Chapter. All this says now is that nothing in section 26 requires modification or withdrawal or rules or orders.

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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

(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

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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~~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 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: 5/7/2015 9:28:35 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: Udall Calls for Senate Vote on Bipartisan Chemical Safety Reform

From: Tom Udall Press Office
Sent: Thursday, May 07, 2015 5:22 PM
To: Tom Udall Press Office
Subject: Udall Calls for Senate Vote on Bipartisan Chemical Safety Reform

For Immediate Release
May 7, 2015
Contact: Jennifer Talhelm
202.228.6870 | news@tomudall.senate.gov | @TomUdallPress

Udall Calls for Senate Vote on Bipartisan Chemical Safety Reform

WASHINGTON – Today, during a speech on the Senate floor on his bipartisan chemical safety reform bill, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, **U.S. Senator Tom Udall** urged Majority Leader Mitch McConnell to bring the bill to a vote by the full Senate. Udall delivered the speech immediately following a press conference announcing 14 new cosponsors of the legislation, which makes the total number of senators now supporting the bill 36. Udall said the Senate needs to take advantage of growing momentum for the bipartisan proposal to overhaul our nation's broken Toxic Substances Control Act of 1976, and give the Environmental Protection Agency the authority to keep American families safe from dangerous chemicals.

VIDEO: https://youtu.be/22Pb-L4sMFU

Below are Udall's remarks as prepared for delivery:

Americans trust that when they go to the grocery store or when they are in their own homes, that the products they reach for are safe. The current system fails that trust. It fails to provide confidence in our regulatory system, and it fails to provide confidence in our consumer products. We cannot let that failure continue.

I rise today to urge support for the Frank R. Lautenberg Chemical Safety for the 21st Century Act. It is the best chance we will have – possibly for many years – to protect our kids from dangerous chemicals.

The Toxic Substances Control Act of 1976 – or TSCA – is supposed to protect American families. It doesn't. There are over 84,000 known chemicals, and hundreds of new ones every year. And how many have been regulated by EPA? Less than a half dozen.

EPA can't even regulate asbestos – a known carcinogen – since losing a court battle in 1991. So, for decades, the risks are there. The dangers are there, but there is no cop on the beat.

Some states are trying to fill the gaps by regulating a few chemicals. But my home state of New Mexico – and the vast majority of others – have no ability to test chemicals. They have no department to write regulations. Without a working federal law, they have no protection.

Even California – which probably has the greatest capacity of all the states to test and regulate – in seven years since California passed a law to regulate chemicals, it has only begun the process on three.

We have an opportunity and an obligation to reform our broken chemical safety law. That is why I and others have worked so hard to find compromise. That is why I introduced the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

I have been privileged to work with Senator Vitter on this bill. I thank him and our colleagues who have worked with us. This is a true bipartisan effort. We don't always agree, but we have one goal. Reform is overdue – 40 years overdue.

Our esteemed former colleague, the late Senator Frank Lautenberg led the way – for many years – with great determination. His bipartisan effort with Senator Vitter to reform TSCA was the last major legislation he introduced.

Two years ago, the New York Times endorsed the Lautenberg-Vitter bill. The Times said – correctly – that previous efforts at reform had gone nowhere – and the bill "deserves to be passed because it would be a significant advance over the current law."

I was honored to take over as the lead Democrat on the bill. Since then, I have listened to concerns. I reached across the aisle. I brought everyone into the room – or at least tried to. And with Senator Vitter, we have improved the bill.

Working with three of our colleagues on the Environment and Public Works Committee – Senators Whitehouse, Merkley and Booker – we made more progress. I want to thank them and Senator Vitter for coming to the table and working with us.

I also want to thank our co-sponsors – over 30 now – from both sides of the aisle. The bill is even stronger now with more protections for consumers, and a stronger role for states to play in keeping their citizens safe.

So, I want to talk for a moment about how this bill moves us forward:

First, the manufacture of a new chemical cannot begin until EPA approves it. More than 700 new chemicals come into commerce each year. Our bill gives EPA the time it needs, and keeps these chemicals out of American homes in the meantime.

Second, current TSCA has no requirement for evaluating existing chemicals. None. Our bill does and includes deadlines – even more aggressive than the EPA itself said it was ready for.

Third, we require a stronger safety standard for all chemicals to be evaluated. No longer will EPA be required to choose the "least burdensome" regulation. Its criteria will be safety, science and public health – never cost or convenience.

Fourth, our bill requires – for the first time – that EPA protect our most vulnerable populations: pregnant women, infants, the elderly, and workers from chemicals in commerce or manufacturing.

Fifth, TSCA is silent on animal welfare and testing. The Lautenberg Act minimizes animal testing and develops a strategy to do so.

Finally, we limit confidential business information protection for industry, so business can't hide information from the public.

So, let's be clear. We have a choice. We can continue with a law that has failed. We can continue to leave the American people unprotected, or we can actually make a difference.

I believe the choice is obvious. Our bill will make Americans safer – not just Americans fortunate to live in states with protections – all Americans, no matter where they live.

For those Americans in states with existing safeguards – that won't change. Those safeguards will stay in place. Any regulations in place as of August of this year will remain. And there is a role for states to play to help with the thousands of chemicals that EPA won't be able to evaluate.

But the EPA has the largest staff on chemical safety of any country in the world. They should be able to put that staff to good use. To do otherwise is wasted opportunity and continued failure.

M/M President, this has not been an easy process, but it is a necessary one.

I believe it will result in a good bill. We welcome a healthy debate. We welcome constructive amendments. At the same time, we should not lose sight of the key goal – to actually pass a bill.

I believe we can do this, and Senator Lautenberg – who was a great environmental champion – he believed we could as well.

We have a historic opportunity to create a chemical law that works and provide American families with the protections they expect and deserve. Let's work together. Let's make that happen. Let's not wait another 40 years.

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Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 10/2/2015 5:41:11 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: Press Release, FYI

NEWS FROM
The United States Senate

FOR IMMEDIATE RELEASE: **October 2, 2015**

Udall, Markey, Durbin Announce Agreement on Chemical Safety Reform Bill

Markey, Durbin to cosponsor after Senate vote, bringing total support to 60 senators

WASHINGTON — Today, as the full Senate prepares to begin debate on a historic bill to overhaul the broken Toxic Substances Control Act of 1976, **U.S. Sens. Tom Udall (D-N.M.), Edward J. Markey (D-Mass.)** and **Richard Durbin (D-Ill.)** announced they have agreed on new improvements to the bill. With the changes, Markey and Durbin have agreed to support the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which Udall wrote with U.S. Sen. David Vitter (R-La.). Their cosponsorship brings the total number of cosponsors for the bipartisan bill to 60 senators representing 38 states. Debate is expected to begin as soon as next week.

Named for the late New Jersey Sen. Frank Lautenberg, a champion for public health and the environment, the Lautenberg bill would be the first significant reform of TSCA since it was passed 39 years ago. It would — for the first time — give the Environmental Protection Agency (EPA) the authority to test and regulate chemicals according to their impact on the most vulnerable among us: children, pregnant women, the elderly and chemical workers. Markey and Durbin worked with Udall and Vitter on changes to the bill that will be added in a substitute amendment when the bill is brought up on the floor. The changes include provisions to increase funding for EPA resources through industry fees, ensure fast industry compliance with EPA regulations, and simplify the waiver process from preemption for states. The agreement also expedites action on work that EPA pursues on chemicals that are known dangers, such as asbestos.

"I'm extremely pleased to announce that Senators Markey and Durbin will support our efforts to reform the nation's broken chemical safety laws," **Udall said.** "This bill is the product of years of work, collaboration and positive input from lawmakers across the country who understand that we need a national solution to our broken chemical safety law — one that will ensure Americans in New Mexico or Illinois or Massachusetts have the same protections as those in all 50 states. The law has been broken for far too long, and as we prepare to begin debate on the Senate floor, I encourage all lawmakers to act to protect families, young children, and pregnant women from dangerous chemicals and support this bill."

"I am pleased by the positive and meaningful progress on improvements to TSCA reauthorization legislation, and I am proud we have secured changes to the bill that will ensure chemical companies comply with mandatory deadlines for safety regulations, expedite regulatory action on the most dangerous chemicals, allow states more flexibility to implement new chemical regulations and give EPA the funds it needs to do the job," **said Senator Markey, Ranking Member of the Superfund, Waste Management and Regulatory Oversight subcommittee.** "Our federal chemical law is outdated and ineffective, and this legislation is a much-needed update that will help protect

families and communities from dangerous chemicals. I thank Senator Durbin for his partnership, and Senators Udall, Vitter and Inhofe for their leadership and collegial efforts to work with us to strengthen the legislation."

"Following a Chicago Tribune series in 2012 that revealed that flame retardant chemicals added to furniture and other household goods are useless and toxic for American families, I began calling for reform of the antiquated law regulating toxic chemicals," **said Durbin.** "Today's agreement reflects a bipartisan effort to give the EPA additional resources and authority to more effectively regulate chemicals and ensure timely compliance with new laws. Further delay in reforming this broken system risks exposing more families to toxic substances and leaves the EPA with little recourse against the aggressive chemical companies that have been exploiting the lack of oversight."

Lautenberg dedicated years to crafting a bill that would finally fix TSCA. In 2012, shortly before he passed away, Lautenberg and Vitter announced a bipartisan agreement. After Lautenberg's death, Udall took up Lautenberg's efforts and strengthened the bill. Their legislation would require EPA to consider only the health and safety impacts of a chemical - never the cost or burden to manufacturers - when assessing chemicals for safety. It ensures consideration of those most vulnerable from chemicals - defined in the bill as pregnant women, infants, the elderly and chemical workers. It sets a new fee so chemical companies will bear a larger share of the cost of evaluating and regulating chemicals. And it provides certainty in the law about when states may step in if EPA does not act to regulate or ban dangerous chemicals.

Details of the agreement with Markey and Durbin:
-Increases the $18 million per year funding cap for industry TSCA Fees to $25 million per year, and creates a process to ensure sufficient resources to defray 25 percent of EPA's chemical safety program costs
-Sets a mandatory compliance deadline of four years for industry compliance with EPA regulations (and allows an extension of up to 18 months if EPA determines that the deadline is technologically or economically infeasible)
-Clarifies and simplifies the process for state waivers from preemption and state co-enforcement of federal chemical safety regulations
-Expedites regulatory action on EPA's TSCA Work Plan chemicals (the 90 chemicals EPA has identified as having the highest potential for exposure and hazard) from the seven years the bill currently allows to generally five years for these chemicals.
-Adds assurances for mandatory protections for vulnerable populations, such as pregnant women, children and workers
-Includes other improvements to the bill's provisions to ensure:
exposure to PBTs is reduced as much as practicable;
parity for judicial review of EPA actions;
EPA has to disclose the information it used to make prioritization decisions; and
improvements to provisions allowing access to CBI for medical professionals and first responders.

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Contacts: Jennifer Talhelm (Udall) 202.228.6870 / Giselle Barry (Markey) 202.224.2742 / Christina Mulka (Durbin) 202.228.5643

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 10/22/2015 2:12:30 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]; Bauserman, Trenton [Trenton_D_Bauserman@ceq.eop.gov]; Billingsley, Tara [Tara_L_Billingsley@who.eop.gov]; Vaught, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c30920bcb6214a91b7e3c1e7810c63e1-Vaught, Laura]
Subject: S.697 - Substitute text
Attachments: S.697 - Inhofe Substitute - Redline to EPW Reported Bill - (10-21-15).doc; S.697 - Inhofe Substitute - Summary - (10-21-15).docx; S.697 - Inhofe Substitute - (10-21-15).pdf

FYI... For your files

The Inhofe Substitute was cleared through the Democratic Cloakroom yesterday for a time agreement - 2 hours, evenly divided, with no amendments.

The Inhofe Substitute includes (post EPW Committee) the EPA T.A., Markey-Durbin-Boxer-Heller-Crapo and others changes.

The Redline is of the Substitute to the EPW reported version.

The summary is a bipartisan staff summary.

Please let me know if you have any questions.

FYI... This has not been broadly circulated to stakeholders. Please only distribute internally for the time being.

AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—114th Cong., 1st Sess.

S. 697

To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Frank R. Lautenberg
5 Chemical Safety for the 21st Century Act".

6 **SEC. 2. FINDINGS, POLICY, AND INTENT.**

7 Section 2(c) of the Toxic Substances Control Act (15
8 U.S.C. 2601(c)) is amended—

9 (1) by striking "It is the intent" and inserting
10 the following:

11 "(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 end the following:

"(2) REFORM.—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.

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 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, 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 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 existing relevant policies, procedures, and guidance, as appropriate and consistent with this Act.

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

"(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 carrying out sections 4, 4A, 5, and 6, the Administrator shall take into consideration information relating to 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, procedures, and guidance for the

1 testing of chemical substances or mixtures under
2 section 4.
3 "(2) GOAL.—A goal of the policies, procedures,
4 and guidance established under paragraph (1) shall
5 be to make the basis of decisions clear to the public.
6 "(3) CONTENTS.—The policies, procedures, and
7 guidance established under paragraph (1) shall—
8 "(A) address how and when the exposure
9 level or exposure potential of a chemical sub-
10 stance would factor into decisions to require
11 new testing, subject to the condition that the
12 Administrator shall not interpret the lack of ex-
13 posure information as a lack of exposure or ex-
14 posure potential; and
15 "(B) describe the manner in which the Ad-
16 ministrator will determine that additional infor-
17 mation is necessary to carry out this Act, in-
18 cluding information relating to potentially ex-
19 posed or susceptible populations.
20 "(4) EPIDEMIOLOGICAL STUDIES.—Before pre-
21 scribing epidemiological studies of employees, the
22 Administrator shall consult with the Director of the
23 National Institute for Occupational Safety and
24 Health.

"(h) SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule and the resources necessary 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.—

"(i) IN GENERAL.—At the beginning of each calendar year, the Administrator shall publish an annual plan.

"(ii) INCLUSIONS.—The annual plan shall—

"(I) identify the substances subject to safety assessments and safety

determinations to be completed that year;

"(II) describe the status of each safety assessment and safety determination that has been initiated but not yet completed, including milestones achieved since the previous annual report; and

"(III) if the schedule for completion of a safety assessment and safety determination prepared pursuant to subparagraph (A) has changed, include an updated schedule for that safety assessment and safety determination.

"(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.—The policies and procedures under this paragraph shall, at a minimum—

"(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 information submitted by interested individuals or entities will be evaluated;

"(ii) require that each draft and final safety assessment and safety determination of the Administrator include a description of—

"(I)(aa) the scope of the safety assessment and safety determination to be conducted under section 6, including the hazards, exposures, and conditions of use of the chemical substance, and potentially exposed and

1 susceptible populations that the Ad-
2 ministrator has identified as relevant;
3 and
4 "(bb) the basis for the scope of
5 the safety assessment and safety de-
6 termination;
7 "(II) the manner in which aggre-
8 gate exposures, or significant subsets
9 of exposures, to a chemical substance
10 under the conditions of use were con-
11 sidered, and the basis for that consid-
12 eration;
13 "(III) the weight of the scientific
14 evidence of risk; and
15 "(IV) the information regarding
16 the impact on health and the environ-
17 ment of the chemical substance that
18 was used to make the assessment or
19 determination, including, as available,
20 mechanistic, animal toxicity, and epi-
21 demiology studies;
22 "(iii) establish a timely and trans-
23 parent process for evaluating whether new
24 information submitted or obtained after
25 the date of a final safety assessment or

1 safety determination warrants reconsider-
2 ation of the safety assessment or safety de-
3 termination; and
4 "(iv) when relevant information is
5 provided or otherwise made available to the
6 Administrator, require the Administrator
7 to consider the extent of Federal regula-
8 tion under other Federal laws.
9 "(D) GUIDANCE.—
10 "(i) IN GENERAL.—Not later than 1
11 year after the date of enactment of the
12 Frank R. Lautenberg Chemical Safety for
13 the 21st Century Act, the Administrator
14 shall develop guidance to assist interested
15 persons in developing their own draft safe-
16 ty assessments and other information for
17 submission to the Administrator, which
18 may be considered by the Administrator.
19 "(ii) REQUIREMENT.—The guidance
20 shall, at a minimum, address the quality of
21 the information submitted and the process
22 to be followed in developing a draft safety
23 assessment for consideration by the Ad-
24 ministrator.

"(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), (e), and (g);

(2) in subsection (f)—

(A) in the first sentence—

(i) by striking "from cancer, gene mutations, or birth defects"; and

(ii) by inserting ", without taking into account cost or other nonrisk factors" before the period at the end; and

(B) by striking the last sentence; and

(3) by inserting before subsection (f) 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.—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 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;

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

"(iii) the deadlines applicable to the Administrator under section 6(a).

"(5) CONSIDERATION OF FEDERAL AGENCY RECOMMENDATIONS.—The Administrator shall consider the recommendations of other Federal agencies regarding the chemical substances and mixtures to which the Administrator shall give priority consideration under this section.

"(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

1 potential) pursuant to this section, the Adminis-
2 trator shall—
3 "(A) identify the need intended to be met
4 by the rule, agreement, or order;
5 "(B) explain why information reasonably
6 available to the Administrator at that time is
7 inadequate to meet that need, including a ref-
8 erence, as appropriate, to the information iden-
9 tified in paragraph (2)(B); and
10 "(C) explain the basis for any decision that
11 requires the use of vertebrate animals.
12 "(2) EXPLANATION IN CASE OF ORDER.—
13 "(A) IN GENERAL.—If the Administrator
14 issues an order under this section, the Adminis-
15 trator shall issue a statement providing a jus-
16 tification for why issuance of an order is war-
17 ranted instead of promulgating a rule or enter-
18 ing into a testing consent agreement.
19 "(B) CONTENTS.—A statement described
20 in subparagraph (A) shall contain a description
21 of—
22 "(i) information that is readily acces-
23 sible to the Administrator, including infor-
24 mation submitted under any other provi-
25 sion 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) prior to making a request or adopting a requirement for testing using vertebrate animals, taking 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

1 "(iv) scientifically reliable and rel-
2 evant alternatives to tests on animals that
3 would provide equivalent information;
4 "(B) encouraging and facilitating—
5 "(i) the use of integrated and tiered
6 testing and assessment strategies;
7 "(ii) the use of best available science
8 in existence on the date on which the test
9 is conducted;
10 "(iii) the use of test methods that
11 eliminate or reduce the use of animals
12 while providing information of high sci-
13 entific quality;
14 "(iv) the grouping of 2 or more chem-
15 ical substances into scientifically appro-
16 priate categories in cases in which testing
17 of a chemical substance would provide reli-
18 able and useful information on other chem-
19 ical substances in the category;
20 "(v) the formation of industry con-
21 sortia to jointly conduct testing to avoid
22 unnecessary duplication of tests; and
23 "(vi) the submission of information
24 from—
25 "(I) animal-based studies; and

1 "(II) emerging methods and
2 models; and
3 "(C) funding research and validation stud-
4 ies to reduce, refine, and replace the use of ani-
5 mal tests in accordance with this subsection.
6 "(2) IMPLEMENTATION OF ALTERNATIVE TEST-
7 ING METHODS.—To promote the development and
8 timely incorporation of new testing methods that are
9 not based on vertebrate animals, the Administrator
10 shall—
11 "(A) not later than 2 years after the date
12 of enactment of the Frank R. Lautenberg
13 Chemical Safety for the 21st Century Act, de-
14 velop a strategic plan to promote the develop-
15 ment and implementation of alternative test
16 methods and testing strategies to generate in-
17 formation under this title that can reduce, re-
18 fine, or replace the use of vertebrate animals,
19 including toxicity pathway-based risk assess-
20 ment, in vitro studies, systems biology, com-
21 putational toxicology, bioinformatics, and high-
22 throughput screening;
23 "(B) as practicable, ensure that the stra-
24 tegic plan developed under subparagraph (A) is

1 reflected in the development of requirements for
2 testing under this section;
3 "(C) identify in the strategic plan devel-
4 oped under subparagraph (A) particular alter-
5 native test methods or testing strategies that do
6 not require new vertebrate animal testing and
7 are scientifically reliable, relevant, and capable
8 of providing information of equivalent scientific
9 reliability and quality to that which would be
10 obtained from vertebrate animal testing;
11 "(D) provide an opportunity for public no-
12 tice and comment on the contents of the plan
13 developed under subparagraph (A), including
14 the criteria for considering scientific reliability,
15 relevance, and equivalent information and the
16 test methods and strategies identified in sub-
17 paragraph (C);
18 "(E) beginning on the date that is 5 years
19 after the date of enactment of the Frank R.
20 Lautenberg Chemical Safety for the 21st Cen-
21 tury Act and every 5 years thereafter, submit to
22 Congress a report that describes the progress
23 made in implementing this subsection and goals
24 for future alternative test methods implementa-
25 tion;

"(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

1 equivalent information, before conducting new
2 animal testing.
3 "(B) EFFECT OF PARAGRAPH.—Nothing
4 in this paragraph—
5 "(i) requires the Administrator to re-
6 view the basis on which the person is con-
7 ducting testing described in subparagraph
8 (A);
9 "(ii) prohibits the use of other test
10 methods or testing strategies by any per-
11 son for purposes other than developing in-
12 formation for submission under this title
13 on a voluntary basis; or
14 "(iii) prohibits the use of other test
15 methods or testing strategies by any per-
16 son, subsequent to the attempt to develop
17 information using the test methods and
18 testing strategies identified by the Admin-
19 istrator under paragraph (2)(C).
20 "(d) TESTING REQUIREMENTS.—
21 "(1) IN GENERAL.—The Administrator may re-
22 quire the development of information by—
23 "(A) manufacturers and processors of the
24 chemical substance or mixture; and

"(B) persons that begin to manufacture or process the chemical substance or mixture after the effective date of the rule, testing consent agreement, or order.

"(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 submission of information by the applicant on the chemical substance or mixture would be duplicative of—

"(i) information on the chemical substance or mixture that—

"(I) has been submitted to the Administrator pursuant to a rule, consent agreement, or order under this section; or

"(II) is being developed by a person designated under paragraph (2); or

"(ii) information on an equivalent chemical substance or mixture that—

"(I) has been submitted to the Administrator pursuant to a rule, consent agreement, or order under this section; or

"(II) 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), before the end of the reimbursement period described in clause (iii), 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.

"(iii) REIMBURSEMENT PERIOD.—For the purposes of this subparagraph, the reimbursement period for any information for a chemical substance or mixture is a period—

"(I) beginning on the date the information is submitted in accordance with a rule, testing consent agreement, or order under this section; and

"(II) ending on the later of—

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

"(bb) the last day of the period that begins on the date referred to in subclause (I) and that is equal to the period that the Administrator determines was necessary to develop the information.

"(C) TERMINATION.—If, after granting an exemption under this paragraph, the Administrator determines that no person 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.".

(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 inserting "(as in effect on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act)" after "Toxic Substances Control Act".

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) PRIORITIZATION SCREENING PROCESS 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 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 AND SUBSEQUENT LISTS 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 shall publish an initial list of high-priority substances and low-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

1 identified by the Administrator as high-pri-
2 ority substances shall be drawn from the
3 list of chemical substances identified by the
4 Administrator in the October 2014 TSCA
5 Work Plan and subsequent updates, until
6 all Work Plan chemicals have been des-
7 ignated under this subsection.
8 "(iii) PREFERENCES.—
9 "(I) IN GENERAL.—In developing
10 the initial list and in identifying addi-
11 tional high-priority substances, the
12 Administrator shall give preference
13 to—
14 "(aa) chemical substances
15 that, with respect to persistence
16 and bioaccumulation, score high
17 for 1 and either high or moderate
18 for the other, pursuant to the
19 TSCA Work Plan Chemicals
20 Methods Document published by
21 the Administrator in February
22 2012; and
23 "(bb) chemical substances
24 listed in the October 2014 TSCA
25 Work Plan and subsequent up-

1 dates that are known human car-
2 cinogens and have high acute and
3 chronic toxicity.
4 "(II) METALS AND METAL COM-
5 POUNDS.—In prioritizing and assess-
6 ing metals and metal compounds, the
7 Administrator shall use the Frame-
8 work for Metals Risk Assessment of
9 the Office of the Science Advisor, Risk
10 Assessment Forum, and dated March
11 2007 (or a successor document), and
12 may use other applicable information
13 consistent with the best available
14 science.
15 "(C) ADDITIONAL CHEMICAL REVIEWS.—
16 The Administrator shall, as soon as practicable
17 and not later than—
18 "(i) 3 years after the date of enact-
19 ment of the Frank R. Lautenberg Chem-
20 ical Safety for the 21st Century Act, add
21 additional high-priority substances suffi-
22 cient to ensure that at least a total of 20
23 high-priority substances have undergone or
24 are undergoing the process established in
25 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 implementing the prioritization screening process established under 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 implementing the prioritization screening process established under 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 chemical substances not designated as high-priority.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

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

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

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

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical 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 consistent with the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in accordance with the deadlines under subsection (a) of that section.

"(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 includes and identifies substances—

"(i) that are being considered in the prioritization screening process and the status of the substances in the prioritization process;

"(ii) for which prioritization decisions have been postponed pursuant to sub-

1 section (b)(5), including the basis for the
2 postponement; and
3 "(iii) that are designated as high-pri-
4 ority substances or low-priority substances,
5 including the bases for such designations.
6 "(4) CRITERIA.—The criteria described in para-
7 graph (1) shall account for—
8 "(A) the recommendation of the Governor
9 of a State or a State agency with responsibility
10 for protecting health or the environment from
11 chemical substances appropriate for
12 prioritization screening;
13 "(B) the hazard and exposure potential of
14 the chemical substance (or category of sub-
15 stances), including persistence, bioaccumulation,
16 and specific scientific classifications and des-
17 ignations by authoritative governmental enti-
18 ties;
19 "(C) the conditions of use or significant
20 changes in the conditions of use of the chemical
21 substance;
22 "(D) evidence and indicators of exposure
23 potential to humans or the environment from
24 the chemical substance, including potentially ex-

1 posed or susceptible populations and storage
2 near significant sources of drinking water;
3 "(E) the volume of a chemical substance
4 manufactured or processed;
5 "(F) whether the volume of a chemical
6 substance as reported pursuant to a rule pro-
7 mulgated pursuant to section 8(a) has signifi-
8 cantly increased or decreased;
9 "(G) the availability of information regard-
10 ing potential hazards and exposures required
11 for conducting a safety assessment or safety de-
12 termination, with limited availability of relevant
13 information to be a sufficient basis for desig-
14 nating a chemical substance as a high-priority
15 substance, subject to the condition that limited
16 availability shall not require designation as a
17 high-priority substance; and
18 "(H) the extent of Federal or State regula-
19 tion of the chemical substance or the extent of
20 the impact of State regulation of the chemical
21 substance on the United States, with existing
22 Federal or State regulation of any uses evalu-
23 ated in the prioritization screening process as a
24 factor in designating a chemical substance to be
25 a high-priority or a low-priority substance.

"(b) PRIORITIZATION SCREENING PROCESS AND DECISIONS.—

"(1) IN GENERAL.—In implementing the prioritization screening process developed under subsection (a), 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) REASONABLY AVAILABLE INFORMATION.—The prioritization screening decision regarding a chemical substance shall consider any hazard and exposure information relating to the chemical substance that is reasonably 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) POSTPONING A DECISION.—If the Administrator determines that additional information is needed to establish the priority of a chemical sub-

1 stance under this section, the Administrator may
2 postpone a prioritization screening decision for a
3 reasonable period—
4 "(A) to allow for the submission of addi-
5 tional information by an interested person and
6 for the Administrator to evaluate the additional
7 information; or
8 "(B) to require the development of infor-
9 mation pursuant to a rule, testing consent
10 agreement, or order issued under section
11 4(a)(2).
12 "(6) DEADLINES FOR SUBMISSION OF INFOR-
13 MATION.—If the Administrator requests the develop-
14 ment or submission of information under this sec-
15 tion, the Administrator shall establish a deadline for
16 submission of the information.
17 "(7) NOTICE AND COMMENT.—The Adminis-
18 trator shall—
19 "(A) publish, including in the Federal Reg-
20 ister, the proposed decisions made under para-
21 graphs (3), (4), and (5) and the basis for the
22 decisions;
23 "(B) identify the information and analysis
24 on which the decisions are based; and
25 "(C) provide 90 days for public comment.

"(8) REVISIONS OF PRIOR DESIGNATIONS.—

"(A) IN GENERAL.—At any time, 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 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) POST-PRIORITIZATION NOTICE.—If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State proposes or takes an administrative action or enacts a statute to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a high-priority substance, after the date on which the deadline established pursuant to subsection

(a) of section 6 for completion of the safety determination under that subsection expires but before the date on which the Administrator publishes the safety determination under that subsection, the Governor or State agency with responsibility for implementing the statute or administrative action shall—

"(i) notify the Administrator; and

"(ii) provide the scientific and legal basis for the action.

"(E) 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.

"(F) 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

1 under this subsection is established, the Adminis-
2 trator shall—
3 "(A) review the process on the basis of ex-
4 perience and taking into consideration resources
5 available to efficiently and effectively screen and
6 prioritize chemical substances; and
7 "(B) if necessary, modify the prioritization
8 screening process.
9 "(11) EFFECT.—Subject to section 18, a des-
10 ignation by the Administrator under this section
11 with respect to a chemical substance shall not af-
12 fect—
13 "(A) the manufacture, processing, distribu-
14 tion in commerce, use, or disposal of the chem-
15 ical substance; or
16 "(B) the regulation of those activities.
17 "(c) ADDITIONAL PRIORITIES FOR SAFETY ASSESS-
18 MENTS AND DETERMINATIONS.—
19 "(1) REQUIREMENTS.—
20 "(A) IN GENERAL.—The rule promulgated
21 under subsection (a) shall—
22 "(i) include a process by which a
23 manufacturer or processor of an active
24 chemical substance that has not been des-
25 ignated 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)(D);

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

"(iii) specify the criteria (which may include criteria identified in subsection (a)(4)) that 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.—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) the number of substances designated to undergo safety assessments and safety determinations under the process and criteria pursuant to paragraph (1) is 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 subsections (a)(2) and (b)(3) (except that if less than 25 percent are received by the Administrator, the Administrator shall grant each request that meets the requirements of 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 currently 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 substances identified under 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 TSCA 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 (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. 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";

(B) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking "subsection (h)" and inserting "paragraph (3) and subsection (h)"; and

(ii) in the matter following subparagraph (B)—

(I) by striking "subsection (d)" and inserting "subsection (c)"; and

(II) by striking "and such person complies with any applicable requirement of subsection (b)"; and

(C) by adding at the end the following:

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

(6) by redesignating subsections (c) and (d) as subsections (d) and (e), respectively, and moving subsection (e) (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 (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) all known or reasonably ascertainable information regarding conditions of use and reasonably anticipated exposures.";

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A)—

(I) by striking "subsection (a)" and inserting "subsection (b)"; and

(II) 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 a 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 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), then notwithstanding any remaining portion 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) consider 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 that does not conform to 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

1 "(II) monitor or conduct such
2 additional tests as are reasonably nec-
3 essary to address potential risks from
4 the manufacture, processing, distribu-
5 tion in commerce, use, or disposal, as
6 applicable, of the chemical substance,
7 subject to section 4;
8 "(iii) a restriction on the quantity of
9 the chemical substance that may be manu-
10 factured, processed, or distributed in com-
11 merce—
12 "(I) in general; or
13 "(II) for a particular use;
14 "(iv) a prohibition or other restriction
15 of—
16 "(I) the manufacture, processing,
17 or distribution in commerce of the
18 chemical substance for a significant
19 new use;
20 "(II) any method of commercial
21 use of the chemical substance; or
22 "(III) any method of disposal of
23 the chemical substance; or
24 "(v) a prohibition or other restriction
25 on the manufacture, processing, or dis-

1 tribution in commerce of the chemical sub-
2 stance—
3 "(I) in general; or
4 "(II) for a particular use.
5 "(D) PERSISTENT AND BIOACCUMULATIVE
6 SUBSTANCES.—For a chemical substance the
7 Administrator determines, with respect to per-
8 sistence and bioaccumulation, scores high for 1
9 and either high or moderate for the other, pur-
10 suant to the TSCA Work Plan Chemicals Meth-
11 ods Document published by the Administrator
12 in February 2012, the Administrator shall, in
13 selecting among prohibitions and other restric-
14 tions that the Administrator determines are
15 sufficient to ensure that the chemical substance
16 is likely to meet the safety standard, reduce po-
17 tential exposure to the substance to the max-
18 imum extent practicable.
19 "(E) WORKPLACE EXPOSURES.—To the
20 extent practicable, the Administrator shall con-
21 sult with the Assistant Secretary of Labor for
22 Occupational Safety and Health prior to adopt-
23 ing any prohibition or other restriction under
24 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.";

(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 (e); 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 submitted under this section or made by the Administrator under this section; and

"(2) all information submitted or issued under this section."; and

(10) in subsection (h)—

(A) in paragraph (1)—

(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 (h) and (i), 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;

"(6) may extend any deadline under paragraph (4) for not more than 1 year, if information relating to the high-priority substance, required to be developed in a rule, order, or consent agreement under section 4—

"(A) has not yet been submitted to the Administrator; or

"(B) was submitted to the Administrator—

"(i) within the time specified in the rule, order, or consent agreement pursuant to section 4(a)(4)(A)(iv); and

"(ii) on or after the date that is 120 days before the expiration of the deadline described in paragraph (4); and

"(7) may extend the deadline under paragraph (5) for not more than 2 years, subject to the condition that the aggregate length of all extensions of deadlines under this subsection 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 restric-

1 tions necessary to ensure that the chemical sub-
2 stance meets the safety standard.
3 "(2) SCOPE.—
4 "(A) IN GENERAL.—The rule promulgated
5 pursuant to this subsection—
6 "(i) may apply to mixtures containing
7 the chemical substance, as appropriate;
8 "(ii) shall include dates by which com-
9 pliance is mandatory, which—
10 "(I) shall be as soon as prac-
11 ticable, but not later than 4 years
12 after the date of promulgation of the
13 rule, except in the case of a use ex-
14 empted under paragraph (5);
15 "(II) in the case of a ban or
16 phase-out of the chemical substance,
17 shall implement the ban or phase-out
18 in as short a period as practicable;
19 "(III) as determined by the Ad-
20 ministrator, may vary for different af-
21 fected persons; and
22 "(IV) following a determination
23 by the Administrator that compliance
24 is technologically or economically in-
25 feasible within the timeframe specified

in subclause (I), shall provide up to an additional 18 months for compliance to be mandatory;

"(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;

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

"(v) shall, when the Administrator determines that the chemical substance does not meet the safety standard for a potentially exposed or susceptible population, apply prohibitions or other restrictions nec-

1 essary to ensure that the substance meets
2 the safety standard for that population.
3 "(B) PERSISTENT AND BIOACCUMULATIVE
4 SUBSTANCES.—For a chemical substance the
5 Administrator determines, with respect to per-
6 sistence and bioaccumulation, scores high for 1
7 and either high or moderate for the other, pur-
8 suant to the TSCA Work Plan Chemicals Meth-
9 ods Document published by the Administrator
10 in February 2012, the Administrator shall, in
11 selecting among prohibitions and other restric-
12 tions that the Administrator determines are
13 sufficient to ensure that the chemical substance
14 meets the safety standard, reduce exposure to
15 the substance to the maximum extent prac-
16 ticable.
17 "(C) WORKPLACE EXPOSURES.—The Ad-
18 ministrator shall consult with the Assistant Sec-
19 retary of Labor for Occupational Safety and
20 Health before adopting any prohibition or other
21 restriction under this subsection to address
22 workplace exposures.
23 "(D) DEFINITION OF REQUIREMENT.—For
24 the purposes of this Act, the term 'requirement'

as used in this section does not displace common law.

"(3) RESTRICTIONS.—Subject to section 18, a restriction under paragraph (1) may include, as appropriate—

"(A) 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 compli-

1 ance with the requirements of any rule
2 under this subsection;
3 "(C) a restriction on the quantity of the
4 chemical substance that may be manufactured,
5 processed, or distributed in commerce;
6 "(D) a requirement to ban or phase out, or
7 otherwise restrict the manufacture, processing,
8 or distribution in commerce of the chemical
9 substance for—
10 "(i) a particular use;
11 "(ii) a particular use at a concentra-
12 tion in excess of a level specified by the
13 Administrator; or
14 "(iii) all uses;
15 "(E) a restriction on the quantity of the
16 chemical substance that may be manufactured,
17 processed, or distributed in commerce for—
18 "(i) a particular use; or
19 "(ii) a particular use at a concentra-
20 tion in excess of a level specified by the
21 Administrator;
22 "(F) a requirement to ban, phase out, or
23 otherwise restrict any method of commercial
24 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

1 or more technically and economically feasible al-
2 ternatives to the chemical substance that the
3 Administrator determines are relevant to the
4 rulemaking.

5 "(C) PUBLIC AVAILABILITY.—In proposing
6 a rule under paragraph (1), the Administrator
7 shall make publicly available any analysis con-
8 ducted under this paragraph.

9 "(D) STATEMENT REQUIRED.—In making
10 final a rule under paragraph (1), the Adminis-
11 trator shall include a statement describing how
12 the analysis considered under subparagraph (A)
13 was taken into account.

14 "(5) EXEMPTIONS.—

15 "(A) IN GENERAL.—The Administrator
16 may, as part of a rule promulgated under para-
17 graph (1) or in a separate rule, exempt 1 or
18 more uses of a chemical substance from any re-
19 striction in a rule promulgated under paragraph
20 (1) if the Administrator determines that—

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

23 "(I) harming national security;

24 "(II) causing significant disrup-
25 tion 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 para-

1 graph for a chemical substance for which a ban
2 or phase-out is included in a proposed or final
3 rule under paragraph (1), the Administrator
4 shall take into consideration, to the extent prac-
5 ticable based on reasonably available informa-
6 tion, the quantifiable and nonquantifiable costs
7 and benefits of the 1 or more alternatives to the
8 chemical substance the Administrator deter-
9 mines to be technically and economically fea-
10 sible and most likely to be used in place of the
11 chemical substance under the conditions of use.
12 "(E) CONDITIONS.—As part of a rule pro-
13 mulgated under this paragraph, the Adminis-
14 trator shall include conditions, including reason-
15 able recordkeeping, monitoring, and reporting
16 requirements, to the extent that the Adminis-
17 trator determines the conditions are necessary
18 to protect health and the environment while
19 achieving the purposes of the exemption.
20 "(F) DURATION.—
21 "(i) IN GENERAL.—The Administrator
22 shall establish, as part of a rule under this
23 paragraph, a time limit on any exemption
24 for a time to be determined by the Admin-

1 istrator as reasonable on a case-by-case
2 basis.
3 "(ii) AUTHORITY OF ADMINIS-
4 TRATOR.—The Administrator, by rule, may
5 extend, modify, or eliminate an exemption
6 if the Administrator determines, on the
7 basis of reasonably available information
8 and after adequate public justification, the
9 exemption warrants extension or is no
10 longer necessary.
11 "(iii) CONSIDERATIONS.—
12 "(I) IN GENERAL.—Subject to
13 subclause (II), the Administrator shall
14 issue exemptions and establish time
15 periods by considering factors deter-
16 mined by the Administrator to be rel-
17 evant to the goals of fostering innova-
18 tion and the development of alter-
19 natives that meet the safety standard.
20 "(II) LIMITATION.—Any renewal
21 of an exemption in the case of a rule
22 under paragraph (1) requiring the
23 ban or phase-out of a chemical sub-
24 stance shall not exceed 5 years.

1 "(e) IMMEDIATE EFFECT.—The Administrator may
2 declare a proposed rule under subsection (d)(1) to be ef-
3 fective on publication of the rule in the Federal Register
4 and until the effective date of final action taken respecting
5 the rule, if—
6 "(1) the Administrator determines that—
7 "(A) the manufacture, processing, distribu-
8 tion in commerce, use, or disposal of the chem-
9 ical substance or mixture subject to the pro-
10 posed rule or any combination of those activi-
11 ties is likely to result in a risk of serious or
12 widespread injury to health or the environment
13 before the effective date; and
14 "(B) making the proposed rule so effective
15 is necessary to protect the public interest; and
16 "(2) in the case of a proposed rule to prohibit
17 the manufacture, processing, or distribution in com-
18 merce of a chemical substance or mixture because of
19 the risk determined under paragraph (1)(A), a court
20 has granted relief in an action under section 7 with
21 respect to that risk associated with the chemical
22 substance or mixture.
23 "(f) FINAL AGENCY ACTION.—Under this section
24 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.

"(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 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 the chemical substance."; and

(4) in subsection (h) (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 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)—

(i) in subparagraph (A)(ii)(I)—

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