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

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

(ii) by adding at the end the following:

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

"(i) review the adequacy of the standards prescribed according to subparagraph (B);

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

"(iii) revise the standards if the Administrator so determines."; 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

1 Frank R. Lautenberg Chemical Safety for
2 the 21st Century Act, the Administrator
3 shall promulgate rules requiring the main-
4 tenance of records and the reporting of ad-
5 ditional information known or reasonably
6 ascertainable by the person making the re-
7 port, including rules applicable to proc-
8 essors so that the Administrator has the
9 information necessary to carry out this
10 title.
11 "(ii) MODIFICATION OF PRIOR
12 RULES.—In carrying out this subpara-
13 graph, the Administrator may modify, as
14 appropriate, rules promulgated before the
15 date of enactment of the Frank R. Lauten-
16 berg Chemical Safety for the 21st Century
17 Act.
18 "(B) CONTENTS.—The rules promulgated
19 pursuant to subparagraph (A)—
20 "(i) may impose different reporting
21 and recordkeeping requirements on manu-
22 facturers and processors; and
23 "(ii) shall include the level of detail
24 necessary to be reported, including the

1 manner by which use and exposure infor-
2 mation may be reported.
3 "(C) ADMINISTRATION.—In implementing
4 the reporting and recordkeeping requirements
5 under this paragraph, the Administrator shall
6 take measures—
7 "(i) to limit the potential for duplica-
8 tion in reporting requirements;
9 "(ii) to minimize the impact of the
10 rules on small manufacturers and proc-
11 essors; and
12 "(iii) to apply any reporting obliga-
13 tions to those persons likely to have infor-
14 mation relevant to the effective implemen-
15 tation of this title.";
16 (2) in subsection (b), by adding at the end the
17 following:
18 "(3) NOMENCLATURE.—
19 "(A) IN GENERAL.—In carrying out para-
20 graph (1), the Administrator shall—
21 "(i) maintain the use of Class 2 no-
22 menclature in use on the date of enact-
23 ment of the Frank R. Lautenberg Chem-
24 ical Safety for the 21st Century Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

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

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

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

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

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

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

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

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

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

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

"(II) develop new guidance that—

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

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

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

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) RULES.—

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

"(ii) ACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

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

"(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—In promulgating the rule established pursuant to subparagraph (A), the Administrator shall—

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

"(ii) require a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufac-

1 turer or processor seeks to maintain any
2 existing claim for protection against disclo-
3 sure of the specific identity of the sub-
4 stance as confidential pursuant to section
5 14; and
6 "(iii) require the substantiation of
7 those claims pursuant to section 14 and in
8 accordance with the review plan described
9 in 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 asserted pursuant to subparagraph
19 (B).
20 "(D) REQUIREMENTS OF REVIEW PLAN.—
21 Under the review plan under subparagraph (C),
22 the Administrator shall—
23 "(i) require, at the time requested by
24 the Administrator, all manufacturers or
25 processors asserting claims under subpara-

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

1 disclosure information for which the
2 Administrator approves such a claim
3 for a period of 10 years, unless, prior
4 to the expiration of the period—
5 "(aa) the person notifies the
6 Administrator that the person is
7 withdrawing the claim, in which
8 case the Administrator shall
9 promptly make the information
10 available to the public; or
11 "(bb) the Administrator oth-
12 erwise becomes aware that the
13 need for protection from disclo-
14 sure can no longer be substan-
15 tiated, in which case the Admin-
16 istrator shall take the actions de-
17 scribed in section 14(g)(2); and
18 "(iii) encourage manufacturers or
19 processors that have previously made
20 claims to protect the specific identities of
21 chemical substances identified as inactive
22 pursuant to subsection (f)(2) to review and
23 either withdraw or substantiate the claims.
24 "(E) TIMELINE FOR COMPLETION OF RE-
25 VIEWS.—

1 "(i) IN GENERAL.—The Administrator
2 shall implement the review plan so as to
3 complete reviews of all claims specified in
4 subparagraph (C) not later than 5 years
5 after the date on which the Administrator
6 compiles the initial list of active substances
7 pursuant to subparagraph (A).
8 "(ii) CONSIDERATIONS.—
9 "(I) IN GENERAL.—The Admin-
10 istrator may extend the deadline for
11 completion of the reviews for not more
12 than 2 additional years, after an ade-
13 quate public justification, if the Ad-
14 ministrator determines that the exten-
15 sion is necessary based on the number
16 of claims needing review and the
17 available resources.
18 "(II) ANNUAL REVIEW GOAL AND
19 RESULTS.—At the beginning of each
20 year, the Administrator shall publish
21 an annual goal for reviews and the
22 number of reviews completed in the
23 prior year.
24 "(5) ACTIVE AND INACTIVE SUBSTANCES.—

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

"(B) CHANGE TO ACTIVE STATUS.—

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

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

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

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

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

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

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

"(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of 10 years, unless, prior to the expiration of the period—

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

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

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

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

"(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the rule required under paragraph (4)(A), the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (as in effect on

1 the date of enactment of the Frank R. Lautenberg
2 Chemical Safety for the 21st Century Act), during
3 the reporting period that most closely preceded the
4 date of enactment of the Frank R. Lautenberg
5 Chemical Safety for the 21st Century Act, as the in-
6 terim list of active substances for the purposes of
7 section 4A.

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

11 "(A) the specific identity of each chemical
12 substance on the nonconfidential portion of the
13 list published under paragraph (1) that the Ad-
14 ministrator has designated as—

15 "(i) an active substance; or

16 "(ii) an inactive substance;

17 "(B) the accession number, generic name,
18 and, if applicable, premanufacture notice case
19 number for each chemical substance on the con-
20 fidential portion of the list published under
21 paragraph (1) for which a claim of confiden-
22 tiality was received; and

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

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

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

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

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

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

"(A) to certify that each notice or substantiation the manufacturer or processor submits complies with the requirements of the rule, and

that any confidentiality claims are true and correct; and

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

(3) in subsection (e)—

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

"(1) IN GENERAL.—Any person"; and

(B) by adding at the end the following:

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

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

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

"(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on

the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

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

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

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

"(3) MANUFACTURE; PROCESS.—The".

SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.

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

(1) in subsection (a)—

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

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

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

(B) in paragraph (2)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"(5) This subsection shall not relieve the Administrator of any obligation to complete a safety as-

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

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

(3) by adding at the end the following:

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

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

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

1 **SEC. 13. EXPORTS.**

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

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

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

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

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

20 "(C) any chemical substance that—

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

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

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

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

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

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

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

"(b) NOTICE.—

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

"(A) a chemical substance or a mixture containing a chemical substance that the Ad-

1 ministrator has determined under section 5 is
2 not likely to meet the safety standard and for
3 which a prohibition or other restriction has
4 been proposed or established under that section;
5 "(B) a chemical substance or a mixture
6 containing a chemical substance that the Ad-
7 ministrator has determined under section 6
8 does not meet the safety standard and for
9 which a prohibition or other restriction has
10 been proposed or established under that section;
11 "(C) a chemical substance for which the
12 United States is obligated by treaty to provide
13 export notification;
14 "(D) a chemical substance or mixture con-
15 taining a chemical substance subject to a pro-
16 posed or promulgated significant new use rule,
17 or a prohibition or other restriction pursuant to
18 a rule, order, or consent agreement in effect
19 under this Act;
20 "(E) a chemical substance or mixture for
21 which the submission of information is required
22 under section 4; or
23 "(F) a chemical substance or mixture for
24 which an action is pending or for which relief
25 has been granted under section 7.

"(2) RULES.—

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

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

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

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

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

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

"(B) for a chemical substance described in paragraph (1)(C), a notice that satisfies the ob-

1 ligation of the United States under the applica-
2 ble treaty; and
3 "(C) for a chemical substance or mixture
4 described in paragraph (1)(E), a notice of avail-
5 ability of the information on the chemical sub-
6 stance or mixture submitted to the Adminis-
7 trator."; and
8 (3) in subsection (c), by striking paragraph (3).
9 **SEC. 14. CONFIDENTIAL INFORMATION.**
10 Section 14 of the Toxic Substances Control Act (15
11 U.S.C. 2613) is amended to read as follows:
12 **"SEC. 14. CONFIDENTIAL INFORMATION.**
13 "(a) IN GENERAL.—Except as otherwise provided in
14 this section, the Administrator shall not disclose informa-
15 tion that is exempt from disclosure pursuant to subsection
16 (a) of section 552 of title 5, United States Code, under
17 subsection (b)(4) of that section—
18 "(1) that is reported to, or otherwise obtained
19 by, the Administrator under this Act; and
20 "(2) for which the requirements of subsection
21 (d) are met.
22 "(b) INFORMATION GENERALLY PROTECTED FROM
23 DISCLOSURE.—The following information specific to, and
24 submitted by, a manufacturer, processor, or distributor
25 that meets the requirements of subsections (a) and (d)

1 shall be presumed to be protected from disclosure, subject
2 to the condition that nothing in this Act prohibits the dis-
3 closure of any such information, or information that is the
4 subject of subsection (g)(3), through discovery, subpoena,
5 other court order, or any other judicial process otherwise
6 allowed under applicable Federal or State law:

7 "(1) Specific information describing the proc-
8 esses used in manufacture or processing of a chem-
9 ical substance, mixture, or article.

10 "(2) Marketing and sales information.

11 "(3) Information identifying a supplier or cus-
12 tomer.

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

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

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

20 "(7) Specific aggregated volumes across manu-
21 facturers, if the Administrator determines that dis-
22 closure of the specific aggregated volumes would re-
23 veal confidential information.

24 "(8) Except as otherwise provided in this sec-
25 tion, the specific identity of a chemical substance

1 prior to the date on which the chemical substance is
2 first offered for commercial distribution, including
3 the chemical name, molecular formula, Chemical Ab-
4 stracts Service number, and other information that
5 would identify a specific chemical substance, if the
6 specific identity was claimed as confidential informa-
7 tion at the time it was submitted in a notice under
8 section 5.

9 "(c) INFORMATION NOT PROTECTED FROM DISCLO-
10 SURE.—

11 "(1) IN GENERAL.—Notwithstanding sub-
12 sections (a) and (b), the following information shall
13 not be protected from disclosure:

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

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

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

21 "(aa) any chemical sub-
22 stance or mixture that, on the
23 date on which the study is to be
24 disclosed, has been offered for
25 commercial distribution; or

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

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

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

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

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

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

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

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

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

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

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

"(iv) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including

information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

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

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

"(4) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5,

1 United States Code, for information that is subject
2 to disclosure under this subsection, the Adminis-
3 trator may not deny the request on the basis of sec-
4 tion 552(b)(4) of title 5, United States Code.
5 "(d) REQUIREMENTS FOR CONFIDENTIALITY
6 CLAIMS.—
7 "(1) ASSERTION OF CLAIMS.—
8 "(A) IN GENERAL.—A person seeking to
9 protect any information submitted under this
10 Act from disclosure (including information de-
11 scribed in subsection (b)) shall assert to the Ad-
12 ministrator a claim for protection concurrent
13 with submission of the information, in accord-
14 ance with such rules regarding a claim for pro-
15 tection from disclosure as the Administrator
16 has promulgated or may promulgate pursuant
17 to this title.
18 "(B) INCLUSION.—An assertion of a claim
19 under subparagraph (A) shall include a state-
20 ment that the person has—
21 "(i) taken reasonable measures to pro-
22 tect the confidentiality of the information;
23 "(ii) determined that the information
24 is not required to be disclosed or otherwise

1 made available to the public under any
2 other Federal law;
3 "(iii) a reasonable basis to conclude
4 that disclosure of the information is likely
5 to cause substantial harm to the competi-
6 tive position of the person; and
7 "(iv) a reasonable basis to believe that
8 the information is not readily discoverable
9 through reverse engineering.
10 "(C) SPECIFIC CHEMICAL IDENTITY.—In
11 the case of a claim under subparagraph (A) for
12 protection against disclosure of a specific chem-
13 ical identity, the claim shall include a struc-
14 turally descriptive generic name for the chem-
15 ical substance that the Administrator may dis-
16 close to the public, subject to the condition that
17 the generic name shall—
18 "(i) be consistent with guidance
19 issued by the Administrator under para-
20 graph (3)(A); and
21 "(ii) describe the chemical structure
22 of the substance as specifically as prac-
23 ticable while protecting those features of
24 the chemical structure—

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

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

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

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

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

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

1 "(B) the content and form of the state-
2 ments of need and agreements required under
3 paragraphs (4), (5), and (6) of subsection (e).
4 "(4) CERTIFICATION.—An authorized official of
5 a person described in paragraph (1)(A) shall certify
6 that the statement required to assert a claim sub-
7 mitted pursuant to paragraph (1)(B) and any infor-
8 mation required to substantiate a claim submitted
9 pursuant to paragraph (2) are true and correct.
10 "(e) EXCEPTIONS TO PROTECTION FROM DISCLO-
11 SURE.—Information described in subsection (a)—
12 "(1) shall be disclosed if the information is to
13 be disclosed to an officer or employee of the United
14 States in connection with the official duties of the
15 officer or employee—
16 "(A) under any law for the protection of
17 health or the environment; or
18 "(B) for a specific law enforcement pur-
19 pose;
20 "(2) shall be disclosed if the information is to
21 be disclosed to a contractor of the United States and
22 employees of that contractor—
23 "(A) if, in the opinion of the Adminis-
24 trator, the disclosure is necessary for the satis-
25 factory performance by the contractor of a con-

1 tract with the United States for the perform-
2 ance of work in connection with this Act; and
3 "(B) subject to such conditions as the Ad-
4 ministrator may specify;
5 "(3) shall be disclosed if the Administrator de-
6 termines that disclosure is necessary to protect
7 health or the environment;
8 "(4) shall be disclosed if the information is to
9 be disclosed to a State or political subdivision of a
10 State, on written request, for the purpose of develop-
11 ment, administration, or enforcement of a law, if 1
12 or more applicable agreements with the Adminis-
13 trator that are consistent with the guidance issued
14 under subsection (d)(3)(B) ensure that the recipient
15 will take appropriate measures, and has adequate
16 authority, to maintain the confidentiality of the in-
17 formation in accordance with procedures comparable
18 to the procedures used by the Administrator to safe-
19 guard the information;
20 "(5) shall be disclosed if a health or environ-
21 mental professional employed by a Federal or State
22 agency or a treating physician or nurse in a non-
23 emergency situation provides a written statement of
24 need and agrees to sign a written confidentiality

1 agreement with the Administrator, subject to the
2 conditions that—
3 "(A) the statement of need and confiden-
4 tiality agreement are consistent with the guid-
5 ance issued under subsection (d)(3)(B);
6 "(B) the written statement of need shall be
7 a statement that the person has a reasonable
8 basis to suspect that—
9 "(i) the information is necessary for,
10 or will assist in—
11 "(I) the diagnosis or treatment of
12 1 or more individuals; or
13 "(II) responding to an environ-
14 mental release or exposure; and
15 "(ii) 1 or more individuals being diag-
16 nosed or treated have been exposed to the
17 chemical substance concerned, or an envi-
18 ronmental release or exposure has oc-
19 curred; and
20 "(C) the confidentiality agreement shall
21 provide that the person will not use the infor-
22 mation for any purpose other than the health or
23 environmental needs asserted in the statement
24 of need, except as otherwise may be authorized
25 by the terms of the agreement or by the person

1 submitting the information to the Adminis-
2 trator, except that nothing in this Act prohibits
3 the disclosure of any such information through
4 discovery, subpoena, other court order, or any
5 other judicial process otherwise allowed under
6 applicable Federal or State law;
7 "(6) shall be disclosed if in the event of an
8 emergency, a treating physician, nurse, agent of a
9 poison control center, public health or environmental
10 official of a State or political subdivision of a State,
11 or first responder (including any individual duly au-
12 thorized by a Federal agency, State, or political sub-
13 division of a State who is trained in urgent medical
14 care or other emergency procedures, including a po-
15 lice officer, firefighter, or emergency medical techni-
16 cian) requests the information, subject to the condi-
17 tions that—
18 "(A) the treating physician, nurse, agent,
19 public health or environmental official of a
20 State or a political subdivision of a State, or
21 first responder shall have a reasonable basis to
22 suspect that—
23 "(i) a medical or public health or en-
24 vironmental emergency exists;

1 "(ii) the information is necessary for,
2 or will assist in, emergency or first-aid di-
3 agnosis or treatment; or
4 "(iii) 1 or more individuals being di-
5 agnosed or treated have likely been ex-
6 posed to the chemical substance concerned,
7 or a serious environmental release of or ex-
8 posure to the chemical substance con-
9 cerned has occurred;
10 "(B) if requested by the person submitting
11 the information to the Administrator, the treat-
12 ing physician, nurse, agent, public health or en-
13 vironmental official of a State or a political sub-
14 division of a State, or first responder shall, as
15 described in paragraph (5)—
16 "(i) provide a written statement of
17 need; and
18 "(ii) agree to sign a confidentiality
19 agreement; and
20 "(C) the written confidentiality agreement
21 or statement of need shall be submitted as soon
22 as practicable, but not necessarily before the in-
23 formation is disclosed;
24 "(7) may be disclosed if the Administrator de-
25 termines that disclosure is relevant in a proceeding

1 under this Act, subject to the condition that the dis-
2 closure shall be made in such a manner as to pre-
3 serve confidentiality to the maximum extent prac-
4 ticable without impairing the proceeding;
5 "(8) shall be disclosed if the information is to
6 be disclosed, on written request of any duly author-
7 ized congressional committee, to that committee; or
8 "(9) shall be disclosed if the information is re-
9 quired to be disclosed or otherwise made public
10 under any other provision of Federal law.
11 "(f) DURATION OF PROTECTION FROM DISCLO-
12 SURE.—
13 "(1) IN GENERAL.—
14 "(A) INFORMATION NOT SUBJECT TO TIME
15 LIMIT FOR PROTECTION FROM DISCLOSURE.—
16 Subject to paragraph (2), the Administrator
17 shall protect from disclosure information de-
18 scribed in subsection (b) that meets the require-
19 ments of subsections (a) and (d), unless—
20 "(i) the person that asserted the claim
21 notifies the Administrator that the person
22 is withdrawing the claim, in which case the
23 Administrator shall promptly make the in-
24 formation available to the public; or

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

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

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

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

1 any actions required under subsection
2 (g)(2).
3 "(C) EXTENSIONS.—
4 "(i) IN GENERAL.—Not later than the
5 date that is 60 days before the expiration
6 of the period described in subparagraph
7 (B), the Administrator shall provide to the
8 person that asserted the claim a notice of
9 the impending expiration of the period.
10 "(ii) STATEMENT.—
11 "(I) IN GENERAL.—Not later
12 than the date that is 30 days before
13 the expiration of the period described
14 in subparagraph (B), a person re-
15 asserting the relevant claim shall sub-
16 mit to the Administrator a request for
17 extension substantiating, in accord-
18 ance with subsection (d)(2), the need
19 to extend the period.
20 "(II) ACTION BY ADMINIS-
21 TRATOR.—Not later than the date of
22 expiration of the period described in
23 subparagraph (B), the Administrator
24 shall, in accordance with subsection
25 (g)(1)(C)—

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

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

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

"(BB) deny the request.

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

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

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

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection of information against disclosure under subsection (a) and require any

1 person that has claimed protection for that in-
2 formation, whether before, on, or after the date
3 of enactment of the Frank R. Lautenberg
4 Chemical Safety for the 21st Century Act, to
5 withdraw or reassert and substantiate or re-
6 substantiate the claim in accordance with this
7 section—
8 "(i) after the chemical substance is
9 identified as a high-priority substance
10 under section 4A;
11 "(ii) for any chemical substance for
12 which the Administrator has made a deter-
13 mination under section 6(c)(1)(C);
14 "(iii) for any inactive chemical sub-
15 stance identified under section 8(b)(5); or
16 "(iv) in limited circumstances, if the
17 Administrator determines that disclosure
18 of certain information currently protected
19 from disclosure would assist the Adminis-
20 trator in conducting safety assessments
21 and safety determinations under sub-
22 sections (b) and (c) of section 6 or promul-
23 gating rules pursuant to section 6(d).
24 "(B) REVIEW REQUIRED.—The Adminis-
25 trator shall review a claim for protection of in-

1 formation against disclosure under subsection
2 (a) and require any person that has claimed
3 protection for that information, whether before,
4 on, or after the date of enactment of the Frank
5 R. Lautenberg Chemical Safety for the 21st
6 Century Act, to withdraw or reassert and sub-
7 stantiate or resubstantiate the claim in accord-
8 ance with this section—
9 "(i) as necessary to determine wheth-
10 er the information qualifies for an exemp-
11 tion from disclosure in connection with a
12 request for information received by the Ad-
13 ministrator under section 552 of title 5,
14 United States Code;
15 "(ii) if the Administrator has a rea-
16 sonable basis to believe that the informa-
17 tion does not qualify for protection against
18 disclosure under subsection (a); or
19 "(iii) for any substance for which the
20 Administrator has made a determination
21 under section 6(c)(1)(B).
22 "(C) ACTION BY RECIPIENT.—If the Ad-
23 ministrator makes a request under subpara-
24 graph (A) or (B), the recipient of the request
25 shall—

"(i) reassert and substantiate or re-substantiate 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 ap-

1 proved, including the expiration date for each
2 such claim;
3 "(C) ensure that any nonconfidential infor-
4 mation received by the Administrator with re-
5 spect to such a chemical substance during the
6 period of protection from disclosure—
7 "(i) is made public; and
8 "(ii) identifies the chemical substance
9 using the unique identifier; and
10 "(D) for each claim for protection of spe-
11 cific chemical identity that has been denied by
12 the Administrator or expired, or that has been
13 withdrawn by the submitter, provide public ac-
14 cess to the specific chemical identity clearly
15 linked to all nonconfidential information re-
16 ceived by the Administrator with respect to the
17 chemical substance.
18 "(g) DUTIES OF ADMINISTRATOR.—
19 "(1) DETERMINATION.—
20 "(A) IN GENERAL.—Except as provided in
21 subsection (b), the Administrator shall, subject
22 to subparagraph (C), not later than 90 days
23 after the receipt of a claim under subsection
24 (d), and not later than 30 days after the receipt
25 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) REASONS FOR DENIAL OR MODIFICA-
4 TION.—If the Administrator denies or modifies
5 a claim or request under subparagraph (A), the
6 Administrator shall provide to the person that
7 submitted the claim or request a written state-
8 ment of the reasons for the denial or modifica-
9 tion of the claim or request.
10 "(C) SUBSETS.—The Administrator
11 shall—
12 "(i) except for claims described in
13 subsection (b)(8), review all claims or re-
14 quests under this section for the protection
15 against disclosure of the specific identity of
16 a chemical substance; and
17 "(ii) review a representative subset,
18 comprising at least 25 percent, of all other
19 claims or requests for protection against
20 disclosure.
21 "(D) EFFECT OF FAILURE TO ACT.—The
22 failure of the Administrator to make a decision
23 regarding a claim or request for protection
24 against disclosure or extension under this sec-
25 tion shall not be the basis for denial or elimi-

1 nation of a claim or request for protection
2 against disclosure.
3 "(2) NOTIFICATION.—
4 "(A) IN GENERAL.—Except as provided in
5 subparagraph (B) and subsections (c), (e), and
6 (f), if the Administrator denies or modifies a
7 claim or request under paragraph (1), intends
8 to release information pursuant to subsection
9 (e), or promulgates a rule under section 6(d)
10 establishing a ban or phase-out of a chemical
11 substance, the Administrator shall notify, in
12 writing and by certified mail, the person that
13 submitted the claim of the intent of the Admin-
14 istrator to release the information.
15 "(B) RELEASE OF INFORMATION.—Except
16 as provided in subparagraph (C), the Adminis-
17 trator shall not release information under this
18 subsection until the date that is 30 days after
19 the date on which the person that submitted the
20 request receives notification under subpara-
21 graph (A).
22 "(C) EXCEPTIONS.—
23 "(i) IN GENERAL.—For information
24 under paragraph (3) or (8) of subsection
25 (e), the Administrator shall not release

1 that information until the date that is 15
2 days after the date on which the person
3 that submitted the claim or request re-
4 ceives a notification, unless the Adminis-
5 trator determines that release of the infor-
6 mation is necessary to protect against an
7 imminent and substantial harm to health
8 or the environment, in which case no prior
9 notification shall be necessary.
10 "(ii) NOTIFICATION AS SOON AS PRAC-
11 TICABLE.—For information under para-
12 graphs (4) and (6) of subsection (e), the
13 Administrator shall notify the person that
14 submitted the information that the infor-
15 mation has been disclosed as soon as prac-
16 ticable after disclosure of the information.
17 "(iii) NO NOTIFICATION REQUIRED.—
18 Notification shall not be required—
19 "(I) for the disclosure of infor-
20 mation under paragraph (1), (2), (7),
21 or (9) of subsection (e); or
22 "(II) for the disclosure of infor-
23 mation for which—

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

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

"(3) REBUTTABLE PRESUMPTION.—

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

"(B) REQUEST FOR NONDISCLOSURE.—A person that receives a notification under para-

1 graph (2) with respect to the information de-
2 scribed in subparagraph (A) may submit to the
3 Administrator, before the date on which the in-
4 formation is to be released pursuant to para-
5 graph (2)(B), a request with supporting docu-
6 mentation describing why the person believes
7 some or all of that information should not be
8 disclosed.

9 "(C) DETERMINATION BY ADMINIS-
10 TRATOR.—

11 "(i) IN GENERAL.—Not later than 30
12 days after the Administrator receives a re-
13 quest under subparagraph (B), the Admin-
14 istrator shall determine whether the docu-
15 mentation provided by the person making
16 the request rebuts or does not rebut the
17 presumption described in subparagraph
18 (A), for all or a portion of the information
19 that the person has requested not be dis-
20 closed.

21 "(ii) OBJECTIVE.—The Administrator
22 shall make the determination with the ob-
23 jective of ensuring that information rel-
24 evant to protection of health and the envi-

1 ronment is disclosed to the maximum ex-
2 tent practicable.
3 "(D) TIMING.—Not later than 30 days
4 after making the determination described in
5 subparagraph (C), the Administrator shall
6 make public the information the Administrator
7 has determined is not to be protected from dis-
8 closure.
9 "(E) NO TIMELY REQUEST RECEIVED.—If
10 the Administrator does not receive, before the
11 date on which the information described in sub-
12 paragraph (A) is to be released pursuant to
13 paragraph (2)(B), a request pursuant to sub-
14 paragraph (B), the Administrator shall prompt-
15 ly make public all of the information.
16 "(4) APPEALS.—
17 "(A) IN GENERAL.—If a person receives a
18 notification under paragraph (2) and believes
19 disclosure of the information is prohibited
20 under subsection (a), before the date on which
21 the information is to be released pursuant to
22 paragraph (2)(B), the person may bring an ac-
23 tion to restrain disclosure of the information
24 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) REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (e) in a format and language that is readily accessible and understandable.

"(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

1 provided information in accordance with subsection
2 (e)(2), including any employee of that contractor,
3 shall be considered to be an employee of the United
4 States.
5 "(i) APPLICABILITY.—
6 "(1) IN GENERAL.—Except as otherwise pro-
7 vided in this section, section 8, or any other applica-
8 ble Federal law, the Administrator shall have no au-
9 thority—
10 "(A) to require the substantiation or re-
11 substantiation of a claim for the protection
12 from disclosure of information reported to or
13 otherwise obtained by the Administrator under
14 this Act before the date of enactment of the
15 Frank R. Lautenberg Chemical Safety for the
16 21st Century Act; or
17 "(B) to impose substantiation or re-
18 substantiation requirements under this Act that
19 are more extensive than those required under
20 this section.
21 "(2) ACTIONS PRIOR TO PROMULGATION OF
22 RULES.—Nothing in this Act prevents the Adminis-
23 trator from reviewing, requiring substantiation or re-
24 substantiation for, or approving, modifying or deny-
25 ing any claim for the protection from disclosure of

information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.''.

SEC. 15. PROHIBITED ACTS.

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

''(1) fail or refuse to comply with—

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

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

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

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

SEC. 16. PENALTIES.

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

(1) in subsection (a)(1)—

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

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

(2) in subsection (b)—

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

"(1) IN GENERAL.—Any person that";

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

(C) by adding at the end the following:

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

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

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

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

SEC. 17. STATE-FEDERAL RELATIONSHIP.

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

"(a) IN GENERAL.—

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

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

"(i) a rule promulgated by the Administrator;

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

"(iii) an order issued by the Administrator.

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

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

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

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

"(2) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of stat-

1 utes and administrative actions applicable to specific
2 substances shall not occur until the effective date of
3 the applicable action described in paragraph (1)
4 taken by the Administrator.

5 "(b) NEW STATUTES OR ADMINISTRATIVE ACTIONS
6 CREATING PROHIBITIONS OR OTHER RESTRICTIONS.—

7 "(1) IN GENERAL.—Except as provided in sub-
8 sections (c), (d), (e), (f), and (g), beginning on the
9 date on which the Administrator defines and pub-
10 lishes the scope of a safety assessment and safety
11 determination under section 6(a)(2) and ending on
12 the date on which the deadline established pursuant
13 to section 6(a) for completion of the safety deter-
14 mination expires, or on the date on which the Ad-
15 ministrator publishes the safety determination under
16 section 6(a), whichever is earlier, no State or polit-
17 ical subdivision of a State may establish a statute or
18 administrative action prohibiting or restricting the
19 manufacture, processing, distribution in commerce
20 or use of a chemical substance that is a high-priority
21 substance designated under section 4A.

22 "(2) EFFECT OF SUBSECTION.—

23 "(A) IN GENERAL.—This subsection does
24 not restrict the authority of a State or political
25 subdivision of a State to continue to enforce

1 any statute enacted, or administrative action
2 taken, prior to the date on which the Adminis-
3 trator defines and publishes the scope of a safe-
4 ty assessment and safety determination under
5 section 6(a)(2).
6 "(B) LIMITATION.—Subparagraph (A)
7 does not allow a State or political subdivision of
8 a State to enforce any new prohibition or re-
9 striction under a statute or administrative ac-
10 tion described in that subparagraph, if the pro-
11 hibition or restriction is established after the
12 date described in that subparagraph.
13 "(c) SCOPE OF PREEMPTION.—Federal preemption
14 under subsections (a) and (b) of statutes and administra-
15 tive actions applicable to specific substances shall apply
16 only to—
17 "(1) the chemical substances or category of
18 substances subject to a rule, order, or consent agree-
19 ment under section 4;
20 "(2) the hazards, exposures, risks, and uses or
21 conditions of use of such substances that are identi-
22 fied by the Administrator as subject to review in a
23 safety assessment and included in the scope of the
24 safety determination made by the Administrator for

1 the substance, or of any rule the Administrator pro-
2 mulgates pursuant to section 6(d); or
3 "(3) the uses of such substances that the Ad-
4 ministrator has specified as significant new uses and
5 for which the Administrator has required notifica-
6 tion pursuant to a rule promulgated under section 5.
7 "(d) EXCEPTIONS.—
8 "(1) NO PREEMPTION OF STATUTES AND AD-
9 MINISTRATIVE ACTIONS.—
10 "(A) IN GENERAL.—Nothing in this Act,
11 nor any amendment made by this Act, nor any
12 rule, standard of performance, safety deter-
13 mination, or scientific assessment implemented
14 pursuant to this Act, shall affect the right of a
15 State or a political subdivision of a State to
16 adopt or enforce any rule, standard of perform-
17 ance, safety determination, scientific assess-
18 ment, or any protection for public health or the
19 environment that—
20 "(i) is adopted or authorized under
21 the authority of any other Federal law or
22 adopted to satisfy or obtain authorization
23 or approval under any other Federal law;
24 "(ii) implements a reporting, moni-
25 toring, disclosure, or other information ob-

1 ligation for the chemical substance not oth-
2 erwise required by the Administrator under
3 this Act or required under any other Fed-
4 eral law;
5 "(iii) is adopted pursuant to authority
6 under a law of the State or political sub-
7 division of the State related to water qual-
8 ity, air quality, or waste treatment or dis-
9 posal, except to the extent that the ac-
10 tion—
11 "(I) imposes a restriction on the
12 manufacture, processing, distribution
13 in commerce, or use of a chemical
14 substance; and
15 "(II)(aa) addresses the same haz-
16 ards and exposures, with respect to
17 the same conditions of use as are in-
18 cluded in the scope of the safety de-
19 termination pursuant to section 6, but
20 is inconsistent with the action of the
21 Administrator; or
22 "(bb) would cause a violation of
23 the applicable action by the Adminis-
24 trator under section 5 or 6; or

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

"(B) IDENTICAL REQUIREMENTS.—

"(i) IN GENERAL.—The penalties and other sanctions applicable under a law of a State or political subdivision of a State in the event of noncompliance with the identical requirement shall be no more stringent than the penalties and other sanctions available to the Administrator under section 16 of this Act.

"(ii) PENALTIES.—In the case of an identical requirement—

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

"(II) if a State or political subdivision of a State has assessed a penalty for a specific violation, the Administrator may not assess a penalty for that violation in an amount that

would cause the total of the penalties assessed for the violation by the State or political subdivision of a State and the Administrator combined to exceed the maximum amount that may be assessed for that violation by the Administrator under section 16.

"(2) APPLICABILITY TO CERTAIN RULES OR ORDERS.—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. Lau-

1 tenberg Chemical Safety for the 21st Century
2 Act) shall govern the preemptive effect of any
3 rule or order that is promulgated or issued re-
4 specting such chemical substance or mixture
5 under section 6 of this Act after that effective
6 date, unless the latter rule or order is with re-
7 spect to a chemical substance or mixture con-
8 taining a chemical substance and follows a des-
9 ignation of that chemical substance as a high-
10 priority substance under subsection (b) or (c) of
11 section 4A or as an additional priority for safe-
12 ty assessment and safety determination under
13 section 4A(c).
14 "(e) PRESERVATION OF CERTAIN LAWS.—
15 "(1) IN GENERAL.—Nothing in this Act, sub-
16 ject to subsection (g) of this section, shall—
17 "(A) be construed to preempt or otherwise
18 affect the authority of a State or political sub-
19 division of a State to continue to enforce any
20 action taken before August 1, 2015, under the
21 authority of a law of the State or political sub-
22 division of the State that prohibits or otherwise
23 restricts manufacturing, processing, distribution
24 in commerce, use, or disposal of a chemical sub-
25 stance; or

1 "(B) be construed to preempt or otherwise
2 affect any action taken pursuant to a State law
3 that was in effect on August 31, 2003.
4 "(2) EFFECT OF SUBSECTION.—This sub-
5 section does not affect, modify, or alter the relation-
6 ship between Federal law and laws of a State or po-
7 litical subdivision of a State pursuant to any other
8 Federal law.
9 "(f) WAIVERS.—
10 "(1) DISCRETIONARY EXEMPTIONS.—Upon ap-
11 plication of a State or political subdivision of a
12 State, the Administrator may by rule, exempt from
13 subsection (a), under such conditions as may be pre-
14 scribed in the rule, a statute or administrative action
15 of that State or political subdivision of the State
16 that relates to the effects of, or exposure to, a chem-
17 ical substance under the conditions of use if the Ad-
18 ministrator determines that—
19 "(A) compelling conditions warrant grant-
20 ing the waiver to protect health or the environ-
21 ment;
22 "(B) compliance with the proposed require-
23 ment of the State or political subdivision of the
24 State would not unduly burden interstate com-
25 merce in the manufacture, processing, distribu-

1 tion in commerce, or use of a chemical sub-
2 stance;
3 "(C) compliance with the proposed require-
4 ment of the State or political subdivision of the
5 State would not cause a violation of any appli-
6 cable Federal law, rule, or order; and
7 "(D) in the judgment of the Adminis-
8 trator, the proposed requirement of the State or
9 political subdivision of the State is designed to
10 address a risk of a chemical substance, under
11 the conditions of use, that was identified—
12 "(i) consistent with the best available
13 science;
14 "(ii) using supporting studies con-
15 ducted in accordance with sound and ob-
16 jective scientific practices; and
17 "(iii) based on the weight of the sci-
18 entific evidence.
19 "(2) REQUIRED EXEMPTIONS.—Upon applica-
20 tion of a State or political subdivision of a State, the
21 Administrator shall exempt from subsection (b) a
22 statute or administrative action of a State or polit-
23 ical subdivision of a State that relates to the effects
24 of exposure to a chemical substance under the condi-
25 tions of use if the Administrator determines that—

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

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

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

"(3) DETERMINATION OF A WAIVER REQUEST.—The duty of the Administrator to grant or deny a waiver application shall be nondelegable and shall be exercised—

"(A) not later than 180 days after the date on which an application under paragraph (1) is submitted; and

"(B) not later than 110 days after the date on which an application under paragraph (2) is submitted.

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

"(5) NOTICE AND COMMENT.—Except in the case of an application approved under paragraph (9), the application of a State or political subdivision of a State shall be subject to public notice and comment.

"(6) FINAL AGENCY ACTION.—The decision of the Administrator on the application of a State or political subdivision of a State shall be—

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

"(B) subject to judicial review.

"(7) DURATION OF WAIVERS.—A waiver granted under paragraph (2) or approved under paragraph (9) shall remain in effect until such time as

1 the Administrator publishes the safety determination
2 under section 6(a)(4).
3 "(8) JUDICIAL REVIEW OF WAIVERS.—Not later
4 than 60 days after the date on which the Adminis-
5 trator makes a determination on an application of a
6 State or political subdivision of a State under para-
7 graph (1) or (2), any person may file a petition for
8 judicial review in the United States Court of Appeals
9 for the District of Columbia Circuit, which shall
10 have exclusive jurisdiction over the determination.
11 "(9) APPROVAL.—
12 "(A) AUTOMATIC APPROVAL.—If the Ad-
13 ministrator fails to meet the deadline estab-
14 lished under paragraph (3)(B), the application
15 of a State or political subdivision of a State
16 under paragraph (2) shall be automatically ap-
17 proved, effective on the date that is 10 days
18 after the deadline.
19 "(B) REQUIREMENTS.—Notwithstanding
20 paragraph (6), approval of a waiver application
21 under subparagraph (A) for failure to meet the
22 deadline under paragraph (3)(B) shall not be
23 considered final agency action or be subject to
24 judicial review or public notice and comment.
25 "(g) SAVINGS.—

1 "(1) NO PREEMPTION OF COMMON LAW OR
2 STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF
3 OR CRIMINAL CONDUCT.—
4 "(A) IN GENERAL.—Nothing in this Act,
5 nor any amendment made by this Act, nor any
6 safety standard, rule, requirement, standard of
7 performance, safety determination, or scientific
8 assessment implemented pursuant to this Act,
9 shall be construed to preempt, displace, or sup-
10 plant any state or Federal common law rights
11 or any state or Federal statute creating a rem-
12 edy for civil relief, including those for civil dam-
13 age, or a penalty for a criminal conduct.
14 "(B) CLARIFICATION OF NO PREEMP-
15 TION.—Notwithstanding any other provision of
16 this Act, nothing in this Act, nor any amend-
17 ments made by this Act, shall preempt or pre-
18 clude any cause of action for personal injury,
19 wrongful death, property damage, or other in-
20 jury based on negligence, strict liability, prod-
21 ucts liability, failure to warn, or any other legal
22 theory of liability under any State law, mari-
23 time law, or Federal common law or statutory
24 theory.
25 "(2) NO EFFECT ON PRIVATE REMEDIES.—

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

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

SEC. 18. JUDICIAL REVIEW.

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

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A)—

(I) in the first sentence—

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

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

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

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

(ii) in subparagraph (B)—

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

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

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

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

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

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

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

(2) in subsection (c)(1)(B)—

(A) in clause (i)—

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

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

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

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

SEC. 19. CITIZENS' CIVIL ACTIONS.

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

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

(2) in subsection (b)—

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

(B) in paragraph (2), by striking the period at the end and inserting ", except that no prior notification shall be required in the case of a civil action brought to compel a decision by the Administrator pursuant to section 18(f)(3)(B); or"; and

(C) by adding at the end the following:

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

SEC. 20. CITIZENS' PETITIONS.

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

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an order under section 4 or 5(d)"; and

(2) in subsection (b)—

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

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

"(B) DE NOVO PROCEEDING.—

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

"(ii) DEMONSTRATION.—

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

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

1 is needed for a purpose identified
2 in section 4(a);
3 "(bb) in the case of a peti-
4 tion to issue an order under sec-
5 tion 5(d), the chemical substance
6 is not likely to meet the safety
7 standard;
8 "(cc) in the case of a peti-
9 tion to initiate a proceeding for
10 the issuance of a rule under sec-
11 tion 6(d), the chemical substance
12 does not meet the safety stand-
13 ard; 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; and

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 paragraph (1) or (4) of section 8(a); or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"(i) the lower of—

"(I) 25 percent of the costs of conducting the activities identified in paragraph (2)(A), other than the costs to conduct and complete safety assessments and determinations under

1 section 6 for chemical substances
2 identified pursuant to section 4A(c);
3 or
4 "(II) $25,000,000 (subject to ad-
5 justment pursuant to subparagraph
6 (F)); and
7 "(ii) the full costs and the 50-percent
8 portion of the costs of safety assessments
9 and safety determinations specified in sub-
10 paragraph (D);
11 "(C) reflect an appropriate balance in the
12 assessment of fees between manufacturers and
13 processors, and allow the payment of fees by
14 consortia of manufacturers or processors;
15 "(D) notwithstanding subparagraph (B)
16 and paragraph (4)(D)—
17 "(i) for substances designated pursu-
18 ant to section 4A(c)(1), establish the fee at
19 a level sufficient to defray the full annual
20 costs to the Administrator of conducting
21 the safety assessment and safety deter-
22 mination under section 6; and
23 "(ii) for substances designated pursu-
24 ant to section 4A(c)(3), establish the fee at
25 a level sufficient to defray 50 percent of

1 the annual costs to the Administrator of
2 conducting the safety assessment and safe-
3 ty determination under section 6;
4 "(E) prior to the establishment or amend-
5 ment of any fees under paragraph (1), consult
6 and meet with parties potentially subject to the
7 fees or their representatives, subject to the con-
8 dition that no obligation under the Federal Ad-
9 visory Committee Act (5 U.S.C. App.) or sub-
10 chapter III of chapter 5 of title 5, United
11 States Code, is applicable with respect to such
12 meetings;
13 "(F) beginning with the fiscal year that is
14 3 years after the date of enactment of the
15 Frank R. Lautenberg Chemical Safety for the
16 21st Century Act, and every 3 years thereafter,
17 after consultation with parties potentially sub-
18 ject to the fees and their representatives pursu-
19 ant to subparagraph (E), increase or decrease
20 the fees established under paragraph (1) as
21 necessary to adjust for inflation and to ensure,
22 based on the audit analysis required under
23 paragraph (5)(B), that funds deposited in the
24 Fund are sufficient to defray—

"(i) approximately but not more than 25 percent of the annual costs to conduct the activities identified in paragraph (2)(A), other than the costs to conduct and complete safety assessments and determinations under section 6 for chemical substances identified pursuant to section 4A(c); and

"(ii) the full annual costs and the 50-percent portion of the annual costs of safety assessments and safety determinations specified in subparagraph (D);

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

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

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

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

and Reduction program project of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for that program project for fiscal year 2014.

"(5) AUDITING.—

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

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

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

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

"(iii) the amounts budgeted, appropriated, collected from fees, and disbursed to meet the requirements of sections 4, 4A, 5, 6, 8, and 14, including the allocation of

full time equivalent employees to each such section or activity; and

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

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

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

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

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

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

(3) adding at the end the following:

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

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

(a) IN GENERAL.—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) NATIONAL COORDINATING ENTITY FOR SUSTAINABLE CHEMISTRY.—

"(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 Director of the Office of Science and Technology Policy shall convene an entity under the National Science and Technology Council with the responsibility to coordinate Federal programs and activities in support of sustainable chemistry, including, as appropriate, at the National Science Foundation, the Department of Energy, the Department of

1 Agriculture, the Environmental Protection Agency,
2 the National Institute of Standards and Technology,
3 the Department of Defense, the National Institutes
4 of Health, and other related Federal agencies.
5 "(2) CHAIRMAN.—The entity described in para-
6 graph (1) shall be chaired by the Director of the Na-
7 tional Science Foundation and the Assistant Admin-
8 istrator for the Office of Research and Development
9 of the Environmental Protection Agency, or their
10 designees.
11 "(3) DUTIES.—
12 "(A) IN GENERAL.—The entity described
13 in paragraph (1) shall—
14 "(i) develop a working definition of
15 sustainable chemistry, after seeking advice
16 and input from stakeholders as described
17 in clause (v);
18 "(ii) oversee the planning, manage-
19 ment, and coordination of the Sustainable
20 Chemistry Initiative described in sub-
21 section (d);
22 "(iii) develop a national strategy for
23 sustainable chemistry as described in sub-
24 section (f);

"(iv) develop an implementation plan for sustainable chemistry as described in subsection (g); and

"(v) consult and coordinate with stakeholders qualified to provide advice and information on the development of the initiative, national strategy, and implementation plan for sustainable chemistry, at least once per year, to carry out activities that may include workshops, requests for information, and other efforts as necessary.

"(B) STAKEHOLDERS.—The stakeholders described in subparagraph (A)(v) shall include representatives from—

"(i) industry (including small- and medium-sized enterprises from across the value chain);

"(ii) the scientific community (including the National Academy of Sciences, scientific professional societies, and academia);

"(iii) the defense community;

"(iv) State, tribal, and local governments;

"(v) State or regional sustainable chemistry programs;

"(vi) nongovernmental organizations; and

"(vii) other appropriate organizations.

"(4) SUNSET.—

"(A) IN GENERAL.—On completion of the national strategy and accompanying implementation plan for sustainable chemistry as described in paragraph (3), the Director of the Office of Science and Technology Policy—

"(i) shall review the need for further work; and

"(ii) may disband the entity described in paragraph (1) if no further efforts are determined to be necessary.

"(B) NOTICE AND JUSTIFICATION.—The Director of the Office of Science and Technology Policy shall provide notice and justification, including an analysis of options to establish the Sustainable Chemistry Initiative described in subsection (d) and the partnerships described in subsection (e) within 1 or more appropriate Federal agencies, regarding a decision to disband the entity not less than 90 days

prior to the termination date to the Committee on Science, Space, and Technology and the 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.

"(d) SUSTAINABLE CHEMISTRY INITIATIVE.—The entity described in subsection (c)(1) shall oversee the establishment of an interagency Sustainable Chemistry Initiative to promote and coordinate activities designed—

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

"(A) coordination and promotion of sustainable chemistry research, development, demonstration, and technology transfer conducted at Federal and national laboratories and Federal agencies and at public and private institutions of higher education; and

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

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

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

"(2) to examine methods by which the Federal Government can offer incentives for consideration and use of sustainable chemistry processes and products that encourage competition and overcoming market barriers, including grants, loans, loan guarantees, and innovative financing mechanisms;

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

"(4) to 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

1 "(D) costs and benefits; and
2 "(5) to support (including through technical as-
3 sistance, participation, financial support, or other
4 forms of support) economic, legal, and other appro-
5 priate social science research to identify barriers to
6 commercialization and methods to advance commer-
7 cialization of sustainable chemistry.
8 "(e) PARTNERSHIPS IN SUSTAINABLE CHEMISTRY.—
9 "(1) IN GENERAL.—The entity described in
10 subsection (c)(1), itself or through an appropriate
11 subgroup designated or established by the entity,
12 shall work through the agencies described in sub-
13 section (c)(1) to support, through financial, tech-
14 nical, or other assistance, the establishment of part-
15 nerships between institutions of higher education,
16 nongovernmental organizations, consortia, and com-
17 panies across the value chain in the chemical indus-
18 try, including small- and medium-sized enterprises—
19 "(A) to establish collaborative research, de-
20 velopment, demonstration, technology transfer,
21 and commercialization programs; and
22 "(B) to train students and retrain profes-
23 sional scientists and engineers in the use of sus-
24 tainable chemistry concepts and strategies by
25 methods including—

"(i) developing curricular materials and courses for undergraduate and graduate levels and for the professional development of scientists and engineers; and

"(ii) publicizing the availability of professional development courses in sustainable chemistry and recruiting scientists and engineers to pursue those courses.

"(2) PRIVATE SECTOR ENTITIES.—To be eligible for support under this section, a partnership in sustainable chemistry shall include at least 1 private sector entity.

"(3) SELECTION OF PARTNERSHIPS.—In selecting partnerships for support under this section, the entity and the agencies described in subsection (c)(1) shall also consider the extent to which the applicants are willing and able to demonstrate evidence of support for, and commitment—

"(A) to achieving the goals of the Sustainable Chemistry Initiative described in subsection (d); and

"(B) to sustaining any new innovations, tools, and resources generated from funding under the program.

"(4) PROHIBITED USE OF FUNDS.—Financial support provided under this section may not be used—

"(A) to support or expand a regulatory chemical management program at an implementing agency under a State law; or

"(B) to construct or renovate a building or structure.

"(f) NATIONAL STRATEGY 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 entity described in subsection (c)(1) shall submit to the Committee on Science, Space, and Technology and the 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, a national strategy that shall include—

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

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

"(C) an analysis of the progress made toward achieving the goals and priorities of the Sustainable Chemistry Initiative described in subsection (d), and recommendations for future initiative activities, including consideration of options to establish the Sustainable Chemistry Initiative and the partnerships described in subsection (e) within 1 or more appropriate Federal agencies;

"(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 establishment of 1 or more dedicated sustainable chemistry centers of excellence or hubs;

"(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 Sustainable Chemistry Initiative; and

"(F) a framework for advancing sustainable chemistry research, development, technology transfer, commercialization, and education and training.

"(2) SUBMISSION TO GAO.—The entity described in subsection (c)(1) shall submit the national strategy described in paragraph (1) to the Government Accountability Office for consideration in future Congressional inquiries.

"(g) IMPLEMENTATION PLAN.—Not later than 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the entity described in subsection (c)(1) shall submit to the Committee on Science, Space, and Technology and the 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, an implementation plan, based on the findings of the national strategy and other assessments, as appropriate, for sustainable chemistry.".

(b) SUSTAINABLE CHEMISTRY BASIC RESEARCH.—Subject to the availability of appropriated funds, the Director of the National Science Foundation shall continue to carry out the Green Chemistry Basic Research program authorized under section 509 of the National Science Foundation Authorization Act of 2010 (42 U.S.C. 1862p–3).

SEC. 25. STATE PROGRAMS.

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

(1) in subsection (b)(1)—

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

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

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

SEC. 26. AUTHORIZATION OF APPROPRIATIONS.

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

SEC. 27. ANNUAL REPORT.

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

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

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

SEC. 28. EFFECTIVE DATE.

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

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

"(a) IN GENERAL.—This"; and

(2) by adding at the end the following:

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

SEC. 29. ELEMENTAL MERCURY.

(a) TEMPORARY GENERATOR ACCUMULATION.—Section 5 of the Mercury Export Ban Act of 2008 (42 U.S.C. 6939f) is amended—

(1) in subsection (a)(2), by striking "2013" and inserting "2019";

(2) in subsection (b)—

(A) in paragraph (1)—

(i) by redesignating subparagraphs (A), (B), and (C), as clauses (i), (ii), and (iii), respectively and indenting appropriately;

(ii) in the first sentence, by striking "After consultation" and inserting the following:

1 "(A) ASSESSMENT AND COLLECTION.—
2 After consultation";
3 (iii) in the second sentence, by strik-
4 ing "The amount of such fees" and insert-
5 ing the following:
6 "(B) AMOUNT.—The amount of the fees
7 described in subparagraph (A)";
8 (iv) in subparagraph (B) (as so des-
9 ignated)—
10 (I) in clause (i) (as so redesig-
11 nated), by striking "publically avail-
12 able not later than October 1, 2012"
13 and inserting "publicly available not
14 later than October 1, 2018";
15 (II) in clause (ii) (as so redesig-
16 nated), by striking "and";
17 (III) in clause (iii) (as so redesig-
18 nated), by striking the period at the
19 end and inserting ", subject to clause
20 (iv); and"; and
21 (IV) by adding at the end the fol-
22 lowing:
23 "(iv) for generators temporarily accu-
24 mulating elemental mercury in a facility
25 subject to subparagraphs (B) and (D)(iv)

of subsection (g)(2) if the facility designated in subsection (a) is not operational by January 1, 2019, shall be adjusted to subtract the cost of the temporary accumulation during the period in which the facility designated under subsection (a) is not operational.''; and

(v) by adding at the end the following:

''(C) CONVEYANCE OF TITLE AND PERMITTING.—If the facility designated in subsection (a) is not operational by January 1, 2020, the Secretary—

''(i) shall immediately accept the conveyance of title to all elemental mercury that has accumulated in facilities in accordance with subsection (g)(2)(D), before January 1, 2020, and deliver the accumulated mercury to the facility designated under subsection (a) on the date on which the facility becomes operational;

''(ii) shall pay any applicable Federal permitting costs, including the costs for permits issued under section 3005(c) of the Solid Waste Disposal Act (42 U.S.C. 6925(c)); and

"(iii) shall store, or pay the cost of storage of, until the time at which a facility designated in subsection (a) is operational, accumulated mercury to which the Secretary has title under this subparagraph in a facility that has been issued a permit under section 3005(c) of the Solid Waste Disposal Act (42 U.S.C. 6925(c)).";

and

(B) in paragraph (2), in the first sentence, by striking "paragraph (1)(C)" and inserting "paragraph (1)(B)(iii)"; and

(3) in subsection (g)(2)—

(A) in the undesignated material at the end, by striking "This subparagraph" and inserting the following:

"(C) Subparagraph (B)";

(B) in subparagraph (C) (as added by paragraph (1)), by inserting "of that subparagraph" before the period at the end; and

(C) by adding at the end the following:

"(D) A generator producing elemental mercury incidentally from the beneficiation or processing of ore or related pollution control activities, may accumulate the mercury produced

1 onsite that is destined for a facility designated
2 by the Secretary under subsection (a), for more
3 than 90 days without a permit issued under
4 section 3005(c) of the Solid Waste Disposal Act
5 (42 U.S.C. 6925(c)), and shall not be subject to
6 the storage prohibition of section 3004(j) of
7 that Act (42 U.S.C. 6924(j)), if—
8 "(i) the Secretary is unable to accept
9 the mercury at a facility designated by the
10 Secretary under subsection (a) for reasons
11 beyond the control of the generator;
12 "(ii) the generator certifies in writing
13 to the Secretary that the generator will
14 ship the mercury to a designated facility
15 when the Secretary is able to accept the
16 mercury;
17 "(iii) the generator certifies in writing
18 to the Secretary that the generator is stor-
19 ing only mercury the generator has pro-
20 duced or recovered onsite and will not sell,
21 or otherwise place into commerce, the mer-
22 cury; and
23 "(iv) the generator has obtained an
24 identification number under section 262.12
25 of title 40, Code of Federal Regulations,

1 and complies with the requirements de-
2 scribed in paragraphs (1) through (4) of
3 section 262.34(a) of title 40, Code of Fed-
4 eral Regulations (as in effect on the date
5 of enactment of this subparagraph).
6 "(E) MANAGEMENT STANDARDS FOR TEM-
7 PORARY STORAGE.—Not later than January 1,
8 2017, the Secretary, after consultation with the
9 Administrator of the Environmental Protection
10 Agency and State agencies in affected States,
11 shall develop and make available guidance that
12 establishes procedures and standards for the
13 management and short-term storage of ele-
14 mental mercury at a generator covered under
15 subparagraph (D), including requirements to
16 ensure appropriate use of flasks or other suit-
17 able containers. Such procedures and standards
18 shall be protective of human health and the en-
19 vironment and shall ensure that the elemental
20 mercury is stored in a safe, secure, and effec-
21 tive manner. A generator may accumulate mer-
22 cury in accordance with subparagraph (D) im-
23 mediately upon enactment of this Act, and not-
24 withstanding that guidance called for by this

1 paragraph (E) has not been developed or made
2 available.".
3 (b) INTERIM STATUS.—Section 5(d)(1) of the Mer-
4 cury Export Ban Act of 2008 (42 U.S.C. 6939f(d)(1)) is
5 amended—
6 (1) in the fourth sentence, by striking "in exist-
7 ence on or before January 1, 2013,"; and
8 (2) in the last sentence, by striking "January
9 1, 2015" and inserting "January 1, 2020".
10 (c) MERCURY INVENTORY.—Section 8(b) of the Toxic
11 Substances Control Act (15 U.S.C. 2607(b)) (as amended
12 by section 10(2)) is amended by adding at the end the
13 following:
14 "(10) MERCURY.—
15 "(A) DEFINITION OF MERCURY.—In this
16 paragraph, notwithstanding section 3(2)(B), the
17 term 'mercury' means—
18 "(i) elemental mercury; and
19 "(ii) a mercury compound.
20 "(B) PUBLICATION.—Not later than April
21 1, 2017, and every 3 years thereafter, the Ad-
22 ministrator shall publish in the Federal Reg-
23 ister an inventory of mercury supply, use, and
24 trade in the United States.

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

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

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

"(D) REPORTING.—

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

"(ii) COORDINATION.—To avoid duplication, the Administrator shall coordinate the reporting under this subparagraph

with the Interstate Mercury Education and Reduction Clearinghouse.

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

(d) PROHIBITION ON EXPORT OF CERTAIN MERCURY COMPOUNDS.—Section 12(c) of the Toxic Substances Control Act (15 U.S.C. 2611(c)) (as amended by section 13(3)) is amended—

(1) in the subsection heading, by inserting "AND MERCURY COMPOUNDS" after "MERCURY"; and

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

"(3) PROHIBITION ON EXPORT OF CERTAIN MERCURY COMPOUNDS.—

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

"(i) Mercury (I) chloride or calomel.

"(ii) Mercury (II) oxide.

"(iii) Mercury (II) sulfate.

1 "(iv) Mercury (II) nitrate.
2 "(v) Cinnabar or mercury sulphide.
3 "(vi) Any mercury compound that the
4 Administrator, at the discretion of the Ad-
5 ministrator, adds to the list by rule, on de-
6 termining that exporting that mercury
7 compound for the purpose of regenerating
8 elemental mercury is technically feasible.
9 "(B) PUBLICATION.—Not later than 90
10 days after the date of enactment of the Frank
11 R. Lautenberg Chemical Safety for the 21st
12 Century Act, and as appropriate thereafter, the
13 Administrator shall publish in the Federal Reg-
14 ister a list of the mercury compounds that are
15 prohibited from export under this paragraph.
16 "(C) PETITION.—Any person may petition
17 the Administrator to add to the list of mercury
18 compounds prohibited from export.
19 "(D) ENVIRONMENTALLY SOUND DIS-
20 POSAL.—This paragraph does not prohibit the
21 export of mercury (I) chloride or calomel for en-
22 vironmentally sound disposal to member coun-
23 tries of the Organization for Economic Coopera-
24 tion and Development, on the condition that no
25 mercury or mercury compounds are to be recov-

1 ered, recycled, or reclaimed for use, or directly
2 reused.
3 "(E) REPORT.—Not later than 5 years
4 after the date of enactment of the Frank R.
5 Lautenberg Chemical Safety for the 21st Cen-
6 tury Act, the Administrator shall evaluate any
7 exports of calomel for disposal that occurred
8 since that date of enactment and shall submit
9 to Congress a report that contains the fol-
10 lowing:
11 "(i) volumes and sources of calomel
12 exported for disposal;
13 "(ii) receiving countries of such ex-
14 ports;
15 "(iii) methods of disposal used;
16 "(iv) issues, if any, presented by the
17 export of calomel;
18 "(v) evaluation of calomel manage-
19 ment options in the United States, if any,
20 that are commercially available and com-
21 parable in cost and efficacy to methods
22 being utilized in the receiving countries;
23 and

"(vi) a recommendation regarding whether Congress should further limit or prohibit the export of calomel for disposal.

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

SEC. 30. TREVOR'S LAW.

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

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

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

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

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

1 **"SEC. 399V–6. DESIGNATION AND INVESTIGATION OF PO-**
2 **TENTIAL CANCER CLUSTERS.**

3 "(a) DEFINITIONS.—In this section:

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

9 "(2) PARTICULAR CANCER.—The term 'par-
10 ticular cancer' means one specific type of cancer or
11 a type of cancers scientifically proven to have the
12 same cause.

13 "(3) POPULATION GROUP.—The term 'popu-
14 lation group' means a group, for purposes of calcu-
15 lating cancer rates, defined by factors such as race,
16 ethnicity, age, or gender.

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

19 "(1) DEVELOPMENT OF CRITERIA.—The Sec-
20 retary shall develop criteria for the designation of
21 potential cancer clusters.

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

24 "(A) a standard for cancer cluster identi-
25 fication and reporting protocols used to deter-

1 mine when cancer incidence is greater than
2 would be typically observed;
3 "(B) scientific screening standards that
4 ensure that a cluster of a particular cancer in-
5 volves the same type of cancer, or types of can-
6 cers;
7 "(C) the population in which the cluster of
8 a particular cancer occurs by factors such as
9 race, ethnicity, age, and gender, for purposes of
10 calculating cancer rates;
11 "(D) the boundaries of a geographic area
12 in which a cluster of a particular cancer occurs
13 so as not to create or obscure a potential clus-
14 ter by selection of a specific area; and
15 "(E) the time period over which the num-
16 ber of cases of a particular cancer, or the cal-
17 culation of an expected number of cases, occurs.
18 "(c) GUIDELINES FOR INVESTIGATION OF POTEN-
19 TIAL CANCER CLUSTERS.—The Secretary, in consultation
20 with the Council of State and Territorial Epidemiologists
21 and representatives of State and local health departments,
22 shall develop, publish, and periodically update guidelines
23 for investigating potential cancer clusters. The guidelines
24 shall—

"(1) require that investigations of cancer clusters—

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

"(B) use the best available science; and

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

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

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

"(d) INVESTIGATION OF CANCER CLUSTERS.—

"(1) SECRETARY DISCRETION.—The Secretary—

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

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

1 "(2) COORDINATION.—In investigating poten-
2 tial cancer clusters, the Secretary shall coordinate
3 with agencies within the Department of Health and
4 Human Services and other Federal agencies, such as
5 the Environmental Protection Agency.
6 "(3) BIOMONITORING.—In investigating poten-
7 tial cancer clusters, the Secretary shall rely on all
8 appropriate biomonitoring information collected
9 under other Federal programs, such as the National
10 Health and Nutrition Examination Survey. The Sec-
11 retary may provide technical assistance for relevant
12 biomonitoring studies of other Federal agencies.
13 "(e) DUTIES.—The Secretary shall—
14 "(1) ensure that appropriate staff of agencies
15 within the Department of Health and Human Serv-
16 ices are prepared to provide timely assistance, to the
17 extent practicable, upon receiving a request to inves-
18 tigate a potential cancer cluster from a State or
19 local health authority;
20 "(2) maintain staff expertise in epidemiology,
21 toxicology, data analysis, environmental health and
22 cancer surveillance, exposure assessment, pediatric
23 health, pollution control, community outreach, health
24 education, laboratory sampling and analysis, spatial
25 mapping, and informatics;

1 "(3) consult with community members as inves-
2 tigations into potential cancer clusters are con-
3 ducted, as the Secretary determines appropriate;
4 "(4) collect, store, and disseminate reports on
5 investigations of potential cancer clusters, the pos-
6 sible causes of such clusters, and the actions taken
7 to address such clusters; and
8 "(5) provide technical assistance for inves-
9 tigating cancer clusters to State and local health de-
10 partments through existing programs, such as the
11 Epi-Aids program of the Centers for Disease Control
12 and Prevention and the Assessments of Chemical
13 Exposures program of the Agency for Toxic Sub-
14 stances and Disease Registry.".

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 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 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.".

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 ~~describe the manner in which the Administrator shall ensure that —~~ **ensure that—**

"(A) decisions made by the Administrator—

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

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

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

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

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

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

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

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

"(D) if appropriate, the recommendations in reports of the National Academy of Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate~~, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.~~ **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 ~~and~~**,** procedures**, and guidance** for the testing of chemical substances or mixtures under section 4.

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

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

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition

that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential; **and**

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

~~"(C) require the Administrator to~~**"(4) EPIDEMIOLOGICAL STUDIES.—Before prescribing epidemiological studies of employees, the Administrator shall** consult with the Director of the National Institute for Occupational Safety and Health**.** ~~prior to prescribing epidemiologic studies of employees; and~~

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

~~"(i) toxicity information;~~

~~"(ii) computational toxicology and bioinformatics;~~

~~* 1 "(iii) high-throughput screening methods and the prediction models of those methods; and~~

~~* 2 "(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 **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.—AT~~ **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.—AT A MINIMUM, THE~~ **REQUIREMENTS.—The** policies and procedures under this paragraph ~~shall—~~ **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 ~~the Administrator—~~ **that each draft and final safety assessment and safety determination of the Administrator include a description of—**

~~"(I)(aa) to define~~**"(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 susceptible populations that the Administrator ~~expects to consider in a safety assessment;~~ **has identified as relevant; and**

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

~~and~~

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

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

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

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

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

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

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

~~"(vi)~~**"(iv)** when relevant information is provided or otherwise made available to the Administrator, ~~shall~~ **require the Administrator to** 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~~ **by** 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), ~~and (g);~~**(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 "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";~~

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

~~(5)~~**(3)** 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.—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;~~ and~~

"(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 potential) pursuant to this section, the Administrator shall—

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

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

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

"(2) EXPLANATION IN CASE OF ORDER.—

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

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a description of—

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

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

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

"(c) Reduction of Testing on Vertebrates.—

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

"(A) ~~encouraging and facilitating—~~ **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;

** 1 "(iii) high-throughput screening methods and the prediction models of

those methods; and

** 2 "(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information~~.~~**;**

"(B) 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)~~**"(C)** 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** ~~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~~

~~* 3 "(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~~ **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

** 3 ~~"(II)~~**"(bb)** the last day of the period that begins on the date referred to in ~~clause (i)~~ **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 ~~striking "section 4(e)" and inserting "section 4(f)".~~ **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 ~~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~~ **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** ~~Administrator—~~

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

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

"(B) REQUIREMENTS.—

"(i) IN GENERAL.—The initial list of chemical substances shall contain at least 10 high-priority substances, at least 5 of which are drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, and at least 10 low-priority substances.

"(ii) SUBSEQUENTLY IDENTIFIED SUBSTANCES.—Insofar as possible, at least 50 percent of all substances subsequently identified by the Administrator as high-priority substances shall be drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, until all Work Plan chemicals have been designated under this subsection.

"(iii) ~~PERSISTENCE AND BIOACCUMULATION.—IN~~ **PREFERENCES.—**

"(I) IN GENERAL.—In developing the initial list and in identifying additional high-priority substances, the Administrator shall give preference ~~to~~ **to—**

"(aa) chemical substances ~~scored as high for~~ **that, with respect to** persistence and bioaccumulation**, score high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012; and**

"(bb) chemical substances listed in the October 2014 TSCA Work Plan and subsequent updates **that are known human carcinogens and have high acute and chronic toxicity.**

"(II) METALS AND METAL COMPOUNDS.—In prioritizing and assessing metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007 (or a successor document), and may use other applicable information consistent with the best available science.

"(C) ADDITIONAL CHEMICAL REVIEWS.—The Administrator shall, as soon as practicable and not later than—

"(i) 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 20 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 20 low-priority substances have been designated; and

"(ii) 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 25 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 25 low-priority substances have been designated.

"(3) IMPLEMENTATION.—

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

"(i) ACTIVE SUBSTANCES.—In ~~carrying out~~ **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 ~~carrying out~~ **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.** ~~high-priority substances.~~

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

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

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

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

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

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

chemical 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~~ **consistent with** the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in ~~a timely manner.~~ **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—~~ **that includes and identifies substances—**

~~"(i)~~ **"(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; and~~ **postponed pursuant to subsection (b)(5), including the basis for the postponement; and**

~~"(ii)~~**"(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 **and storage near significant sources of drinking water**;

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

"(F) whether the volume of a chemical substance as reported ~~under~~ **pursuant to** a rule promulgated pursuant to section 8(a) has significantly increased or decreased

~~during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance~~;

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

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

"(b) Prioritization Screening Process and Decisions.—

"(1) IN ~~GENERAL.—THE~~ **GENERAL.—In implementing 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 ~~required~~ **needed** to establish the priority of a chemical substance under this section, the Administrator may ~~defer the~~ **postpone a** 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) identify the information and analysis on which the decisions are based; and**

~~"(B)~~ **"(C)** provide 90 days for public comment.

"(8) REVISIONS OF PRIOR DESIGNATIONS.—

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

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

"(9) OTHER INFORMATION RELEVANT TO PRIORITIZATION.—

"(A) IN GENERAL.—If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State proposes an administrative action or enacts a statute or takes an administrative action to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not 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.

~~"(E)~~**"(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 under this subsection is established, the Administrator shall—

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

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

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

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

"(B) the regulation of those activities.

"(c) Additional Priorities for Safety Assessments and Determinations.—

"(1) REQUIREMENTS.—

"(A) IN GENERAL.—The ~~prioritization screening process developed~~ **rule promulgated** 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)~~ **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) ~~if a sufficient number of additional priority requests meet the requirements of paragraph (1),~~ **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) ~~are substances designated under the process and criteria pursuant to paragraph (1);~~**(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 ~~the~~ 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 (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) **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 ~~any necessary~~ **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), ~~at the end~~ **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) ~~take into consideration~~ **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~~, or of the chemical substance for a new use, that is not in compliance with~~ **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

"(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~~**, with respect to** persistence and bioaccumulation, **scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012,** 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~~ **EXPOSURES.—To the extent practicable, the** Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

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

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

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

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

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

"(D) on receipt of information the Administrator finds supports the determination

under paragraph (3), shall promptly make the determination.";

(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 ~~of~~ **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 ~~(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) 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 ~~a~~ **any necessary** final rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; ~~and~~

"(6) may extend any deadline under paragraph (4) ~~or (5) for a reasonable period of time after an adequate public justification~~ **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~~, plus any deferral under subsection (c)(2),~~ does not exceed 2 years.

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

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination ~~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 **pursuant to section 3A(h)(2)(D)**, and subject to section 18**(g)**, the Administrator shall ~~determine that—~~ **determine—**

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

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

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

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

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

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

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

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

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

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

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

"(d) Rule.—

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

"(2) SCOPE.—

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

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

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

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

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

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

"(IV) following a determination by the Administrator that compliance is technologically or economically infeasible 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; ~~and~~

"(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 necessary to ensure that the substance meets the safety standard for that population.

"(B) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines ~~ranks high for~~**, with respect to** persistence and bioaccumulation, **scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012,** 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~~ **RESTRICTIONS.—Subject to section 18, a** restriction under paragraph (1) may include, as appropriate—

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

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

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

the chemical substance;

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

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

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

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

"(i) a particular use;

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

"(iii) all uses;

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

"(i) a particular use; or

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

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

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

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

"(4) ANALYSIS FOR RULEMAKING.—

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

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

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the

Administrator shall make publicly available any analysis conducted under this paragraph.

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

"(5) EXEMPTIONS.—

"(A) IN GENERAL.—The Administrator may ~~exempt 1 or more uses of a chemical substance from any restriction in~~**, 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 ~~rule~~ **restriction** cannot be complied with, without—

"(I) harming national security;

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

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

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

"(B) EXEMPTION ANALYSIS.—In proposing a rule under ~~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 **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 **this** paragraph~~(1)~~, the Administrator shall include conditions ~~in any exemption established under this paragraph~~, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are

necessary to protect health and the environment while achieving the purposes of the exemption.

"(F) DURATION.—

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

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

"(iii) CONSIDERATIONS.—

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

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

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

"(1) the Administrator determines that—

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

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

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

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

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

"(2) a final rule promulgated under subsection (d)(1), and the associated safety assessment and safety determination that a chemical substance does not meet the safety

standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final ~~rule."; and~~ **rule.**

~~(4) in subsection (g)~~**"(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)~~**(3)**—

(i) in subparagraph (A)(ii)(I)—

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

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

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

(ii) by adding at the end the following:

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

"(i) review the adequacy of the standards prescribed according to subparagraph (B);

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

"(iii) revise the standards if the Administrator so determines."; 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 ~~requiring~~ **applicable to** 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 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.";** ~~title.~~

~~"(5) Guidance.—The Administrator shall develop guidance relating to the information required to be reported under the rules promulgated under this subsection.";~~

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

"(3) NOMENCLATURE.—

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

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

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

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

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

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

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

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

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

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

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

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

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

"(II) develop new guidance that—

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

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

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

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) RULES.—

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

"(ii) ACTIVE SUBSTANCES.—The Administrator shall~~, pursuant to paragraph (5)(A),~~ designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(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.—THE RULE PROMULGATED BY THE ADMINISTRATOR~~ **SUBSTANCES.—In promulgating the rule established** pursuant to subparagraph (A) ~~shall require—~~**, the Administrator shall—**

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

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

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

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

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

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

"(ii) ~~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~~ **REVIEW GOAL AND RESULTS.—At the**

beginning of each year, the Administrator shall publish an annual goal for **reviews and** the number of reviews ~~to be completed over the course of implementation of the plan.~~ **completed in the prior year.**

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

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

"(B) ~~UPDATE.—THE ADMINISTRATOR SHALL UPDATE THE LIST OF CHEMICAL SUBSTANCES DESIGNATED AS ACTIVE SUBSTANCES AS SOON AS PRACTICABLE AFTER THE DATE OF PUBLICATION OF THE MOST RECENT DATA REPORTED UNDER—~~

~~"(I) PART 711 OF TITLE 40, CODE OF FEDERAL REGULATIONS (OR SUCCESSOR REGULATIONS); AND~~

~~"(II) THE RULES PROMULGATED PURSUANT TO SUBSECTION (A)(4).~~

~~"(C)~~ CHANGE TO ACTIVE STATUS.—

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

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

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

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

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

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

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

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

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

"(bb) the Administrator otherwise becomes aware that the need for

protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

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

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

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

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

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

"(i) an active substance; or

"(ii) an inactive substance;

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

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

"(i) ~~no~~ **a** claim ~~of~~ **for** protection against disclosure of the specific identity of the active ~~substance pursuant to this subsection was received;~~ **chemical substance was not asserted, as required under this subsection or subsection (d) or (f) of section 14;**

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

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

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

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

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

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

(3) in subsection (e)—

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

"(1) IN GENERAL.—Any person"; and

(B) by adding at the end the following:

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

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

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

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

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

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

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

"(3) MANUFACTURE; PROCESS.—The".

SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.

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

(1) in subsection (a)—

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

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

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

(B) in paragraph ~~(2),~~**(2)**—

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

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

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

~~and~~

~~(C) in~~**(C) by redesignating** paragraph (3) **as paragraph (6);**

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

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

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

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

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

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

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

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

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

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

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

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

(3) by adding at the end the following:

"(e) Exposure Information.—If the Administrator obtains information related to exposures or releases of a chemical substance that may be prevented or reduced under another Federal law,

including laws not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.".

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

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

SEC. 13. EXPORTS.

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

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

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

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

~~"(A) under section 5 is not likely to meet the safety standard; or~~**"(B) any chemical substance that the Administrator determines presents or will present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; or**

~~"(B) under section 6 does not meet the safety standard.~~**"(C) any chemical substance that—**

~~"(3) Waivers.—For~~**"(i) the Administrator determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; and**

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

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

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

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

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

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

"(b) Notice.—

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

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

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

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

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

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

~~"(7)~~**"(8)** Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, **if** ~~if—~~

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

~~"(B) the claim—~~

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

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

"(c) Information Not Protected From ~~Disclosure.—Notwithstanding~~ **Disclosure.—**

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

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

~~"(A)~~**"(i)** IN GENERAL.—Subject to ~~subparagraph (B), subsection (a) does not prohibit the disclosure of—~~ **clause (ii)—**

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

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

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

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

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

~~"(ii)~~**"(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).~~ **item (aa) or (bb) of subclause (I).**

~~"(B)~~**"(ii)** EFFECT OF ~~PARAGRAPH.—NOTHING~~ **SUBPARAGRAPH.—Nothing** in this ~~paragraph~~ **subparagraph** 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.

~~* 4 "(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)~~**"(B)** OTHER INFORMATION NOT PROTECTED FROM ~~DISCLOSURE.—THE FOLLOWING INFORMATION IS NOT PROTECTED FROM DISCLOSURE UNDER THIS SECTION:~~ **DISCLOSURE.—**

~~"(A)~~**"(i)** For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered

for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

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

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

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

~~"(4)~~**"(2)** MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is ~~otherwise~~ eligible for protection under this section and ~~contained in a submission of~~ **is submitted with** information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

~~"(5)~~**"(3)** BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.

**** 4** ~~"(2)~~**"(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 ~~described in paragraph (1) that is not described in paragraph (1)(B)~~ **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) ~~conform~~ **be consistent** with guidance ~~prescribed~~ **issued** by the Administrator under paragraph (3)(A); and

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

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

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

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

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in ~~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 ~~information that has been submitted is~~ **statement required to assert a claim submitted pursuant to paragraph (1)(B) and any information required to substantiate a claim submitted pursuant to paragraph (2) are** true and correct.

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

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

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

"(B) for a specific law enforcement purpose;

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

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

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

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

"(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, **if** ~~if—~~

~~"(A)~~ 1 or more applicable agreements with the Administrator that ~~conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; ~~and~~

~~"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;~~

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

"(A) the statement of need and confidentiality agreement ~~shall conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B);

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

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

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

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

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

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

"(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent

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

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

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

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

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

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

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

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

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

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

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

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

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION ~~PROTECTED~~ **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 ~~subsection (d) for a period of 10 years, unless, prior to the expiration of the period—~~ **subsections (a) and (d), unless—**

~~"(i) an affected person~~ **"(i) 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 ~~the~~ **any** actions ~~described in~~ **required under** subsection (g)(2).

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

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

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

"(C) EXTENSIONS.—

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

"(ii) STATEMENT.—

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

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

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

"(bb) make a determination regarding whether the ~~information~~ **claim** for which the request ~~is made~~ **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.~~ **request.**

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

~~(B)(ii)(I)~~ **(C)(ii)(I)**—

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

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

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection **of information** against disclosure under subsection (a) ~~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~~ **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) as necessary to ~~comply~~ **determine whether the information qualifies for an exemption from disclosure in connection** with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(ii) if ~~information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met;~~ **the Administrator has a reasonable basis to believe that the information does not qualify for protection against disclosure under subsection (a);** or

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

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

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

"(ii) withdraw the claim.

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

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

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

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

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

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

"(i) is made public; and

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

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator ~~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 DENIAL OR MODIFICATION.—If the Administrator denies or modifies a claim or request under subparagraph (A)** ~~Denial or modification.—~~

~~"(i) In general.—Except as provided in subsections (c) and (f)~~, the Administrator shall **provide to the person that submitted the claim or request** ~~deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).~~

~~"(ii) Reasons for denial or modification.—The Administrator shall provide to a person that has submitted a claim described in clause (i)~~ a written statement of the reasons for the denial or modification of the claim **or request**.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection ~~(b)(7)~~**(b)(8)**, review all claims **or requests** under this section for the protection against disclosure of the specific identity of a chemical substance; and

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

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

"(2) NOTIFICATION.—

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

"(B) RELEASE OF **INFORMATION.—Except** ~~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).

~~"(ii)~~**"(C)** EXCEPTIONS.—

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

"(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information under paragraphs (4) and (6) of subsection (e), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

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

"(I) for the disclosure of~~"(II) No notification.—For~~ information under paragraph (1), (2), ~~(6),~~(7), or (9) of subsection (e)~~, no prior notification shall be necessary.~~**; or**

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

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

"(bb) no request was received by the Administrator on or before

the date of expiration of the period for which protection from disclosure applies.

"(3) REBUTTABLE PRESUMPTION.—

"(A) IN GENERAL.—With respect to notifications provided by the Administrator ~~pursuant to subsection (c)(5)~~ **under paragraph (2) with respect to information pertaining to a chemical substance subject to a rule as described in subsection (c)(3)**, there shall be a rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.

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

"(C) DETERMINATION BY ADMINISTRATOR.—

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

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

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

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

"(4) APPEALS.—

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

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

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

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

"(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).~~ **REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (e) in a format and language that is readily accessible and understandable.**

"(h) Criminal Penalty for Wrongful Disclosure.—

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

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

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

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

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

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

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

"(i) Applicability.—

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

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

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

"(2) ~~PRIOR ACTIONS.—NOTHING~~ **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,** ~~sentence—~~

~~(i) by inserting "this Act or a rule or order promulgated or issued pursuant to this Act, including" after "a provision of"; and~~

~~(ii)~~ by striking "$25,000" and inserting "$37,500"; and

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

(2) in subsection (b)—

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

"(1) IN GENERAL.—Any person that";

(B) ~~by striking "section 15 or 409" and inserting "this Act";~~

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

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

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

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of ~~this Act~~ **section 15 or 409**, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be

subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

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

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

SEC. 17. STATE-FEDERAL RELATIONSHIP.

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

"(a) In General.—

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

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

"(i) a rule promulgated by the Administrator;

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

"(iii) an order issued by the Administrator.

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

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

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

"(C) SIGNIFICANT NEW USE.—A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a

significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(2) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of ~~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), **(f), and (g),** beginning on the date on which the Administrator defines **and publishes** the scope of a safety assessment and safety determination under section 6(a)(2) and ending on the date on which the **deadline established pursuant to section 6(a) for completion of the safety determination expires, or on the date on which the** Administrator publishes the safety determination **under section 6(a), whichever is earlier**, 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 **and publishes** the scope of a safety assessment and safety determination under section 6(a)(2).

"(B) LIMITATION.—Subparagraph (A) does not allow a State or political subdivision of a State to enforce any new prohibition or restriction under a ~~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 **hazards, exposures, risks, and** 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~~ **a law of a State or political subdivision of a State** in the event of noncompliance with the identical requirement shall be no more stringent than the penalties and other sanctions available to the Administrator under section 16 of this Act.

"(ii) PENALTIES.—In the case of an identical ~~requirement, no State may~~ **requirement**—

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

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

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

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

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

"(e) Preservation of Certain ~~State Law.—~~ **Laws.—**

"(1) IN GENERAL.—Nothing in this Act, subject to subsection (g) of this section, shall—

"(A) be construed to preempt or otherwise affect the authority of a State or political subdivision of a State to continue to enforce any action taken before August 1, 2015, under the authority of a ~~State law~~ **law of the State or political subdivision of the State** that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance; or

"(B) be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003.

"(2) EFFECT OF SUBSECTION.—This subsection does not affect, modify, or alter the relationship between ~~State and Federal law~~ **Federal law and laws of a State or political subdivision of a State** 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~~ **in** 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~~ **designed to address a risk of a chemical substance, under the conditions of use, that was identified—**

"(i) consistent with the best available science**;**

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

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

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

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

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

"(C) the State or political subdivision of ~~a~~ **the** 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~~ **110** days after the date on which an application under paragraph (2) is submitted.

"(4) FAILURE TO MAKE DETERMINATION.—If the Administrator fails to make a determination under paragraph (3)(B) during the ~~90~~ **110**-day period beginning on the date on which an application under paragraph (2) is submitted, the ~~State~~ statute or administrative action **of the State or political subdivision of the State** that was the subject of the application shall not be considered to be an existing statute or administrative action for purposes of subsection (b) by reason of the failure of the Administrator to make a determination.

"(5) NOTICE AND COMMENT.—Except in the case of an application approved under paragraph (9), the application of a State or political subdivision of ~~the~~ **a** State shall be subject to public notice and comment.

"(6) FINAL AGENCY ACTION.—The decision of the Administrator on the application of a State or political subdivision of ~~the~~ **a** State shall be—

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

"(B) subject to judicial review.

"(7) DURATION OF **WAIVERS.—A** ~~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** ~~effect—~~

~~"(i)~~ until such time as the ~~safety assessment and safety determination is completed; or~~ **Administrator publishes the safety determination under section 6(a)(4).**

~~"(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~~**"(8) JUDICIAL REVIEW OF WAIVERS.—Not later than 60** 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~~ **a** 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~~ **AUTOMATIC APPROVAL.—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**, effective on the date that is 10 days after the deadline**.

"(B) REQUIREMENTS.—Notwithstanding paragraph (6), approval of a waiver application under subparagraph (A) for failure to meet the ~~deadlines under section 6(a)(4) (including an extension granted under section 6(a)(6))~~ **deadline under paragraph (3)(B)** 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.~~

~~* 5 "(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),~~**(A)**—

(I) in the first sentence—

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

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

~~(ii) in subparagraph (B),~~**(cc) by striking "judicial review of such**

rule" and inserting "judicial review of such rule or order"; and

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

(ii) in subparagraph (B)—

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

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

~~* 6 (B) in paragraph (2), in the first sentence, by striking "paragraph (1)(A)" and inserting "paragraph (1)"; and~~

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

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

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

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

**** 5** "(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.~~ **paragraph."; and**

(2) in subsection (c)(1)(B)—

(A) in clause (i)—

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

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

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

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

SEC. 19. **CITIZENS' CIVIL ACTIONS.**

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

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

(2) in subsection (b)—

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

(B) in paragraph (2), by striking the period at the end and inserting ", except that no prior notification shall be required in the case of a civil action brought to compel a decision by the Administrator pursuant to section 18(f)(3)(B); or"; and

(C) by adding at the end the following:

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

SEC. 20. CITIZENS' PETITIONS.

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

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an order under section 4 or 5(d)"; and

(2) in subsection (b)—

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

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

"(B) DE NOVO PROCEEDING.—

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

"(ii) DEMONSTRATION.—

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

"(aa) in the case of a petition to initiate a proceeding for the issuance of a rule or order under section 4, the information ~~available to the Administrator is insufficient for the Administrator to perform an action described in section 4, 4A, 5, or 6(d);~~ **is needed for a purpose identified in section 4(a);**

"(bb) in the case of a petition to issue an order under section 5(d), ~~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~~ **does** not meet the safety standard; or

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

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

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

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

SEC. ~~20~~ **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. ~~21.~~ **22.** STUDIES.

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

SEC. ~~22.~~ **23.** ADMINISTRATION.

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

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

"(b) Fees.—

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

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

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

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

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

"(iii) is required to report information pursuant to the rules promulgated under

paragraph (1) or (4) of section 8(a)~~(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);~~

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

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

"(i) the lower of—

"(I) 25 percent of the costs of conducting the activities identified in paragraph (2)(A), ~~not to exceed $18,000,000, not including fees under subparagraph (E) of this paragraph;~~ **other than the costs to conduct and complete safety assessments and determinations under section 6 for chemical substances identified pursuant to section 4A(c); or**

~~"(D)~~**"(II) $25,000,000 (subject to adjustment pursuant to subparagraph (F)); and**

"(ii) the full costs and the 50-percent portion of the costs of safety

assessments and safety determinations specified in subparagraph (D);

"(C) reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

"(D) notwithstanding subparagraph (B) and paragraph (4)(D)—

"(i)~~"(E)~~ for substances designated ~~as additional priorities~~ pursuant to section 4A(c)**(1)**, establish the fee at a level sufficient to defray the full **annual** costs to the Administrator of conducting the safety assessment and safety determination under section 6~~, except that~~**; and**

"(ii) for substances ~~subject~~ **designated pursuant** to section 4A(c)(3), ~~the Administrator shall~~ establish the fee at a level sufficient to defray 50 percent of ~~those costs;~~ **the annual costs to the Administrator of conducting the safety assessment and safety determination under section 6;**

~~"(F)~~**"(E)** prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) or subchapter III of chapter 5 of title 5, United States Code, is applicable with respect to such meetings;

~~"(G)~~**"(F)** beginning with the fiscal year that is 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives **pursuant to subparagraph (E)**, increase or decrease the fees established under paragraph (1) as **necessary to adjust for inflation and to ensure, based on the audit analysis required under paragraph (5)(B),** ~~necessary—~~

~~"(i) to ensure~~ that funds deposited in the Fund are sufficient to **defray**—

"(i) approximately but not more than 25 percent of the annual costs to conduct the activities identified in paragraph (2)(A) ~~and the full~~ **, other than the costs to conduct and complete safety assessments and determinations under section 6 for chemical substances identified pursuant to section 4A(c); and**

"(ii) the full annual costs and the 50-percent portion of the **annual** costs of safety assessments and safety determinations ~~pursuant to~~ **specified in** subparagraph ~~(E); and~~**(D);**

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

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

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

"(4) TSCA IMPLEMENTATION FUND.—

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

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

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

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

"(B) CREDITING AND AVAILABILITY OF FEES.—

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

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

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

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

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

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

"(i) maintained readily available or on deposit;

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

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

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

"(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~~ **24**. DEVELOPMENT AND EVALUATION OF TEST METHODS AND SUSTAINABLE CHEMISTRY.

~~Section~~**(a) In General.—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~~ **National Coordinating Entity for Sustainable Chemistry.—**

"(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 Director of the Office of Science and Technology Policy shall convene an entity under the National Science and Technology Council with the responsibility to coordinate Federal programs and activities in support of sustainable chemistry, including, as appropriate,

at the National Science Foundation, the Department of Energy, the Department of Agriculture, the Environmental Protection Agency, the National Institute of Standards and Technology, the Department of Defense, the National Institutes of Health, and other related Federal agencies.

"(2) CHAIRMAN.—The entity described in paragraph (1) shall be chaired by the Director of the National Science Foundation and the Assistant Administrator for the Office of Research and Development of the Environmental Protection Agency, or their designees.

"(3) DUTIES.—

"(A) IN GENERAL.—The entity described in paragraph (1) shall—

"(i) develop a working definition of sustainable chemistry, after seeking advice and input from stakeholders as described in clause (v);

"(ii) oversee the planning, management, and coordination of the Sustainable Chemistry Initiative described in subsection (d);

"(iii) develop a national strategy for sustainable chemistry as described in subsection (f);

"(iv) develop an implementation plan for sustainable chemistry as described in subsection (g); and

"(v) consult and coordinate with stakeholders qualified to provide advice and information on the development of the initiative, national strategy, and implementation plan for sustainable chemistry, at least once per year, to carry out activities that may include workshops, requests for information, and other efforts as necessary.

"(B) STAKEHOLDERS.—The stakeholders described in subparagraph (A)(v) shall include representatives from—

"(i) industry (including small- and medium-sized enterprises from across the value chain);

"(ii) the scientific community (including the National Academy of Sciences, scientific professional societies, and academia);

"(iii) the defense community;

"(iv) State, tribal, and local governments;

"(v) State or regional sustainable chemistry programs;

"(vi) nongovernmental organizations; and

"(vii) other appropriate organizations.

"(4) SUNSET.—

"(A) IN GENERAL.—On completion of the national strategy and accompanying implementation plan for sustainable chemistry as described in paragraph (3), the Director of the Office of Science and Technology Policy—

"(i) shall review the need for further work; and

"(ii) may disband the entity described in paragraph (1) if no further efforts are determined to be necessary.

"(B) NOTICE AND JUSTIFICATION.—The Director of the Office of Science and Technology Policy shall provide notice and justification, including an analysis of options to establish the Sustainable Chemistry Initiative described in subsection (d) and the partnerships described in subsection (e) within 1 or more appropriate Federal agencies, regarding a decision to disband the entity not less than 90 days prior to the termination date to the Committee on Science, Space, and Technology and the 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.

"(d) Sustainable Chemistry Initiative.—The entity described in subsection (c)(1) shall oversee the establishment of an interagency Sustainable Chemistry ~~Program~~ **Initiative** to promote and coordinate ~~Federal sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities.~~ **activities designed—**

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

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

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

Federal agencies and at public and private institutions of higher education; and

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

"(i) the conduct of Federal ~~and~~, State**, and private** science and engineering research and development; and

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

"(2) **to** examine methods by which the Federal Government can ~~create~~ **offer** incentives for consideration and use of sustainable chemistry processes and products~~, including~~ **that encourage competition and overcoming market barriers, including grants, loans, loan guarantees, and** innovative financing mechanisms;

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

"(4) **to** 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; **and**

"(5) **to** 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.—~~ **Partnerships in Sustainable Chemistry.—**

~~"(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 (~~**"(1) IN GENERAL.—The entity described in subsection (c)(1), itself or through an appropriate subgroup designated or established by the entity, shall work through the agencies described in subsection (c)(1) to support, through financial, technical, or other assistance, the establishment of partnerships between institutions of higher education, nongovernmental organizations, consortia, and companies across the value chain in the chemical industry,** 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~~ **enterprises—**

"(A) to establish collaborative research, development, demonstration, technology transfer, and commercialization programs; and

"(B) to train students and retrain professional scientists and engineers in the use of sustainable chemistry concepts and strategies by methods including—

"(i) developing curricular materials and courses for undergraduate and graduate levels and for the professional development of scientists and engineers; and

"(ii) publicizing the availability of professional development courses in sustainable chemistry and recruiting scientists and engineers to pursue those courses.

"(2) PRIVATE SECTOR ENTITIES.—To be eligible for support under this section, a partnership in sustainable chemistry shall include at least 1 private sector entity.

"(3) SELECTION OF PARTNERSHIPS.—In selecting partnerships for support under this section, the entity and the agencies described in subsection (c)(1) shall also consider the extent to which the applicants are willing and able to demonstrate evidence of support for, and commitment—

"(A) to achieving the goals of the Sustainable Chemistry Initiative described in subsection (d); and

"(B) to sustaining any new innovations, tools, and resources generated from funding under the program.

"(4) PROHIBITED USE OF FUNDS.—Financial support provided under this section may not be used—

"(A) to support or expand a regulatory chemical management program at an implementing agency under a State law; or

"(B) to construct or renovate a building or structure.

"(f) National Strategy 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~~

entity described in subsection (c)(1) shall submit ~~a report~~ to the Committee on Science, Space, and Technology and **the** 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**, a national strategy** that shall include—

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

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

"(C) an analysis of the progress made toward achieving the goals and priorities of the ~~program established pursuant to~~ **Sustainable Chemistry Initiative described in** subsection ~~(c)~~**(d)**, and recommendations for future ~~program activities;~~ **initiative activities, including consideration of options to establish the Sustainable Chemistry Initiative and the partnerships described in subsection (e) within 1 or more appropriate Federal agencies;**

"(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~~ **establishment** 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.~~

Sustainable Chemistry Initiative; and

"(F) a framework for advancing sustainable chemistry research, development, technology transfer, commercialization, and education and training.

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

~~SEC. 24~~**"(g) Implementation Plan.—Not later than 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the entity described in subsection (c)(1) shall submit to the Committee on Science, Space, and Technology and the 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, an implementation plan, based on the findings of the national strategy and other assessments, as appropriate, for sustainable chemistry.".**

(b) Sustainable Chemistry Basic Research.—Subject to the availability of appropriated funds, the Director of the National Science Foundation shall continue to carry out the Green Chemistry Basic Research program authorized under section 509 of the National Science Foundation Authorization Act of 2010 (42 U.S.C. 1862p–3).

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. ~~25~~ 26. AUTHORIZATION OF APPROPRIATIONS.

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

SEC. ~~26~~ 27. ANNUAL REPORT.

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

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

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

SEC. ~~27~~ 28. EFFECTIVE DATE.

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

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

"(a) In General.—This"; and

(2) by adding at the end the following:

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

SEC. 29. ELEMENTAL MERCURY.

(a) Temporary Generator Accumulation.—Section 5 of the Mercury Export Ban Act of 2008 (42 U.S.C. 6939f) is amended—

(1) in subsection (a)(2), by striking "2013" and inserting "2019";

(2) in subsection (b)—

(A) in paragraph (1)—

(i) by redesignating subparagraphs (A), (B), and (C), as clauses (i), (ii), and (iii), respectively and indenting appropriately;

(ii) in the first sentence, by striking "After consultation" and inserting the following:

"(A) ASSESSMENT AND COLLECTION.—After consultation";

(iii) in the second sentence, by striking "The amount of such fees" and inserting the following:

"(B) AMOUNT.—The amount of the fees described in subparagraph (A)";

(iv) in subparagraph (B) (as so designated)—

(I) in clause (i) (as so redesignated), by striking "publically available not later than October 1, 2012" and inserting "publicly available not later than October 1, 2018";

(II) in clause (ii) (as so redesignated), by striking "and";

(III) in clause (iii) (as so redesignated), by striking the period at the end and inserting ", subject to clause (iv); and"; and

(IV) by adding at the end the following:

"(iv) for generators temporarily accumulating elemental mercury in a facility subject to subparagraphs (B) and (D)(iv) of subsection (g)(2) if the facility designated in subsection (a) is not operational by January 1, 2019, shall be adjusted to subtract the cost of the temporary accumulation during the period in which the facility designated under subsection (a) is not operational."; and

(v) by adding at the end the following:

"(C) CONVEYANCE OF TITLE AND PERMITTING.—If the facility designated in subsection (a) is not operational by January 1, 2020, the Secretary—

"(i) shall immediately accept the conveyance of title to all elemental mercury that has accumulated in facilities in accordance with subsection (g)(2)(D), before January 1, 2020, and deliver the accumulated mercury to the facility designated under subsection (a) on the date on which the facility becomes operational;

"(ii) shall pay any applicable Federal permitting costs, including the costs for permits issued under section 3005(c) of the Solid Waste Disposal Act (42 U.S.C. 6925(c)); and

"(iii) shall store, or pay the cost of storage of, until the time at which a facility designated in subsection (a) is operational, accumulated mercury to which the Secretary has title under this subparagraph in a facility that has been issued a permit under section 3005(c) of the Solid Waste Disposal Act (42 U.S.C. 6925(c))."; and

** 6 (B) in paragraph (2), in the first sentence, by striking "paragraph ~~(1)(A)"~~**(1)(C)"** and inserting "paragraph ~~(1)";~~**(1)(B)(iii)"**; and

(3) in subsection (g)(2)—

(A) in the undesignated material at the end, by striking "This subparagraph" and inserting the following:

"(C) Subparagraph (B)";

(B) in subparagraph (C) (as added by paragraph (1)), by inserting "of that subparagraph" before the period at the end; and

(C) by adding at the end the following:

"(D) A generator producing elemental mercury incidentally from the beneficiation or processing of ore or related pollution control activities, may accumulate the mercury produced onsite that is destined for a facility designated by the Secretary under subsection (a), for more than 90 days without a permit issued under section 3005(c) of the Solid Waste Disposal Act (42 U.S.C. 6925(c)), and shall not be subject to the storage prohibition of section 3004(j) of that Act (42 U.S.C. 6924(j)), if—

"(i) the Secretary is unable to accept the mercury at a facility designated by the Secretary under subsection (a) for reasons beyond the control of the generator;

"(ii) the generator certifies in writing to the Secretary that the generator will ship the mercury to a designated facility when the Secretary is able to accept the mercury;

"(iii) the generator certifies in writing to the Secretary that the generator is storing only mercury the generator has produced or recovered onsite and will not sell, or otherwise place into commerce, the mercury; and

"(iv) the generator has obtained an identification number under section 262.12 of title 40, Code of Federal Regulations, and complies with the requirements described in paragraphs (1) through (4) of section 262.34(a) of title 40, Code of Federal Regulations (as in effect on the date of enactment of this subparagraph).

"(E) MANAGEMENT STANDARDS FOR TEMPORARY STORAGE.—Not later than January 1, 2017, the Secretary, after consultation with the Administrator of the Environmental Protection Agency and State agencies in affected States, shall develop and make available guidance that establishes procedures and standards for the management and short-term storage of elemental mercury at a generator covered under subparagraph (D), including requirements to ensure appropriate use of flasks or other suitable containers. Such procedures and standards shall be protective of human health and the environment and shall ensure that the elemental mercury is stored in a safe, secure, and effective manner. A generator may accumulate mercury in accordance with subparagraph (D) immediately upon enactment of this Act, and notwithstanding that guidance called for by this paragraph (E) has not been developed or made available.".

(b) Interim Status.—Section 5(d)(1) of the Mercury Export Ban Act of 2008 (42 U.S.C. 6939f(d)(1)) is amended—

(1) in the fourth sentence, by striking "in existence on or before January 1, 2013,"; and

(2) in the last sentence, by striking "January 1, 2015" and inserting "January 1,

2020".

(c) Mercury Inventory.—Section 8(b) of the Toxic Substances Control Act (15 U.S.C. 2607(b)) (as amended by section 10(2)) is amended by adding at the end the following:

"(10) MERCURY.—

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

"(i) elemental mercury; and

"(ii) a mercury compound.

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

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

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

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

"(D) REPORTING.—

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

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

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

(d) Prohibition on Export of Certain Mercury Compounds.—Section 12(c) of the Toxic Substances Control Act (15 U.S.C. 2611(c)) (as amended by section 13(3)) is amended—

(1) in the subsection heading, by inserting "and Mercury Compounds" after "Mercury"; and

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

"(3) PROHIBITION ON EXPORT OF CERTAIN MERCURY COMPOUNDS.—

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

"(i) Mercury (I) chloride or calomel.

"(ii) Mercury (II) oxide.

"(iii) Mercury (II) sulfate.

"(iv) Mercury (II) nitrate.

"(v) Cinnabar or mercury sulphide.

"(vi) Any mercury compound that the Administrator, at the discretion of the Administrator, adds to the list by rule, on determining that exporting that mercury compound for the purpose of regenerating elemental mercury is technically feasible.

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

"(C) PETITION.—Any person may petition the Administrator to add to the list of mercury compounds prohibited from export.

"(D) ENVIRONMENTALLY SOUND DISPOSAL.—This paragraph does not prohibit the export of mercury (I) chloride or calomel for environmentally sound disposal to member countries of the Organization for Economic Cooperation and Development, on the condition that no mercury or mercury compounds are to be recovered, recycled, or reclaimed for use, or directly reused.

"(E) REPORT.—Not later than 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall evaluate any exports of calomel for disposal that occurred since that date of enactment and shall submit to Congress a report that contains the following:

"(i) volumes and sources of calomel exported for disposal;

"(ii) receiving countries of such exports;

"(iii) methods of disposal used;

"(iv) issues, if any, presented by the export of calomel;

"(v) evaluation of calomel management options in the United States, if any, that are commercially available and comparable in cost and efficacy to methods being utilized in the receiving countries; and

"(vi) a recommendation regarding whether Congress should further limit or prohibit the export of calomel for disposal.

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

SEC. 30. TREVOR'S LAW.

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

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

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

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

(b) Designation and Investigation of Potential Cancer Clusters.—Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

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

"(a) Definitions.—In this section:

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

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

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

"(b) Criteria for Designation of Potential Cancer Clusters.—

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

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

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

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

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

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

"(E) the time period over which the number of cases of a particular cancer, or

the calculation of an expected number of cases, occurs.

"(c) Guidelines for Investigation of Potential Cancer Clusters.—The Secretary, in consultation with the Council of State and Territorial Epidemiologists and representatives of State and local health departments, shall develop, publish, and periodically update guidelines for investigating potential cancer clusters. The guidelines shall—

"(1) require that investigations of cancer clusters—

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

"(B) use the best available science; and

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

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

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

"(d) Investigation of Cancer Clusters.—

"(1) SECRETARY DISCRETION.—The Secretary—

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

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

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

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

"(e) Duties.—The Secretary shall—

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

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

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

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

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

How the Frank R. Lautenberg Chemical Safety for the 21st Century Act, S. 697 amends the Toxic Substances Control Act of 1976 (TSCA)
and
Changes made since the Committee Reported Substitute w/ Technical Corrections

Updated safety standard: Ensures that only human and environmental health are considered in assessing the safety of chemicals, replacing TSCA's current standard which requires a cost-benefit balancing during safety review. Ensures that costs and other non-risk factors are to be considered only in deciding *how* to regulate a chemical found not to meet the health-based safety standard.

Vulnerable populations: Requires EPA to identify groups of individuals the Administrator identifies as relevant in assessing the safety of a chemical, to assess risks any relevant populations, and to ensure their protection.

Safety reviews of existing chemicals: Establishes for the first time a mandate for EPA to review the safety of all chemicals in active commerce, in contrast to TSCA's grandfathering-in of chemicals then in use without any safety review. The key steps in the review process are:

- Companies are to identify all chemicals they are currently manufacturing or processing.
- EPA is to establish the priority (high or low) of all active chemicals, at a pace commensurate with agency resources and capacity.
    - High-priority chemicals undergo full safety assessments and safety determinations against the updated safety standard.
    - For any chemical found not to meet the safety standard, EPA must impose restrictions sufficient for the chemical to meet the safety standard, and where restrictions cannot be imposed to ensure the chemical can meet the safety standard, EPA must either ban or phase it out.
    - Low-priority chemicals are those EPA concludes have sufficient information to establish that the chemical is likely to meet the safety standard.
- In identifying high-priority chemicals, EPA is to give preference to chemicals on its Work Plan that are persistent and bioaccumulative and those that are known human carcinogens and have high acute and chronic toxicity. EPA's criteria also must account for recommendations of the Governor of a State, hazard and exposure potential of a chemical substance, and storage near significant sources of drinking water.
- Companies may also request and provide funds for EPA to assess their chemicals; EPA must conduct a minimum number of such reviews and the maximum number is capped to ensure EPA-identified chemicals remain the primary focus.
- All steps in the review and regulatory process are subject to full notice and comment rulemaking, judicially enforceable deadlines, and minimum numbers of chemicals to be reviewed are specified, which rise over time as program implementation is completed and experience is gained.

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More effective authority to require testing of chemicals: Eliminates TSCA's *Catch-22* requirement that EPA first have evidence of risk to require testing. Provides for EPA to issue an order requiring testing, rather than having to promulgate a rule, which can be a multiyear process. Testing authority applies to both new and existing chemicals and in limited instances for purposes of prioritization, specifying that EPA cannot require testing to establish minimum information sets for chemicals.

Review of new chemicals: Upgrades EPA's review of new chemicals while retaining a balance with the need not to unduly impede innovation and speed to market. Requires for the first time that EPA make an affirmative safety finding – that a new chemical is likely to meet the safety standard – as a condition for market entry. Maintains current TSCA's 90-day review period for new chemicals and shortens that period when EPA makes a positive safety determination.

Regulation of chemicals presenting significant risks: Strikes TSCA's unworkable mandate that EPA demonstrate that its regulations impose the "least burdensome" possible requirements. Requires EPA to consider, based on existing information, costs and the availability of alternatives in selecting among regulatory options while ensuring that EPA's regulations are sufficient to address identified risks.

Confidential business information (CBI): Requires EPA to review past CBI claims for active chemicals on the TSCA Inventory, the identities of which are not publicly available. Requires that certain CBI claims be substantiated when made, expire after 10 years unless re-substantiated, and are to be reviewed by EPA. Identifies specific types of proprietary information for which claims do not require substantiation or re-substantiation. Specifies types of information, including health and safety data, that are not eligible for CBI protection. Requires EPA to review all new CBI claims and require substantiation for chemicals found not to meet the safety standard, and creates a rebuttable presumption of disclosure for a chemical that EPA bans or phases out. For the first time, provides that CBI is to be shared with state governments, health and environmental professionals and first responders, subject to adequate protections and nondisclosure agreements.

User fees: Requires EPA to collect fees for the review of new and existing chemicals to defray a portion of the costs of implementing the program. Specifies that fees are capped at 25% of relevant EPA program costs, and that companies are to pay 100% of the costs of safety assessments they request (50% for those already on EPA's Work Plan).

Federal-State authority: Establishes preemption of state authority that is chemical-specific, applies only when EPA take up a chemical, and is confined to the hazards, exposures, risks, uses and conditions of use of a chemical that are included in EPA's safety assessment and safety determination (and, where required, risk management rule).

Preemption applies only to state statutes or administrative actions restricting a chemical, not to requirements for reporting, monitoring or disclosure. States can impose restrictions that are identical to a Federal requirement, adopted under the authority of a federal law, or adopted under a state air or water quality or waste treatment or disposal law, unless they conflict with federal requirements.

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States can enforce existing restrictions until EPA takes final action on a chemical, but cannot impose new restrictions during EPA review of a chemical.

State actions taken on a chemical prior to August 1, 2015, or taken under a law in effect on August 31, 2003, remain in place regardless of EPA action. After enactment, states can: impose new restrictions on a chemical until and unless EPA begins to review that same chemical and addresses the same uses; continue to enforce existing restrictions on the chemical until EPA's review is completed; and, if EPA finds the chemical does not meet the safety standard, impose new or continue to enforce existing restrictions until EPA issues its regulation.

States can seek waivers to act during or after EPA review. EPA decisions on waivers, or its failure to make a decision by a specified deadline, can be challenged by anyone in court.

Other important provisions:

- *Animal testing:* Requires EPA to minimize animal testing where scientifically reliable alternatives exist that would generate equivalent information.
- *Small Business:* Requires EPA to minimize the impacts of rules on small manufacturers and processors.
- *Sustainable chemistry:* Establishes a federal Sustainable Chemistry Program and National Sustainable Chemistry Initiative.
- *Articles:* Mandates EPA only apply prohibitions or other restrictions to articles to the extent necessary to address identified risks from exposure to the chemical substance from the article.
- *Persistent and bioaccumulative substances:* Such substances are given preference in prioritization process and, when found not likely to meet the safety standard, EPA is required to impose restrictions to reduce exposure to the maximum extent practicable.

<u>Changes made since the Committee Reported Substitute w/ Technical Corrections</u>

- **Prioritization**
  - Directs EPA to use its Framework for Metals Risk Assessment in prioritizing and assessing metals and metal compounds.
  - Requires EPA to identify the information and analysis on which its prioritization decisions, and any decision to postpone a prioritization decision, are based.
  - Adds two additional prioritization criteria: chemicals that are known human carcinogens and have high acute and chronic toxicity; and chemicals stored near significant sources of drinking water.

- **Safety Assessments and Safety Determinations**
  - Specifies that the annual plan for safety assessments and safety determinations identifies, for each assessment and determination, the resources needed for completion, its status and milestones met, and any updates to the schedule for completion.
  - Clarifies that determinations that a substance both meets and does not meet the safety standard are to be judicially reviewable under the same 'substantial evidence' standard of review.
  - Shortens the extension available to EPA for completion of safety determinations from 2 years to 1 year, and limits such extensions to cases where required information has not yet been

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received or was submitted late in the time period allotted for the safety determination. For Work Plan chemicals, limits EPA from extending deadlines for completing a safety determination and for promulgating a rule, unless EPA publicly justifies the extension by demonstrating that the safety determination or rule cannot be adequately completed without additional information.
  - Requires compliance with risk management regulations within 4 years for uses not exempted by the Administrator, extendable by up to 18 months if EPA determines that such compliance is technologically or economically infeasible.
  - Clarifies that when the Administrator identifies a relevant potentially exposed or susceptible population and finds a chemical substance does not meet the safety standard for that population, prohibitions or other restrictions must be applied to ensure the substance meets the safety standard for that population.
  - Conforms the definition of a high persistent, bioaccumulative and toxic chemical to EPA's current practice.

- **Information Collection and Reporting**
  - Requires EPA to periodically review, and revise as needed, its standards for identifying small manufacturers and processors (which are exempt from or subject to reduced reporting requirements).

- **Relationship to Other Federal Laws**
  - Mandates EPA to act if another federal agency to which it has referred a finding that a chemical does not meet the safety standard does not take required actions with the requisite time periods.

- **Confidential business Information**
  - Requires EPA to develop a request and notification system to facilitate access to confidential information allowed to be disclosed to health and environmental professionals.

- **State-Federal Relationship**
  - Clarifies preemption triggered by EPA safety assessments and safety determinations to state actions is applicable to the hazards, exposures and risks – as well as the uses or conditions of use – of a chemical that are identified by EPA and included in its safety determination and any requisite risk management rule.
  - Modifies the "science" showing a state must make to be granted a waiver to act after final EPA action to clarify that scientific evidence must support the identification of the risk being addressed, rather than the restriction being imposed.
  - Modifies that states applying for waivers must show compelling conditions warrant granting the waiver to protect health or the environment.
  - Simplified the process for a state to impose new restrictions while EPA is reviewing a chemical substance by lifting preemption following an EPA-missed deadline for publication of the safety determination instead of requiring EPA to automatically approve state waiver applications.
  - Eliminates the prior bill's on-again/off-again of the waivers during judicial review of EPA's waiver inaction.
  - Clarifies that a failure by EPA to decide on a waiver request is subject to a citizen's civil action because it is a failure of EPA to perform a mandatory duty.

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- Specifies that a waiver granted by EPA stays in effect until EPA completes its safety determination for a chemical, EPA misses its deadline for publishing its safety determination, or a court directs EPA to deny the waiver in response to a judicial challenge.
- Both EPA and States enforcing their own identical regulations can collect penalties for violations, although the combined total State and Federal penalty cannot exceed the federal statutory maximum.

- **User Fees**
  - Requires that fees be set at a level sufficient to annually defray:
    - the lower of 25 percent of the costs of the activities for which fees can be used, or $25 million;
    - the full costs and the 50-percent portion of the costs of safety assessments and safety determinations requested by industry for chemicals not on, or on, EPA's Work Plan, respectively.
  - Clarifies that EPA can adjust the fees in the future both for inflation and to ensure the fees remain sufficient to defray 25 percent of relevant costs even if the fees would exceed the initial $25 million cap.

- **Mercury**
  - Requires development of a long-term storage facility for elemental mercury, and provides for interim storage by generators; creates an inventory of supply, use, and trade of mercury ;and prohibits export of certain mercury compounds.

- **Trevor's Law**
  - The bill provides improved direction for identification, designation, and investigation of potential cancer clusters.

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Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 9/30/2015 12:40:08 PM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
Subject: FW: Emailing: S.697 - Substitute - Confidential Draft - Administration Review - V.1.0
Attachments: S.697 - Substitute - Confidential Draft - Administration Review - V.1.0.pdf

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From: Black, Jonathan (Tom Udall)
Sent: Wednesday, September 30, 2015 8:39 AM
To: Billingsley, Tara ; Bauserman, Trenton ; Kaiser, Sven-Erik ; Laura Vaught (vaught.laura@epa.gov)
Cc: Karakitsos, Dimitri (EPW) ; Black, Jonathan (Tom Udall)
Subject: Emailing: S.697 - Substitute - Confidential Draft - Administration Review - V.1.0

Please find attached the draft version of the Substitute that we plan to circulate on the Hotline.

We would appreciate your attention to a Statement of Administration Policy as soon as possible. We hope to have agreement to proceed to the Substitute as early as today, although that is subject to several other factors.

The only change that has occurred from the previous version you have seen [Orion v.11.0] is the added Sec.29 at the end. This language was negotiated and agreed to by Sens. Reid, Heller and Whitehouse.

Your message is ready to be sent with the following file or link attachments:

S.697 - Substitute - Confidential Draft - Administration Review - V.1.0

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

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 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

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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 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.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

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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 ~~describe the manner in which the Administrator shall ensure that:—~~ **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.

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"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate~~, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.~~ **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 ~~and~~**,** procedures**, and guidance** for the testing of chemical substances or mixtures under section 4.

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

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

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition

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that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential; **and**

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

~~"(C) require the Administrator to~~**"(4) EPIDEMIOLOGICAL STUDIES.—Before prescribing epidemiological studies of employees, the Administrator shall** consult with the Director of the National Institute for Occupational Safety and Health**.** ~~prior to prescribing epidemiologic studies of employees; and~~

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

~~"(i) toxicity information;~~

~~"(ii) computational toxicology and bioinformatics;~~

~~* 1 "(iii) high-throughput screening methods and the prediction models of those methods; and~~

~~* 2 "(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 **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.—AT~~ **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

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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.—AT A MINIMUM, THE~~ **REQUIREMENTS.—The** policies and procedures under this paragraph ~~shall—~~ **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 ~~the Administrator—~~ **that each draft and final safety assessment and safety determination of the Administrator include a description of—**

~~"(I)(aa) to define~~**"(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 susceptible populations that the Administrator ~~expects to consider in a safety assessment;~~ **has identified as relevant; and**

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

~~and~~

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

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

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

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

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

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

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

~~"(vi)~~**"(iv)** when relevant information is provided or otherwise made available to the Administrator, ~~shall~~ **require the Administrator to** 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~~ **by** 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

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other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

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

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

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking subsections (a), (b), (c), (d), ~~and (g),~~**(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 "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";~~

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

~~(5)~~**(3)** 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;

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"(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; ~~and~~

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

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"(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 potential) pursuant to this section, the Administrator shall—

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

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

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

"(2) EXPLANATION IN CASE OF ORDER.—

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

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a description of—

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

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

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

"(c) Reduction of Testing on Vertebrates.—

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

"(A) ~~encouraging and facilitating—~~ **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;

**** 1** "(iii) high-throughput screening methods and the prediction models of

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those methods; and

**** 2** "(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information~~.~~**;**

"(B) 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)~~**"(C)** 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

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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

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"(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** ~~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~~

~~* 3 "(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~~ **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**

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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

** 3 ~~"(II)~~**"(bb)** the last day of the period that begins on the date referred to in ~~clause (i)~~ **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

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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)".~~ **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 ~~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~~ **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** ~~Administrator—~~

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

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

"(B) REQUIREMENTS.—

"(i) IN GENERAL.—The initial list of chemical substances shall contain at least 10 high-priority substances, at least 5 of which are drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, and at least 10 low-priority substances.

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"(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~~ **PREFERENCES.—**

"(I) IN GENERAL.—In developing the initial list and in identifying additional high-priority substances, the Administrator shall give preference ~~to~~ **to—**

"(aa) chemical substances ~~scored as high for~~ **that, with respect to** persistence and bioaccumulation**, score high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012; and**

"(bb) chemical substances listed in the October 2014 TSCA Work Plan and subsequent updates **that are known human carcinogens and have high acute and chronic toxicity.**

"(II) METALS AND METAL COMPOUNDS.—In prioritizing and assessing metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007 (or a successor document), and may use other applicable information consistent with the best available science.

"(C) ADDITIONAL CHEMICAL REVIEWS.—The Administrator shall, as soon as practicable and not later than—

"(i) 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 20 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 20 low-priority substances have been designated; and

"(ii) 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 25 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 25 low-priority substances have been designated.

"(3) IMPLEMENTATION.—

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

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

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

"(ii) INACTIVE SUBSTANCES.—In ~~carrying out~~ **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.** ~~high-priority substances.~~

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

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

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

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

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

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

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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~~ **consistent with** the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in ~~a timely manner.~~ **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—~~ **that includes and identifies substances—**

~~"(i)~~ **"(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; and~~ **postponed pursuant to subsection (b)(5), including the basis for the postponement; and**

~~"(ii)~~**"(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 **and storage near significant sources of drinking water**;

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

"(F) whether the volume of a chemical substance as reported ~~under~~ **pursuant to** a rule promulgated pursuant to section 8(a) has significantly increased or decreased

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~~during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance~~;

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

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

"(b) Prioritization Screening Process and Decisions.—

"(1) IN ~~GENERAL.—THE~~ **GENERAL.—In implementing 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

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standard.

"(5) ~~DEFERRING~~ **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 the~~ **postpone a** 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) identify the information and analysis on which the decisions are based; and**

~~"(B)~~ **"(C)** provide 90 days for public comment.

"(8) REVISIONS OF PRIOR DESIGNATIONS.—

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

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

"(9) OTHER INFORMATION RELEVANT TO PRIORITIZATION.—

"(A) IN GENERAL.—If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State proposes an administrative action or enacts a statute or takes an administrative action to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not 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

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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.

~~"(E)~~**"(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 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.

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

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

"(B) the regulation of those activities.

"(c) Additional Priorities for Safety Assessments and Determinations.—

"(1) REQUIREMENTS.—

"(A) IN GENERAL.—The ~~prioritization screening process developed~~ **rule promulgated** 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)~~ **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) ~~if a sufficient number of additional priority requests meet the requirements of paragraph (1),~~ **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) ~~are substances designated under the process and criteria pursuant to paragraph (1);~~**(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

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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(f) 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

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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 **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 (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) **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

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period prescribed by subsection (a), (b), or (c)" and inserting "subsection (b) and for which the notification period prescribed by subsection (b) or (d)";

(8) by striking subsection (d) (as redesignated by paragraph (6)) and inserting the following:

"(d) Review of Notice.—

"(1) INITIAL REVIEW.—

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

"(i) conduct an initial review of the notice;

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

"(iii) make ~~any necessary~~ **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

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prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the restrictions specified in the consent agreement or order that the Administrator determines are sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard; and

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

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

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

"(i) ~~take into consideration~~ **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~~, or of the chemical substance for a new use, that is not in compliance with~~ **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

"(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

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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~~**, with respect to** persistence and bioaccumulation, **scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012,** 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~~ **EXPOSURES.—To the extent practicable, the** Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

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

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

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

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

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

"(D) on receipt of information the Administrator finds supports the determination

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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 ~~of~~ **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;

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(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)~~**(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) 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 ~~a~~ **any necessary** final rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; ~~and~~

"(6) may extend any deadline under paragraph (4) ~~or (5) for a reasonable period of time after an adequate public justification~~ **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

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"(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~~, plus any deferral under subsection (c)(2),~~ does not exceed 2 years.

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

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination ~~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 **pursuant to section 3A(h)(2)(D)**, and subject to section 18**(g)**, the Administrator shall ~~determine that—~~ **determine—**

~~"(A)~~ **"(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

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

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

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

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

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

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

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

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

"(d) Rule.—

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

"(2) SCOPE.—

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

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

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

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

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

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

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"(IV) following a determination by the Administrator that compliance is technologically or economically infeasible 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; ~~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**; 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 necessary to ensure that the substance meets the safety standard for that population.~~.~~

"(B) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines ~~ranks high for~~**, with respect to** persistence and bioaccumulation, **scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012,** 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~~ **RESTRICTIONS.—Subject to section 18, 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

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the chemical substance;

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

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

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

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

"(i) a particular use;

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

"(iii) all uses;

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

"(i) a particular use; or

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

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

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

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

"(4) ANALYSIS FOR RULEMAKING.—

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

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

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the

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Administrator shall make publicly available any analysis conducted under this paragraph.

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

"(5) EXEMPTIONS.—

"(A) IN GENERAL.—The Administrator may ~~exempt 1 or more uses of a chemical substance from any restriction in~~**, 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 ~~rule~~ **restriction** cannot be complied with, without—

"(I) harming national security;

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

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

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

"(B) EXEMPTION ANALYSIS.—In proposing a rule under ~~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 **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 **this** 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

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necessary to protect health and the environment while achieving the purposes of the exemption.

"(F) DURATION.—

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

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

"(iii) CONSIDERATIONS.—

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

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

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

"(1) the Administrator determines that—

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

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

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

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

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

"(2) a final rule promulgated under subsection (d)(1), and the associated safety assessment and safety determination that a chemical substance does not meet the safety

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standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final ~~rule."; and~~ **rule.**

~~(4) in subsection (g)~~**"(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—

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(1) in subsection (a)—

(A) in paragraph ~~(3)~~**(3)**—

(i) in subparagraph (A)(ii)(I)—

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

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

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

(ii) by adding at the end the following:

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

"(i) review the adequacy of the standards prescribed according to subparagraph (B);

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

"(iii) revise the standards if the Administrator so determines."; 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 ~~requiring~~ **applicable to** 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 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;

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"(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.";** ~~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).

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

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) RULES.—

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

"(ii) ACTIVE SUBSTANCES.—The Administrator shall~~, pursuant to paragraph (5)(A),~~ designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(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.—THE RULE PROMULGATED BY THE ADMINISTRATOR~~ **SUBSTANCES.—In promulgating the rule established** pursuant to subparagraph (A) ~~shall require—~~**, the Administrator shall—**

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

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

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

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

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

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"(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~~ **REVIEW GOAL AND RESULTS.—At the**

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beginning of each year, the Administrator shall publish an annual goal for **reviews and** the number of reviews ~~to be completed over the course of implementation of the plan.~~ **completed in the prior year.**

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

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

"(B) ~~UPDATE.—THE ADMINISTRATOR SHALL UPDATE THE LIST OF CHEMICAL SUBSTANCES DESIGNATED AS ACTIVE SUBSTANCES AS SOON AS PRACTICABLE AFTER THE DATE OF PUBLICATION OF THE MOST RECENT DATA REPORTED UNDER—~~

~~"(I) PART 711 OF TITLE 40, CODE OF FEDERAL REGULATIONS (OR SUCCESSOR REGULATIONS); AND~~

~~"(II) THE RULES PROMULGATED PURSUANT TO SUBSECTION (A)(4).~~

~~"(C)~~ CHANGE TO ACTIVE STATUS.—

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

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

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

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

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

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

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

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

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

"(bb) the Administrator otherwise becomes aware that the need for

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

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

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

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

"(i) an active substance; or

"(ii) an inactive substance;

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

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

"(i) ~~no~~ **a** claim ~~of~~ **for** protection against disclosure of the specific identity of the active ~~substance pursuant to this subsection was received;~~ **chemical substance was not asserted, as required under this subsection or subsection (d) or (f) of section 14;**

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

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

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

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

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

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

(3) in subsection (e)—

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

"(1) IN GENERAL.—Any person"; and

(B) by adding at the end the following:

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

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

"(1) ACTIVE SUBSTANCE.—The term 'active substance' means a chemical substance—

"(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(B) that is added to the list published under subsection (b)(1) after that date of enactment; or

"(C) for which a notice is received under subsection (b)(5)(C).

"(2) INACTIVE SUBSTANCE.—The term 'inactive substance' means a chemical substance on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).

"(3) MANUFACTURE; PROCESS.—The".

SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.

Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the first sentence—

(i) by striking "presents or will present an unreasonable risk to health or the environment" and inserting "does not **or will not** meet the safety standard"; and

(ii) by striking "such risk" the first place it appears and inserting "the risk posed by the substance or mixture";

(B) in paragraph ~~(2),~~**(2)**—

(i) in subparagraph (A), by inserting "within the time period specified by the Administrator in the report" after "issues an order";

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(ii) in subparagraph (B), by inserting "responds within the time period specified by the Administrator in the report and" before "initiates, within 90 days"; and

(iii) in the matter following subparagraph (B), by striking "section 6 or 7" and inserting "section 6(d) or section 7";

~~and~~

~~(C) in~~**(C) by redesignating** paragraph (3) **as paragraph (6);**

(D) in paragraph (6) (as so redesignated), by striking "section 6 or 7" and inserting "section 6(d) or 7"; **and**

(E) by inserting after paragraph (2) the following:

"(3) The Administrator shall take the actions described in paragraph (4) if the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which the report was made does not—

"(A) issue the order described in paragraph (2)(A) within the time period specified by the Administrator in the report; or

"(B)(i) respond under paragraph (1) within the time frame specified by the Administrator in the report; and

"(ii) initiate action within 90 days of publication in the Federal Register of the response described in clause (i).

"(4) If an agency to which a report under paragraph (1) does not take the actions described in subparagraphs (A) or (B) of paragraph (3), the Administrator shall—

"(A) if a safety assessment and safety determination for the substance under section 6 has not been completed, complete the safety assessment and safety determination;

"(B) if the Administrator has determined or determines that the chemical substance does not meet the safety standard, initiate action under section 6(d) with respect to the risk; or

"(C) take any action authorized or required under section 7, as appropriate.

"(5) This subsection shall not relieve the Administrator of any obligation to complete a safety assessment and safety determination or take any required action under section 6(d) or 7 to address risks from the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of those activities, that are not identified in a report issued by the Administrator under paragraph (1).";

(2) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and inserting "Health and Human Services"; and

(3) by adding at the end the following:

"(e) Exposure Information.—If the Administrator obtains information related to exposures or releases of a chemical substance that may be prevented or reduced under another Federal law,

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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 to~~—

"(A) any **new** chemical substance that the Administrator ~~determines—~~ **determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors;**

~~"(A) under section 5 is not likely to meet the safety standard, or~~**"(B) any chemical substance that the Administrator determines presents or will present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; or**

~~"(B) under section 6 does not meet the safety standard.~~**"(C) any chemical substance that—**

~~"(3) Waivers.—For~~**"(i) the Administrator determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; and**

"(ii) is subject to restriction under section 5(d)(4).

"(3) WAIVERS FOR CERTAIN MIXTURES AND ARTICLES.—For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—

"(A) determine that paragraph (1) shall not apply to the mixture or article; or

"(B) establish a threshold concentration in a mixture or article at which paragraph (1) shall not apply.

"(4) TESTING.—The Administrator may require testing under section 4 of any chemical substance or mixture exempted from this Act under paragraph (1) for the purpose of determining whether the chemical substance ~~or mixture~~ meets the safety standard within the United States.";

(2) by striking subsection (b) and inserting the following:

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"(b) Notice.—

"(1) IN GENERAL.—A person shall notify the Administrator that the person is exporting or intends to export to a foreign country—

"(A) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 5 is not likely to meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(B) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 6 does not meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(C) a chemical substance for which the United States is obligated by treaty to provide export notification;

"(D) a chemical substance or mixture **containing a chemical substance** subject to a **proposed or promulgated** significant new use rule, or a prohibition or other restriction pursuant to a rule, order, or consent agreement in effect under this Act; ~~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, 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

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(3) in subsection **(c)**,~~(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 ~~and specific~~**.**

"(7) Specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

~~"(7)~~**"(8)** Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, **if** ~~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—~~

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~~"(i) is not subject to an exception under subsection (e); or~~

~~"(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (f)(2) or (g)~~.

"(c) Information Not Protected From ~~Disclosure.—Notwithstanding~~ **Disclosure.—**

"(1) IN GENERAL.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

~~"(1)~~**"(A)** INFORMATION FROM HEALTH AND SAFETY STUDIES.—

~~"(A)~~**"(i)** IN GENERAL.—Subject to ~~subparagraph (B), subsection (a) does not prohibit the disclosure of—~~ **clause (ii)—**

~~"(i)~~**"(I)** any health and safety study that is submitted under this Act with respect to—

~~"(I)~~**"(aa)** any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

~~"(II)~~**"(bb)** any chemical substance or mixture for which—

~~"(aa)~~**"(AA)** testing is required under section 4; or

~~"(bb)~~**"(BB)** a notification is required under section 5; or

~~"(ii)~~**"(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).~~ **item (aa) or (bb) of subclause (I).**

~~"(B)~~**"(ii)** ~~EFFECT OF PARAGRAPH.—NOTHING~~ **SUBPARAGRAPH.—Nothing** in this ~~paragraph~~ **subparagraph** 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.

~~* 4 "(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)~~**"(B)** OTHER INFORMATION NOT PROTECTED FROM ~~DISCLOSURE.—THE FOLLOWING INFORMATION IS NOT PROTECTED FROM DISCLOSURE UNDER THIS SECTION:~~ **DISCLOSURE.—**

~~"(A)~~**"(i)** For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered

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for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

~~"(B)~~**"(ii)** A safety assessment developed, or a safety determination made, under section 6.

~~"(C)~~**"(iii)** Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

~~"(D)~~**"(iv)** A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

~~"(4)~~**"(2)** MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—Any information that is ~~otherwise~~ eligible for protection under this section and ~~contained in a submission of~~ **is submitted with** information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

~~"(5)~~**"(3)** BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.

**** 4** ~~"(2)~~**"(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 ~~described in paragraph (1) that is not described in paragraph (1)(B)~~ **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;

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"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name shall—

"(i) ~~conform~~ **be consistent** with guidance ~~prescribed~~ **issued** by the Administrator under paragraph (3)(A); and

"(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are considered to be confidential; and

"(II) the disclosure of which would be likely to **cause substantial** harm **to** the competitive position of the person.

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in ~~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 ~~information that has been submitted is~~ **statement required to assert a claim submitted pursuant to paragraph (1)(B) and any information required to substantiate a claim submitted pursuant to paragraph (2) are** true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a)—

"(1) shall be disclosed if the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

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"(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** ~~if—~~

~~"(A)~~ 1 or more applicable agreements with the Administrator that ~~conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; ~~and~~

~~"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;~~

"(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement ~~shall conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent

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of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) shall be disclosed if the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

"(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION ~~PROTECTED~~ **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 ~~subsection (d) for a period of 10 years, unless, prior to the expiration of the period—~~ **subsections (a) and (d), unless—**

~~"(i) an affected person~~ **"(i) 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

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"(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 ~~the~~ **any** actions ~~described in~~ **required under** subsection (g)(2).

"(B) **INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information, other than information described in subsection (b), that meets the requirements of subsections (a) and (d) for a period of 10 years, unless, prior to the expiration of the period—**

"(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)(2).

"(C) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, a person reasserting the relevant claim shall submit to the Administrator a ~~statement~~ **request for extension** substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date ~~that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—~~ **of expiration of the period described in subparagraph (B), the Administrator shall, in accordance with subsection (g)(1)(C)—**

"(aa) review the request **submitted under subclause (I)**;

"(bb) make a determination regarding whether the ~~information~~ **claim** for which the request ~~is made~~ **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.~~ **request.**

~~"(C)~~**"(D)** NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph ~~(B)~~**(C)**, if the Administrator determines that the relevant ~~statement~~ **request** under subparagraph

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~~(B)(ii)(I)~~ **(C)(ii)(I)**—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection **of information** against disclosure under subsection (a) ~~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~~ **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) as necessary to ~~comply~~ **determine whether the information qualifies for an exemption from disclosure in connection** with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(ii) if ~~information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met;~~ **the Administrator has a reasonable basis to believe that the information does not qualify for protection against disclosure under subsection (a);** or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

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"(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 DENIAL OR MODIFICATION.—If the Administrator denies or modifies a claim or request under subparagraph (A)** ~~Denial or modification.—~~

~~"(i) In general.—Except as provided in subsections (c) and (f)~~, the Administrator shall **provide to the person that submitted the claim or request** ~~deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).~~

~~"(ii) Reasons for denial or modification.—The Administrator shall provide to a person that has submitted a claim described in clause (i)~~ a written statement of the reasons for the denial or modification of the claim **or request**.

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"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection ~~(b)(7)~~**(b)(8)**, review all claims **or requests** under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims **or requests** for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim **or request** for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim **or request** for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim **or request** under paragraph (1), **intends to release information pursuant to subsection (e),** or promulgates a rule under section 6(d) establishing a ban or phase-out of a chemical substance, the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

"(B) RELEASE OF **INFORMATION.—Except** ~~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).

~~"(ii)~~**"(C)** EXCEPTIONS.—

~~"(I)~~**"(i)** IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim **or request** receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

"(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information under paragraphs (4) and (6) of subsection (e), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

"(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

"(I) for the disclosure of ~~"(II) No notification.—For~~ information under paragraph (1), (2), ~~(6),~~(7), or (9) of subsection (e)~~, no prior notification shall be necessary.~~**; or**

"(II) for the disclosure of information for which—

"(aa) a notice under subsection (f)(1)(C)(i) was received; and

"(bb) no request was received by the Administrator on or before

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the date of expiration of the period for which protection from disclosure applies.

"(3) REBUTTABLE PRESUMPTION.—

"(A) IN GENERAL.—With respect to notifications provided by the Administrator ~~pursuant to subsection (c)(5)~~ **under paragraph (2) with respect to information pertaining to a chemical substance subject to a rule as described in subsection (c)(3)**, there shall be a rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.

"(B) REQUEST FOR NONDISCLOSURE.—A person that receives a notification under paragraph (2) with respect to the information described in subparagraph (A) may submit to the Administrator, before the date on which the information is to be released **pursuant to paragraph (2)(B)**, a request with supporting documentation describing why the person believes some or all of that information should not be disclosed.

"(C) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—Not later than 30 days after the Administrator receives a request under subparagraph (B), the Administrator shall determine~~, at the discretion of the Administrator,~~ whether the documentation provided by the person making the request rebuts or does not rebut the presumption described in subparagraph (A), for all or a portion of the information that the person has requested not be disclosed.

"(ii) OBJECTIVE.—The Administrator shall make the determination with the objective of ensuring that information relevant to protection of health and the environment is disclosed to the maximum extent practicable.

"(D) TIMING.—Not later than 30 days after making the determination described in subparagraph (C), the Administrator shall make public the information the Administrator has determined is not to be protected from disclosure.

"(E) NO TIMELY REQUEST RECEIVED.—If the Administrator does not receive, before the date on which the information described in subparagraph (A) is to be released **pursuant to paragraph (2)(B)**, a request pursuant to subparagraph (B), the Administrator shall promptly make public all of the information.

"(4) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released **pursuant to paragraph (2)(B)**, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

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"(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).~~ **REQUEST AND NOTIFICATION SYSTEM.—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (e) in a format and language that is readily accessible and understandable.**

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information ~~submitted to~~ **reported to or otherwise obtained by** the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

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"(2) ~~PRIOR ACTIONS.—NOTHING~~ **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,** ~~sentence—~~

~~(i) by inserting "this Act or a rule or order promulgated or issued pursuant to this Act, including" after "a provision of"; and~~

~~(ii)~~ by striking "$25,000" and inserting "$37,500"; and

~~(B)~~ in the second sentence, by striking" violation of section 15 or 409" and inserting "violation of this Act"; and

~~(2) in subsection (b)—~~

(A) by striking "Any person who" and inserting the following:

"(1) IN GENERAL.—Any person that";

(B) ~~by striking "section 15 or 409" and inserting "this Act";~~

~~(C)~~ by striking "$25,000" and inserting "$50,000"; and

~~(D)~~**(C)** by adding at the end the following:

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of ~~this Act~~ **section 15 or 409**, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be

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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.".~~ **"(C) INCORPORATION OF CORRESPONDING PROVISIONS.—Subparagraphs (B) through (F) of section 113(c)(5) of the Clean Air Act (42 U.S.C. 7413(c)(5)) shall apply to the prosecution of a violation under this paragraph.".**

SEC. 17. STATE-FEDERAL RELATIONSHIP.

Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following:

"(a) In General.—

"(1) ESTABLISHMENT OR ENFORCEMENT.—Except as provided in subsections (c), (d), (e), (f), and (g), and subject to paragraph (2), no State or political subdivision of a State may establish or continue to enforce any of the following:

"(A) ~~TESTING AND INFORMATION COLLECTION.—A~~ **TESTING.—A** statute or administrative action to require the development of information on a chemical substance or category of substances that is reasonably likely to produce the same information required under section 4, 5, or 6 in—

"(i) a rule promulgated by the Administrator;

"(ii) a testing consent agreement entered into by the Administrator; or

"(iii) an order issued by the Administrator.

"(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

"(i) found to meet the safety standard and consistent with the scope of the determination made under section 6; or

"(ii) found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

"(C) SIGNIFICANT NEW USE.—A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a

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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), **(f), and (g),** beginning on the date on which the Administrator defines **and publishes** the scope of a safety assessment and safety determination under section 6(a)(2) and ending on the date on which the **deadline established pursuant to section 6(a) for completion of the safety determination expires, or on the date on which the** Administrator publishes the safety determination **under section 6(a), whichever is earlier**, 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 **and publishes** the scope of a safety assessment and safety determination under section 6(a)(2).

"(B) LIMITATION.—Subparagraph (A) does not allow a State or political subdivision of a State to enforce any new prohibition or restriction under a ~~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 **hazards, exposures, risks, and** 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

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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~~ **a law of a State or political subdivision of a State** in the event of noncompliance with the identical requirement shall be no more stringent than the penalties and other sanctions available to the Administrator under section 16 of this Act.

"(ii) PENALTIES.—In the case of an identical ~~requirement, no State may~~ **requirement—**

"(I) a State or political subdivision of a State may not assess a penalty for a specific violation for which the Administrator has ~~already~~ assessed ~~a~~ **an adequate** penalty under section 16~~, and~~ **; and**

"(II) if a State or political subdivision of a State has assessed a penalty for a specific violation, the Administrator may not assess a penalty ~~under section 16 for a specific violation for which a State has already assessed a penalty.~~ **for that violation in an amount that would cause the total of the penalties assessed for the violation by the State or political subdivision of a State and the Administrator combined to exceed the maximum amount that may be assessed for that violation by the Administrator under section 16.**

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"(2) APPLICABILITY TO CERTAIN RULES OR ORDERS.—Notwithstanding subsection (e)—

"(A) nothing in this section shall be construed as modifying the effect under this section, as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, of any rule or order promulgated or issued under this Act prior to that effective date; and

"(B) with respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 6 prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act with regards to manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance, this section (as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after that effective date, unless the latter rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under **subsection (b) or (c) of** section 4A~~(b)~~ or as an additional priority for safety assessment and safety determination under section 4A(c).

"(e) Preservation of Certain ~~State Law.—~~ **Laws.—**

"(1) IN GENERAL.—Nothing in this Act, subject to subsection (g) of this section, shall—

"(A) be construed to preempt or otherwise affect the authority of a State or political subdivision of a State to continue to enforce any action taken before August 1, 2015, under the authority of a ~~State law~~ **law of the State or political subdivision of the State** that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance; or

"(B) be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003.

"(2) EFFECT OF SUBSECTION.—This subsection does not affect, modify, or alter the relationship between ~~State and Federal law~~ **Federal law and laws of a State or political subdivision of a State** 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

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of the State would not cause a violation of any applicable Federal law, rule, or order; and

"(D) ~~based on~~ **in** 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~~ **designed to address a risk of a chemical substance, under the conditions of use, that was identified—**

"(i) consistent with the best available science**;**

"(ii) using supporting studies conducted in accordance with sound and objective scientific practices; and

"(iii) based on the weight of the scientific evidence.

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

"(A) compliance with the proposed requirement of the State ~~will~~ **or political subdivision of the State would** not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(B) compliance with the proposed requirement **of the State or political subdivision of the State** would not cause a violation of any applicable Federal law, rule, or order; and

"(C) the State or political subdivision of ~~a~~ **the** 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~~ **110** days after the date on which an application under paragraph (2) is submitted.

"(4) FAILURE TO MAKE DETERMINATION.—If the Administrator fails to make a determination under paragraph (3)(B) during the ~~90~~ **110**-day period beginning on the date on which an application under paragraph (2) is submitted, the ~~State~~ statute or administrative action **of the State or political subdivision of the State** that was the subject of the application shall not be considered to be an existing statute or administrative action for purposes of subsection (b) by reason of the failure of the Administrator to make a determination.

"(5) NOTICE AND COMMENT.—Except in the case of an application approved under paragraph (9), the application of a State or political subdivision of ~~the~~ **a** State shall be subject to public notice and comment.

"(6) FINAL AGENCY ACTION.—The decision of the Administrator on the application of a State or political subdivision of ~~the~~ **a** State shall be—

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"(A) considered to be a final agency action; and

"(B) subject to judicial review.

"(7) DURATION OF **WAIVERS.—A** ~~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** ~~effect—~~

~~"(i)~~ until such time as the ~~safety assessment and safety determination is completed, or~~ **Administrator publishes the safety determination under section 6(a)(4).**

~~"(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~~**"(8) JUDICIAL REVIEW OF WAIVERS.—Not later than 60** 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~~ **a** 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~~ **AUTOMATIC APPROVAL.—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**, effective on the date that is 10 days after the deadline**.

"(B) REQUIREMENTS.—Notwithstanding paragraph (6), approval of a waiver application under subparagraph (A) for failure to meet the ~~deadlines under section 6(a)(4) (including an extension granted under section 6(a)(6))~~ **deadline under paragraph (3)(B)** 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.~~

~~* 5 "(B) Jurisdiction.—The United States Court of Appeals for the District of Columbia~~

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~~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),~~**(A)**—

(I) in the first sentence—

(aa) by striking "Not" and inserting "Except as otherwise provided in this title, not";

(bb) by striking "section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting ~~"section 4(a), 5(d), 6(c), 6(d), 6(g), or 8, or title II or IV"; and~~**"this title or title II or IV, or an order under section 6(c)(1)(A)"; and**

~~(ii) in subparagraph (B),~~**(cc) by striking "judicial review of such**

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rule" and inserting "judicial review of such rule or order"; and

(II) in the second sentence, by striking "such a rule" and inserting "such a rule or order"; and

(ii) in subparagraph (B)—

(I) by striking "Courts" and inserting "Except as otherwise provided in this title, courts"; and

(II) by striking "an order issued under subparagraph (A) or (B) of section 6(b)(1)" and inserting "an order issued under this title"; ~~and~~

~~* 6 (B) in paragraph (2), in the first sentence, by striking "paragraph (1)(A)" and inserting "paragraph (1)"; and~~

(B) in paragraph (2), in the second sentence, by striking "the filing of the rulemaking record of proceedings on which the Administrator based the rule being reviewed" and inserting "the filing of the record of proceedings on which the Administrator based the rule or order being reviewed"; and

(C) by striking paragraph (3) ~~; and~~ **and inserting the following:**

"(3) JUDICIAL REVIEW OF LOW-PRIORITY DECISIONS.—

"(A) IN GENERAL.—Not later than 60 days after the publication of a designation under section 4A(b)(4), or a designation under section 4A(b)(8) of a chemical substance as a low-priority substance, any person may commence a civil action to challenge the designation.

**** 5** "(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.~~ **paragraph."; and**

(2) in subsection (c)(1)(B)—

(A) in clause (i)—

(I) by striking "section 4(a), 5(b)(4), 6(a), or 6(e)" and inserting "section 4(a), ~~5(d), 6(d), or 6(g)"~~; **6(d), or 6(g), or an order under section 6(c)(1)(A)";** and

(ii) by striking "evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;" and inserting "evidence (including any matter) in the rulemaking record, taken as a whole; and"; and

(B) by striking clauses (ii) and (iii) and the matter following clause (iii) and inserting the following:

"(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule, except as part of the rulemaking record, taken as a whole.".

SEC. 19. CITIZENS' CIVIL ACTIONS.

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Section 20 of the Toxic Substances Control Act (15 U.S.C. 2619) is amended—

(1) in subsection (a)(1), by striking "or order issued under section 5" and inserting "or order issued under section 4 or 5"; and

(2) in subsection (b)—

(A) in paragraph (1)(B), by striking "or" at the end;

(B) in paragraph (2), by striking the period at the end and inserting "; except that no prior notification shall be required in the case of a civil action brought to compel a decision by the Administrator pursuant to section 18(f)(3)(B); or"; and

(C) by adding at the end the following:

"(3) in the case of a civil action brought to compel a decision by the Administrator pursuant to section 18(f)(3)(B), after the date that is 60 days after the deadline specified in section 18(f)(3)(B).".

SEC. 20. CITIZENS' PETITIONS.

Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an order under section 4 or 5(d)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "an order under section 4 or 5(d)"; and

(B) in paragraph (4), by striking subparagraph (B) and inserting the following:

"(B) DE NOVO PROCEEDING.—

"(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to ~~promulgate~~ **issue** a rule pursuant to section 4, 5, 6, or 8 or issue an order under section 4 or 5(d), the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.

"(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a rule or order under section 4, the information ~~available to the Administrator is insufficient for the Administrator to perform an action described in section 4, 4A, 5, or 6(d);~~ **is needed for a purpose identified in section 4(a);**

"(bb) in the case of a petition to issue an order under section 5(d), ~~there is a reasonable basis to conclude that~~ the chemical substance is not likely to meet the safety standard;

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"(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~~ **does** not meet the safety standard; or

"(dd) in the case of a petition to initiate a proceeding for the issuance of a rule under section 8, there is a reasonable basis to conclude that the rule is necessary to protect health or the environment or ensure that the chemical substance meets the safety standard.

"(II) DEFERMENT.—The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

"(aa) the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act; and

"(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.".

SEC. ~~20~~ **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. ~~21.~~ **22.** STUDIES.

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.

SEC. ~~22.~~ **23.** ADMINISTRATION.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) by striking subsection (b) and inserting the following:

"(b) Fees.—

"(1) IN GENERAL.—The Administrator shall establish, not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, by rule—

"(A) the payment of 1 or more reasonable fees as a condition of submitting a notice or requesting an exemption under section 5; **and**

"(B) the payment of 1 or more reasonable fees by a manufacturer or processor that—

"(i) is required to submit a notice pursuant to the rule promulgated under section 8(b)(4)(A)(i) identifying a chemical substance as active;

"(ii) is required to submit a notice pursuant to section 8(b)(5)(B)(i) changing the status of a chemical substance from inactive to active;

"(iii) is required to report information pursuant to the rules promulgated under

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paragraph (1) or (4) of 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);~~

"~~(B)~~ prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

"~~(C)~~**"(B)** set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to ~~defray approximately~~ **annually defray—**

"(i) the lower of—

"(I) 25 percent of the costs of conducting the activities identified in paragraph (2)(A), ~~not to exceed $18,000,000, not including fees under subparagraph (E) of this paragraph;~~ **other than the costs to conduct and complete safety assessments and determinations under section 6 for chemical substances identified pursuant to section 4A(c); or**

"~~(D)~~**"(II) $25,000,000 (subject to adjustment pursuant to subparagraph (F)); and**

"(ii) the full costs and the 50-percent portion of the costs of safety

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assessments and safety determinations specified in subparagraph (D);

"(C) reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

"(D) notwithstanding subparagraph (B) and paragraph (4)(D)—

"(i)~~"(E)~~ for substances designated ~~as additional priorities~~ pursuant to section 4A(c)**(1)**, establish the fee at a level sufficient to defray the full **annual** costs to the Administrator of conducting the safety assessment and safety determination under section 6~~, except that~~**; and**

"(ii) for substances ~~subject~~ **designated pursuant** to section 4A(c)(3), ~~the Administrator shall~~ establish the fee at a level sufficient to defray 50 percent of ~~those costs;~~ **the annual costs to the Administrator of conducting the safety assessment and safety determination under section 6;**

~~"(F)~~**"(E)** prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) or subchapter III of chapter 5 of title 5, United States Code, is applicable with respect to such meetings;

~~"(G)~~**"(F)** beginning with the fiscal year that is 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives **pursuant to subparagraph (E)**, increase or decrease the fees established under paragraph (1) as **necessary to adjust for inflation and to ensure, based on the audit analysis required under paragraph (5)(B),** ~~necessary—~~

~~"(i) to ensure~~ that funds deposited in the Fund are sufficient to **defray**—

"(i) approximately but not more than 25 percent of the annual costs to conduct the activities identified in paragraph (2)(A) ~~and the full~~ **, other than the costs to conduct and complete safety assessments and determinations under section 6 for chemical substances identified pursuant to section 4A(c); and**

"(ii) the full annual costs and the 50-percent portion of the **annual** costs of safety assessments and safety determinations ~~pursuant to~~ **specified in** subparagraph ~~(E); and~~**(D);**

~~"(ii) to account for inflation;~~

~~"(H)~~**"(G)** adjust fees established under paragraph (1) as necessary to vary on account of differing circumstances, including reduced fees or waivers in appropriate circumstances, to reduce the burden on manufacturing or processing, remove barriers to innovation, or where the costs to the Administrator of collecting the fees exceed the fee revenue anticipated to be collected; and

~~"(I)~~**"(H)** if a notice submitted under section 5 is refused or subsequently withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

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"(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~~ **the Chemical Risk Review and Reduction program project** of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for ~~covered functions for fiscal year 2015 (excluding the amount of any fees appropriated for the fiscal year).~~ **that program project for fiscal year 2014.**

"(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

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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~~ **24**. DEVELOPMENT AND EVALUATION OF TEST METHODS AND SUSTAINABLE CHEMISTRY.

~~Section~~**(a) In General.—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~~ **National Coordinating Entity for Sustainable Chemistry.—**

"(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 Director of the Office of Science and Technology Policy shall convene an entity under the National Science and Technology Council with the responsibility to coordinate Federal programs and activities in support of sustainable chemistry, including, as appropriate,

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at the National Science Foundation, the Department of Energy, the Department of Agriculture, the Environmental Protection Agency, the National Institute of Standards and Technology, the Department of Defense, the National Institutes of Health, and other related Federal agencies.

"(2) CHAIRMAN.—The entity described in paragraph (1) shall be chaired by the Director of the National Science Foundation and the Assistant Administrator for the Office of Research and Development of the Environmental Protection Agency, or their designees.

"(3) DUTIES.—

"(A) IN GENERAL.—The entity described in paragraph (1) shall—

"(i) develop a working definition of sustainable chemistry, after seeking advice and input from stakeholders as described in clause (v);

"(ii) oversee the planning, management, and coordination of the Sustainable Chemistry Initiative described in subsection (d);

"(iii) develop a national strategy for sustainable chemistry as described in subsection (f);

"(iv) develop an implementation plan for sustainable chemistry as described in subsection (g); and

"(v) consult and coordinate with stakeholders qualified to provide advice and information on the development of the initiative, national strategy, and implementation plan for sustainable chemistry, at least once per year, to carry out activities that may include workshops, requests for information, and other efforts as necessary.

"(B) STAKEHOLDERS.—The stakeholders described in subparagraph (A)(v) shall include representatives from—

"(i) industry (including small- and medium-sized enterprises from across the value chain);

"(ii) the scientific community (including the National Academy of Sciences, scientific professional societies, and academia);

"(iii) the defense community;

"(iv) State, tribal, and local governments;

"(v) State or regional sustainable chemistry programs;

"(vi) nongovernmental organizations; and

"(vii) other appropriate organizations.

"(4) SUNSET.—

"(A) IN GENERAL.—On completion of the national strategy and accompanying implementation plan for sustainable chemistry as described in paragraph (3), the Director of the Office of Science and Technology Policy—

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"(i) shall review the need for further work; and

"(ii) may disband the entity described in paragraph (1) if no further efforts are determined to be necessary.

"(B) NOTICE AND JUSTIFICATION.—The Director of the Office of Science and Technology Policy shall provide notice and justification, including an analysis of options to establish the Sustainable Chemistry Initiative described in subsection (d) and the partnerships described in subsection (e) within 1 or more appropriate Federal agencies, regarding a decision to disband the entity not less than 90 days prior to the termination date to the Committee on Science, Space, and Technology and the 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.

"(d) Sustainable Chemistry Initiative.—The entity described in subsection (c)(1) shall oversee the establishment of an interagency Sustainable Chemistry ~~Program~~ **Initiative** to promote and coordinate ~~Federal sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities.~~ **activities designed—**

~~"(d) Program Activities.—The activities of the Program shall be designed to—~~

~~"(1)~~ **"(1) to** provide sustained support for sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training through—

"(A) coordination **and promotion** of sustainable chemistry research, development, demonstration, and technology transfer conducted at Federal **and national** laboratories and ~~agencies; and~~

Federal agencies and at public and private institutions of higher education; and

"(B) to the extent practicable, encouragement of consideration of sustainable chemistry in, as appropriate—

"(i) the conduct of Federal ~~and~~, State**, and private** science and engineering research and development; and

"(ii) the solicitation and evaluation of applicable proposals for science and engineering research and development;

"(2) **to** examine methods by which the Federal Government can ~~create~~ **offer** incentives for consideration and use of sustainable chemistry processes and products~~, including~~ **that encourage competition and overcoming market barriers, including grants, loans, loan guarantees, and** innovative financing mechanisms;

"(3) **to** expand the education and training of undergraduate and graduate students and professional scientists and engineers, including through partnerships with industry **as described in subsection (e)**, in sustainable chemistry science and engineering;

"(4) **to** collect and disseminate information on sustainable chemistry research, development, and technology transfer, including information on—

"(A) incentives and impediments to development, manufacturing, and

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commercialization;

"(B) accomplishments;

"(C) best practices; and

"(D) costs and benefits; **and**

"(5) **to** 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.—~~ **Partnerships in Sustainable Chemistry.**—

~~"(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 (~~**"(1) IN GENERAL.—The entity described in subsection (c)(1), itself or through an appropriate subgroup designated or established by the entity, shall work through the agencies described in subsection (c)(1) to support, through financial, technical, or other assistance, the establishment of partnerships between institutions of higher education, nongovernmental organizations, consortia, and companies across the value chain in the chemical industry,** 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.—~~

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~~"(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~~ **enterprises—**

"(A) to establish collaborative research, development, demonstration, technology transfer, and commercialization programs; and

"(B) to train students and retrain professional scientists and engineers in the use of sustainable chemistry concepts and strategies by methods including—

"(i) developing curricular materials and courses for undergraduate and graduate levels and for the professional development of scientists and engineers; and

"(ii) publicizing the availability of professional development courses in sustainable chemistry and recruiting scientists and engineers to pursue those courses.

"(2) PRIVATE SECTOR ENTITIES.—To be eligible for support under this section, a partnership in sustainable chemistry shall include at least 1 private sector entity.

"(3) SELECTION OF PARTNERSHIPS.—In selecting partnerships for support under this section, the entity and the agencies described in subsection (c)(1) shall also consider the extent to which the applicants are willing and able to demonstrate evidence of support for, and commitment—

"(A) to achieving the goals of the Sustainable Chemistry Initiative described in subsection (d); and

"(B) to sustaining any new innovations, tools, and resources generated from funding under the program.

"(4) PROHIBITED USE OF FUNDS.—Financial support provided under this section may not be used—

"(A) to support or expand a regulatory chemical management program at an implementing agency under a State law; or

"(B) to construct or renovate a building or structure.

"(f) National Strategy 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~~

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entity described in subsection (c)(1) shall submit ~~a report~~ to the Committee on Science, Space, and Technology and **the** 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**, a national strategy** that shall include—

"(A) a summary of federally funded sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities;

"(B) a summary of the financial resources allocated to sustainable chemistry initiatives;

"(C) an analysis of the progress made toward achieving the goals and priorities of the ~~program established pursuant to~~ **Sustainable Chemistry Initiative described in** subsection ~~(c)~~**(d)**, and recommendations for future ~~program activities;~~ **initiative activities, including consideration of options to establish the Sustainable Chemistry Initiative and the partnerships described in subsection (e) within 1 or more appropriate Federal agencies;**

"(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~~ **establishment** 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.~~

Sustainable Chemistry Initiative; and

"(F) a framework for advancing sustainable chemistry research, development, technology transfer, commercialization, and education and training.

"(2) SUBMISSION TO GAO.—The ~~Interagency Working Group shall also submit the report~~ **entity described in subsection (c)(1) shall submit the national strategy** described in paragraph (1) to the Government Accountability Office for consideration in future Congressional ~~inquiries.".~~ **inquiries.**

~~SEC. 24~~**"(g) Implementation Plan.—Not later than 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the entity described in subsection (c)(1) shall submit to the Committee on Science, Space, and Technology and the 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, an implementation plan, based on the findings of the national strategy and other assessments, as appropriate, for sustainable chemistry.".**

(b) Sustainable Chemistry Basic Research.—Subject to the availability of appropriated funds, the Director of the National Science Foundation shall continue to carry out the Green Chemistry Basic Research program authorized under section 509 of the National Science Foundation Authorization Act of 2010 (42 U.S.C. 1862p–3).

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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. ~~25~~ **26**. AUTHORIZATION OF APPROPRIATIONS.

Section 29 of the Toxic Substances Control Act (15 U.S.C. 2628) is repealed.

SEC. ~~26~~ **27**. ANNUAL REPORT.

Section 30 of the Toxic Substances Control Act (15 U.S.C. 2629) is amended by striking paragraph (2) and inserting the following:

"(2)(A) the number of notices received during each year under section 5; and

"(B) the number of the notices described in subparagraph (A) for chemical substances subject to a rule, testing consent agreement, or order under section 4.".

SEC. ~~27~~ **28**. EFFECTIVE DATE.

Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601 note; Public Law 94–469) is amended—

(1) by striking "Except as provided in section 4(f), this" and inserting the following:

"(a) In General.—This"; and

(2) by adding at the end the following:

"(b) Retroactive Applicability.—Nothing in this Act shall be interpreted to apply retroactively to any State, Federal, or maritime legal action commenced prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

SEC. 29. ELEMENTAL MERCURY.

(a) Temporary Generator Accumulation.—Section 5 of the Mercury Export Ban Act of 2008 (42 U.S.C. 6939f) is amended—

(1) in subsection (a)(2), by striking "2013" and inserting "2019";

(2) in subsection (b)—

(A) in paragraph (1)—

(i) by redesignating subparagraphs (A), (B), and (C), as clauses (i), (ii), and (iii), respectively and indenting appropriately;

(ii) in the first sentence, by striking "After consultation" and inserting the following:

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"(A) ASSESSMENT AND COLLECTION.—After consultation";

(iii) in the second sentence, by striking "The amount of such fees" and inserting the following:

"(B) AMOUNT.—The amount of the fees described in subparagraph (A)";

(iv) in subparagraph (B) (as so designated)—

(I) in clause (i) (as so redesignated), by striking "publically available not later than October 1, 2012" and inserting "publicly available not later than October 1, 2018";

(II) in clause (ii) (as so redesignated), by striking "and";

(III) in clause (iii) (as so redesignated), by striking the period at the end and inserting ", subject to clause (iv); and"; and

(IV) by adding at the end the following:

"(iv) for generators temporarily accumulating elemental mercury in a facility subject to subparagraphs (B) and (D)(iv) of subsection (g)(2) if the facility designated in subsection (a) is not operational by January 1, 2019, shall be adjusted to subtract the cost of the temporary accumulation during the period in which the facility designated under subsection (a) is not operational."; and

(v) by adding at the end the following:

"(C) CONVEYANCE OF TITLE AND PERMITTING.—If the facility designated in subsection (a) is not operational by January 1, 2020, the Secretary—

"(i) shall immediately accept the conveyance of title to all elemental mercury that has accumulated in facilities in accordance with subsection (g)(2)(D), before January 1, 2020, and deliver the accumulated mercury to the facility designated under subsection (a) on the date on which the facility becomes operational;

"(ii) shall pay any applicable Federal permitting costs, including the costs for permits issued under section 3005(c) of the Solid Waste Disposal Act (42 U.S.C. 6925(c)); and

"(iii) shall store, or pay the cost of storage of, until the time at which a facility designated in subsection (a) is operational, accumulated mercury to which the Secretary has title under this subparagraph in a facility that has been issued a permit under section 3005(c) of the Solid Waste Disposal Act (42 U.S.C. 6925(c))."; and

** 6 (B) in paragraph (2), in the first sentence, by striking "paragraph ~~(1)(A)"~~**(1)(C)"** and inserting "paragraph ~~(1)";~~**(1)(B)(iii)";** and

(3) in subsection (g)(2)—

(A) in the undesignated material at the end, by striking "This subparagraph" and inserting the following:

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"(C) Subparagraph (B)";

(B) in subparagraph (C) (as added by paragraph (1)), by inserting "of that subparagraph" before the period at the end; and

(C) by adding at the end the following:

"(D) A generator producing elemental mercury incidentally from the beneficiation or processing of ore or related pollution control activities, may accumulate the mercury produced onsite that is destined for a facility designated by the Secretary under subsection (a), for more than 90 days without a permit issued under section 3005(c) of the Solid Waste Disposal Act (42 U.S.C. 6925(c)), and shall not be subject to the storage prohibition of section 3004(j) of that Act (42 U.S.C. 6924(j)), if—

"(i) the Secretary is unable to accept the mercury at a facility designated by the Secretary under subsection (a) for reasons beyond the control of the generator;

"(ii) the generator certifies in writing to the Secretary that the generator will ship the mercury to a designated facility when the Secretary is able to accept the mercury;

"(iii) the generator certifies in writing to the Secretary that the generator is storing only mercury the generator has produced or recovered onsite and will not sell, or otherwise place into commerce, the mercury; and

"(iv) the generator has obtained an identification number under section 262.12 of title 40, Code of Federal Regulations, and complies with the requirements described in paragraphs (1) through (4) of section 262.34(a) of title 40, Code of Federal Regulations (as in effect on the date of enactment of this subparagraph).

"(E) MANAGEMENT STANDARDS FOR TEMPORARY STORAGE.—Not later than January 1, 2017, the Secretary, after consultation with the Administrator of the Environmental Protection Agency and State agencies in affected States, shall develop and make available guidance that establishes procedures and standards for the management and short-term storage of elemental mercury at a generator covered under subparagraph (D), including requirements to ensure appropriate use of flasks or other suitable containers. Such procedures and standards shall be protective of human health and the environment and shall ensure that the elemental mercury is stored in a safe, secure, and effective manner. A generator may accumulate mercury in accordance with subparagraph (D) immediately upon enactment of this Act, and notwithstanding that guidance called for by this paragraph (E) has not been developed or made available.".

(b) Interim Status.—Section 5(d)(1) of the Mercury Export Ban Act of 2008 (42 U.S.C. 6939f(d)(1)) is amended—

(1) in the fourth sentence, by striking "in existence on or before January 1, 2013,"; and

(2) in the last sentence, by striking "January 1, 2015" and inserting "January 1,

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2020".

(c) Mercury Inventory.—Section 8(b) of the Toxic Substances Control Act (15 U.S.C. 2607(b)) (as amended by section 10(2)) is amended by adding at the end the following:

"(10) MERCURY.—

"(A) DEFINITION OF MERCURY.—In this paragraph, notwithstanding section 3(2)(B), the term 'mercury' means—

"(i) elemental mercury; and

"(ii) a mercury compound.

"(B) PUBLICATION.—Not later than April 1, 2017, and every 3 years thereafter, the Administrator shall publish in the Federal Register an inventory of mercury supply, use, and trade in the United States.

"(C) PROCESS.—In carrying out the inventory under subparagraph (B), the Administrator shall—

"(i) identify any remaining manufacturing processes or products that intentionally add mercury; and

"(ii) recommend actions, including proposed revisions of Federal law (including regulations), to achieve further reductions in mercury use.

"(D) REPORTING.—

"(i) IN GENERAL.—To assist in the preparation of the inventory under subparagraph (B), any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process shall make periodic reports to the Administrator, at such time and including such information as the Administrator shall determine by rule promulgated not later than 2 years after the date of enactment of this paragraph.

"(ii) COORDINATION.—To avoid duplication, the Administrator shall coordinate the reporting under this subparagraph with the Interstate Mercury Education and Reduction Clearinghouse.

"(iii) EXEMPTION.—This subparagraph shall not apply to a person engaged in the generation, handling, or management of mercury-containing waste, unless that person manufactures or recovers mercury in the management of that waste."

(d) Prohibition on Export of Certain Mercury Compounds.—Section 12(c) of the Toxic Substances Control Act (15 U.S.C. 2611(c)) (as amended by section 13(3)) is amended—

(1) in the subsection heading, by inserting "and Mercury Compounds" after "Mercury"; and

(2) by inserting after paragraph (2) the following:

"(3) PROHIBITION ON EXPORT OF CERTAIN MERCURY COMPOUNDS.—

"(A) IN GENERAL.—Effective January 1, 2020, the export of the following mercury compounds is prohibited:

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"(i) Mercury (I) chloride or calomel.

"(ii) Mercury (II) oxide.

"(iii) Mercury (II) sulfate.

"(iv) Mercury (II) nitrate.

"(v) Cinnabar or mercury sulphide.

"(vi) Any mercury compound that the Administrator, at the discretion of the Administrator, adds to the list by rule, on determining that exporting that mercury compound for the purpose of regenerating elemental mercury is technically feasible.

"(B) PUBLICATION.—Not later than 90 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and as appropriate thereafter, the Administrator shall publish in the Federal Register a list of the mercury compounds that are prohibited from export under this paragraph.

"(C) PETITION.—Any person may petition the Administrator to add to the list of mercury compounds prohibited from export.

"(D) ENVIRONMENTALLY SOUND DISPOSAL.—This paragraph does not prohibit the export of mercury (I) chloride or calomel for environmentally sound disposal to member countries of the Organization for Economic Cooperation and Development, on the condition that no mercury or mercury compounds are to be recovered, recycled, or reclaimed for use, or directly reused.

"(E) REPORT.—Not later than 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall evaluate any exports of calomel for disposal that occurred since that date of enactment and shall submit to Congress a report that contains the following:

"(i) volumes and sources of calomel exported for disposal;

"(ii) receiving countries of such exports;

"(iii) methods of disposal used;

"(iv) issues, if any, presented by the export of calomel;

"(v) evaluation of calomel management options in the United States, if any, that are commercially available and comparable in cost and efficacy to methods being utilized in the receiving countries; and

"(vi) a recommendation regarding whether Congress should further limit or prohibit the export of calomel for disposal.

"(F) EFFECT ON OTHER LAW.—Nothing in this paragraph shall be construed to affect the authority of the Administrator under Solid Waste Disposal Act (42 U.S.C. 6901 et seq.).".

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Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 9/16/2015 5:38:36 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]
CC: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Emailing: EPA TA - Orion - EJMDD discussion draft - (9-16-15) - redline - v.7.0
Attachments: EPA TA - Orion - EJMDD discussion draft - (9-16-15) - redline - v.7.0.doc

Jim and Sven, would like you to have a copy of the latest state of play in discussions.

The redline changes show all changes that have been done to the EPW reported bill (as modified with technical amendments).
The redline changes reflect the latest state of play in discussions for a substitute version of the bill for Floor consideration.

Your message is ready to be sent with the following file or link attachments:

EPA TA - Orion - EJMDD discussion draft - (9-16-15) - redline - v.7.0

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

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 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 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.".

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 ~~describe the manner in which the Administrator shall ensure that —~~ **ensure that—**

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;

"(B) to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate~~, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.~~ **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 ~~and~~**,** procedures**, and guidance** for the testing of chemical substances or mixtures under section 4.

"(2) GOAL.—A goal of the policies ~~and~~**,** procedures**, and guidance** established under paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) CONTENTS.—The policies ~~and~~**,** procedures**, and guidance** established under paragraph (1) shall—

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition

that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential; **and**

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations~~;~~**.**

~~"(C) require the Administrator to~~**"(4) EPIDEMIOLOGICAL STUDIES.—Before prescribing epidemiological studies of employees, the Administrator shall** consult with the Director of the National Institute for Occupational Safety and Health**.** ~~prior to prescribing epidemiologic studies of employees; and~~

~~"(D) require that prior to making a request or adopting a requirement for testing using vertebrate animals, the Administrator shall take into consideration, as appropriate and to the extent practicable, reasonably available—~~

~~"(i) toxicity information;~~

~~"(ii) computational toxicology and bioinformatics;~~

~~* 1 "(iii) high-throughput screening methods and the prediction models of those methods; and~~

~~* 2 "(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.~~

"(h) Safety Assessments and Safety Determinations.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(C) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall identify the substances subject to safety assessments and safety determinations to be completed that year.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(A) IN GENERAL.—The Administrator shall establish, by rule, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

"(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

"(C) MINIMUM ~~REQUIREMENTS.—AT A MINIMUM, THE~~ **REQUIREMENTS.—The** policies and procedures under this paragraph ~~shall—~~ **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 ~~the Administrator—~~ **that each draft and final safety assessment and safety determination of the Administrator include a description of—**

~~"(I)(aa) to define~~**"(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 susceptible populations that the Administrator ~~expects to consider in a safety assessment;~~ **has identified as relevant; and**

~~"(bb) to explain~~**"(bb)** the basis for the scope of the safety assessment and safety determination;

~~and~~

~~"(cc) to accept comments regarding the scope of the safety assessment and safety determination; and~~

~~"(II)(aa) to identify the items described in subclause (I) that the Administrator has considered in the final safety assessment; and~~

~~"(bb) to explain the basis for the consideration of those items;~~

~~"(iii) describe~~**"(II)** the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the 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—~~

~~"(I) a description of~~**"(III)** the weight of the scientific evidence of risk; and

~~"(II) a summary of~~**"(IV)** the information regarding the impact on health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies;

~~"(v)~~**"(iii)** establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination; and

~~"(vi)~~**"(iv)** when relevant information is provided or otherwise made available to the Administrator, ~~shall~~ **require the Administrator to** 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~~ **by** 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), ~~and (g);~~**(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 "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";~~

~~(4) in subsection (g) (as so redesignated)—~~**(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

~~(5)~~**(3)** 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.—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; and

"(ii) the reasonably foreseeable availability of facilities and personnel required to perform the testing.

"(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 potential) pursuant to this section, the Administrator shall—

"(A) identify the need intended to be met by the rule, agreement, or order;

"(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of vertebrate animals.

"(2) EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an order is warranted instead of promulgating a rule or entering into a testing consent agreement.

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a description of—

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

"(ii) the extent to which the Administrator has obtained or attempted to obtain the information through voluntary submissions; and

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) ~~encouraging and facilitating—~~ **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;

**** 1** "(iii) high-throughput screening methods and the prediction models of those methods; and

**** 2** "(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information~~.~~**;**

"(B) 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)~~**"(C)** 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** ~~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~~

~~* 3 "(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~~ **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

**** 3** ~~"(II)~~**"(bb)** the last day of the period that begins on the date referred to in ~~clause (i)~~ **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 ~~striking "section 4(e)" and inserting "section 4(f)".~~ **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 ~~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~~ **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** ~~Administrator—~~

~~"(i) shall take into consideration and~~ publish an initial list of high-priority substances and low-priority substances~~; and~~

~~"(ii) pursuant to section 6(b), may initiate or continue safety assessments and safety determinations for those high-priority substances~~.

"(B) REQUIREMENTS.—

"(i) IN GENERAL.—The initial list of chemical substances shall contain at least 10 high-priority substances, at least 5 of which are drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, and at least 10 low-priority substances.

"(ii) SUBSEQUENTLY IDENTIFIED SUBSTANCES.—Insofar as possible, at least 50 percent of all substances subsequently identified by the Administrator as high-priority substances shall be drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, until all Work Plan chemicals have been designated under this subsection.

"(iii) PERSISTENCE AND ~~BIOACCUMULATION.—IN~~ **BIOACCUMULATION.—**

"(I) IN GENERAL.—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.

"(II) METALS AND METAL COMPOUNDS.—In prioritizing and assessing metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007 (or a successor

document), and may use other applicable information consistent with the best available science.

"(C) ADDITIONAL CHEMICAL REVIEWS.—The Administrator shall, as soon as practicable and not later than—

"(i) 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 20 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 20 low-priority substances have been designated; and

"(ii) 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 25 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 25 low-priority substances have been designated.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In ~~carrying out~~ **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 ~~carrying out~~ **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.** ~~high-priority substances.~~

~~"(III) Low-priority substances.—If a low-priority substance is subsequently designated as a high-priority substance, the Administrator shall remove that substance from the list of low-priority substances.~~

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) except as provided under paragraph (2), not later than 180 days after the effective date of the final rule under paragraph (1), begin the prioritization screening process; and

"(II) make every effort to complete the designation of all active substances as high-priority substances or low-priority substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical 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 a list of chemical substances ~~that—~~ **that includes and identifies substances—**

~~"(i)~~ **"(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; and~~ **postponed**

pursuant to subsection (b)(5), including the basis for the postponement; and

"~~(ii)~~**"(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 ~~under~~ **pursuant to** a rule promulgated pursuant to section 8(a) has significantly increased or decreased ~~during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance~~;

"(G) the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

"(H) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a high-priority or a low-priority substance.

"(b) Prioritization Screening Process and Decisions.—

"(1) IN ~~GENERAL.—THE~~ **GENERAL.—In implementing 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 ~~required~~ **needed** to establish the priority of a chemical substance under this section, the Administrator may ~~defer the~~ **postpone a** 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) identify the information and analysis on which the decisions are based; and**

~~"(B)~~ **"(C)** provide 90 days for public comment.

"(8) REVISIONS OF PRIOR DESIGNATIONS.—

"(A) IN GENERAL.—At any time, ~~and at the discretion of the Administrator,~~ the Administrator may revise the designation of a chemical substance as a high-priority substance or a low-priority substance based on information available to the Administrator after the date of the determination under paragraph (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.

"(9) OTHER INFORMATION RELEVANT TO PRIORITIZATION.—

"(A) IN GENERAL.—If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State proposes an administrative action or enacts a statute or takes an administrative action to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not designated as a high-priority substance, the Governor or State agency with responsibility for implementing the statute or administrative action shall notify the Administrator.

"(B) REQUESTS FOR INFORMATION.—Following receipt of a notification provided under subparagraph (A), the Administrator may request any available information from the Governor or the State agency with respect to—

"(i) scientific evidence related to the hazards, exposures and risks of the chemical substance under the conditions of use which the statute or administrative action is intended to address;

"(ii) any State or local conditions which warranted the statute or administrative action;

"(iii) the statutory or administrative authority on which the action is based; and

"(iv) any other available information relevant to the prohibition or other restriction, including information on any alternatives considered and their hazards, exposures, and risks.

"(C) PRIORITIZATION SCREENING.—The Administrator shall conduct a prioritization screening under this subsection for all substances that—

"(i) are the subject of notifications received under subparagraph (A); and

"(ii) the Administrator determines—

"(I) are likely to have significant health or environmental impacts;

"(II) are likely to have significant impact on interstate commerce; or

"(III) have been subject to a prohibition or other restriction under a statute or administrative action in 2 or more States.

"(D) AVAILABILITY TO PUBLIC.—Subject to section 14 and any applicable State law regarding the protection of confidential information provided to the State or to the Administrator, the Administrator shall make information received from a Governor or State agency under subparagraph (A) publicly available.

"(E) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall preempt a State statute or administrative action, require approval of a State statute or administrative action, or apply section 15 to a State.

"(10) REVIEW.—Not less frequently than once every 5 years after the date on which the

process under this subsection is established, the Administrator shall—

"(A) review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and

"(B) if necessary, modify the prioritization screening process.

"(11) EFFECT.—Subject to section 18, a designation by the Administrator under this section with respect to a chemical substance shall not affect—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance; or

"(B) the regulation of those activities.

"(c) Additional Priorities for Safety Assessments and Determinations.—

"(1) REQUIREMENTS.—

"(A) IN GENERAL.—The ~~prioritization screening process developed~~ **rule promulgated** 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)~~ **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) ~~if a sufficient number of additional priority requests meet the requirements of paragraph (1),~~ **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) ~~are substances designated under the process and criteria pursuant to paragraph (1);~~**(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 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 ~~the~~ 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 (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) **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 ~~any necessary~~ **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), 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~~ **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~~, or of the chemical substance for a new use, that is not in compliance with~~ **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

"(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~~**, with respect to** persistence and bioaccumulation, **scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012,** 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~~ **EXPOSURES.—To the extent practicable, the** Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(F) DEFINITION OF REQUIREMENT.—For purposes of this Act, the term 'requirement' as used in this section does not displace common law.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

"(B) may, by agreement with the submitter, extend the review period for a

reasonable time to allow the development and submission of the additional information;

"(C) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

"(D) on receipt of information the Administrator finds supports the determination under paragraph (3), shall promptly make the determination.";

(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 ~~of~~ **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 ~~(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) 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 ~~a~~ **any necessary** final rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; and

"(6) may extend any deadline under paragraph (4) or (5) for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under this subsection, plus any deferral under subsection (c)(2), does not exceed 2 years.

"(b) Prior Actions and Notice of Existing Information.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination ~~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 **pursuant to section 3A(h)(2)(D)**, and subject to section 18**(g)**, the Administrator shall ~~determine that—~~ **determine—**

~~"(A)~~ **"(A) by order, that** the relevant chemical substance meets the safety standard;

"(B) **that** the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by rule under subsection (d)—

"(i) impose restrictions necessary to ensure that the chemical substance meets the safety standard under the conditions of use; or

"(ii) if the safety standard cannot be met with the application of **other** restrictions **under subsection (d)(3)**, ban or phase out the chemical substance, as appropriate; or

"(C) **that** additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is necessary to make a safety assessment or safety determination for a high-priority substance, the Administrator—

"(A) shall provide an opportunity for interested persons to submit the additional information;

"(B) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

"(C) may defer, for a reasonable period consistent with the deadlines described in subsection (a), a safety assessment and safety determination until after receipt of the information; and

"(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety determination, shall make a determination under paragraph (1).

"(3) ESTABLISHMENT OF DEADLINE.—In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.

"(d) Rule.—

"(1) IMPLEMENTATION.—If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a rule establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

"(2) SCOPE.—

"(A) IN GENERAL.—The rule promulgated pursuant to this subsection—

"(i) may apply to mixtures containing the chemical substance, as appropriate;

"(ii) shall include dates by which compliance is mandatory, which—

"(I) shall be as soon as practicable**, but not later than 4 years after the date of promulgation of the rule, except in the case of a use exempted under paragraph (5)**;

"(II) in the case of a ban or phase-out of the chemical substance, shall implement the ban or phase-out in as short a period as practicable;~~ and~~

"(III) as determined by the Administrator, may vary for different affected persons; and

"(IV) following a determination by the Administrator that compliance is technologically or economically infeasible 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;~~ 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**; 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 necessary to ensure that the substance meets the safety standard for that population.~~.~~

"(B) PERSISTENT AND BIOACCUMULATIVE SUBSTANCES.—For a chemical substance the Administrator determines ~~ranks high for~~**, with respect to** persistence and bioaccumulation, **scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012,** the Administrator shall, in selecting among prohibitions and other restrictions that the Administrator determines are sufficient to ensure that the chemical substance meets the safety standard, reduce exposure to the substance to the maximum extent practicable.

"(C) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(D) DEFINITION OF REQUIREMENT.—For the purposes of this Act, the term 'requirement' as used in this section does not displace common law.

"(3) RESTRICTIONS.—A restriction under paragraph (1) may include, as appropriate—

"(A) subject to section 18, a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator;

"(B) a requirement that manufacturers or processors of the chemical substance shall—

"(i) make and retain records of the processes used to manufacture or process the chemical substance;

"(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or

"(iii) monitor or conduct tests that are reasonably necessary to ensure compliance with the requirements of any rule under this subsection;

"(C) a restriction on the quantity of the chemical substance that may be

manufactured, processed, or distributed in commerce;

"(D) a requirement to ban or phase out, or ~~any other rule regarding,~~ **otherwise restrict** the manufacture, processing, or distribution in commerce of the chemical substance for—

"(i) a particular use;

"(ii) a particular use at a concentration in excess of a level specified by the Administrator; or

"(iii) all uses;

"(E) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—

"(i) a particular use; or

"(ii) a particular use at a concentration in excess of a level specified by the Administrator;

"(F) a requirement to ban, phase out, or otherwise restrict any method of commercial use of the chemical substance;

"(G) a requirement to ban, phase out, or otherwise restrict any method of disposal of the chemical substance or any article containing the chemical substance; and

"(H) a requirement directing manufacturers or processors of the chemical substance to give notice of the Administrator's determination under subsection (c)(1)(B) to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

"(5) EXEMPTIONS.—

"(A) IN GENERAL.—The Administrator may ~~exempt 1 or more uses of a chemical substance from any restriction in~~**, 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 ~~rule~~ **restriction** cannot be complied with, without—

"(I) harming national security;

"(II) causing significant disruption in the national economy due to the lack of availability of a chemical substance; or

"(III) interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or

"(ii) the use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

"(B) EXEMPTION ANALYSIS.—In proposing a rule under ~~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 **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 **this** paragraph~~(1)~~, the Administrator shall include conditions ~~in any exemption established under this paragraph~~, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption.

"(F) DURATION.—

"(i) IN GENERAL.—The Administrator shall establish, as part of a rule under ~~paragraph (1) that contains an exemption under~~ this paragraph, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis.

"(ii) AUTHORITY OF ADMINISTRATOR.—The Administrator, by rule, may extend, modify, or eliminate ~~the~~ **an** exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or is no longer necessary.

"(iii) CONSIDERATIONS.—

"(I) IN GENERAL.—Subject to subclause (II), the Administrator shall issue exemptions and establish time periods by considering factors determined by the Administrator to be relevant to the goals of fostering innovation and the development of alternatives that meet the safety standard.

"(II) LIMITATION.—Any renewal of an exemption in the case of a rule **under paragraph (1)** requiring the ban or phase-out of a chemical substance shall not exceed 5 years.

"(e) Immediate Effect.—The Administrator may declare a proposed rule under subsection (d)(1) to be effective on publication of the rule in the Federal Register and until the effective date of final action taken respecting the rule, if—

"(1) the Administrator determines that—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to the proposed rule or any combination of those activities is likely to result in a risk of serious or widespread injury to health or the environment before the effective date; and

"(B) making the proposed rule so effective is necessary to protect the public interest; and

"(2) in the case of a proposed rule to prohibit the manufacture, processing, or distribution in commerce of a chemical substance or mixture because of the risk determined under paragraph (1)(A), a court has granted relief in an action under section 7 with respect to that risk associated with the chemical substance or mixture.

"(f) Final Agency Action.—Under this section and subject to section 18—

"(1) a safety determination, and the associated safety assessment, for a chemical substance that the Administrator determines under subsection (c) meets the safety standard, shall be considered to be a final agency action, effective beginning on the date of issuance of the final safety determination; and

"(2) a final rule promulgated under subsection (d)(1), and the associated safety assessment and safety determination that a chemical substance does not meet the safety standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final ~~rule."; and~~ **rule.**

~~(4) in subsection (g)~~**"(g) Extension of Deadlines for Certain Chemical Substances.—The Administrator may not extend any deadline under subsection (a) for a chemical substance designated as a high priority that is listed in the 2014 update of the TSCA Work Plan without adequate public justification under subsection (a)(6) that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot adequately complete a safety assessment and safety determination,**

or a final rule pursuant to subsection (d), without additional information regarding 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)~~**(3)**—

(i) in subparagraph (A)(ii)(I)—

~~(i)~~**(I)** by striking "5(b)(4)" and inserting "5";

~~(ii)~~**(II)** by inserting "section 4 or" after "in effect under"; and

~~(iii)~~**(III)** by striking "5(e)," and inserting "5(d)(4);"; and

(ii) by adding at the end the following:

"(C) Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and not less frequently than once every 10 years thereafter, the Administrator, after consultation with the Administrator of the Small Business Administration, shall—

"(i) review the adequacy of the standards prescribed according to subparagraph (B);

"(ii) after providing public notice and an opportunity for comment, make a determination as to whether revision of the standards is warranted; and

"(iii) revise the standards if the Administrator so determines."; 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 ~~requiring~~ **applicable to** 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 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.";** ~~title.~~

~~"(5) Guidance.—The Administrator shall develop guidance relating to the information required to be reported under the rules promulgated under this subsection.";~~

(2) in subsection (b), by adding at the end the following:

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

"(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

"(I) cement, Portland, chemicals, CAS No. 65997–15–1;

"(II) cement, alumina, chemicals, CAS No. 65997–16–2;

"(III) glass, oxide, chemicals, CAS No. 65997–17–3;

"(IV) frits, chemicals, CAS No. 65997–18–4;

"(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

"(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature conventions, the Administrator shall—

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

"(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) RULES.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator, by rule, shall require manufacturers and processors to notify the Administrator, by not later than 180 days after the date of promulgation of the rule, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(ii) ACTIVE SUBSTANCES.—The Administrator shall~~, pursuant to paragraph (5)(A),~~ designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(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.—THE RULE PROMULGATED BY THE ADMINISTRATOR~~ **SUBSTANCES.—In promulgating the rule established** pursuant to subparagraph (A) ~~shall require—~~**, the Administrator shall—**

~~"(i) the Administrator to~~**"(i)** maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

"(ii) **require** a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

"(iii) **require** the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C).

"(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are ~~notified~~ **asserted** pursuant to subparagraph ~~(A) or identified as active substances under subsection (f)(1).~~**(B).**

"(D) REQUIREMENTS OF REVIEW ~~PLAN.—THE~~ **PLAN.—Under the** review plan under subparagraph (C)**, the Administrator** shall—

"(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

"(ii) ~~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~~ **REVIEW GOAL AND RESULTS.—At the beginning of each year, the** Administrator shall publish an annual goal for **reviews and** the number of reviews ~~to be completed over the course of implementation of the plan.~~ **completed in the prior year.**

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

"(A) IN GENERAL.—The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).

"(B) ~~UPDATE.—THE ADMINISTRATOR SHALL UPDATE THE LIST OF CHEMICAL SUBSTANCES DESIGNATED AS ACTIVE SUBSTANCES AS SOON AS PRACTICABLE AFTER THE DATE OF PUBLICATION OF THE MOST RECENT DATA REPORTED UNDER—~~

~~"(I) PART 711 OF TITLE 40, CODE OF FEDERAL REGULATIONS (OR SUCCESSOR REGULATIONS); AND~~

~~"(II) THE RULES PROMULGATED PURSUANT TO SUBSECTION (A)(4).~~

~~"(C)~~ CHANGE TO ACTIVE STATUS.—

"(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

"(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the inactive substance as confidential, the person shall—

"(I) in the notice submitted under clause (i), assert the claim; and

"(II) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

"(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

"(I) designate the applicable chemical substance as an active substance;

"(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific identity of the chemical substance and approve, modify, or deny the claim;

"(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of ~~not less than~~ 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the ~~confidentiality~~ claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines to be necessary.

"~~(D)~~**"(C)** CATEGORY STATUS.—The list of inactive substances shall not be

considered to be a category for purposes of section 26(c).

"(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the rule required under paragraph (4)(A), the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations ~~(or successor regulations)~~**(as in effect on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act)**, during the reporting period that most closely preceded the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as the interim list of active substances for the purposes of section 4A.

"(7) PUBLIC ~~PARTICIPATION.—SUBJECT~~ **INFORMATION.—Subject** to this subsection, the Administrator shall make available to the public—

"(A) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—

"(i) an active substance; or

"(ii) an inactive substance;

"(B) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received ~~and approved by the Administrator pursuant to section 14~~; and

"(C) subject to **subsections (f) and (g) of** section 14~~(g)~~, the specific identity of any active substance for which—

"(i) ~~no~~ **a** claim ~~of~~ **for** protection against disclosure of the specific identity of the active ~~substance pursuant to this subsection was received;~~ **chemical substance was not asserted, as required under this subsection or subsection (d) or (f) of section 14;**

"(ii) a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or

"(iii) the time period for protection against disclosure of the specific identity of the active substance has expired.

"(8) LIMITATION.—No person may assert a new claim under this subsection for protection from disclosure of a specific identity of any active or inactive chemical substance for which a notice is received under paragraph (4)(A)(i) or (5)(C)(i) that is not on the confidential portion of the list published under paragraph (1).

"(9) CERTIFICATION.—Under the rules promulgated under this subsection, manufacturers and processors shall be required—

"(A) to certify that each ~~report~~ **notice or substantiation** the manufacturer or processor submits complies with the requirements of the rule, and that any confidentiality claims are true and correct; and

"(B) to retain a record supporting the certification for a period of 5 years beginning on the last day of the submission period.";

(3) in subsection (e)—

(A) by striking "Any person" and inserting the following:

"(1) IN GENERAL.—Any person"; and

(B) by adding at the end the following:

"(2) ~~APPLICABILITY.—ANY~~ **ADDITIONAL INFORMATION.—Any** person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of injury to health and the environment."; and

(4) in subsection (f), by striking "For purposes of this section, the" and inserting the following: "In this section:

"(1) ACTIVE SUBSTANCE.—The term 'active substance' means a chemical substance—

"(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(B) that is added to the list published under subsection (b)(1) after that date of enactment; or

"(C) for which a notice is received under subsection (b)(5)(C).

"(2) INACTIVE SUBSTANCE.—The term 'inactive substance' means a chemical substance on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).

"(3) MANUFACTURE; PROCESS.—The".

SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.

Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the first sentence—

(i) by striking "presents or will present an unreasonable risk to health or the environment" and inserting "does not **or will not** meet the safety standard"; and

(ii) by striking "such risk" the first place it appears and inserting "the risk posed by the substance or mixture";

(B) in paragraph ~~(2),~~**(2)**—

(i) in subparagraph (A), by inserting "within the time period specified by the Administrator in the report" after "issues an order";

(ii) in subparagraph (B), by inserting "responds within the time period specified by the Administrator in the report and" before "initiates, within 90 days"; and

(iii) in the matter following subparagraph (B), by striking "section 6 or 7" and inserting "section 6(d) or section 7";

~~and~~

~~(C) in~~**(C) by redesignating** paragraph (3) **as paragraph (6);**

(D) in paragraph (6) (as so redesignated), by striking "section 6 or 7" and inserting "section 6(d) or 7"; **and**

(E) by inserting after paragraph (2) the following:

"(3) The Administrator shall take the actions described in paragraph (4) if the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which the report was made does not—

"(A) issue the order described in paragraph (2)(A) within the time period specified by the Administrator in the report; or

"(B)(i) respond under paragraph (1) within the time frame specified by the Administrator in the report; and

"(ii) initiate action within 90 days of publication in the Federal Register of the response described in clause (i).

"(4) If an agency to which a report under paragraph (1) does not take the actions described in subparagraphs (A) or (B) of paragraph (3), the Administrator shall—

"(A) if a safety assessment and safety determination for the substance under section 6 has not been completed, complete the safety assessment and safety determination;

"(B) if the Administrator has determined or determines that the chemical substance does not meet the safety standard, initiate action under section 6(d) with respect to the risk; or

"(C) take any action authorized or required under section 7, as appropriate.

"(5) This subsection shall not relieve the Administrator of any obligation to complete a safety assessment and safety determination or take any required action under section 6(d) or 7 to address risks from the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of those activities, that are not identified in a report issued by the Administrator under paragraph (1).";

(2) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and inserting "Health and Human Services"; and

(3) by adding at the end the following:

"(e) Exposure Information.—If the Administrator obtains information related to exposures or releases of a chemical substance that may be prevented or reduced under another Federal law, including laws not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.".

SEC. 12. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA.

Section 10 of the Toxic Substances Control Act (15 U.S.C. 2609) is amended by striking

"Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".

SEC. 13. EXPORTS.

Section 12 of the Toxic Substances Control Act (15 U.S.C. 2611) is amended—

(1) in subsection (a), by striking paragraph (2) and inserting the following:

"(2) EXCEPTION.—Paragraph (1) shall not apply ~~to~~ **to—**

"(A) any **new** chemical substance that the Administrator ~~determines—~~ **determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors;**

~~"(A) under section 5 is not likely to meet the safety standard; or~~**"(B) any chemical substance that the Administrator determines presents or will present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; or**

~~"(B) under section 6 does not meet the safety standard.~~**"(C) any chemical substance that—**

~~"(3) Waivers.—For~~**"(i) the Administrator determines is likely to present an unreasonable risk of injury to health within the United States or to the environment of the United States, without taking into account cost or other non-risk factors; and**

"(ii) is subject to restriction under section 5(d)(4).

"(3) WAIVERS FOR CERTAIN MIXTURES AND ARTICLES.—For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—

"(A) determine that paragraph (1) shall not apply to the mixture or article; or

"(B) establish a threshold concentration in a mixture or article at which paragraph (1) shall not apply.

"(4) TESTING.—The Administrator may require testing under section 4 of any chemical substance or mixture exempted from this Act under paragraph (1) for the purpose of determining whether the chemical substance ~~or mixture~~ meets the safety standard within the United States.";

(2) by striking subsection (b) and inserting the following:

"(b) Notice.—

"(1) IN GENERAL.—A person shall notify the Administrator that the person is exporting or intends to export to a foreign country—

"(A) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 5 is not likely to meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(B) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 6 does not meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(C) a chemical substance for which the United States is obligated by treaty to provide export notification;

"(D) a chemical substance or mixture **containing a chemical substance** subject to a **proposed or promulgated** significant new use rule, or a prohibition or other restriction pursuant to a rule, order, or consent agreement in effect under this Act;~~ 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, 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 ~~and specific~~**.**

"(7) Specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

~~"(7)~~**"(8)** Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, **if** ~~if—~~

~~"(A)~~ the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5~~; and~~

~~"(B) the claim—~~

~~"(i) is not subject to an exception under subsection (e); or~~

~~"(ii) has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (f)(2) or (g)~~.

"(c) Information Not Protected From ~~Disclosure.—Notwithstanding~~ **Disclosure.—**

"(1) IN GENERAL.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

~~"(1)~~**"(A)** INFORMATION FROM HEALTH AND SAFETY STUDIES.—

~~"(A)~~**"(i)** IN GENERAL.—Subject to ~~subparagraph (B), subsection (a) does not prohibit the disclosure of—~~ **clause (ii)—**

~~"(i)~~**"(I)** any health and safety study that is submitted under this Act with respect to—

~~"(I)~~**"(aa)** any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

~~"(II)~~**"(bb)** any chemical substance or mixture for which—

~~"(aa)~~**"(AA)** testing is required under section 4; or

~~"(bb)~~**"(BB)** a notification is required under section 5; or

~~"(ii)~~**"(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).~~ **item (aa) or (bb) of subclause (I).**

~~"(B)~~**"(ii)** EFFECT OF ~~PARAGRAPH.—NOTHING~~ **SUBPARAGRAPH.—Nothing** in this ~~paragraph~~ **subparagraph** 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.

~~* 4 "(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)~~**"(B)** OTHER INFORMATION NOT PROTECTED FROM ~~DISCLOSURE.—THE FOLLOWING INFORMATION IS NOT PROTECTED FROM DISCLOSURE UNDER THIS SECTION:~~ **DISCLOSURE.—**

~~"(A)~~**"(i)** For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

~~"(B)~~**"(ii)** A safety assessment developed, or a safety determination made, under section 6.

~~"(C)~~**"(iii)** Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information,

expressed in ranges.

~~"(D)~~**"(iv)** A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

~~"(4)~~**"(2)** MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION .—Any information that is ~~otherwise~~ eligible for protection under this section and ~~contained in a submission of~~ **is submitted with** information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

~~"(5)~~**"(3)** BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance, subject to paragraphs (2), (3), and (4) of subsection (g), any protection from disclosure provided under this section with respect to the specific identity of the chemical substance and other information relating to the chemical substance shall no longer apply.

**** 4** ~~"(2)~~**"(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 ~~described in paragraph (1) that is not described in paragraph (1)(B)~~ **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) ~~conform~~ **be consistent** with guidance ~~prescribed~~ **issued** by the Administrator under paragraph (3)(A); and

"(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are considered to be confidential; and

"(II) the disclosure of which would be likely to **cause substantial** harm **to** the competitive position of the person.

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in ~~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 ~~information that has been submitted is~~ **statement required to assert a claim submitted pursuant to paragraph (1)(B) and any information required to substantiate a claim submitted pursuant to paragraph (2) are** true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a)—

"(1) shall be disclosed if the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) shall be disclosed if the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment;

"(4) shall be disclosed if the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, **if** ~~if—~~

~~"(A)~~ 1 or more applicable agreements with the Administrator that ~~conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; ~~and~~

~~"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;~~

"(5) shall be disclosed if a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement ~~shall conform~~ **are consistent** with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) shall be disclosed if in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable

basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) shall be disclosed if the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

"(9) shall be disclosed if the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION ~~PROTECTED~~ **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 ~~subsection (d) for a period of 10 years, unless, prior to the expiration of the period—~~ **subsections (a) and (d), unless—**

~~"(i) an affected person~~ **"(i) 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 ~~the~~ **any** actions ~~described in~~ **required under** subsection (g)(2).

"(B) **INFORMATION SUBJECT TO TIME LIMIT FOR PROTECTION FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from**

disclosure information, other than information described in subsection (b), that meets the requirements of subsections (a) and (d) for a period of 10 years, unless, prior to the expiration of the period—

"(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the information does not qualify or no longer qualifies for protection against disclosure under subsection (a), in which case the Administrator shall take any actions required under subsection (g)(2).

"(C) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph ~~(A)~~**(B)**, a person reasserting the relevant claim shall submit to the Administrator a ~~statement~~ **request for extension** substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date ~~that is 30 days after the date of receipt of a statement under subclause (I), the Administrator shall—~~ **of expiration of the period described in subparagraph (B), the Administrator shall, in accordance with subsection (g)(1)(C)—**

"(aa) review the request **submitted under subclause (I)**;

"(bb) make a determination regarding whether the ~~information~~ **claim** for which the request ~~is made~~ **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.~~ **request.**

~~"(C)~~**"(D)** NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph ~~(B)~~**(C)**, if the Administrator determines that the relevant ~~statement~~ **request** under subparagraph ~~(B)(ii)(I)~~ **(C)(ii)(I)—**

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection **of information** against disclosure under subsection (a) ~~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~~ **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) as necessary to ~~comply~~ **determine whether the information qualifies for an exemption from disclosure in connection** with a request for information received by the Administrator under section 552 of title 5, United States Code;

"(ii) if ~~information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met;~~ **the Administrator has a reasonable basis to believe that the information does not qualify for protection against disclosure under subsection (a);** or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator ~~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 DENIAL OR MODIFICATION.—If the Administrator denies or modifies a claim or request under subparagraph (A)** ~~Denial or modification.—~~

~~"(i) In general.—Except as provided in subsections (c) and (f)~~, the Administrator shall **provide to the person that submitted the claim or request** ~~deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).~~

~~"(ii) Reasons for denial or modification.—The Administrator shall provide to a person that has submitted a claim described in clause (i)~~ a written statement of the reasons for the denial or modification of the claim **or request**.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection ~~(b)(7)~~**(b)(8)**, review all claims **or requests** under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims **or requests** for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim **or request** for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim **or request** for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim **or request** under paragraph (1), **intends to release information pursuant to subsection (e),** or promulgates a rule under section 6(d) establishing a ban or phase-out of a chemical substance, the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

"(B) RELEASE OF **INFORMATION.—Except** ~~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).

~~"(ii)~~**"(C)** EXCEPTIONS.—

~~"(I)~~**"(i)** IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim **or request** receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

"(ii) NOTIFICATION AS SOON AS PRACTICABLE.—For information under paragraphs (4) and (6) of subsection (e), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

"(iii) NO NOTIFICATION REQUIRED.—Notification shall not be required—

"(I) for the disclosure of~~"(II) No notification.—For~~ information under paragraph (1), (2), ~~(6),~~(7), or (9) of subsection (e)~~, no prior notification shall be necessary.~~**; or**

"(II) for the disclosure of information for which—

"(aa) a notice under subsection (f)(1)(C)(i) was received; and

"(bb) no request was received by the Administrator on or before the date of expiration of the period for which protection from disclosure applies.

"(3) REBUTTABLE PRESUMPTION.—

"(A) IN GENERAL.—With respect to notifications provided by the Administrator ~~pursuant to subsection (e)(5)~~ **under paragraph (2) with respect to information pertaining to a chemical substance subject to a rule as described in subsection**

(c)(3), there shall be a rebuttable presumption that the public interest in disclosing confidential information related to a chemical substance subject to a rule promulgated under section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of the substance outweighs the proprietary interest in maintaining the protection from disclosure of that information.

"(B) REQUEST FOR NONDISCLOSURE.—A person that receives a notification under paragraph (2) with respect to the information described in subparagraph (A) may submit to the Administrator, before the date on which the information is to be released **pursuant to paragraph (2)(B)**, a request with supporting documentation describing why the person believes some or all of that information should not be disclosed.

"(C) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—Not later than 30 days after the Administrator receives a request under subparagraph (B), the Administrator shall determine~~, at the discretion of the Administrator,~~ whether the documentation provided by the person making the request rebuts or does not rebut the presumption described in subparagraph (A), for all or a portion of the information that the person has requested not be disclosed.

"(ii) OBJECTIVE.—The Administrator shall make the determination with the objective of ensuring that information relevant to protection of health and the environment is disclosed to the maximum extent practicable.

"(D) TIMING.—Not later than 30 days after making the determination described in subparagraph (C), the Administrator shall make public the information the Administrator has determined is not to be protected from disclosure.

"(E) NO TIMELY REQUEST RECEIVED.—If the Administrator does not receive, before the date on which the information described in subparagraph (A) is to be released **pursuant to paragraph (2)(B)**, a request pursuant to subparagraph (B), the Administrator shall promptly make public all of the information.

"(4) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released **pursuant to paragraph (2)(B)**, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(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).~~ **REQUEST AND NOTIFICATION SYSTEM.—The**

Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that allows for expedient and swift access to information under paragraphs (5) and (6) of subsection (e) in a format and language that is readily accessible and understandable.

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information ~~submitted to~~ **reported to or otherwise obtained by** the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section.

"(2) ~~PRIOR ACTIONS.—NOTHING~~ **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,** ~~sentence—~~

~~(i) by inserting "this Act or a rule or order promulgated or issued pursuant to this Act, including" after "a provision of"; and~~

~~(ii)~~ by striking "$25,000" and inserting "$37,500"; and

(B) in the second sentence, by striking" violation of section 15 or 409" and inserting "violation of this Act"; and

(2) in subsection (b)—

(A) by striking "Any person who" and inserting the following:

"(1) IN GENERAL.—Any person that";

(B) ~~by striking "section 15 or 409" and inserting "this Act";~~

~~(C)~~ by striking "$25,000" and inserting "$50,000"; and

~~(D)~~**(C)** by adding at the end the following:

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of ~~this Act~~ **section 15 or 409**, and that knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury, shall be subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

"(B) ORGANIZATIONS.—An organization that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation.

~~"(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.".~~**"(C) INCORPORATION OF CORRESPONDING PROVISIONS.—Subparagraphs (B) through (F) of section 113(c)(5) of the Clean Air Act (42 U.S.C. 7413(c)(5)) shall apply to the prosecution of a violation under this paragraph.".**

SEC. 17. STATE-FEDERAL RELATIONSHIP.

Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following:

"(a) In General.—

"(1) ESTABLISHMENT OR ENFORCEMENT.—Except as provided in subsections (c), (d), (e), (f), and (g), and subject to paragraph (2), no State or political subdivision of a State may establish or continue to enforce any of the following:

"(A) ~~TESTING AND INFORMATION COLLECTION.—A~~ **TESTING.—A** statute or administrative action to require the development of information on a chemical substance or category of substances that is reasonably likely to produce the same information required under section 4, 5, or 6 in—

"(i) a rule promulgated by the Administrator;

"(ii) a testing consent agreement entered into by the Administrator; or

"(iii) an order issued by the Administrator.

"(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

"(i) found to meet the safety standard and consistent with the scope of the determination made under section 6; or

"(ii) found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

"(C) SIGNIFICANT NEW USE.—A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(2) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of ~~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), **(f), and (g),** beginning on the date on which the Administrator defines **and publishes** the scope of a safety assessment and safety determination under section 6(a)(2) and ending on the date on which the Administrator publishes the safety determination **under section 6(a)(4)**, no State or political subdivision of a State may establish a statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance designated under section 4A.

"(2) EFFECT OF SUBSECTION.—

"(A) IN GENERAL.—This subsection does not restrict the authority of a State or political subdivision of a State to continue to enforce any ~~State~~ statute enacted, or administrative action taken, prior to the date on which the Administrator defines **and publishes** the scope of a safety assessment and safety determination under section 6(a)(2).

"(B) LIMITATION.—Subparagraph (A) does not allow a State or political subdivision of a State to enforce any new prohibition or restriction under a ~~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~~ **a law of a State or political subdivision of a State** in the event of noncompliance with the identical requirement shall be no more stringent than the penalties and other sanctions available to the Administrator under section 16 of this Act.

"(ii) PENALTIES.—In the case of an identical ~~requirement, no State may~~ **requirement**—

"(I) a State or political subdivision of a State may not assess a penalty for a specific violation for which the Administrator has ~~already~~ assessed ~~a~~ **an adequate** penalty under section 16~~, and~~ **; and**

"(II) if a State or political subdivision of a State has assessed a penalty for a specific violation, the Administrator may not assess a penalty ~~under section 16 for a specific violation for which a State has already assessed a penalty.~~ **for that violation in an amount that would cause the total of the penalties assessed for the violation by the State or political subdivision of a State and the Administrator combined to exceed the maximum amount that may be assessed for that violation by the Administrator under section 16.**

"(2) APPLICABILITY TO CERTAIN RULES OR ORDERS.—Notwithstanding subsection (e)—

"(A) nothing in this section shall be construed as modifying the effect under this section, as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, of any rule or order promulgated or issued under this Act prior to that effective date; and

"(B) with respect to a chemical substance or mixture for which any rule or order was

promulgated or issued under section 6 prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act with regards to manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance, this section (as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after that effective date, unless the latter rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under **subsection (b) or (c) of** section 4A~~(b)~~ or as an additional priority for safety assessment and safety determination under section 4A(c).

"(e) Preservation of Certain ~~State Law.—~~ **Laws.—**

"(1) IN GENERAL.—Nothing in this Act, subject to subsection (g) of this section, shall—

"(A) be construed to preempt or otherwise affect the authority of a State or political subdivision of a State to continue to enforce any action taken before August 1, 2015, under the authority of a ~~State law~~ **law of the State or political subdivision of the State** that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance; or

"(B) be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003.

"(2) EFFECT OF SUBSECTION.—This subsection does not affect, modify, or alter the relationship between ~~State and Federal law~~ **Federal law and laws of a State or political subdivision of a State** 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~~ **in** 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~~ **designed to address a risk of a chemical substance, under the conditions of use, that was identified—**

"(i) consistent with the best available science**;**

"(ii) using supporting studies conducted in accordance with sound and objective scientific practices; and

"(iii) based on the weight of the scientific evidence.

"(2) REQUIRED EXEMPTIONS.—Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

"(A) compliance with the proposed requirement of the State ~~will~~ **or political subdivision of the State would** not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(B) compliance with the proposed requirement **of the State or political subdivision of the State** would not cause a violation of any applicable Federal law, rule, or order; and

"(C) the State or political subdivision of ~~a~~ **the** 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~~ **110** days after the date on which an application under paragraph (2) is submitted.

"(4) FAILURE TO MAKE DETERMINATION.—If the Administrator fails to make a determination under paragraph (3)(B) during the ~~90~~ **110**-day period beginning on the date on which an application under paragraph (2) is submitted, the ~~State~~ statute or administrative action **of the State or political subdivision of the State** that was the subject of the application shall not be considered to be an existing statute or administrative action for purposes of subsection (b) by reason of the failure of the Administrator to make a determination.

"(5) NOTICE AND COMMENT.—Except in the case of an application approved under paragraph (9), the application of a State or political subdivision of ~~the~~ **a** State shall be subject to public notice and comment.

"(6) FINAL AGENCY ACTION.—The decision of the Administrator on the application of a State or political subdivision of ~~the~~ **a** State shall be—

"(A) considered to be a final agency action; and

"(B) subject to judicial review.

"(7) DURATION OF **WAIVERS.—A** ~~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** ~~effect—~~

~~"(i)~~ until such time as the ~~safety assessment and safety determination is completed; or~~ **Administrator publishes the safety determination under section 6(a)(4).**

~~"(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~~**"(8) JUDICIAL REVIEW OF WAIVERS.—Not later than 60** 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~~ **a** 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~~ **AUTOMATIC APPROVAL.—**

"(i) If the Administrator fails to meet the deadline **established** under section 6(a)(4) (including an extension granted under section 6(a)(6)), ~~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.

"(ii) If the Administrator fails to meet the deadline established under paragraph (3)(B), the application of a State or political subdivision of a State under paragraph (2) shall be automatically approved, effective on the date that is 10 days after the deadline.

"(B) REQUIREMENTS.—Notwithstanding paragraph (6), approval of a waiver application under subparagraph (A) for failure to meet the deadlines under section 6(a)(4) (including an extension granted under section 6(a)(6)) **or paragraph (3)(B)** shall not be considered final agency action or be subject to judicial review or public notice and comment.

~~"(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.~~

~~* 5 "(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),~~**(A)**—

(I) in the first sentence—

(aa) by striking "Not" and inserting "Except as otherwise provided in this title, not";

(bb) by striking "section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting ~~"section 4(a), 5(d), 6(c), 6(d), 6(g), or 8, or title II or IV"; and~~**"this title or title II or IV, or an order under section 6(c)(1)(A)"; and**

~~(ii) in subparagraph (B),~~**(cc) by striking "judicial review of such rule" and inserting "judicial review of such rule or order"; and**

(II) in the second sentence, by striking "such a rule" and inserting

"such a rule or order"; and

(ii) in subparagraph (B)—

(I) by striking "Courts" and inserting "Except as otherwise provided in this title, courts"; and

(II) by striking "an order issued under subparagraph (A) or (B) of section 6(b)(1)" and inserting "an order issued under this title"; ~~and~~

(B) in paragraph (2), in the ~~first~~ **second** sentence, by striking ~~"paragraph (1)(A)" and inserting "paragraph (1)"~~**"the filing of the rulemaking record of proceedings on which the Administrator based the rule being reviewed" and inserting "the filing of the record of proceedings on which the Administrator based the rule or order being reviewed"**; and

(C) by striking paragraph (3) ~~; and~~ **and inserting the following:**

"(3) JUDICIAL REVIEW OF LOW-PRIORITY DECISIONS.—

"(A) IN GENERAL.—Not later than 60 days after the publication of a designation under section 4A(b)(4), or a designation under section 4A(b)(8) of a chemical substance as a low-priority substance, any person may commence a civil action to challenge the designation.

**** 5** "(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.~~ **paragraph."; and**

(2) in subsection (c)(1)(B)—

(A) in clause (i)—

(i) by striking "section 4(a), 5(b)(4), 6(a), or 6(e)" and inserting "section 4(a), ~~5(d), 6(d), or 6(g)";~~ **6(d), or 6(g), or an order under section 6(c)(1)(A)";** and

(ii) by striking "evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;" and inserting "evidence (including any matter) in the rulemaking record, taken as a whole; and"; and

(B) by striking clauses (ii) and (iii) and the matter following clause (iii) and inserting the following:

"(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule, except as part of the rulemaking record, taken as a whole.".

SEC. 19. CITIZENS' CIVIL ACTIONS.

Section 20 of the Toxic Substances Control Act (15 U.S.C. 2619) is amended—

(1) in subsection (a)(1), by striking "or order issued under section 5" and inserting "or order issued under section 4 or 5"; and

(2) in subsection (b)—

(A) in paragraph (1)(B), by striking "or" at the end;

(B) in paragraph (2), by striking the period at the end and inserting ", except that no prior notification shall be required in the case of a civil action brought to compel a decision by the Administrator pursuant to section 18(f)(3)(B); or"; and

(C) by adding at the end the following:

"(3) in the case of a civil action brought to compel a decision by the Administrator pursuant to section 18(f)(3)(B), after the date that is 60 days after the deadline specified in section 18(f)(3)(B).".

SEC. 20. CITIZENS' PETITIONS.

Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an order under section 4 or 5(d)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "an order under section 4 or 5(d)"; and

(B) in paragraph (4), by striking subparagraph (B) and inserting the following:

"(B) DE NOVO PROCEEDING.—

"(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to ~~promulgate~~ **issue** a rule pursuant to section 4, 5, 6, or 8 or issue an order under section 4 or 5(d), the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.

"(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a rule or order under section 4, the information ~~available to the Administrator is insufficient for the Administrator to perform an action described in section 4, 4A, 5, or 6(d);~~ **is needed for a purpose identified in section 4(a);**

"(bb) in the case of a petition to issue an order under section 5(d), ~~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~~ **does** not meet the safety standard; or

"(dd) in the case of a petition to initiate a proceeding for the issuance of a rule under section 8, there is a reasonable basis to conclude that the

rule is necessary to protect health or the environment or ensure that the chemical substance meets the safety standard.

"(II) DEFERMENT.—The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

"(aa) the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act; and

"(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.".

SEC. ~~20~~ **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. ~~21.~~ **22.** STUDIES.

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.

SEC. ~~22.~~ **23.** ADMINISTRATION.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) by striking subsection (b) and inserting the following:

"(b) Fees.—

"(1) IN GENERAL.—The Administrator shall establish, not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, by rule—

"(A) the payment of 1 or more reasonable fees as a condition of submitting a notice or requesting an exemption under section 5; **and**

"(B) the payment of 1 or more reasonable fees by a manufacturer or processor that—

"(i) is required to submit a notice pursuant to the rule promulgated under section 8(b)(4)(A)(i) identifying a chemical substance as active;

"(ii) is required to submit a notice pursuant to section 8(b)(5)(B)(i) changing the status of a chemical substance from inactive to active;

"(iii) is required to report information pursuant to the rules promulgated under **paragraph (1) or (4) of** section 8(a)~~(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);~~

~~"(B)~~ prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

~~"(C)~~**"(B)** set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to ~~defray approximately~~ **annually defray—**

"(i) the lower of—

"(I) 25 percent of the costs of conducting the activities identified in paragraph (2)(A), ~~not to exceed $18,000,000, not including fees under subparagraph (E) of this paragraph;~~ **other than the costs to conduct and complete safety assessments and determinations under section 6 for chemical substances identified pursuant to section 4A(c); or**

~~"(D)~~**"(II) $25,000,000 (subject to adjustment pursuant to subparagraph (F)); and**

"(ii) the full costs and the 50-percent portion of the costs of safety assessments and safety determinations specified in subparagraph (D);

"(C) reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

"(D) notwithstanding subparagraph (B) and paragraph (4)(D)—

"(i)"~~(E)~~ for substances designated ~~as additional priorities~~ pursuant to section 4A(c)**(1)**, establish the fee at a level sufficient to defray the full **annual** costs to the Administrator of conducting the safety assessment and safety determination under section 6~~, except that~~**; and**

"(ii) for substances ~~subject~~ **designated pursuant** to section 4A(c)(3), ~~the Administrator shall~~ establish the fee at a level sufficient to defray 50 percent of ~~those costs;~~ **the annual costs to the Administrator of conducting the safety assessment and safety determination under section 6;**

"~~(F)~~**"(E)** prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) or subchapter III of chapter 5 of title 5, United States Code, is applicable with respect to such meetings;

"~~(G)~~**"(F)** beginning with the fiscal year that is 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives **pursuant to subparagraph (E)**, increase or decrease the fees established under paragraph (1) as **necessary to adjust for inflation and to ensure, based on the audit analysis required under paragraph (5)(B),** ~~necessary—~~

"~~(i) to ensure~~ that funds deposited in the Fund are sufficient to **defray**—

"(i) approximately but not more than 25 percent of the annual costs to conduct the activities identified in paragraph (2)(A) ~~and the full~~ **, other than the costs to conduct and complete safety assessments and determinations under section 6 for chemical substances identified pursuant to section 4A(c); and**

"(ii) the full annual costs and the 50-percent portion of the **annual** costs of safety assessments and safety determinations ~~pursuant to~~ **specified in** subparagraph ~~(E); and~~**(D);**

"~~(ii) to account for inflation;~~

"~~(H)~~**"(G)** adjust fees established under paragraph (1) as necessary to vary on account of differing circumstances, including reduced fees or waivers in appropriate circumstances, to reduce the burden on manufacturing or processing, remove barriers to innovation, or where the costs to the Administrator of collecting the fees exceed the fee revenue anticipated to be collected; and

"~~(I)~~**"(H)** if a notice submitted under section 5 is refused or subsequently withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

"(4) TSCA IMPLEMENTATION FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the 'TSCA Implementation Fund' (referred to in this subsection as the 'Fund'), consisting of—

"(i) such amounts as are deposited in the Fund under paragraph (2)(C); and

"(ii) any interest earned on the investment of amounts in the Fund; and

"(iii) any proceeds from the sale or redemption of investments held in the Fund.

"(B) CREDITING AND AVAILABILITY OF FEES.—

"(i) IN GENERAL.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation.

"(ii) REQUIREMENTS.—Fees collected under this section shall not—

"(I) be made available or obligated for any purpose other than to defray the costs of conducting the activities identified in paragraph (2)(A);

"(II) otherwise be available for any purpose other than implementation of this Act; and

"(III) so long as amounts in the Fund remain available, be subject to restrictions on expenditures applicable to the Federal government as a whole.

"(C) UNUSED FUNDS.—Amounts in the Fund not currently needed to carry out this subsection shall be—

"(i) maintained readily available or on deposit;

"(ii) invested in obligations of the United States or guaranteed by the United States; or

"(iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

"(D) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for ~~salaries, contracts, and expenses for the functions (as in existence in fiscal year 2015) of the Office of Pollution Prevention and Toxics~~ **the Chemical Risk Review and Reduction program project** of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for ~~covered functions for fiscal year 2015 (excluding the amount of any fees appropriated for the fiscal year).~~ **that program project for fiscal year 2014.**

"(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~~ **24**. DEVELOPMENT AND EVALUATION OF TEST METHODS AND SUSTAINABLE CHEMISTRY.

Section 27 of the Toxic Substances Control Act (15 U.S.C. 2626) is amended—

(1) in subsection (a), in the first sentence by striking "Health, Education, and Welfare" and inserting "Health and Human Services"; and

(2) by adding at the end the following:

"(c) Sustainable Chemistry Program.—The President shall establish an interagency Sustainable Chemistry Program to promote and coordinate Federal sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities.

"(d) Program Activities.—The activities of the Program shall be designed to—

"(1) provide sustained support for sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training through—

"(A) coordination of sustainable chemistry research, development, demonstration, and technology transfer conducted at Federal laboratories and agencies; and

"(B) to the extent practicable, encouragement of consideration of sustainable chemistry in, as appropriate—

"(i) the conduct of Federal and State science and engineering research and development; and

"(ii) the solicitation and evaluation of applicable proposals for science and engineering research and development;

"(2) examine methods by which the Federal Government can create incentives for consideration and use of sustainable chemistry processes and products, including innovative financing mechanisms;

"(3) expand the education and training of undergraduate and graduate students and professional scientists and engineers, including through partnerships with industry, in sustainable chemistry science and engineering;

"(4) collect and disseminate information on sustainable chemistry research, development, and technology transfer including information on—

"(A) incentives and impediments to development, manufacturing, and commercialization;

"(B) accomplishments;

"(C) best practices; and

"(D) costs and benefits;

"(5) support (including through technical assistance, participation, financial support, or other forms of support) economic, legal, and other appropriate social science research to identify barriers to commercialization and methods to advance commercialization of sustainable chemistry.

"(e) Interagency Working Group.—

"(1) ESTABLISHMENT.—Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the President, in consultation with the Office of Science and Technology Policy, shall establish an Interagency Working Group that shall include representatives from the National Science Foundation, the National Institute of Standards and Technology, the Department of Energy, the Environmental Protection Agency, the Department of Agriculture, the Department of Defense, the National Institutes of Health, and any other agency that the President may designate to oversee the planning, management, and coordination of the Program.

"(2) GOVERNANCE.—The Director of the National Science Foundation and the Assistant Administrator for Research and Development of the Environmental Protection Agency, or their designees, shall serve as co-chairs of the Interagency Working Group.

"(3) RESPONSIBILITIES.—In overseeing the planning, management, and coordination of the Program, the Interagency Working Group shall—

"(A) establish goals and priorities for the Program, in consultation with the Advisory Council;

"(B) provide for interagency coordination, including budget coordination, of activities under the Program;

"(C) meet not later than 90 days from its establishment and periodically thereafter; and

"(D) establish and consult with an Advisory Council on a regular basis.

"(4) MEMBERSHIP.—The Advisory Council members shall not be employees of the Federal Government and shall include a diverse representation of knowledgeable individuals from the private sector (including small- and medium-sized enterprises from across the value chain), academia, State and tribal governments, and nongovernmental organizations and others who are in a position to provide expertise.

"(f) Agency Budget Requests.—

"(1) IN GENERAL.—Each Federal agency and department participating in the Program shall, as part of its annual request for appropriations to the Office of Management and Budget, submit a report to the Office of Management and Budget that—

"(A) identifies the activities of the agency or department that contribute directly to the Program; and

"(B) states the portion of the agency or department's request for appropriations that is allocated to those activities.

"(2) ANNUAL BUDGET REQUEST TO CONGRESS.—The President shall include in the annual budget request to Congress a statement of the portion of the annual budget request for each agency or department that will be allocated to activities undertaken pursuant to the Program.

"(g) Report to Congress.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Interagency Working Group shall submit a report to the Committee on Science, Space, and Technology and Committee on Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works and the Committee on Commerce, Science, and Transportation of the Senate that shall include—

"(A) a summary of federally funded sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities;

"(B) a summary of the financial resources allocated to sustainable chemistry initiatives;

"(C) an analysis of the progress made toward achieving the goals and priorities of the program established pursuant to subsection (c), and recommendations for future program activities;

"(D) an assessment of the benefits of expanding existing, federally-supported regional innovation and manufacturing hubs to include sustainable chemistry and the value of directing the creation of 1 or more dedicated sustainable chemistry centers of excellence or hubs; and

"(E) an evaluation of steps taken and future strategies to avoid duplication of efforts, streamline interagency coordination, facilitate information sharing, and spread best practices between participating agencies in the Program.

"(2) SUBMISSION TO GAO.—The Interagency Working Group shall also submit the report described in paragraph (1) to the Government Accountability Office for consideration in future Congressional inquiries.".

SEC. ~~24~~ **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. ~~25~~ **26**. AUTHORIZATION OF APPROPRIATIONS.

Section 29 of the Toxic Substances Control Act (15 U.S.C. 2628) is repealed.

SEC. ~~26~~ **27**. ANNUAL REPORT.

Section 30 of the Toxic Substances Control Act (15 U.S.C. 2629) is amended by striking paragraph (2) and inserting the following:

"(2)(A) the number of notices received during each year under section 5; and

"(B) the number of the notices described in subparagraph (A) for chemical substances subject to a rule, testing consent agreement, or order under section 4;".

SEC. ~~27~~ **28**. EFFECTIVE DATE.

Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601 note; Public Law 94–469) is amended—

(1) by striking "Except as provided in section 4(f), this" and inserting the following:

"(a) In General.—This"; and

(2) by adding at the end the following:

"(b) Retroactive Applicability.—Nothing in this Act shall be interpreted to apply retroactively to any State, Federal, or maritime legal action commenced prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 9/16/2015 9:44:41 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: Imports, FYI...
Attachments: removed.txt

Daniel Rosenberg's Blog

What They Are Not Telling You: The Senate TSCA Bill Would Weaken EPA's Ability to Stop Importation of Products with Unsafe Chemicals

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Posted September 16, 2015

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cancer, carcinogens, chemcials, publichealth, righttoknow, saferchemicalshealthyfamilies, takeouttoxics, toxicchemicals, TSCA

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The Senate is poised to take up a bill to amend the Toxic Substances Control Act (TSCA), perhaps as early as next week. Supporters of the bill continue to overstate (see also here) the benefits of the legislation, while downplaying or ignoring its flaws - flaws that have led almost the entire environmental community to withhold its support, including more than 400 organizations that are part of the Safer Chemicals Healthy Families coalition. (NRDC is a member.) Supporters of the Senate bill generically claim that it will "protect America's families, especially children, from harmful chemicals that are present in everyday consumer products." But one key provision of the bill will actually make it *harder* for EPA to identify uses of chemicals of concern in everyday products, and to prevent their importation from overseas. And industry is pushing this precisely because EPA is finally starting to act to protect the public against imported products that contain toxic chemicals.

Those who recall the Senate mark-up of the bill may be surprised to hear this. At the mark-up, industry-written (or supported) language that weakened EPA's current import authority was removed from the bill, which was an important improvement. But as part of that deal, new language was added that weakens EPA's current authority under a different part of the law, but is designed to have a similar, and arguably worse, effect.

The current provision creates additional legal hurdles before EPA can require notification about products that contain toxic chemicals the agency believes could harm public health or the environment. The new provision is

directed at EPA's authority to issue Significant New Use Rules (or "SNURs"). These are rules EPA issues when the agency wants advance notice about the new use of a chemical that could have potential to harm human health or the environment.

Under current law, one of the few effective steps EPA can take to protect the public is to require notice before a new use of a chemical is adopted, which EPA does by issuing a SNUR. A SNUR requires EPA to be notified at least 90 days before a significant new use of the identified chemical (or group of chemicals) begins. This gives EPA an opportunity to obtain more information if necessary and make a decision whether limitations should be imposed on the production or use of the chemical to protect public health or the environment. This kind of assessment cannot typically be done up-front, because EPA does not at that point have the information about the potential use, or the full universe of potential uses, to sufficiently analyze the hazards and exposures attendant to that new use. If EPA does not act within 90 days of receiving the notice, then the entity that submitted the notice is free to use the chemical as proposed.

EPA has issued about 2,000 Significant New Use Rules since TSCA became law. EPA estimates that it receives only about seven Significant New Use Notices (SNUNs) proposing new uses of those chemicals of concern, each year, and that after EPA evaluates information on the potential exposures resulting from the specific proposed use, many of these Notices expire without any restrictions being imposed on the proposed use of the chemical.

Although SNURs are deeply in the weeds of TSCA policy, they are an important means of informing the agency and protecting the public. They ensure that EPA has an opportunity to address the potential use of a chemical of concern *before* it causes problems to human health or the environment. Most SNURs are issued because EPA is concerned about the toxicity of a chemical and the potential harm to health and the environment that it may cause. SNURs can also serve as an important signal to the marketplace to move toward use of safer chemicals. Even if you never know it is there, the Significant New Use Program is operating to protect the public from greater exposure to unsafe chemicals.

So why are companies like Honda, Intel, and GE trying to weaken the program?

When EPA initially adopted its rules for how to implement the Significant New Use program in the early 1980s during the Reagan Administration, it adopted a default exemption for chemicals that were imported in "articles" (without going further down a legal and policy rabbit hole, an "article" essentially means a formulated item or product). The exemption was adopted on an extremely thin and flimsy rationale - literally one sentence -- which would not hold up to scrutiny if it was offered today: "This decision was made in response to a comment received on this issue and because the identified risks from uses of these substances in articles are not likely to occur." (49 FR 35017, September 5, 1984) Unsurprisingly, the one comment received promoting the default exemption for articles came from the Chemical Manufacturers' Association, which later rebranded itself as the American Chemistry Council. (Forget it, Jake, it was the Ann Burford era). As a result, for the vast majority of Significant New Use Rules issued by EPA, entities interested in importing a chemical of concern for a new use in an article have not been required to notify EPA in advance. In fact, until last year, out of some 2,000 Significant New Use Rules, EPA had only lifted the articles exemption for *two chemicals*: mercury and erionite fibers - a fiber with properties and health effects similar to asbestos.

However, despite the agency's default policy of excluding imported articles from reporting requirements for significant new uses, the agency has always retained its existing authority to lift the exemption "if EPA decides that review under a SNUR is warranted for specific substances...in articles." (79 FR 77897 ellipsis in original)

In recent years, it has become clearer to everyone - industry, EPA, state regulators and legislators, public health professionals, environmental groups, and academics and researchers of various types - that we are frequently exposed to chemicals of concern from many types of products (or "articles"), including those that we have in our homes, our workplaces, our schools, and in our modes of transportation. The scientific and popular

literature is replete with examples of sources of human and/or environmental exposure including toys, carpets, clothes, seat cushions, furniture, cleaning supplies, computers, building materials and auto parts. These products have all been identified as potential sources of exposure to one or more problematic chemicals, including brominated flame retardants, formaldehyde, phthalates, non-stick and non-stain chemicals (perfluorinated), mercury, cadmium and a host of other substances.

In short, our understanding of how we are typically exposed to chemicals has expanded since the 1980s - and EPA has begun to shift its approach accordingly. The agency is starting to look more carefully at instances when the default exemption from Significant New Use Notification requirements for chemicals imported in articles should be lifted.

In December, EPA finalized a Significant New Use Rule for of benzidine dyes - these dyes have been found to break down into their component chemical, benzidine, which is classified as a *known human carcinogen*. "[T]he primary human health concern for consumers is exposure to the benzidine-based chemical substances through oral, dermal, or inhalation routes. Evidence from animal studies suggests that there is early life susceptibility to benzidine carcinogenesis. Cancer potency for benzidine was substantially increased when the dose was given in early life as compared to adults." (77 Fed. Reg. 18756, March 28, 2012)

Because of concern about the toxicity of the chemical EPA opted to "lift" the articles exemption, so that any proposed new uses of the benzidine dyes - including importing articles containing benzidine dyes -- will need EPA review and approval via a Significant New Use Notice.

"Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency's action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use." (77 Fed. Reg. 18758)

It is in reaction (and opposition) to these recent steps by EPA that industry is now pressuring Congress to revise TSCA and make it harder for EPA to require reporting of potential new uses of chemicals of concern imported in products. A lobbying entity called the Chemical Users Coalition, which comprises nine major corporations, has been lobbying to weaken EPA's authority under existing TSCA. The other member companies of the Chemical Users Coalition are: Procter & Gamble, Lockheed Martin, PPG, Hewlett Packard, IBM, and Boeing.

Under current law, EPA is authorized to designate a use of a chemical as a significant new use requiring notification after it has considered all relevant factors including:

- The projected volume of manufacturing and processing of the chemical;
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical;
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical;
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of chemical.

These are all factors related to the form and substance of a chemical, the potential life cycle use of the chemical, and the potential for increased exposure from a new use of a chemical. The law does not now require a particular determination about the likelihood of exposure from a particular source, or product, or class of products.

The new provision goes well beyond these general factors for consideration, and imposes a new limitation on EPA - that it cannot impose a significant new use reporting requirement on an article being imported or processed in the U.S. unless the Administrator makes "an affirmative finding" that "the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification."

Thus, under the new language in the Senate bill, EPA would now have to make a specified finding on a case-by-case basis on the "reasonable potential for exposure" before requiring notice of a new use of a chemical in an article or category of articles. This is a substantial shift in the burden of proof the agency must meet before obtaining simple notice about a potential new use of a chemical in an article. The new language gives the industry a stronger legal basis to challenge a significant new use requirement in court and raises the bar as to what the agency would have to show about the potential for exposure to a substance, prior to having any concrete information about the potential new use. In essence, the provision requires EPA to evaluate something before the agency even knows what it is. It also gives ammunition to EPA's frequent opponents in the inter-agency process, including OMB and the Small Business Administration Advocacy Office.

Currently, if EPA has a concern about the toxicity (health or environmental effects) of a chemical, and therefore a generalized concern about increased human or environmental exposure, it can adopt a new use notice requirement, including for new use in an article to be imported into the U.S. It may be that industry could successfully sue to overturn a significant new use requirement under the current language of TSCA, but it hasn't happened yet and there is no question that the new language raises the legal bar on EPA. Industry is seeking this language for a reason.

Some supporters of the Senate bill have argued that, while the new provision does change current law, it will have no practical effect on how EPA currently administers its SNUR program. This is incorrect. EPA would have a more difficult time adopting new use notice requirements under the new language in the Senate bill for the substances for which it has previously required notice of potential new use of a chemical in articles. For example, in its proposal to require notice for any new use of erionite fibers, EPA focused almost exclusively on the serious toxicity of the fibers ("In inhalation or injection studies in the rat and mouse, erionite fibers are more potent than crocidolite or chrysotile asbestos in inducing malignant mesothelioma." 56 FR 2890). EPA noted that there were no current known uses of the fibers in the U.S. and that, because of the serious health concerns the fibers raised, any new use, including importing in an article, would pose a risk of exposure and a potential health threat that warranted agency notice. EPA finalized a significant new use rule that applied to any new use, and "lifted" the articles exemption making the notice requirement applicable to imported articles. As a result, the public has been protected from any exposure to these cancer-causing fibers.

Under the new Senate language, EPA would now have to affirmatively identify any potential use of erionite fibers and then make a determination -- subject to legal challenge and judicial review if it made it through the OMB gauntlet --regarding the reasonable potential of exposure to the fibers from any article or category of articles before it could require notification of its potential new use in an imported article. If EPA neglected to correctly predict one or more potential uses of erinonite fibers -using crystal ball gazing technology for the 21st Century -- it could not then impose a new use notification requirement for those uses. Failure to imagine in advance *every potential use* would leave the public vulnerable to importation of new articles that the Administrator did not anticipate or predict.

Or consider EPA's recent significant new use rule for benzidine dyes, finalized last December. EPA identified the breakdown products of benzidine dyes as known human carcinogens, and referenced evidence of potential exposure from the dyes in clothes and textile-related uses. Based on the available information EPA had regarding the chemical's toxicity, and the potential for exposure from clothing, footwear and textiles, EPA imposed a new use notice requirement for any new use of benzidine dyes, and lifted the articles exemption, making the notice requirement applicable to potential new uses of benzidine dyes in articles (products) to be imported into the U.S.

Under the new Senate language, EPA *might* be able to issue the same notice requirement for use of benzidine dyes in clothes, footwear and textiles - as long as it could clear the new hurdle of demonstrating satisfactorily (to a court reviewing EPA's action in a legal challenge brought by industry) that it had identified a reasonable potential for exposure to benzidine dyes from each of those types of articles. But for any other articles, or category or articles for which EPA could not as easily identify a "reasonable potential for exposure" from the chemical -- for example, other categories of articles for which EPA did not already have some exposure information -- a court might rule that EPA did not have the authority to extend notice requirements to those uses, despite the agency's concerns about the chemicals' potential harm to health or the environment. Relying on the argument that EPA *might* prevail in such a lawsuit as an excuse for not flatly rejecting the proposed weakening of current law is simply irresponsible. The new Senate language in fact makes it more likely that articles containing chemicals of concern to EPA will be imported into the U.S. It is also directly contrary to what the drafters of the original TSCA intended.

In the Committee report filed when TSCA was originally passed in 1976, the Senate Commerce Committee (which handled TSCA then) noted the heightened concern about chemicals causing cancer, birth defects and other harms to health and the environment and the limited scope of other existing laws that touched in various ways on the problem of chemical pollution including the Clean Air Act, Clean Water Act, Occupational Safety and Health Act and the Consumer Product Safety Act: "None of these statutes provide the means for discovering adverse effects on health and environment before manufacture of new chemical substances. Under these other statutes, the Government regulator's only response to chemical dangers is to impose restrictions after manufacture begins. The most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture. It is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest....If hazards are to be discovered and prevented prior to the manufacture of new chemical substances or prior to the imposition of significant new uses of existing substances, premarket notification is an essential provision... the pre-market notification provisions of the committee bill forms [sic] the backbone of the preventive aspects of health protection sought by this legislation."

EPA is currently working on several other Significant New Use Rules, for which it also has proposed to lift the default regulatory exemption for new uses of the chemical in articles to be imported into the U.S. These include new use notice requirements for:

- (take a deep breath before you say this one) Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances (LCPFACs) - a group of substances that are persistent, bioaccumulative and toxic (PBTs);
- Toluene Diisocyanates (TDI) and related compounds - that are dermal and inhalation sensitizers that can cause asthma and lung damage;
- Hexabromocyclododecane (HBCD) - a flame retardant ingredient linked to hormone disruption, aquatic toxicity and a possible reproductive toxin that is already subject to authorization (meaning likely phase out) under the European Union's REACH regulation and a global phase-out under the Persistent Organic Pollutants (POPs) treaty;
- Polybrominated Diphenyl Ethers (PBDEs) - another group of flame retardants that are persistent, bioaccumulative and toxic.

In short, EPA is proposing to be notified before new uses of these chemicals - some of the "worst of the worst" that EPA has identified through its existing prioritization process - are introduced into the United States, including in the use of articles imported from China and other countries, to *prevent* people or the environment from being harmed by these toxic substances -- *exactly what the agency should be doing under TSCA*. EPA cannot possibly predict all the potential uses of these substances in advance -- or fully evaluate the hazards and risk of those that it can predict - without the information that the agency would receive in a significant new use notice from an entity seeking to use the chemical.

Efforts to limit EPA's ability to obtain information about potential new uses of chemicals of concern in products before they reach the market, are swimming against the tide of chemical regulation around the world, as well as consumer satisfaction and acceptance. Public demand (and therefore retailer demand) to know what chemicals are used in products is not going away. Contrary to the hopes of many in industry who are salivating for passage of the Udall/Vitter bill, flawed TSCA reform legislation will not stem that tide. EPA's existing authority to obtain information about potential new uses of chemicals of concern before they are imported into the U.S. in products is a modest and effective method of ensuring some degree of protection for the public. Constraining EPA's authority to target articles for significant new use notification is the industry's over-reaction to EPA's exercising its authority in a handful of instances. But increasing the burden on EPA and limiting its ability to take these steps will be met with its own reaction - more action at the state level, and in the marketplace - something these same industries should seriously contemplate before taking a step that could easily backfire.

Members of Congress who consider themselves supporters and protectors of EPA's role in protecting public health and the environment should carefully consider (or reconsider) their support for legislation containing this very problematic provision. If the Senate does not have the fortitude to tell these companies that this special interest provision to weaken current TSCA is an early Christmas gift that they cannot have, then the White House should make clear that it needs to come out of the bill before TSCA reform legislation reaches the President's desk.

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 4/16/2016 1:58:54 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: Section 6
Attachments: 04-14-16Section 6toHLC rd.docx

Importance: High

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Richard Denison
Sent: Saturday, April 16, 2016 8:51 AM
To: Deveny, Adrian (Merkley); Black, Jonathan (Tom Udall)
Cc: joanna
Subject: Section 6

Guys: I am pretty concerned about section 6 – not only because of what we discussed last night per the text below, but because I don't know where other parts stand. I don't know which draft is being worked off of any longer as base text – House or Senate? The inclusion of cost-effective AND sub (C) below suggest a shift to House language. Is that right?
My concerns:

1. The language below gets back so close to least burdensome that I fear it will make it almost impossible for EPA to ban a chemical. It borders on paralysis-by-analysis and creates so many legal challenge hooks.

2. Given that, it is **vitally important** to be crystal clear that:

   a. where EPA finds UR, it MUST impose conditions sufficient to eliminate the risk despite consideration of all the factors below. *Michigan v. EPA* makes this even more essential.

i. I haven't seen subsection (a) in a while, but despite the cross-reference to it, I feel a much more explicit inclusion, either in (2) or in (2)(B), of the sufficiency of rule is needed, more than just referring to the rule in (a). In (2)(B), something like this:

- In deciding which requirements to impose in the rule promulgated under subsection (a) that are sufficient to ensure the chemical substance or mixture no longer presents an unreasonable risk, the Administrator shall take into consideration, to the extent practicable, the considerations under subparagraph (A).

   b. All required EPA analyses:

i. are limited using this or very similar language: "to the extent practicable based on reasonably available information."

ii. are limited to regulatory or chemical alternatives deemed relevant by EPA.

Otherwise, these become endless do-loops and are highly vulnerable to legal challenge as inadequate.

3. What is happening to the exemptions language and the analyses that are part of that? Much of that would be duplicative of what is now in (c)(2). Will it be deleted?

4. Does subsection (a) include or clearly cross-reference to a full description of the UR risk finding with explicit references to exclusion of costs and vulnerable subpopulations? That is vital as well.

    a. Our last version read "determines in accordance with subsection (b)(4)(A)" – is this still the case, and is that subsection still intact?

5. I provided comments (attached) to Michal's list of changes needed to the last draft of 6 that was to go to HLC, but don't know what happened to those comments. DK and MW also provided comments some of which took opposite positions to mine. How are those being resolved??

I am raising this because I know the ability to make changes is dwindling. **It would be really helpful if I could see what you're working off of.**
I understand the political and time pressure you are under, and can only imagine how hard it is to deal with a House D stature that wants to or is going along with gutting these provisions.
Best, Richard

From: Deveny, Adrian (Merkley) [mailto:Adrian_Deveny@merkley.senate.gov]
Sent: Friday, April 15, 2016 9:48 PM
To: Richard Denison
Subject:
Costs (includes both chemical alternatives assessment and cost-effectiveness)
(2) REQUIREMENTS FOR RULE.—

(A) In promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;

(iii) the benefits of the chemical substance or mixture for various uses;

And

(v) the reasonably ascertainable economic consequences of the rule, after consideration of:

(I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; ~~and~~

(II) the quantifiable and non-quantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and

(III) the cost-effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

(B) In deciding which requirements to impose in the rule promulgated in accordance with subsection (a), the Administrator shall take into consideration, to the extent practicable, the considerations under subparagraph (A).

"(C) based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific use of a chemical substance or mixture and in setting an appropriate transition period for such action, consider whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect;

Adrian Deveny
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Sign up for Senator Merkley's E-newsletter
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Section 6 – to 4/12 3:45 PM HLC draft

Page 3 line 7 – delete "categories" and replace with "a category"

Page 3 line 12 -13 – EPA feels that "significant changes in the conditions of use" should be deleted because the definition of "conditions of use" include those that are reasonably foreseeable and this is confusing text. Ok to delete?

Commented [B1]: I disagree with deleting this. It is the change in use pattern could change the priority of a given chemical.

Page 3 line 22 – drop comma after "concludes", make clause read "Administrator concludes may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, because of potential …."

Page 4 line 9-10 Make read "with respect to which the Administrator has sufficient information to determine that" and move the "without consideration of costs or other nonrisk factors" to after "environment," as above (this is a conforming change that should be made more globally), and also, move conditions of use to AFTER "nonrisk factors". For clarity here it is, but will refer to it as "UR conforming change" hereafter. "unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator"

Commented [B2]: OK

Page 4 line 14 – insert "of injury" after "risk"

Page 5 line 1-2 – make read " high hazard and widespread exposure"

Page 6 line 25 – make read "have undergone risk evaluations, until"

Commented [B3]: OK

Page 8 line 4: from EPA TA that I do not understand but believe we do not need to address. "(b)(3)(B-D) fall outside the scope of this heading and seem to actually fall within the scope of the heading for (b)(2). While the organization is confusing, (b)(3)(B-D) are still comprehensible in their current location."

Commented [B4]: OK

Page 9 line 8 – checking to ensure this x-ref matches with "testing for prioritization" section in latest section 4

Page 9 line 24 – page 10 line 16 – UR conforming change

Page 11 line 3-5 – should be paragraph 2(A)

Page 11 line 25 – EPA TA they say "Seems like this should drop. Isn't the point that the number of industry initiated requests should be between 25% and 50% of the total? And the industry initiated evaluations can't be a percentage of the evaluations under (i), because they are not under (i) – the percentage of industry evaluations under (i) will always be 0."

Commented [B5]: Disagree with changing this. They are wrong that it is to be "between 25% and 50% of the total". It is to be between 25% and 50% of the number that EPA initiates.

Page 12 line 14-17 – EPA TA: Consider dropping this (the allocate resources part). Depending on the complexity of the evaluations, this could over- or under-fund industry evaluations. The "shall not provide special treatment" proviso seems to cover this.

Commented [B6]: OK to strike:
"allocate resources for such risk evaluations consistent with the percentage requirements specified in clause (i) and"

Page 14 lines 9-11 – change to "not consider costs or other nonrisk factors" for consistency

Commented [B7]: Agree with change

Page 14 line 24 – change "a" to "the"

Page 15 lines 1-2 – just cite to (4)(C), delete "(2) or"

Commented [B8]: I think it's better to keep both

Page 15 line lines 6-9: change "required to be developed in a ….section 4" to "is required to be developed in a rule, order or consent agreement under section 4 by ~~after~~ the deadline" to avoid implication that deadline could be extended if info not received. NEED CAREFUL REVIEW OF THIS EPA SUGGESTION

Commented [B9]: Agree with intent of change. Would be clearer to say: "by the deadline" instead of "after the deadline."

Page 16 line 3 change to "shall publish in the Federal register a proposed rule"

Page 18 line 12 – delete "proposed" because (2)(A) relates to promulgation not proposal

Commented [B10]: Agree

Page 18 line 16 and page 19 line 12 is it "deciding which requirements" or "in selecting among prohibitions and other restrictions" – need to make consistent

Commented [B11]: I prefer "deciding which requirements"

Page 19 line 21 – should read "unreasonable risk of injury to health or the environment"

Page 20 lines 15-18 per EPA Consider dropping this. Depending on the complexity of the evaluations, this could over- or under-fund industry evaluations. The "shall not provide special treatment" proviso seems to cover this. Why would EPA have to publish the statement required under (a) (the initial unreasonable risk determination) when it is modifying or repealing a rule?

Commented [B12]: You have inserted some wrong TA here, which relates to earlier language on p. 12. Assume the TA is the 2nd sentence?

I agree it would be better dropping this.

Page 21 lines 21-22 –UR conforming change. PLEASE REVIEW THIS ONE

Should be a conforming change to 6(e)(4) to change paragraphs (2), (3) and (4) into paragraph (3). I don't have your conforming changes to check this.

Commented [B13]: I don't understand this comment.

Page 24 lines 18-20 EPA says that "necessary to protect health and the environment" shd be changed to "necessary to protect health and the environment to the extent practicable while achieving" in order to ensure that the UR risk standard is the right one

Commented [B14]: OK with change, but this is an exemption for a chemical that is found to present UR, so that standard can't apply, can it? Otheriwse if the UR standard could be met the exemption wouldn't be needed.

Page 25 line 8 EPA TA on this. I agree w them. This formulation will support an argument that the unreasonable risk determination follows from and is separate from the risk evaluation (and could therefore include cost considerations), since this provides that the determination is merely "based on" the evaluation. Consider changing to "a determination by the Administrator under subsection (b)(4)(A) that a chemical substance. . . ."

Commented [B15]: Agree

Page 25 line17-19 – same as per above

Commented [B16]: Agree

Page 26 line 6 – section 6, not 5

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 4/16/2016 8:22:58 PM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
Subject: FW: EDF's perspective on long-term impacts of this new Section 6

Give a buzz when free. 224-6722.

From: Richard Denison [mailto:rdenison@edf.org]
Sent: Saturday, April 16, 2016 3:42 PM
To: Black, Jonathan (Tom Udall) ; Deveny, Adrian (Merkley)
Cc: joanna
Subject: EDF's perspective on long-term impacts of this new Section 6

Jonathan and Adrian:

I understand the constraints you are operating under, but feel I must make clear our perspective on the possible long-term/big picture consequences of the changes to Section 6 and EPA's authority to regulate chemicals.

Given that EPA has been operating under the onus of these kinds of requirements for a very long time, I understand their proclivity to say, this really isn't any different than what we do now in terms of analysis required. They are also so used to being sued over everything they do that they underestimate the very real costs, in terms of delay and diverted resources, necessary to defend themselves in court.

And while the bill would improve their chances of prevailing in a court case, I think there is a real risk that 8 or 10 years from now, a bad court could have overturned one of EPA's first regulatory bans under the new TSCA on the grounds that they did not sufficiently justify it based on the requirements confided in the law. If that happens, it could turn the clock back to 1991 a la *Corrosion Proof Fittings v. EPA*.

Not only would that have an impact on whether existing chemicals can be regulated, it would also impact whether this effort is seen as a successful reauthorization of TSCA or not.

I don't think we are the only NGO that will notice or be deeply concerned by this language. While one could argue that they should have spoken out against the provision in the House bill, that doesn't mean that their criticism will be muted.

I don't say any of this to discourage you from pushing forward. I just wanted to be clear that we think this language in section 6 could fundamentally impact the long term success of the new law.

Happy to talk more, and again, I greatly appreciate all you are doing and fully understand the huge pressures and constraints you're operating under.

Best, Richard

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dissemination or use of this information by a person other than the intended recipient is unauthorized and may be illegal.

Message

From: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Sent: 4/14/2016 10:31:27 AM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
Subject: Re: section 6 comments

Also - on mixtures - it is our view that a condition of use would absolutely include mixtures. Would a reference to conditions of use in 6(c) help with this?

Also fyi, since I am not anticipating a conference report, I plan an extensive CR insert signed by my boss as subcommittee Ranker and key megotiator that describes congressional intent across a range of issues. I will add conditions of use/mixtures to that list.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Jones, Jim
Sent: Thursday, April 14, 2016 5:04 AM
To: Freedhoff, Michal (Markey)
Subject: Fwd: section 6 comments

Michal, I hear you are an early riser so I am breaking protocol to send the sec 6 TA. Sven, will send a version which i believe will make the commenter anonymous. Please use the one he sends for distribution. Given the time crunch I wanted to get this to you as soon as possible. You should get that version by 7 am. The only change will be the commenter won't be named. Jim

Sent from my iPhone

Begin forwarded message:

> **From:** "Grant, Brian" <Grant.Brian@epa.gov>
> **Date:** April 13, 2016 at 11:35:22 PM EDT
> **To:** "Mclean, Kevin" <Mclean.Kevin@epa.gov>, "Jones, Jim" <Jones.Jim@epa.gov>, "Cleland-Hamnett, Wendy" <Cleland-Hamnett.Wendy@epa.gov>, "Schmit, Ryan" <schmit.ryan@epa.gov>, "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
> **Cc:** "Berol, David" <Berol.David@epa.gov>
> **Subject: section 6 comments**

Brian Grant
Office of General Counsel
202-564-5503

Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 4/11/2016 10:57:10 PM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
Subject: FW: Top 10 arguments on chemID issue

I think we discussed yesterday (see highlight).

From: Richard Denison [mailto:rdenison@edf.org]
Sent: Monday, April 11, 2016 6:53 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Cc: joanna <joannaslaney@gmail.com>
Subject: Top 10 arguments on chemID issue

I'll stop at 10 though I could go on ….

1. **The House language would be a significant weakening of current TSCA**. Even if one believes the current law is ambiguous, deciding this issue in industry's favor would be a weakening of current law. EPA does NOT believe it is ambiguous and articulated a clear disclosure policy (and elegant rationale for it) in 2010 (https://www.gpo.gov/fdsys/pkg/FR-2010-05-27/pdf/2010-12646.pdf). Long before that, two sets of EPA regulations defined chemical identity as "an integral part of a health and safety study."
2. **The Senate bill already includes a major concession on chemical identity: For chemicals prior to commercialization, not just allowing but presuming protection from disclosure, even in health and safety studies.** TSCA itself makes no distinction between new and existing chemicals on this issue. As part of the CBI compromise, we accepted settling that issue in industry favor pre-commercialization in exchange for preserving the status quo post-commercialization. This information presumed proprietary and protection is allowed during the most sensitive time.
3. **Congress clearly intended for the public to have access to meaningful health and safety information on chemicals.** Why else would it have gone out of its way to carve out H&S studies and data from the scope of CBI in Section 14? Essentially Congress said that public interest trumps private interest when it comes to such information, whereas for most other information, it provided, through allowing CBI claims, for private interests to trump public interests. EPA's 2010 policy states: "EPA believes that Congress generally intended for the public to be able to know the identities of chemical substances for which health and safety studies have been submitted." (The "generally" in that sentence alludes to the exceptions to disclosure of H&S data provided for in TSCA and preserved in the Senate bill; see next point.)
4. **The primary concern of SOCMA, that information on manufacturing processes be protected, is fully preserved by the Senate language.** TSCA's existing exception to disclosure of H&S studies for process information (as well as for portion-in-a-mixture information) is not altered at all.
5. **The Senate language would not require any information to be disclosed that would tie a particular chemical to a specific company or product.** Any such information could be claimed CBI and would have to be redacted from any disclosed health and safety study.
6. **The speculative argument that any disclosed information that might in some fashion help someone discern process or some other information that is CBI must be protected has been appropriately rejected by EPA**:

   > "EPA, however, questions the assertion that when disclosing a chemical identity of a chemical substance inspires a competitor to ascertain a process for manufacturing the chemical substance, such disclosure is equivalent to disclosing the process itself. *Disclosing the end product of a process (i.e., a chemical identity) is not the same thing as disclosing the process to make that end product.* The process

information would come from the competitor's expertise, research, or publicly available sources, not from EPA. Although some companies might find such use of a chemical identity undesirable, EPA does not believe that TSCA section 14(b) was intended to limit the uses of information from a health and safety study. (emphasis added)

7. **The House language would gut EPA's current policy and its associated declassification of hundreds of health and safety studies.** This language would immediately reverse these very positive developments that took place after decades of a passive, overly permissive culture of excessive CBI allowances at EPA.
8. **Limiting public access to health and safety information including chemical identity will have real-world adverse consequences.** It will eliminate workers' and consumers' ability to act to reduce their own exposures, prevents researchers from studying such chemicals, including health effects and environmental releases and exposures, and precludes companies from making smarter decisions about chemicals. Under even a revitalized TSCA, the number of chemicals EPA will be able to address will be only a fraction of those affecting or needing to be able to be scrutinized by the public, workers, consumers, researchers and the business community.
9. **The House proposal could readily lead to companies hiding data indicating their chemicals pose risks and revealing information indicating they don't.** Why wouldn't a company do just this, if allowed to? Ensuring a level playing field demands equal access to health and safety information.
10. **Denying the public the identity of chemicals in health and safety studies will hugely bias the public comment process in industry's favor.** When EPA is assessing or regulating a chemical, it and the company making or using the chemical would know its identity and be able to access available information, while the public would not be able to do so.

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Message

From: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Sent: 4/9/2016 3:47:53 PM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
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SEC. 6. REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES.

(a) SCOPE OF REGULATION.—If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines under subsection (b) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents, or will present an unreasonable risk of injury to health or the environment, or designates a chemical substance under subsection (i)(2), the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary ~~to protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance no longer presents or will present an unreasonable risk, including an identified unreasonable risk to a potentially exposed subpopulation:

(1) A requirement (A) prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement—

(A) prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests pursuant to section 4(a) which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

(6)(A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.

(B) A requirement under subparagraph (A) may not require any person to take any action which would be in

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violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

(7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such risk of injury, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Any requirement (or combination of requirements) imposed under this subsection may be limited in application to specified geographic areas.

(b) RISK EVALUATIONS.—

(1) IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this subsection to determine whether or not a chemical substance presents or will present, in the absence of requirements under subsection (a), an unreasonable risk of injury to health or the environment.

(2) APPLYING REQUIREMENTS.—The Administrator shall apply requirements with respect to a chemical substance through a rule under subsection (a) only if the Administrator determines through a risk evaluation under this subsection, without consideration of costs or other non-risk factors, that the chemical substance presents or will present, in the absence of such requirements, an unreasonable risk of injury to health or the environment.

(3) CONDUCTING RISK EVALUATION.—

(A) REQUIRED RISK EVALUATIONS.—Subject to subparagraph (C), tThe Administrator shall conduct and publish the results of a risk evaluation under this subsection for a chemical substance if—

(iA) the Administrator determines that the chemical substance may present an unreasonable risk of injury to health or the environment because of potential hazard and a potential route of exposure under the intended conditions of use; or

(iiB) a manufacturer of the chemical substance requests such a risk evaluation in a form and manner prescribed by the Administrator.

(B) TSCA WORK PLAN CHEMICALS.—The Administrator may, without making a determination under subparagraph (A)(i), conduct and publish the results of a risk evaluation under this subsection for a chemical substance that, on the date of enactment of the TSCA Modernization Act of 2015, is listed in the TSCA Work Plan for Chemical Assessments published by the Administrator.

"(C) LIMITATION.—

"(i) PERCENTAGE REQUIREMENTS.—The Administrator shall ensure that, of the chemical substances that undergo a risk evaluation under this paragraph (other than chemical substances described in clause (ii)), the percentage of

chemical substances undergoing a risk evaluation under clause (ii) of subparagraph (A) is—

"(I) not less than 25 percent, if sufficient requests are made under such clause; and

"(II) not more than 50 percent.

"(ii) EXCLUSION.—In calculating percentages under clause (i), the Administrator shall not consider—

"(I) chemical substances described in subparagraph (B); or

"(II) chemical substances described in section 5(a)(1)(A) or which a risk evaluation is requested pursuant to section 5(i).

"(D) SCOPE.—Not later than 6 months making a determination under subparagraph (A)(i), receiving a request under subparagraph (A)(ii), or beginning a risk evaluation under subparagraph (B), the Administrator shall define and publish the scope of the risk evaluation to be conducted under this subsection, including the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations that the Administrator expects to consider.

(4) REQUIREMENTS.—In conducting a risk evaluation under this subsection, the Administrator shall—

(A) integrate and assess information on hazards and exposures for ~~all of~~ the ~~intended~~ conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed subpopulations;,

(B) not consider information on cost and other factors not directly related to health or the environment;

(C) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the intended conditions of use of the chemical substance that are subject to risk evaluation;

(D) describe the weight of the scientific evidence for identified hazard and exposure;

(E) consider whether the weight of the scientific evidence supports the identification of doses of the chemical substance below which no adverse effects can be expected to occur; and

(F) in the case of a risk evaluation requested by a manufacturer under paragraph (3)(A)(ii), ensure that the costs to the Environmental Protection Agency, ~~including contractor costs,~~ of conducting the risk evaluation are paid for by the manufacturer.

(5) DEADLINES.—

(A) RISK EVALUATIONS.—The Administrator shall conduct and publish a risk evaluation under this subsection for a chemical substance as soon as reasonably possible, subject to the availability of resources, but not later than—

(i) 3 years after the date on which the Administrator—

(I) makes a determination under paragraph (3)(A)(i); or

(II) begins the risk evaluation under paragraph (3)(B); or

(ii) in the case of a risk evaluation requested by a manufacturer under paragraph (3)(A)(ii), 2 years after the later of the date on which—

(I) the manufacturer requests the risk evaluation; or

(II) if applicable, the risk evaluation is initiated pursuant to subparagraph (B).

(B) DEADLINE ADJUSTMENT.—If the Administrator receives more requests for risk evaluations under paragraph (3)(A)(ii) than the Administrator has resources to conduct by the deadline under subparagraph (A)(ii)(I) (taking into account the requirement in paragraph (4)(F)), or if the number of such requests exceeds the percentage allowed under paragraph (3)(C), the Administrator shall—

(i)(I) initiate risk evaluations that exceed the Administrator's allotted resources as soon as resources for such risk evaluations are available; ~~and~~or

(II) in the case of a risk evaluation that exceeds the allowed percentage, initiate such risk evaluation in accordance with paragraph (3)(C);

(ii) not collect a fee under section 260 from the manufacturer for a risk evaluation until the Administrator initiates the risk evaluation.

(C) SUBSECTION (a) RULES.—If, based on a risk evaluation conducted under this subsection, the Administrator determines, without consideration of costs or other non-risk factors, that a chemical substance presents or will present, in the absence of a rule under subsection (a), an unreasonable risk of injury to health or the environment, the Administrator shall—

(i) propose a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the risk evaluation regarding such chemical substance is published under subparagraph (A); and

(ii) publish in the Federal Register a final rule not later than 2 years after the date on which the risk evaluation regarding the chemical substance is published under subparagraph (A).

(D) EXTENSION.—If the Administrator determines that additional information is necessary to make a risk evaluation determination under this subsection, the Administrator may extend the deadlines under subparagraph (A) accordingly, except that the deadline may not be extended to a date that is later than—

(i) 90 days after receipt of such additional information; or

(ii) 2 years after the ~~original~~ deadline being extended under this subparagraph.

(6) DETERMINATIONS OF NO UNREASONABLE RISK.—

(A) NOTICE AND COMMENT.—Not later than 30 days before publishing a final determination under this subsection that a chemical substance does not and will not

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present an unreasonable risk of injury to health or the environment under the conditions of use considered in the risk evaluation, the Administrator shall make a preliminary determination to such effect and provide public notice of, and an opportunity for comment regarding, such preliminary determination.

(B) POTENTIALLY EXPOSED SUBPOPULATIONS.—The Administrator shall not make a determination under this subsection that a chemical substance will not present an unreasonable risk of injury to health or the environment if the Administrator determines that the chemical substance, under the ~~intended~~ conditions of use, presents or will present an unreasonable risk of injury to 1 or more potentially exposed subpopulations.

(C) FINAL ACTION.—A final determination under this subsection that a chemical substance will not present an unreasonable risk of injury to health or the environment shall be considered a final agency action.

(7) MINIMUM NUMBER.—Subject to the availability of appropriations, the Administrator shall initiate 10 or more risk evaluations under paragraph (3)(A)(i) or (3)(B) in each fiscal year beginning in the fiscal year of the date of enactment of the ~~TSCA Modernization Act of 2015~~Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(8) SCREENING PROCESS.—

"(A) 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 establish, by rule, a risk-based screening process, including criteria for selecting chemical substances for risk evaluation under paragraph (3)(A)(i) or for designation under subparagraph (B)(v)(II). Such process shall include—

"(i) consideration of—

"(I) the hazard and exposure potential (including persistence and bioaccumulation) of a chemical substance or categories of chemical sub stances;

"(II) potentially exposed or susceptible subpopulations;

"(III) storage near significant sources of drinking water;

"(IV) the conditions of use and significant changes in the conditions of use of the chemical substance; and

"(V) the volume or significant changes in the volume of a chemical substance manufactured or processed; and

"(ii) public identification of chemical substances that are being considered for a determination under paragraph (3)(A)(i) or a designation under subparagraph (B)(v)(II).

"(B) DETERMINATION OR DESIGNATION.—

"(i) DEADLINE.—Not later than 1 year after publicly identifying a chemical substance as under consideration for a determination under paragraph (3)(A)(i) or a designation under clause (v)(II), the

Administrator shall make such determination or designation, as applicable.

"(ii) CONSIDERATION.—In considering a chemical substance under clause (i), the Administrator shall—

"(I) request interested persons to submit to the Administrator information that could inform the Administrator's decisionmaking process under this paragraph; and

"(II) publish each determination and designation described in clause (i).

"(iii) EXTENSION OF DEADLINE.—The Administrator may extend the deadline in clause (i) by not more than 6 months in order to receive and evaluate information required to be submitted under section 4(h).

"(iv) PROCEDURE FOR EXTENDED DEADLINE.—If the Administrator extends the deadline in clause (i)—

"(I) not later than 90 days after the date on which the Administrator receives the information required to be developed under section 4(h), the Administrator shall make a determination under paragraph (3)(A)(i) or a designation under clause (v)(II) with respect to the chemical substance under consideration; and

"(II) if information received prior to the end of the extension is not sufficient to determine that the chemical substance under consideration is not likely to present an unreasonable risk of injury to health or the environment, the Administrator shall make a determination under paragraph (3)(A)(i) with respect to the chemical substance.

"(v) ACTION BASED ON SCREENING PROCESS.—At the end of the screening process for a chemical substance under this paragraph, the Administrator shall—

"(I) make a determination under paragraph (3)(A)(i) with respect to the chemical substance; or

"(II) designate the chemical substance as not likely to present an unreasonable risk to human health or the environment. ***is this for ALL intended conditions of use? the answer to this may affect (vi) below***

"(vi) DETERMINATION AFTER DESIGNATION.—The Administrator may make a determination under paragraph (3)(A)(i) with respect to a chemical substance that has been designated under clause (v)(II) only if the Administrator receives information after the date on which such designation was made that provides a basis for such determination."

~~(b) QUALITY CONTROL.—If the Administrator has a reasonable basis to conclude that a particular manufacturer or processor is manufacturing or processing a chemical substance or mixture in a manner which unintentionally causes the chemical substance or mixture to present or which will cause it~~

~~to present an unreasonable risk of injury to health or the environment—~~

~~(1) the Administrator may by order require such manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of such chemical substance or mixture; and~~

~~(2) if the Administrator determines—~~

~~(A) that such quality control procedures are inadequate to prevent the chemical substance or mixture from presenting such risk of injury, the Administrator may order the manufacturer or processor to revise such quality control procedures to the extent necessary to remedy such inadequacy; or~~

~~(B) that the use of such quality control procedures has resulted in the distribution in commerce of chemical substances or mixtures which present an unreasonable risk of injury to health or the environment, the Administrator may order the manufacturer or processor to (i) give notice of such risk to processors or distributors in commerce of any such substance or mixture, or to both, and, to the extent reasonably ascertainable, to any other person in possession of or exposed to any such substance, (ii) to give public notice of such risk, and (iii) to provide such replacement or repurchase of any such substance or mixture as is necessary to adequately protect health or the environment.~~

~~A determination under subparagraph (A) or (B) of paragraph (2) shall be made on the record after opportunity for hearing in accordance with section 554 of title 5, United States Code. Any manufacturer or processor subject to a requirement to replace or repurchase a chemical substance or mixture may elect either to replace or repurchase the substance or mixture and shall take either such action in the manner prescribed by the Administrator.~~

(c) PROMULGATION OF SUBSECTION (a) RULES.

(1) REQUIREMENTS FOR RULE.—In promulgating any rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall—

(A) consider and publish a statement with respect to—

(i)~~(A)~~ the effects of ~~such~~ the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical ~~such~~ substance or mixture;

(ii)~~(B)~~ the effects of the chemical~~such~~ substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;

(iii)~~(C)~~ the benefits of ~~such~~ the chemical substance or mixture for various uses; and ~~the availability of substitutes for such uses, and~~

(iv) ~~(D)~~ the reasonably ascertainable economic consequences of the rule, including ~~after~~ consideration of the likely effect ~~on~~ of the rule on the national economy, small business, technological innovation, the environment, and public health;

(B) impose requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are

necessary to protect against the ~~identified~~ risk identified in a risk evaluation conducted under subsection (b) for the chemical substance or for a chemical substance contained in a mixture;

(C) based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific use of a chemical substance or mixture and in setting an appropriate transition period for such action, determine whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect;

(D) exempt replacement parts, for complex durable goods, designed prior to the date of publication in the Federal Register of the rule unless the Administrator finds such replacement parts contribute significantly to the ~~identified~~ risk identified in a risk evaluation conducted under subsection (b) for the chemical substance or for a chemical substance contained in a mixture, including identified risk to identified potentially exposed ~~or susceptible~~ subpopulations; and

(E) in selecting among prohibitions and other restrictions to address a~~n identified~~ risk identified in a risk evaluation conduction under subsection (b) for the chemical substance or for a chemical substance contained in a mixture, apply prohibitions or other restrictions to articles, or a category of articles, on the basis of a chemical substance or mixture contained in the articles, only to the extent necessary to ~~mitigate~~ protect against ~~the~~such identified risk from exposure to the chemical substance or mixture from the articles.

~~If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule under subsection (a) to protect against such risk of injury unless the Administrator finds, in the Administrator's discretion, that it is in the public interest to protect against such risk under this Act. In making such a finding the Administrator shall consider (i) all relevant aspects of the risk, as determined by the Administrator in the Administrator's discretion, (ii) a comparison of the estimated costs of complying with actions taken under this Act and under such law (or laws), and (iii) the relative efficiency of actions under this Act and under such law (or laws) to protect against such risk of injury.~~

(2) PROCEDURES.—When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5, United States Code (without regard to any reference in such section to sections 556 and 557 of such title), and shall also (A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule; (B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available; (C) ~~provide an opportunity for an informal hearing in accordance with paragraph (3); (D)~~ promulgate, if

appropriate, a final rule based on the matter in the rulemaking record (as defined in section 19(a)); and (D~~E~~) make and publish with the rule the finding described in subsection (a).

~~(3) Informal hearings required by paragraph (2)(C) shall be conducted by the Administrator in accordance with the following requirements:~~

~~(A) Subject to subparagraph (B), an interested person is entitled—~~

~~(i) to present such person's position orally or by documentary submissions (or both), and~~

~~(ii) if the Administrator determines that there are disputed issues of material fact it is necessary to resolve, to present such rebuttal submissions and to conduct (or have conducted under subparagraph (B)(ii)) such cross-examination of persons as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to such issues.~~

~~(B) The Administrator may prescribe such rules and make such rulings concerning procedures in such hearings to avoid unnecessary costs or delay. Such rules or rulings may include (i) the imposition of reasonable time limits on each interested person's oral presentations, and (ii) requirements that any cross-examination to which a person may be entitled under subparagraph (A) be conducted by the Administrator on behalf of that person in such manner as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to disputed issues of material fact.~~

~~(C)(i) Except as provided in clause (ii), if a group of persons each of whom under subparagraphs (A) and (B) would be entitled to conduct (or have conducted) cross-examination and who are determined by the Administrator to have the same or similar interests in the proceeding cannot agree upon a single representative of such interests for purposes of cross-examination, the Administrator may make rules and rulings (I) limiting the representation of such interest for such purposes, and (II) governing the manner in which such cross-examination shall be limited.~~

~~(ii) When any person who is a member of a group with respect to which the Administrator has made a determination under clause (i) is unable to agree upon group representation with the other members of the group, then such person shall not be denied under the authority of clause (i) the opportunity to conduct (or have conducted) cross-examination as to issues affecting the person's particular interests if (I) the person satisfies the Administrator that the person has made a reasonable and good faith effort to reach agreement upon group representation with the other members of the group and (II) the Administrator determines that there are substantial and relevant issues which are not adequately presented by the group representative.~~

~~(D) A verbatim transcript shall be taken of any oral presentation made, and cross-examination conducted in any informal hearing under this subsection. Such transcript shall be available to the public.~~

~~(4)(A) The Administrator may, pursuant to rules prescribed by the Administrator, provide compensation for reasonable attorneys' fees, expert witness fees, and other costs of participating in a~~

~~rulemaking proceeding for the promulgation of a rule under subsection (a) to any person—~~

~~(i) who represents an interest which would substantially contribute to a fair determination of the issues to be resolved in the proceeding, and~~

~~(ii) if—~~

~~(I) the economic interest of such person is small in comparison to the costs of effective participation in the proceeding by such person, or~~

~~(II) such person demonstrates to the satisfaction of the Administrator that such person does not have sufficient resources adequately to participate in the proceeding without compensation under this subparagraph.~~

~~In determining for purposes of clause (i) if an interest will substantially contribute to a fair determination of the issues to be resolved in a proceeding, the Administrator shall take into account the number and complexity of such issues and the extent to which representation of such interest will contribute to widespread public participation in the proceeding and representation of a fair balance of interests for the resolution of such issues.~~

~~(B) In determining whether compensation should be provided to a person under subparagraph (A) and the amount of such compensation, the Administrator shall take into account the financial burden which will be incurred by such person in participating in the rulemaking proceeding. The Administrator shall take such action as may be necessary to ensure that the aggregate amount of compensation paid under this paragraph in any fiscal year to all persons who, in rulemaking proceedings in which they receive compensation, are persons who either—~~

~~(i) would be regulated by the proposed rule, or~~

~~(ii) represent persons who would be so regulated,~~

~~may not exceed 25 per centum of the aggregate amount paid as compensation under this paragraph to all persons in such fiscal year.~~

(~~3~~5) ~~Paragraphs (1), (2), (3), and (4)~~ APPLICATION.—Paragraphs (1) and (2) of this subsection apply to the promulgation of a rule repealing, or making a substantive amendment to, a rule promulgated under subsection (a).

(d) EFFECTIVE DATE.—(1) The Administrator shall specify in any rule under subsection (a)— ~~the date on which it shall take effect, which date shall be as soon as feasible.~~

"(A) the date on which it shall take effect, which date shall be as soon as feasible; and

"(B) the dates by which compliance is mandatory, which shall, subject to the requirements in subsections (a) and (c), begin not later than 5 years after the date on which the final rule is published in the Federal Register."

(2)(A) The Administrator may declare a proposed rule under subsection (a) to be effective upon its publication in the Federal Register and until the effective date of final action taken, in accordance with subparagraph (B), respecting such rule if—

(i) the Administrator determines that—

(I) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before such effective date; and

(II) making such proposed rule so effective is necessary to protect the public interest; and

(ii) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under clause (i)(I), a court has in an action under section 7 granted relief with respect to such risk associated with such substance or mixture.

Such a proposed rule which is made so effective shall not, for purposes of judicial review, be considered final agency action.

(B) If the Administrator makes a proposed rule effective upon its publication in the Federal Register, the Administrator shall, as expeditiously as possible, give interested persons prompt notice of such action, ~~in accordance with paragraph (2) of subsection (c), provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), for a hearing on such rule,~~ and either promulgate such rule (as proposed or with modifications) or revoke it~~; and if such a hearing is requested, the Administrator shall commence the hearing within five days from the date such request is made unless the Administrator and the person making the request agree upon a later date for the hearing to begin, and after the hearing is concluded the Administrator shall, within ten days of the conclusion of the hearing, either promulgate such rule (as proposed or with modifications) or revoke it.~~ Any rule promulgated under subsection (a) shall provide for a reasonable transition period.

(e) POLYCHLORINATED BIPHENYLS.—(1) Within six months after the effective date of this Act the Administrator shall promulgate rules to—

(A) prescribe methods for the disposal of polychlorinated biphenyls, and

(B) require polychlorinated biphenyls to be marked with clear and adequate warnings, and instructions with respect to their processing, distribution in commerce, use, or disposal or with respect to any combination of such activities.

Requirements prescribed by rules under this paragraph shall be consistent with the requirements of paragraphs (2) and (3).

(2)(A) Except as provided under subparagraph (B), effective one year after the effective date of this Act no person may manufacture, process, or distribute in commerce or use any polychlorinated biphenyl in any manner other than in a totally enclosed manner.

(B) The Administrator may by rule authorize the manufacture, processing, distribution in commerce or use (or any combination of such activities) of any polychlorinated biphenyl in a manner other than in a totally enclosed manner if the Administrator finds that such manufacture, processing, distribution in commerce, or use (or combination of such

activities) will not present an unreasonable risk of injury to health or the environment.

(C) For the purposes of this paragraph, the term "totally enclosed manner" means any manner which will ensure that any exposure of human beings or the environment by the polychlorinated biphenyl will be insignificant as determined by the Administrator by rule.

(3)(A) Except as provided in subparagraphs (B) and (C)—

(i) no person may manufacture any polychlorinated biphenyl after two years after the effective date of this Act, and

(ii) no person may process or distribute in commerce any polychlorinated biphenyl after two and one-half years after such date.

(B) Any person may petition the Administrator for an exemption from the requirements of subparagraph (A), and the Administrator may grant by rule such an exemption if the Administrator finds that—

(i) an unreasonable risk of injury to health or environment would not result, and

(ii) good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl.

An exemption granted under this subparagraph shall be subject to such terms and conditions as the Administrator may prescribe and shall be in effect for such period (but not more than one year from the date it is granted) as the Administrator may prescribe.

(C) Subparagraph (A) shall not apply to the distribution in commerce of any polychlorinated biphenyl if such polychlorinated biphenyl was sold for purposes other than resale before two and one-half years after the date of enactment of this Act.

(D) The Administrator may extend an exemption granted pursuant to subparagraph (B) that has not yet expired for a period not to exceed 60 days for the purpose of authorizing the Secretary of Defense and the Secretaries of the military departments to provide for the transportation into the customs territory of the United States of polychlorinated biphenyls generated by or under the control of the Department of Defense for purposes of their disposal, treatment, or storage in the customs territory of the United States if those polychlorinated biphenyls are already in transit from their storage locations but the Administrator determines, in the sole discretion of the Administrator, they would not otherwise arrive in the customs territory of the United States within the period of the original exemption. The Administrator shall promptly publish notice of such extension in the Federal Register.

(4) Any rule under paragraph (1), (2)(B), or (3)(B) shall be promulgated in accordance with paragraph~~s~~ (2)~~, (3), and (4)~~ of subsection (c).