

114TH CONGRESS
1ST SESSION

S. 697

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

IN THE SENATE OF THE UNITED STATES

MARCH 10, 2015

Mr. UDALL (for himself, Mr. VITTER, Mr. MANCHIN, Mr. INHOFE, Mr. CARPER, Mr. BLUNT, Mr. COONS, Mr. BOOZMAN, Mr. DONNELLY, Mrs. CAPITO, Mr. HEINRICH, Mr. CASSIDY, Ms. HEITKAMP, Mr. CRAPO, Ms. STABENOW, Mr. HOEVEN, and Mr. PORTMAN) introduced the following bill; which was read twice and referred to the Committee on Environment and Public Works

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

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

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

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

1 (1) by striking “It is the intent” and inserting
2 the following:

3 “(1) ADMINISTRATION.—It is the intent”;

4 (2) in paragraph (1) (as so redesignated), by
5 inserting “, as provided under this Act” before the
6 period at the end; and

7 (3) by adding at the following:

8 “(2) REFORM.—It is the intent of Congress
9 that reform of this Act in accordance with the
10 amendments made by the Frank R. Lautenberg
11 Chemical Safety for the 21st Century Act—

12 “(A) shall be administered in a manner
13 that—

14 “(i) protects the health of children,
15 pregnant women, the elderly, workers, con-
16 sumers, the general public, and the envi-
17 ronment from the risks of harmful expo-
18 sures to chemical substances and mixtures;
19 and

20 “(ii) ensures that appropriate infor-
21 mation on chemical substances and mix-
22 tures is available to public health officials
23 and first responders in the event of an
24 emergency; and

1 “(B) shall not displace or supplant com-
2 mon law rights of action or remedies for civil
3 relief.”.

4 **SEC. 3. DEFINITIONS.**

5 Section 3 of the Toxic Substances Control Act (15
6 U.S.C. 2602) is amended—

7 (1) by redesignating paragraphs (4), (5), (6),
8 (7), (8), (9), (10), (11), (12), (13), and (14) as
9 paragraphs (5), (6), (7), (8), (9), (10), (12), (13),
10 (17), (18), and (19), respectively;

11 (2) by inserting after paragraph (3) the fol-
12 lowing:

13 “(4) CONDITIONS OF USE.—The term ‘condi-
14 tions of use’ means the intended, known, or reason-
15 ably foreseeable circumstances the Administrator de-
16 termines a chemical substance is manufactured,
17 processed, distributed in commerce, used, or dis-
18 posed of.”;

19 (3) by inserting after paragraph (10) (as so re-
20 designated) the following:

21 “(11) POTENTIALLY EXPOSED OR SUSCEPTIBLE
22 POPULATION.—The term ‘potentially exposed or sus-
23 ceptible population’ means 1 or more groups—

24 “(A) of individuals within the general pop-
25 ulation who may be—

1 “(i) differentially exposed to chemical
2 substances under the conditions of use; or

3 “(ii) susceptible to greater adverse
4 health consequences from chemical expo-
5 sures than the general population; and

6 “(B) that when identified by the Adminis-
7 trator may include such groups as infants, chil-
8 dren, pregnant women, workers, and the elder-
9 ly.”; and

10 (4) by inserting after paragraph (13) (as so re-
11 designated) the following:

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

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

22 “(16) SAFETY STANDARD.—The term ‘safety
23 standard’ means a standard that ensures, without
24 taking into consideration cost or other nonrisk fac-
25 tors, that no unreasonable risk of harm to health or

1 the environment will result from exposure to a chem-
2 ical substance under the conditions of use, including
3 no unreasonable risk of harm to—

4 “(A) the general population; or

5 “(B) any potentially exposed or susceptible
6 population that the Administrator has identified
7 as relevant to the safety assessment and safety
8 determination for a chemical substance.”.

9 **SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.**

10 The Toxic Substances Control Act is amended by in-
11 serting after section 3 (15 U.S.C. 2602) the following:

12 **“SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.**

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

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

24 “(c) USE OF SCIENCE.—

1 “(1) IN GENERAL.—The Administrator shall es-
2 tablish policies, procedures, and guidance on the use
3 of science in making decisions under sections 4, 4A,
4 5, and 6.

5 “(2) GOAL.—A goal of the policies and proce-
6 dures described in paragraph (1) shall be to make
7 the basis of decisions clear to the public.

8 “(3) REQUIREMENTS.—The policies, proce-
9 dures, and guidance issued under this section shall
10 describe the manner in which the Administrator
11 shall ensure that—

12 “(A) decisions made by the Adminis-
13 trator—

14 “(i) are based on information, proce-
15 dures, measures, methods, and models em-
16 ployed in a manner consistent with the
17 best available science;

18 “(ii) take into account the extent to
19 which—

20 “(I) assumptions and methods
21 are clearly and completely described
22 and documented;

23 “(II) variability and uncertainty
24 are evaluated and characterized; and

1 “(III) the information has been
2 subject to independent verification
3 and peer review; and

4 “(iii) are based on the weight of the
5 scientific evidence, by which the Adminis-
6 trator considers all information in a sys-
7 tematic and integrative framework to con-
8 sider the relevance of different informa-
9 tion;

10 “(B) to the extent practicable and if ap-
11 propriate, the use of peer review, standardized
12 test design and methods, consistent data eval-
13 uation procedures, and good laboratory prac-
14 tices will be encouraged;

15 “(C) a clear description of each individual
16 and entity that funded the generation or assess-
17 ment of information, and the degree of control
18 those individuals and entities had over the gen-
19 eration, assessment, and dissemination of infor-
20 mation (including control over the design of the
21 work and the publication of information) is
22 made available; and

23 “(D) if appropriate, the recommendations
24 in reports of the National Academy of Sciences
25 that provide advice regarding assessing the haz-

1 ards, exposures, and risks of chemical sub-
2 stances are considered.

3 “(d) EXISTING EPA POLICIES, PROCEDURES, AND
4 GUIDANCE.—The policies, procedures, and guidance de-
5 scribed in subsection (b) shall incorporate, as appropriate,
6 existing relevant hazard, exposure, and risk assessment
7 guidelines and methodologies, data evaluation and quality
8 criteria, testing methodologies, and other relevant guide-
9 lines and policies of the Environmental Protection Agency.

10 “(e) REVIEW.—Not later than 5 years after the date
11 of enactment of this section, and not less frequently than
12 once every 5 years thereafter, the Administrator shall—

13 “(1) review the adequacy of any policies, proce-
14 dures, and guidance developed under this section, in-
15 cluding animal, nonanimal, and epidemiological test
16 methods and procedures for assessing and deter-
17 mining risk under this Act; and

18 “(2) after providing public notice and an oppor-
19 tunity for comment, revise the policies, procedures,
20 and guidance if necessary to reflect new scientific
21 developments or understandings.

22 “(f) SOURCES OF INFORMATION.—In making any de-
23 cision with respect to a chemical substance under section
24 4, 4A, 5, or 6, the Administrator shall take into consider-
25 ation information relating to the hazards and exposures

1 of a chemical substance under the conditions of use that
2 is reasonably available to the Administrator, including in-
3 formation that is—

4 “(1) submitted to the Administrator pursuant
5 to any rule, consent agreement, order, or other re-
6 quirement of this Act, or on a voluntary basis, in-
7 cluding pursuant to any request made under this
8 Act, by—

9 “(A) manufacturers or processors of a sub-
10 stance;

11 “(B) the public;

12 “(C) other Federal departments or agen-
13 cies; or

14 “(D) the Governor of a State or a State
15 agency with responsibility for protecting health
16 or the environment;

17 “(2) submitted to a governmental entity in any
18 jurisdiction pursuant to a governmental requirement
19 relating to the protection of health or the environ-
20 ment; or

21 “(3) identified through an active search by the
22 Administrator of information sources that are pub-
23 licly available or otherwise accessible by the Admin-
24 istrator.

1 “(g) TESTING OF CHEMICAL SUBSTANCES AND MIX-
2 TURES.—

3 “(1) IN GENERAL.—The Administrator shall es-
4 tablish policies and procedures for the testing of
5 chemical substances or mixtures under section 4.

6 “(2) GOAL.—A goal of the policies and proce-
7 dures established under paragraph (1) shall be to
8 make the basis of decisions clear to the public.

9 “(3) CONTENTS.—The policies and procedures
10 established under paragraph (1) shall—

11 “(A) address how and when the exposure
12 level or exposure potential of a chemical sub-
13 stance would factor into decisions to require
14 new testing, subject to the condition that the
15 Administrator shall not interpret the lack of ex-
16 posure information as a lack of exposure or ex-
17 posure potential;

18 “(B) describe the manner in which the Ad-
19 ministrator will determine that additional infor-
20 mation is necessary to carry out this Act, in-
21 cluding information relating to potentially ex-
22 posed or susceptible populations;

23 “(C) require the Administrator to consult
24 with the Director of the National Institute for

1 Occupational Safety and Health prior to pre-
2 scribing epidemiologic studies of employees; and

3 “(D) prior to adopting a requirement for
4 testing using vertebrate animals, require the
5 Administrator to take into consideration, as ap-
6 propriate and to the extent practicable, reason-
7 ably available—

8 “(i) toxicity information;

9 “(ii) computational toxicology and
10 bioinformatics;

11 “(iii) high-throughput screening meth-
12 ods and the prediction models of those
13 methods; and

14 “(iv) scientifically reliable and rel-
15 evant alternatives to tests on animals that
16 would provide equivalent information.

17 “(4) TIERED TESTING.—

18 “(A) IN GENERAL.—Except as provided in
19 subparagraph (D), the Administrator shall em-
20 ploy a tiered screening and testing process,
21 under which the results of screening-level tests
22 or assessments of available information inform
23 the decision as to whether 1 or more additional
24 tests are necessary.

25 “(B) SCREENING-LEVEL TESTS.—

1 “(i) IN GENERAL.—The screening-
2 level tests required for a chemical sub-
3 stance or mixture may include tests for
4 hazard (which may include in silico, in
5 vitro, and in vivo tests), environmental and
6 biological fate and transport, and measure-
7 ments or modeling of exposure or exposure
8 potential, as appropriate.

9 “(ii) USE.—Screening-level tests shall
10 be used—

11 “(I) to screen chemical sub-
12 stances or mixtures for potential ad-
13 verse effects; and

14 “(II) to inform a decision of the
15 Administrator regarding whether
16 more complex or targeted additional
17 testing is necessary.

18 “(C) ADDITIONAL TESTING.—If the Ad-
19 ministrator determines under subparagraph (B)
20 that additional testing is necessary to provide
21 more definitive information for safety assess-
22 ments or safety determinations, the Adminis-
23 trator may require more advanced tests for po-
24 tential health or environmental effects or expo-
25 sure potential.

1 “(D) ADVANCED TESTING WITHOUT
2 SCREENING.—The Administrator may require
3 more advanced testing without conducting
4 screening-level testing when other information
5 available to the Administrator justifies the ad-
6 vanced testing, pursuant to guidance developed
7 by the Administrator under this section.

8 “(h) SAFETY ASSESSMENTS AND SAFETY DETER-
9 MINATIONS.—

10 “(1) SCHEDULE.—

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

17 “(B) DIFFERING TIMES.—The Adminis-
18 trator may allot different times for different
19 chemical substances in the schedules under this
20 paragraph, subject to the condition that all
21 schedules shall comply with the deadlines estab-
22 lished under section 6.

23 “(C) ANNUAL PLAN.—At the beginning of
24 each calendar year, the Administrator shall
25 identify the substances subject to safety assess-

1 ments and safety determinations to be com-
2 pleted that year.

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

5 “(A) IN GENERAL.—The Administrator
6 shall establish, by rule, policies and procedures
7 regarding the manner in which the Adminis-
8 trator shall carry out section 6.

9 “(B) GOAL.—A goal of the policies and
10 procedures under this paragraph shall be to
11 make the basis of decisions of the Adminis-
12 trator clear to the public.

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

16 “(i) describe—

17 “(I) the manner in which the Ad-
18 ministrators will identify informational
19 needs and seek that information from
20 the public;

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

1 “(III) the criteria by which that
2 information will be evaluated;
3 “(ii) require the Administrator—
4 “(I)(aa) to define the scope of
5 the safety assessment and safety de-
6 termination to be conducted under
7 section 6, including the hazards, expo-
8 sures, conditions of use, and poten-
9 tially exposed and susceptible popu-
10 lations that the Administrator expects
11 to consider in a safety assessment;
12 “(bb) to explain the basis for the
13 scope of the safety assessment and
14 safety determination; and
15 “(cc) to accept comments regard-
16 ing the scope of the safety assessment
17 and safety determination; and
18 “(II)(aa) to identify the items de-
19 scribed in subclause (I) that the Ad-
20 ministrator has considered in the final
21 safety assessment; and
22 “(bb) to explain the basis for the
23 consideration of those items;
24 “(iii) describe the manner in which
25 aggregate exposures, or significant subsets

1 of exposures, to a chemical substance
2 under the conditions of use will be consid-
3 ered, and explain the basis for that consid-
4 eration in the final safety assessment;

5 “(iv) require that each safety assess-
6 ment and safety determination shall in-
7 clude—

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

10 “(II) a summary of the informa-
11 tion regarding the impact on health
12 and the environment of the chemical
13 substance that was used to make the
14 assessment or determination, includ-
15 ing, as available, mechanistic, animal
16 toxicity, and epidemiology studies;

17 “(v) establish a timely and trans-
18 parent process for evaluating whether new
19 information submitted or obtained after
20 the date of a final safety assessment or
21 safety determination warrants reconsider-
22 ation of the safety assessment or safety de-
23 termination; and

24 “(vi) when relevant information is
25 provided or otherwise made available to the

1 Administrator, shall consider the extent of
2 Federal regulation under other Federal
3 laws.

4 “(D) GUIDANCE.—

5 “(i) IN GENERAL.—Not later than 1
6 year after the date of enactment of the
7 Frank R. Lautenberg Chemical Safety for
8 the 21st Century Act, the Administrator
9 shall develop guidance to assist interested
10 persons in developing draft safety assess-
11 ments and other information for submis-
12 sion to the Administrator, which may be
13 considered at the discretion of the Admin-
14 istrator.

15 “(ii) REQUIREMENT.—The guidance
16 shall, at a minimum, address the quality of
17 the information submitted and the process
18 to be followed in developing a draft assess-
19 ment for consideration by the Adminis-
20 trator.

21 “(3) ARTICLES.—If the Administrator intends
22 to prohibit or otherwise restrict an article on the
23 basis of a chemical substance contained in that arti-
24 cle, the Administrator shall have evidence of signifi-

1 cant exposure to the chemical substance from such
2 article.

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

5 “(1) make publicly available a nontechnical
6 summary, and the final version, of each safety as-
7 sessment and safety determination;

8 “(2) provide public notice and an opportunity
9 for comment on each proposed safety assessment
10 and safety determination; and

11 “(3) make public in a final safety assessment
12 and safety determination—

13 “(A) the list of studies considered by the
14 Administrator in carrying out the safety assess-
15 ment or safety determination; and

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

19 “(j) CONSULTATION WITH SCIENCE ADVISORY COM-
20 MITTEE ON CHEMICALS.—

21 “(1) ESTABLISHMENT.—Not later than 1 year
22 after the date of enactment of this section, the Ad-
23 ministrator shall establish an advisory committee, to
24 be known as the ‘Science Advisory Committee on

1 Chemicals' (referred to in this subsection as the
2 'Committee').

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

8 “(3) COMPOSITION.—The Committee shall be
9 composed of representatives of such science, govern-
10 ment, labor, public health, public interest, animal
11 protection, industry, and other groups as the Admin-
12 istrator determines to be advisable, including, at a
13 minimum, representatives that have specific sci-
14 entific expertise in the relationship of chemical expo-
15 sures to women, children, and other potentially ex-
16 posed or susceptible populations.

17 “(4) SCHEDULE.—The Administrator shall con-
18 vene the Committee in accordance with such sched-
19 ule as the Administrator determines to be appro-
20 priate, but not less frequently than once every 2
21 years.

22 “(5) RELATIONSHIP TO OTHER LAW.—All pro-
23 ceedings and meetings of the Committee shall be
24 subject to the Federal Advisory Committee Act (5
25 U.S.C. App.).”.

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

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

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

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

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

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

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

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

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

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

20 (B) by striking the last sentence; and

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

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

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

1 a chemical substance or mixture in accordance with
2 this section if the Administrator determines that the
3 information is necessary—

4 “(A) to review a notice under section 5(d)
5 or to perform a safety assessment or safety de-
6 termination under section 6;

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

11 “(C) pursuant to section 12(a)(4); or

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

15 “(2) LIMITED TESTING FOR PRIORITIZATION
16 PURPOSES.—

17 “(A) IN GENERAL.—Except as provided in
18 subparagraph (B), the Administrator may re-
19 quire the development of new information for
20 the purposes of section 4A.

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

1 “(C) LIMITATION.—The Administrator
2 may require the development of new informa-
3 tion pursuant to subparagraph (A) only if the
4 Administrator determines that additional infor-
5 mation is necessary to establish the priority of
6 a chemical substance.

7 “(3) FORM.—Subject to section 3A(h), the Ad-
8 ministrator may require the development of informa-
9 tion described in paragraph (1) or (2) by—

10 “(A) promulgating a rule;

11 “(B) entering into a testing consent agree-
12 ment; or

13 “(C) issuing an order.

14 “(4) CONTENTS.—

15 “(A) IN GENERAL.—A rule, testing con-
16 sent agreement, or order issued under this sub-
17 section shall include—

18 “(i) identification of the chemical sub-
19 stance or mixture for which testing is re-
20 quired;

21 “(ii) identification of the persons re-
22 quired to conduct the testing;

23 “(iii) test protocols and methodologies
24 for the development of test data and infor-
25 mation for the chemical substance or mix-

1 ture, including specific reference to reliable
2 nonanimal test procedures; and

3 “(iv) specification of the period within
4 which individuals and entities required to
5 conduct the testing shall submit to the Ad-
6 ministrator the information developed in
7 accordance with the procedures described
8 in clause (iii).

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

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

16 “(ii) the reasonably foreseeable avail-
17 ability of facilities and personnel required
18 to perform the testing.

19 “(b) STATEMENT OF NEED.—

20 “(1) IN GENERAL.—In promulgating a rule, en-
21 tering into a testing consent agreement, or issuing
22 an order for the development of additional informa-
23 tion (including information on exposure or exposure
24 potential) pursuant to this section, the Adminis-
25 trator shall—

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

3 “(B) explain why information reasonably
4 available to the Administrator at that time is
5 inadequate to meet that need, including a ref-
6 erence, as appropriate, to the information iden-
7 tified in paragraph (2)(B); and

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

10 “(2) EXPLANATION IN CASE OF ORDER.—

11 “(A) IN GENERAL.—If the Administrator
12 issues an order under this section, the Adminis-
13 trator shall issue a statement providing a jus-
14 tification for why issuance of an order is war-
15 ranted instead of promulgating a rule or enter-
16 ing into a testing consent agreement.

17 “(B) CONTENTS.—A statement described
18 in subparagraph (A) shall contain a description
19 of—

20 “(i) information that is readily acces-
21 sible to the Administrator, including infor-
22 mation submitted under any other provi-
23 sion of law;

24 “(ii) the extent to which the Adminis-
25 trator has obtained or attempted to obtain

1 the information through voluntary submis-
2 sions; and

3 “(iii) any information relied on in
4 safety assessments for other chemical sub-
5 stances relevant to the chemical substances
6 that would be the subject of the order.

7 “(c) REDUCTION OF TESTING ON VERTEBRATES.—

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

12 “(A) encouraging and facilitating—

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

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

18 “(iii) the use of test methods that
19 eliminate or reduce the use of animals
20 while providing information of high sci-
21 entific quality;

22 “(iv) the grouping of 2 or more chem-
23 ical substances into scientifically appro-
24 priate categories in cases in which testing
25 of a chemical substance would provide reli-

1 able and useful information on other chem-
2 ical substances in the category;

3 “ (v) the formation of industry con-
4 sortia to jointly conduct testing to avoid
5 unnecessary duplication of tests; and

6 “ (vi) the submission of information
7 from—

8 “ (I) animal-based studies; and

9 “ (II) emerging methods and
10 models; and

11 “ (B) funding research and validation stud-
12 ies to reduce, refine, and replace the use of ani-
13 mal tests in accordance with this subsection.

14 “ (2) IMPLEMENTATION OF ALTERNATIVE TEST-
15 ING METHODS.—To promote the development and
16 timely incorporation of new testing methods that are
17 not based on vertebrate animals, the Administrator
18 shall—

19 “ (A) after providing an opportunity for
20 public comment, develop a strategic plan to pro-
21 mote the development and implementation of al-
22 ternative test methods and testing strategies to
23 generate information under this title that can
24 reduce, refine, or replace the use of vertebrate
25 animals, including toxicity pathway-based risk

1 assessment, in vitro studies, systems biology,
2 computational toxicology, bioinformatics, and
3 high-throughput screening;

4 “(B) as practicable, ensure that the stra-
5 tegic plan developed under subparagraph (A) is
6 reflected in the development of requirements for
7 testing under this section;

8 “(C) beginning on the date that is 5 years
9 after the date of enactment of the Frank R.
10 Lautenberg Chemical Safety for the 21st Cen-
11 tury Act and every 5 years thereafter, submit to
12 Congress a report that describes the progress
13 made in implementing this subsection and goals
14 for future alternative test methods implementa-
15 tion; and

16 “(D) fund and carry out research, develop-
17 ment, performance assessment, and
18 translational studies to accelerate the develop-
19 ment of test methods and testing strategies that
20 reduce, refine, or replace the use of vertebrate
21 animals in any testing under this title.

22 “(3) CRITERIA FOR ADAPTING OR WAIVING ANI-
23 MAL TESTING REQUIREMENTS.—On request from a
24 manufacturer or processor that is required to con-
25 duct testing of a chemical substance or mixture on

1 vertebrate animals under this section, the Adminis-
2 trator may adapt or waive the requirement, if the
3 Administrator determines that—

4 “(A) there is sufficient evidence from sev-
5 eral independent sources of information to sup-
6 port a conclusion that a chemical substance or
7 mixture has, or does not have, a particular
8 property if the information from each individual
9 source alone is insufficient to support the con-
10 clusion;

11 “(B) as a result of 1 or more physical or
12 chemical properties of the chemical substance
13 or mixture or other toxicokinetic consider-
14 ations—

15 “(i) the substance cannot be absorbed;

16 or

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

19 “(C) a chemical substance or mixture can-
20 not be tested in vertebrate animals at con-
21 centrations that do not result in significant
22 pain or distress, because of physical or chemical
23 properties of the chemical substance or mixture,
24 such as a potential to cause severe corrosion or
25 severe irritation to the tissues of the animal.

1 “(d) TESTING REQUIREMENTS.—

2 “(1) IN GENERAL.—The Administrator may re-
3 quire the development of information by—

4 “(A) manufacturers and processors of the
5 chemical substance or mixture; and

6 “(B) persons that begin to manufacture or
7 process the chemical substance or mixture—

8 “(i) after the effective date of the
9 rule, testing consent agreement, or order;
10 but

11 “(ii) subject to paragraph (3), before
12 the period ending on the date that is 180
13 days after the end of the period described
14 in this section.

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

19 “(A) to develop the information; and

20 “(B) to submit the information on behalf
21 of the persons making the designation.

22 “(3) EXEMPTIONS.—

23 “(A) IN GENERAL.—A person otherwise
24 subject to a rule, testing consent agreement, or
25 order under this section may submit to the Ad-

1 administrator an application for an exemption on
2 the basis that the information is being devel-
3 oped by a person designated under paragraph
4 (2).

5 “(B) FAIR AND EQUITABLE REIMBURSE-
6 MENT TO DESIGNEE.—

7 “(i) IN GENERAL.—If the Adminis-
8 trator accepts an application submitted
9 under subparagraph (A), the Adminis-
10 trator shall direct the applicant to provide
11 to the person designated under paragraph
12 (2) fair and equitable reimbursement, as
13 agreed to between the applicant and the
14 designee.

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

20 “(C) TERMINATION.—If, after granting an
21 exemption under this paragraph, the Adminis-
22 trator determines that a person covered by the
23 exemption has failed to comply with the rule,
24 testing consent agreement, or order, the Admin-
25 istrator shall—

1 “(i) by order, terminate the exemp-
2 tion; and

3 “(ii) notify in writing each person
4 that received an exemption of the require-
5 ments with respect to which the exemption
6 was granted.

7 “(e) TRANSPARENCY.—Subject to section 14, the Ad-
8 ministrators shall make available to the public all testing
9 consent agreements and orders and all information sub-
10 mitted under this section.”.

11 (b) CONFORMING AMENDMENT.—Section
12 104(i)(5)(A) of the Comprehensive Environmental Re-
13 sponse, Compensation, and Liability Act of 1980 (42
14 U.S.C. 9604(i)(5)(A)) is amended in the third sentence
15 by striking “section 4(e)” and inserting “section 4(f)”.

16 **SEC. 6. PRIORITIZATION SCREENING.**

17 The Toxic Substances Control Act is amended by in-
18 serting after section 4 (15 U.S.C. 2603) the following:

19 **“SEC. 4A. PRIORITIZATION SCREENING.**

20 “(a) ESTABLISHMENT AND LIST OF SUBSTANCES.—

21 “(1) IN GENERAL.—Not later than 1 year after
22 the date of enactment of this section, the Adminis-
23 trator shall establish, by rule, a risk-based screening
24 process and explicit criteria for identifying existing
25 chemical substances that are—

1 “(A) a high priority for a safety assess-
2 ment and safety determination under section 6
3 (referred to in this Act as ‘high-priority sub-
4 stances’); and

5 “(B) a low priority for a safety assessment
6 and safety determination (referred to in this
7 Act as ‘low-priority substances’).

8 “(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY
9 SUBSTANCES.—

10 “(A) IN GENERAL.—Before the date of
11 promulgation of the rule under paragraph (1)
12 and not later than 180 days after the date of
13 enactment of this section, the Administrator—

14 “(i) shall take into consideration and
15 publish an initial list of high-priority sub-
16 stances and low-priority substances; and

17 “(ii) pursuant to section 6(b), may
18 initiate or continue safety assessments and
19 safety determinations for those high-pri-
20 ority substances.

21 “(B) REQUIREMENTS.—

22 “(i) IN GENERAL.—The initial list of
23 chemical substances shall contain at least
24 10 high-priority substances, at least 5 of
25 which are drawn from the list of chemical

1 substances identified by the Administrator
2 in the October, 2014 TSCA Work Plan
3 and subsequent updates, and at least 10
4 low-priority substances.

5 “(ii) SUBSEQUENTLY IDENTIFIED
6 SUBSTANCES.—Insofar as possible, at least
7 50 percent of all substances subsequently
8 identified by the Administrator as high-pri-
9 ority substances shall be drawn from the
10 list of chemical substances identified by the
11 Administrator in the October, 2014 TSCA
12 Work Plan and subsequent updates, until
13 all Work Plan chemicals have been des-
14 ignated under this subsection.

15 “(C) ADDITIONAL CHEMICAL REVIEWS.—

16 The Administrator shall—

17 “(i) 3 years after the date of enact-
18 ment of the Frank R. Lautenberg Chem-
19 ical Safety for the 21st Century Act, add
20 additional high-priority substances suffi-
21 cient to ensure that at least a total of 20
22 high-priority substances have undergone or
23 are undergoing the process established in
24 section 6(a), and additional low-priority
25 substances sufficient to ensure that at

1 least a total of 20 low-priority substances
2 have been designated; and

3 “(ii) as soon as practicable and not
4 later than 5 years after the date of enact-
5 ment of the Frank R. Lautenberg Chem-
6 ical Safety for the 21st Century Act, add
7 additional high-priority substances suffi-
8 cient to ensure that at least a total of 25
9 high-priority substances have undergone or
10 are undergoing the process established in
11 section 6(a), and additional low-priority
12 substances sufficient to ensure that at
13 least a total of 25 low-priority substances
14 have been designated.

15 “(3) IMPLEMENTATION.—

16 “(A) CONSIDERATION OF ACTIVE AND IN-
17 ACTIVE SUBSTANCES.—

18 “(i) ACTIVE SUBSTANCES.—In car-
19 rying out paragraph (1), the Administrator
20 shall take into consideration active sub-
21 stances, as determined under section 8,
22 which may include chemical substances on
23 the interim list of active substances estab-
24 lished under that section.

1 “(ii) INACTIVE SUBSTANCES.—In car-
2 rying out paragraph (1), the Administrator
3 may take into consideration inactive sub-
4 stances, as determined under section 8,
5 that the Administrator determines—

6 “(I)(aa) have not been subject to
7 a regulatory or other enforceable ac-
8 tion by the Administrator to ban or
9 phase out the substances; and

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

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

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

21 “(iii) REPOPULATION.—

22 “(I) IN GENERAL.—On the com-
23 pletion of a safety determination
24 under section 6 for a chemical sub-
25 stance, the Administrator shall re-

1 move the chemical substance from the
2 list of high-priority substances estab-
3 lished under this subsection.

4 “(II) ADDITIONS.—The Adminis-
5 trator shall add at least 1 chemical
6 substance to the list of high-priority
7 substances for each chemical sub-
8 stance removed from the list of high-
9 priority substances established under
10 this subsection, until a safety assess-
11 ment and safety determination is com-
12 pleted for all high-priority substances.

13 “(III) LOW-PRIORITY SUB-
14 STANCES.—If a low-priority substance
15 is subsequently designated as a high-
16 priority substance, the Administrator
17 shall remove that substance from the
18 list of low-priority substances.

19 “(B) TIMELY COMPLETION OF
20 PRIORITIZATION SCREENING PROCESS.—

21 “(i) IN GENERAL.—The Administrator
22 shall—

23 “(I) not later than 180 days
24 after the effective date of the final

1 rule under paragraph (1), begin the
2 prioritization screening process; and

3 “(II) make every effort to com-
4 plete the designation of all active sub-
5 stances as high-priority substances or
6 low-priority substances in a timely
7 manner.

8 “(ii) DECISIONS ON SUBSTANCES SUB-
9 JECT TO TESTING FOR PRIORITIZATION
10 PURPOSES.—Not later than 90 days after
11 the date of receipt of information regard-
12 ing a chemical substance complying with a
13 rule, testing consent agreement, or order
14 issued under section 4(a)(2), the Adminis-
15 trator shall designate the chemical sub-
16 stance as a high-priority substance or low-
17 priority substance.

18 “(iii) CONSIDERATION.—

19 “(I) IN GENERAL.—The Admin-
20 istrator shall screen substances and
21 designate high-priority substances
22 taking into consideration the ability of
23 the Administrator to schedule and
24 complete safety assessments and safe-

1 ty determinations under section 6 in a
2 timely manner.

3 “(II) ANNUAL GOAL.—The Ad-
4 ministrator shall publish an annual
5 goal for the number of chemical sub-
6 stances to be subject to the
7 prioritization screening process.

8 “(C) SCREENING OF CATEGORIES OF SUB-
9 STANCES.—The Administrator may screen cat-
10 egories of chemical substances to ensure an effi-
11 cient prioritization screening process to allow
12 for timely and adequate designations of high-
13 priority substances and low-priority substances
14 and safety assessments and safety determina-
15 tions for high-priority substances.

16 “(D) PUBLICATION OF LIST OF CHEMICAL
17 SUBSTANCES.—Not less frequently than once
18 each year, the Administrator shall publish a list
19 of chemical substances that—

20 “(i) are being considered in the
21 prioritization screening process and the
22 status of the chemical substances in the
23 prioritization process, including those
24 chemical substances for which

1 prioritization decisions have been deferred;
2 and

3 “(ii) are designated as high-priority
4 substances or low-priority substances, in-
5 cluding the bases for such designations.

6 “(4) CRITERIA.—The criteria described in para-
7 graph (1) shall account for—

8 “(A) the recommendation of the Governor
9 of a State or a State agency with responsibility
10 for protecting health or the environment from
11 chemical substances appropriate for
12 prioritization screening;

13 “(B) the hazard and exposure potential of
14 the chemical substance (or category of sub-
15 stances), including specific scientific classifica-
16 tions and designations by authoritative govern-
17 mental entities;

18 “(C) the conditions of use or significant
19 changes in the conditions of use of the chemical
20 substance;

21 “(D) evidence and indicators of exposure
22 potential to humans or the environment from
23 the chemical substance, including potentially ex-
24 posed or susceptible populations;

1 “(E) the volume of a chemical substance
2 manufactured or processed;

3 “(F) whether the volume of a chemical
4 substance as reported under a rule promulgated
5 pursuant to section 8(a) has significantly in-
6 creased or decreased during the period begin-
7 ning on the date of a previous report or the
8 date on which a notice has been submitted
9 under section 5(b) for that chemical substance;

10 “(G) the availability of information regard-
11 ing potential hazards and exposures required
12 for conducting a safety assessment or safety de-
13 termination, with limited availability of relevant
14 information to be a sufficient basis for desig-
15 nating a chemical substance as a high-priority
16 substance, subject to the condition that limited
17 availability shall not require designation as a
18 high-priority substance; and

19 “(H) the extent of Federal or State regula-
20 tion of the chemical substance or the extent of
21 the impact of State regulation of the chemical
22 substance on the United States, with existing
23 Federal or State regulation of any uses evalu-
24 ated in the prioritization screening process as a

1 factor in designating a chemical substance to be
2 a low-priority substance.

3 “(b) PRIORITIZATION SCREENING PROCESS AND DE-
4 CISIONS.—

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

8 “(A) identify the chemical substances
9 being considered for prioritization;

10 “(B) request interested persons to supply
11 information regarding the chemical substances
12 being considered;

13 “(C) apply the criteria identified in sub-
14 section (a)(4); and

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

20 “(2) INTEGRATION OF INFORMATION.—The
21 prioritization screening decision regarding a chem-
22 ical substance shall integrate any hazard and expo-
23 sure information relating to the chemical substance
24 that is available to the Administrator.

1 “(3) IDENTIFICATION OF HIGH-PRIORITY SUB-
2 STANCES.—The Administrator—

3 “(A) shall identify as a high-priority sub-
4 stance a chemical substance that, relative to
5 other chemical substances, the Administrator
6 determines has the potential for high hazard
7 and widespread exposure;

8 “(B) may identify as a high-priority sub-
9 stance a chemical substance that, relative to
10 other chemical substances, the Administrator
11 determines has the potential for high hazard or
12 widespread exposure; and

13 “(C) may identify as a high-priority sub-
14 stance an inactive substance, as determined
15 under subsection (a)(3)(A)(ii) and section 8(b),
16 that the Administrator determines warrants a
17 safety assessment and safety determination
18 under section 6.

19 “(4) IDENTIFICATION OF LOW-PRIORITY SUB-
20 STANCES.—The Administrator shall identify as a
21 low-priority substance a chemical substance that the
22 Administrator concludes has information sufficient
23 to establish that the chemical substance is likely to
24 meet the applicable safety standard.

1 “(5) DEFERRING A DECISION.—If the Adminis-
2 trator determines that additional information is re-
3 quired to establish the priority of a chemical sub-
4 stance under this section, the Administrator may
5 defer the prioritization screening decision for a rea-
6 sonable period—

7 “(A) to allow for the submission of addi-
8 tional information by an interested person and
9 for the Administrator to evaluate the additional
10 information; or

11 “(B) to require the development of infor-
12 mation pursuant to a rule, testing consent
13 agreement, or order issued under section
14 4(a)(2).

15 “(6) DEADLINES FOR SUBMISSION OF INFOR-
16 MATION.—If the Administrator requests the develop-
17 ment or submission of information under this sec-
18 tion, the Administrator shall establish a deadline for
19 submission of the information.

20 “(7) NOTICE AND COMMENT.—The Adminis-
21 trator shall—

22 “(A) publish the proposed decisions made
23 under paragraphs (3), (4), and (5) and the
24 basis for the decisions; and

1 “(B) provide an opportunity for public
2 comment.

3 “(8) REVISIONS OF PRIOR DESIGNATIONS.—

4 “(A) IN GENERAL.—At any time, and at
5 the discretion of the Administrator, the Admin-
6 istrator may revise the designation of a chem-
7 ical substance as a high-priority substance or a
8 low-priority substance based on information
9 available to the Administrator after the date of
10 the determination under paragraph (3) or (4).

11 “(B) LIMITED AVAILABILITY.—If limited
12 availability of relevant information was a basis
13 in the designation of a chemical substance as a
14 high-priority substance, the Administrator shall
15 reevaluate the prioritization screening of the
16 chemical substance on receiving the relevant in-
17 formation.

18 “(9) OTHER INFORMATION RELEVANT TO
19 PRIORITIZATION.—

20 “(A) IN GENERAL.—If, after the date of
21 enactment of the Frank R. Lautenberg Chem-
22 ical Safety for the 21st Century Act, a State
23 proposes an administrative action or enacts a
24 statute or takes an administrative action to pro-
25 hibit or otherwise restrict the manufacturing,

1 processing, distribution in commerce, or use of
2 a chemical substance that the Administrator
3 has not as designated a high-priority substance,
4 the Governor or State agency with responsi-
5 bility for implementing the statute or adminis-
6 trative action shall notify the Administrator.

7 “(B) REQUESTS FOR INFORMATION.—Fol-
8 lowing receipt of a notification provided under
9 subparagraph (A), the Administrator may re-
10 quest any available information from the Gov-
11 ernor or the State agency with respect to—

12 “(i) scientific evidence related to the
13 hazards, exposures and risks of the chem-
14 ical substance under the conditions of use
15 which the statute or administrative action
16 is intended to address;

17 “(ii) any State or local conditions
18 which warranted the statute or administra-
19 tive action;

20 “(iii) the statutory or administrative
21 authority on which the action is based; and

22 “(iv) any other available information
23 relevant to the prohibition or other restric-
24 tion, including information on any alter-

1 natives considered and their hazards, expo-
2 sures, and risks.

3 “(C) PRIORITIZATION SCREENING.—The
4 Administrator shall conduct a prioritization
5 screening under this subsection for all sub-
6 stances that—

7 “(i) are the subject of notifications re-
8 ceived under subparagraph (A); and

9 “(ii) the Administrator determines—

10 “(I) are likely to have significant
11 health or environmental impacts;

12 “(II) are likely to have signifi-
13 cant impact on interstate commerce;
14 or

15 “(III) have been subject to a pro-
16 hibition or other restriction under a
17 statute or administrative action in 2
18 or more States.

19 “(D) AVAILABILITY TO PUBLIC.—Subject
20 to section 14 and any applicable State law re-
21 garding the protection of confidential informa-
22 tion provided to the State or to the Adminis-
23 trator, the Administrator shall make informa-
24 tion received from a Governor or State agency
25 under subparagraph (A) publicly available.

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

6 “(10) REVIEW.—Not less frequently than once
7 every 5 years after the date on which the process
8 under this subsection is established, the Adminis-
9 trator shall—

10 “(A) review the process on the basis of ex-
11 perience and taking into consideration resources
12 available to efficiently and effectively screen and
13 prioritize chemical substances; and

14 “(B) if necessary, modify the prioritization
15 screening process.

16 “(11) EFFECT.—Subject to section 18, a des-
17 ignation by the Administrator under this section
18 with respect to a chemical substance shall not af-
19 fect—

20 “(A) the manufacture, processing, distribu-
21 tion in commerce, use, or disposal of the chem-
22 ical substance; or

23 “(B) the regulation of those activities.

24 “(c) ADDITIONAL PRIORITIES FOR SAFETY ASSESS-
25 MENTS AND DETERMINATIONS.—

1 “(1) IN GENERAL.—The prioritization screening
2 process developed under subsection (a) shall—

3 “(A) include a process by which a manu-
4 facturer or processor of an active chemical sub-
5 stance that has not been designated a high-pri-
6 ority substance, or that has not been subject to
7 or is not in the process of a prioritization
8 screening by the Administrator, may request
9 that the Administrator designate the substance
10 for a safety assessment and safety determina-
11 tion, subject to the payment of fees pursuant to
12 section 26(b)(3)(E); and

13 “(B) provide guidance to submitters on the
14 information to be provided in such requests,
15 and specify the criteria the Administrator shall
16 use to determine whether or not to grant such
17 a request, which shall include whether the sub-
18 stance is subject to restrictions imposed by stat-
19 utes enacted or administrative actions taken by
20 1 or more States on the manufacture, proc-
21 essing, distribution in commerce, or use of the
22 substance.

23 “(2) PREFERENCE.—Subject to paragraph (3),
24 in deciding whether to grant requests under this
25 subsection the Administrator shall give a preference

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

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

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

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

23 “(4) REQUIREMENTS.—

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

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

9 “(C) ASSESSMENT AND DETERMINA-
10 TION.—If the Administrator grants a request
11 under this subsection, the safety assessment
12 and safety determination—

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

16 “(ii) shall not be expedited or other-
17 wise subject to special treatment relative to
18 high-priority substances designated pursu-
19 ant to subsection (b)(3) that are under-
20 going safety assessments and safety deter-
21 minations.

22 “(5) EXCEPTIONS.—Requests granted under
23 this subsection shall not be subject to subsection
24 (a)(3)(A)(iii) or section 18(b).”.

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

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

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

6 **“SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.”;**

7 (2) by striking subsection (b);

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

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

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

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

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

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

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

23 (6) by redesignating subsections (c) and (d) as
24 subsection (d) and (c), respectively, and moving sub-
25 section (c) (as so redesigned) so as appear after sub-
26 section (b) (as redesignated by paragraph (3));

1 (7) in subsection (c) (as so redesignated)—

2 (A) by striking paragraph (1) and insert-
3 ing the following:

4 “(1) IN GENERAL.—The notice required by sub-
5 section (a) shall include, with respect to a chemical
6 substance—

7 “(A) the information required by sections
8 720.45 and 720.50 of title 40, Code of Federal
9 Regulations (or successor regulations); and

10 “(B) information regarding conditions of
11 use and reasonably anticipated exposures.”;

12 (B) in paragraph (2)—

13 (i) in the matter preceding subpara-
14 graph (A), by striking “or of data under
15 subsection (b)”;

16 (ii) in subparagraph (A), by adding
17 “and” after the semicolon at the end;

18 (iii) in subparagraph (B), by striking
19 “; and” and inserting a period; and

20 (iv) by striking subparagraph (C); and

21 (C) in paragraph (3), by striking “sub-
22 section (a) and for which the notification period
23 prescribed by subsection (a), (b), or (c)” and
24 inserting “subsection (b) and for which the no-

1 tification period prescribed by subsection (b) or
2 (d)”;

3 (8) by striking subsection (d) (as redesignated
4 by paragraph (6)) and inserting the following:

5 “(d) REVIEW OF NOTICE.—

6 “(1) INITIAL REVIEW.—

7 “(A) IN GENERAL.—Subject to subpara-
8 graph (B), not later than 90 days after the date
9 of receipt of a notice submitted under sub-
10 section (b), the Administrator shall—

11 “(i) conduct an initial review of the
12 notice;

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

17 “(iii) make any necessary determina-
18 tion under paragraph (3).

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

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

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

6 “(B) any other relevant additional infor-
7 mation available to the Administrator.

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

13 “(A) the relevant chemical substance or
14 significant new use is not likely to meet the
15 safety standard, in which case the Adminis-
16 trator shall take appropriate action under para-
17 graph (4);

18 “(B) the relevant chemical substance or
19 significant new use is likely to meet the safety
20 standard, in which case the Administrator shall
21 allow the review period to expire without addi-
22 tional restrictions; or

23 “(C) additional information is necessary in
24 order to make a determination under subpara-
25 graph (A) or (B), in which case the Adminis-

1 trator shall take appropriate action under para-
2 graph (5).

3 “(4) RESTRICTIONS.—

4 “(A) DETERMINATION BY ADMINIS-
5 TRATOR.—

6 “(i) IN GENERAL.—If the Adminis-
7 trator makes a determination under sub-
8 paragraph (A) or (C) of paragraph (3)
9 with respect to a notice submitted under
10 subsection (b)—

11 “(I) the Administrator, before
12 the end of the applicable period for re-
13 view under paragraph (1) and by con-
14 sent agreement or order, as appro-
15 priate, shall prohibit or otherwise re-
16 strict the manufacture, processing,
17 use, distribution in commerce, or dis-
18 posal (as applicable) of the chemical
19 substance, or of the chemical sub-
20 stance for a significant new use, with-
21 out compliance with the restrictions
22 specified in the consent agreement or
23 order that the Administrator deter-
24 mines are sufficient to ensure that the
25 chemical substance or significant new

1 use is likely to meet the safety stand-
2 ard; and

3 “(II) no person may commence
4 manufacture of the chemical sub-
5 stance, or manufacture or processing
6 of the chemical substance for a sig-
7 nificant new use, except in compliance
8 with the restrictions specified in the
9 consent agreement or order.

10 “(ii) LIKELY TO MEET STANDARD.—If
11 the Administrator makes a determination
12 under subparagraph (B) of paragraph (3)
13 with respect to a chemical substance or
14 significant new use for which a notice was
15 submitted under subsection (b), at the end
16 of the applicable period for review under
17 paragraph (1), the submitter of the notice
18 may commence manufacture for commer-
19 cial purposes of the chemical substance or
20 manufacture or processing of the chemical
21 substance for a significant new use.

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

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

10 “(ii)(I) initiate a rulemaking described
11 in clause (i); or

12 “(II) publish a statement describing
13 the reasons of the Administrator for not
14 initiating a rulemaking.

15 “(C) INCLUSIONS.—A prohibition or other
16 restriction under subparagraph (A) may in-
17 clude, as appropriate—

18 “(i) subject to section 18(g), a re-
19 quirement that a chemical substance shall
20 be marked with, or accompanied by, clear
21 and adequate minimum warnings and in-
22 structions with respect to use, distribution
23 in commerce, or disposal, or any combina-
24 tion of those activities, with the form and
25 content of the minimum warnings and in-

1 instructions to be prescribed by the Adminis-
2 trator;

3 “(ii) a requirement that manufactur-
4 ers or processors of the chemical substance
5 shall—

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

10 “(II) monitor or conduct such
11 additional tests as are reasonably nec-
12 essary to address potential risks from
13 the manufacture, processing, distribu-
14 tion in commerce, use, or disposal, as
15 applicable, of the chemical substance,
16 subject to section 4;

17 “(iii) a restriction on the quantity of
18 the chemical substance that may be manu-
19 factured, processed, or distributed in com-
20 merce—

21 “(I) in general; or

22 “(II) for a particular use;

23 “(iv) a prohibition or other restriction
24 of—

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

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

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

9 “(v) a prohibition or other restriction
10 on the manufacture, processing, or dis-
11 tribution in commerce of the chemical sub-
12 stance—

13 “(I) in general; or

14 “(II) for a particular use.

15 “(D) WORKPLACE EXPOSURES.—The Ad-
16 ministrators shall consult with the Assistant Sec-
17 retary of Labor for Occupational Safety and
18 Health prior to adopting any prohibition or
19 other restriction under this subsection to ad-
20 dress workplace exposures.

21 “(E) DEFINITION OF REQUIREMENT.—For
22 purposes of this Act, the term ‘requirement’ as
23 used in this section does not displace common
24 law.

1 “(5) ADDITIONAL INFORMATION.—If the Ad-
2 ministrators determine under paragraph (3)(C) that
3 additional information is necessary to conduct a re-
4 view under this subsection, the Administrator—

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

8 “(B) may, by agreement with the sub-
9 mitter, extend the review period for a reason-
10 able time to allow the development and submis-
11 sion of the additional information;

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

16 “(D) on receipt of information the Admin-
17 istrator finds supports the determination under
18 paragraph (3), shall promptly make the deter-
19 mination.”;

20 (9) by striking subsections (e) through (g) and
21 inserting the following:

22 “(e) NOTICE OF COMMENCEMENT.—

23 “(1) IN GENERAL.—Not later than 30 days
24 after the date on which a manufacturer that has
25 submitted a notice under subsection (b) commences

1 nonexempt commercial manufacture of a chemical
2 substance, the manufacturer shall submit to the Ad-
3 ministrator a notice of commencement that identi-
4 fies—

5 “(A) the name of the manufacturer; and

6 “(B) the initial date of nonexempt com-
7 mercial manufacture.

8 “(2) WITHDRAWAL.—A manufacturer or proc-
9 essor that has submitted a notice under subsection
10 (b), but that has not commenced nonexempt com-
11 mercial manufacture or processing of the chemical
12 substance, may withdraw the notice.

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

16 “(1) a notice of commencement for a chemical
17 substance under subsection (c); or

18 “(2) new information regarding the chemical
19 substance.

20 “(g) TRANSPARENCY.—Subject to section 14, the Ad-
21 ministrator shall make available to the public—

22 “(1) all notices, determinations, consent agree-
23 ments, rules, and orders of the Administrator; and

24 “(2) all information submitted or issued under
25 this section.”; and

1 (10) in subsection (h)—

2 (A) in paragraph (1), in the matter pre-
3 ceding subparagraph (A), by striking “(a) or”;

4 (B) by striking paragraph (2);

5 (C) by redesignating paragraphs (3)
6 through (6) as paragraphs (2) through (5), re-
7 spectively;

8 (D) in paragraph (2) (as so redesignated),
9 in the matter preceding subparagraph (A), by
10 striking “subsections (a) and (b)” and inserting
11 “subsection (b)”;

12 (E) in paragraph (3) (as so redesign-
13 ated)—

14 (i) in the first sentence, by striking
15 “will not present an unreasonable risk of
16 injury to health or the environment” and
17 inserting “will meet the safety standard”;
18 and

19 (ii) by striking the second sentence;

20 (F) in paragraph (4) (as so redesignated),
21 by striking “subsections (a) and (b)” and in-
22 serting “subsection (b)”;

23 (G) in paragraph (5) (as so redesignated),
24 in the first sentence, by striking “paragraph (1)
25 or (5)” and inserting “paragraph (1) or (4)”.

1 **SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINA-**
2 **TIONS.**

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

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

7 **“SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINA-**
8 **TIONS.”;**

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

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

13 “(a) IN GENERAL.—The Administrator—

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

18 “(2) shall, as soon as practicable and not later
19 than 6 months after the date on which a chemical
20 substance is designated as a high-priority substance,
21 define the scope of the safety assessment and safety
22 determination to be conducted pursuant to this sec-
23 tion, including the hazards, exposures, conditions of
24 use, and potentially exposed or susceptible popu-
25 lations that the Administrator expects to consider;

1 “(3) as appropriate based on the results of a
2 safety determination, shall establish restrictions pur-
3 suant to subsection (d);

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

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

12 “(6) may extend any deadline under this sub-
13 section for a reasonable period of time after an ade-
14 quate public justification, subject to the condition
15 that the aggregate length of all extensions of dead-
16 lines under paragraphs (4) and (5) and any deferral
17 under subsection (c)(2) does not exceed 2 years.

18 “(b) PRIOR ACTIONS.—

19 “(1) PRIOR-INITIATED ASSESSMENTS.—

20 “(A) IN GENERAL.—Nothing in this Act
21 prevents the Administrator from initiating a
22 safety assessment or safety determination re-
23 garding a chemical substance, or from con-
24 tinuing or completing such a safety assessment
25 or safety determination that was initiated be-

1 fore the date of enactment of the Frank R.
2 Lautenberg Chemical Safety for the 21st Cen-
3 tury Act, prior to the effective date of the poli-
4 cies and procedures required to be established
5 by the Administrator under section 3A or 4A.

6 “(B) INTEGRATION OF PRIOR POLICIES
7 AND PROCEDURES.—As policies and procedures
8 under section 3A and 4A are established, to the
9 maximum extent practicable, the Administrator
10 shall integrate the policies and procedures into
11 ongoing safety assessments and safety deter-
12 minations.

13 “(2) ACTIONS COMPLETED PRIOR TO COMPLE-
14 TION OF POLICIES AND PROCEDURES.—Nothing in
15 this Act requires the Administrator to revise or with-
16 draw a completed safety assessment, safety deter-
17 mination, or rule solely because the action was com-
18 pleted prior to the completion of a policy or proce-
19 dure established under section 3A or 4A, and the va-
20 lidity of a completed assessment, determination, or
21 rule shall not be determined based on the content of
22 such a policy or procedure.

23 “(c) SAFETY DETERMINATIONS.—

24 “(1) IN GENERAL.—Based on a review of the
25 information available to the Administrator, including

1 draft safety assessments submitted by interested
2 persons, and subject to section 18, the Adminis-
3 trator shall determine that—

4 “(A) the relevant chemical substance meets
5 the safety standard;

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

10 “(i) impose restrictions necessary to
11 ensure that the chemical substance meets
12 the safety standard under the conditions of
13 use; or

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

18 “(C) additional information is necessary in
19 order to make a determination under subpara-
20 graph (A) or (B), in which case the Adminis-
21 trator shall take appropriate action under para-
22 graph (2).

23 “(2) ADDITIONAL INFORMATION.—If the Ad-
24 ministrator determines that additional information is
25 necessary to make a safety assessment or safety de-

1 termination for a high-priority substance, the Ad-
2 ministrator—

3 “(A) shall provide an opportunity for inter-
4 ested persons to submit the additional informa-
5 tion;

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

10 “(C) may defer, for a reasonable period
11 consistent with the deadlines described in sub-
12 section (a), a safety assessment and safety de-
13 termination until after receipt of the informa-
14 tion; and

15 “(D) consistent with the deadlines de-
16 scribed in subsection (a), on receipt of informa-
17 tion the Administrator finds supports the safety
18 assessment and safety determination, shall
19 make a determination under paragraph (1).

20 “(3) ESTABLISHMENT OF DEADLINE.—In re-
21 questing the development or submission of informa-
22 tion under this section, the Administrator shall es-
23 tablish a deadline for the submission of the informa-
24 tion.

25 “(d) RULE.—

1 “(1) IMPLEMENTATION.—If the Administrator
2 makes a determination under subsection (c)(1)(B)
3 with respect to a chemical substance, the Adminis-
4 trator shall promulgate a rule establishing restric-
5 tions necessary to ensure that the chemical sub-
6 stance meets the safety standard.

7 “(2) SCOPE.—The rule promulgated pursuant
8 to this subsection—

9 “(A) may—

10 “(i) apply to mixtures containing the
11 chemical substance, as appropriate; and

12 “(ii) exempt replacement parts for ar-
13 ticles manufactured prior to the applicable
14 compliance deadline; and

15 “(B) shall include dates by which compli-
16 ance is mandatory, which—

17 “(i) shall be as soon as practicable;
18 and

19 “(ii) as determined by the Adminis-
20 trator, may vary for different affected per-
21 sons.

22 “(C) WORKPLACE EXPOSURES.—The Ad-
23 ministrator shall consult with the Assistant Sec-
24 retary of Labor for Occupational Safety and
25 Health before adopting any prohibition or other

1 restriction under this subsection to address
2 workplace exposures.

3 “(D) DEFINITION OF REQUIREMENT.—For
4 the purposes of this Act, the term ‘requirement’
5 as used in this section does not displace com-
6 mon law.

7 “(3) RESTRICTIONS.—A restriction under para-
8 graph (1) may include, as appropriate—

9 “(A) subject to section 18, a requirement
10 that a chemical substance shall be marked with,
11 or accompanied by, clear and adequate min-
12 imum warnings and instructions with respect to
13 use, distribution in commerce, or disposal, or
14 any combination of those activities, with the
15 form and content of the minimum warnings and
16 instructions to be prescribed by the Adminis-
17 trator;

18 “(B) a requirement that manufacturers or
19 processors of the chemical substance shall—

20 “(i) make and retain records of the
21 processes used to manufacture or process
22 the chemical substance;

23 “(ii) describe and apply the relevant
24 quality control procedures followed in the

1 manufacturing or processing of the sub-
2 stance; or

3 “(iii) monitor or conduct tests that
4 are reasonably necessary to ensure compli-
5 ance with the requirements of any rule
6 under this subsection;

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

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

14 “(i) a particular use;

15 “(ii) a particular use at a concentra-
16 tion in excess of a level specified by the
17 Administrator; or

18 “(iii) all uses;

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

22 “(i) a particular use; or

23 “(ii) a particular use at a concentra-
24 tion in excess of a level specified by the
25 Administrator;

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

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

8 “(H) a requirement directing manufactur-
9 ers or processors of the chemical substance to
10 give notice of the Administrator’s determination
11 under subsection (c)(1)(B) to distributors in
12 commerce of the chemical substance and, to the
13 extent reasonably ascertainable, to other per-
14 sons in the chain of commerce in possession of
15 the chemical substance.

16 “(4) ANALYSIS FOR RULEMAKING.—

17 “(A) CONSIDERATIONS.—In deciding
18 which restrictions to impose under paragraph
19 (3) as part of developing a rule under para-
20 graph (1), the Administrator shall take into
21 consideration, to the extent practicable based on
22 reasonably available information, the quantifi-
23 able and nonquantifiable costs and benefits of
24 the proposed regulatory action and of the 1 or

1 more primary alternative regulatory actions
2 considered by the Administrator.

3 “(B) ALTERNATIVES.—As part of the
4 analysis, the Administrator shall review any 1
5 or more technically and economically feasible al-
6 ternatives to the chemical substance that the
7 Administrator determines are relevant to the
8 rulemaking.

9 “(C) PUBLIC AVAILABILITY.—In proposing
10 a rule under paragraph (1), the Administrator
11 shall make publicly available any analysis con-
12 ducted under this paragraph.

13 “(D) STATEMENT REQUIRED.—In making
14 final a rule under paragraph (1), the Adminis-
15 trator shall include a statement describing how
16 the analysis considered under subparagraph (A)
17 was taken into account.

18 “(5) EXEMPTIONS.—

19 “(A) IN GENERAL.—The Administrator
20 may exempt 1 or more uses of a chemical sub-
21 stance from any restriction in a rule promul-
22 gated under paragraph (1) if the Administrator
23 determines that—

24 “(i) the rule cannot be complied with,
25 without—

1 “(I) harming national security;
2 “(II) causing significant disrup-
3 tion in the national economy due to
4 the lack of availability of a chemical
5 substance; or

6 “(III) interfering with a critical
7 or essential use for which no tech-
8 nically and economically feasible safer
9 alternative is available, taking into
10 consideration hazard and exposure; or

11 “(ii) the use of the chemical sub-
12 stance, as compared to reasonably available
13 alternatives, provides a substantial benefit
14 to health, the environment, or public safe-
15 ty.

16 “(B) EXEMPTION ANALYSIS.—In pro-
17 posing a rule under paragraph (1) that includes
18 an exemption under this paragraph, the Admin-
19 istrator shall make publicly available any anal-
20 ysis conducted under this paragraph to assess
21 the need for the exemption.

22 “(C) STATEMENT REQUIRED.—In making
23 final a rule under paragraph (1) that includes
24 an exemption under this paragraph, the Admin-
25 istrator shall include a statement describing

1 how the analysis considered under subpara-
2 graph (B) was taken into account.

3 “(D) ANALYSIS IN CASE OF BAN OR
4 PHASE-OUT.—In determining whether an ex-
5 emption should be granted under this para-
6 graph for a chemical substance for which a ban
7 or phase-out is proposed, the Administrator
8 shall take into consideration, to the extent prac-
9 ticable based on reasonably available informa-
10 tion, the quantifiable and nonquantifiable costs
11 and benefits of the 1 or more technically and
12 economically feasible alternatives to the chem-
13 ical substance most likely to be used in place of
14 the chemical substance under the conditions of
15 use if the rule is promulgated.

16 “(E) CONDITIONS.—As part of a rule pro-
17 mulgated under paragraph (1), the Adminis-
18 trator shall include conditions in any exemption
19 established under this paragraph, including rea-
20 sonable recordkeeping, monitoring, and report-
21 ing requirements, to the extent that the Admin-
22 istrator determines the conditions are necessary
23 to protect health and the environment while
24 achieving the purposes of the exemption.

25 “(F) DURATION.—

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

8 “(ii) AUTHORITY OF ADMINIS-
9 TRATOR.—The Administrator, by rule, may
10 extend, modify, or eliminate the exemption
11 if the Administrator determines, on the
12 basis of reasonably available information
13 and after adequate public justification, the
14 exemption warrants extension or is no
15 longer necessary.

16 “(iii) CONSIDERATIONS.—

17 “(I) IN GENERAL.—Subject to
18 subclause (II), the Administrator shall
19 issue exemptions and establish time
20 periods by considering factors deter-
21 mined by the Administrator to be rel-
22 evant to the goals of fostering innova-
23 tion and the development of alter-
24 natives that meet the safety standard.

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

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

11 “(1) the Administrator determines that—

12 “(A) the manufacture, processing, distribu-
13 tion in commerce, use, or disposal of the chem-
14 ical substance or mixture subject to the pro-
15 posed rule or any combination of those activi-
16 ties is likely to result in an unreasonable risk
17 of serious or widespread harm to health or the
18 environment before the effective date; and

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

21 “(2) in the case of a proposed rule to prohibit
22 the manufacture, processing, or distribution of a
23 chemical substance or mixture because of the risk
24 determined under paragraph (1)(A), a court has
25 granted relief in an action under section 7 with re-

1 spect to that risk associated with the chemical sub-
2 stance or mixture.

3 “(f) FINAL AGENCY ACTION.—Under this section
4 and subject to section 18—

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

11 “(2) a final rule promulgated under subsection
12 (d), and the associated safety assessment and safety
13 determination that a chemical substance does not
14 meet the safety standard, shall be considered to be
15 a final agency action, effective beginning on the date
16 of promulgation of the final rule.”; and

17 (4) in subsection (g) (as redesignated by para-
18 graph (2))—

19 (A) by striking paragraph (4); and

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

22 **SEC. 9. IMMINENT HAZARDS.**

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

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

3 “(a) CIVIL ACTIONS.—

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

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

10 “(B) relief (as authorized by subsection
11 (b)) against any person that manufactures,
12 processes, distributes in commerce, uses, or dis-
13 poses of, an imminently hazardous chemical
14 substance or mixture or any article containing
15 the chemical substance or mixture; or

16 “(C) both seizure described in subpara-
17 graph (A) and relief described in subparagraph
18 (B).

19 “(2) RULE, ORDER, OR OTHER PROCEEDING.—
20 A civil action may be commenced under this para-
21 graph, notwithstanding—

22 “(A) the existence of—

23 “(i) a decision by the Administrator
24 under section 4A, 5(d)(3), or 6(c)(1); or

1 “(ii) a rule, testing consent agree-
2 ment, or order under section 4, 5(d)(4),
3 6(d), or 6(h); or

4 “(B) the pendency of any administrative or
5 judicial proceeding under any provision of this
6 Act.”;

7 (2) in subsection (d), by striking “section 6(a)”
8 and inserting “section 6(c)”; and

9 (3) in subsection (f), in the first sentence, by
10 striking “and unreasonable”.

11 **SEC. 10. INFORMATION COLLECTION AND REPORTING.**

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

14 (1) in subsection (a)—

15 (A) in paragraph (3)(A)(ii)(I)—

16 (i) by striking “5(b)(4)” and inserting
17 “5”;

18 (ii) by inserting “section 4 or” after
19 “in effect under”; and

20 (iii) by striking “5(e),” and inserting
21 “5(d)(4);”; and

22 (B) by adding at the end the following:

23 “(4) RULES.—

24 “(A) DEADLINE.—

1 “(i) IN GENERAL.—Not later than 2
2 years after the date of enactment of the
3 Frank R. Lautenberg Chemical Safety for
4 the 21st Century Act, the Administrator
5 shall promulgate rules requiring the main-
6 tenance of records and the reporting of in-
7 formation known or reasonably ascertain-
8 able by the person making the report, in-
9 cluding rules requiring processors to report
10 information, so that the Administrator has
11 the information necessary to carry out sec-
12 tions 4 and 6.

13 “(ii) MODIFICATION OF PRIOR
14 RULES.—In carrying out this subpara-
15 graph, the Administrator may modify, as
16 appropriate, rules promulgated before the
17 date of enactment of the Frank R. Lauten-
18 berg Chemical Safety for the 21st Century
19 Act.

20 “(B) CONTENTS.—The rules promulgated
21 pursuant to subparagraph (A)—

22 “(i) may impose different reporting
23 and recordkeeping requirements on manu-
24 facturers and processors; and

1 “(ii) shall include the level of detail
2 necessary to be reported, including the
3 manner by which use and exposure infor-
4 mation may be reported.

5 “(C) ADMINISTRATION.—In implementing
6 the reporting and recordkeeping requirements
7 under this paragraph, the Administrator shall
8 take measures—

9 “(i) to limit the potential for duplica-
10 tion in reporting requirements;

11 “(ii) to minimize the impact of the
12 rules on small manufacturers and proc-
13 essors; and

14 “(iii) to apply any reporting obliga-
15 tions to those persons likely to have infor-
16 mation relevant to the effective implemen-
17 tation of this title.

18 “(5) GUIDANCE.—The Administrator shall de-
19 velop guidance relating to the information required
20 to be reported under the rules promulgated under
21 this subsection.”;

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

24 “(3) NOMENCLATURE.—

1 “(A) IN GENERAL.—In carrying out para-
2 graph (1), the Administrator shall—

3 “(i) maintain the use of Class 2 no-
4 menclature in use on the date of enact-
5 ment of the Frank R. Lautenberg Chem-
6 ical Safety for the 21st Century Act;

7 “(ii) maintain the use of the Soap and
8 Detergent Association Nomenclature Sys-
9 tem, published in March 1978 by the Ad-
10 ministrator in section 1 of addendum III
11 of the document entitled ‘Candidate List of
12 Chemical Substances’, and further de-
13 scribed in the appendix A of volume I of
14 the 1985 edition of the Toxic Substances
15 Control Act Substances Inventory (EPA
16 Document No. EPA-560/7-85-002a); and

17 “(iii) treat all components of cat-
18 egories that are considered to be statutory
19 mixtures under this Act as being included
20 on the list published under paragraph (1)
21 under the Chemical Abstracts Service
22 numbers for the respective categories, in-
23 cluding, without limitation—

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

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

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

5 “(IV) frits, chemicals, CAS No.
6 65997-18-4;

7 “(V) steel manufacture, chemi-
8 cals, CAS No. 65997-19-5; and

9 “(VI) ceramic materials and
10 wares, chemicals, CAS No. 66402-
11 68-4.

12 “(B) MULTIPLE NOMENCLATURE CONVEN-
13 TIONS.—

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

17 “(I) maintain the nomenclature
18 conventions for substances; and

19 “(II) develop new guidance
20 that—

21 “(aa) establishes equivalency
22 between the nomenclature con-
23 ventions for chemical substances
24 on the list published under para-
25 graph (1); and

1 “(bb) permits persons to
2 rely on the new guidance for pur-
3 poses of determining whether a
4 chemical substance is on the list
5 published under paragraph (1).

6 “(ii) MULTIPLE CAS NUMBERS.—For
7 any chemical substance appearing multiple
8 times on the list under different Chemical
9 Abstracts Service numbers, the Adminis-
10 trator shall develop guidance recognizing
11 the multiple listings as a single chemical
12 substance.

13 “(4) CHEMICAL SUBSTANCES IN COMMERCE.—

14 “(A) RULES.—

15 “(i) IN GENERAL.—Not later than 1
16 year after the date of enactment of the
17 Frank R. Lautenberg Chemical Safety for
18 the 21st Century Act, the Administrator,
19 by rule, shall require manufacturers and
20 processors to notify the Administrator, by
21 not later than 180 days after the date of
22 promulgation of the rule, of each chemical
23 substance on the list published under para-
24 graph (1) that the manufacturer or proc-
25 essor, as applicable, has manufactured or

1 processed for a nonexempt commercial pur-
2 pose during the 10-year period ending on
3 the day before the date of enactment of the
4 Frank R. Lautenberg Chemical Safety for
5 the 21st Century Act.

6 “(ii) ACTIVE SUBSTANCES.—The Ad-
7 ministrator shall, pursuant to paragraph
8 (5)(A), designate chemical substances for
9 which notices are received under clause (i)
10 to be active substances on the list pub-
11 lished under paragraph (1).

12 “(B) CONFIDENTIAL CHEMICAL SUB-
13 STANCES.—The rule promulgated by the Ad-
14 ministrator pursuant to subparagraph (A) shall
15 require—

16 “(i) the Administrator to maintain the
17 list under paragraph (1), which shall in-
18 clude a confidential portion and a noncon-
19 fidential portion consistent with this sec-
20 tion and section 14;

21 “(ii) a manufacturer or processor that
22 is submitting a notice pursuant to sub-
23 paragraph (A) for a chemical substance on
24 the confidential portion of the list pub-
25 lished under paragraph (1) to indicate in

1 the notice whether the manufacturer or
2 processor seeks to maintain any existing
3 claim for protection against disclosure of
4 the specific identity of the substance as
5 confidential pursuant to section 14; and

6 “(iii) the substantiation of those
7 claims pursuant to section 14 and in ac-
8 cordance with the review plan described in
9 subparagraph (C).

10 “(C) REVIEW PLAN.—Not later than 1
11 year after the date on which the Administrator
12 compiles the initial list of active substances pur-
13 suant to subparagraph (A), the Administrator
14 shall promulgate a rule that establishes a plan
15 to review all claims to protect the specific iden-
16 tities of chemical substances on the confidential
17 portion of the list published under paragraph
18 (1) that are notified pursuant to subparagraph
19 (A) or identified as active substances under
20 subsection (f)(1).

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

24 “(i) require, at the time requested by
25 the Administrator, all manufacturers or

1 processors asserting claims under subpara-
2 graph (B) to substantiate the claim unless
3 the manufacturer or processor has sub-
4 stantiated the claim in a submission made
5 to the Administrator during the 5-year pe-
6 riod ending on the date of the request by
7 the Administrator;

8 “(ii) require the Administrator, in ac-
9 cordance with section 14—

10 “(I) to review each substan-
11 tiation—

12 “(aa) submitted pursuant to
13 clause (i) to determine if the
14 claim warrants protection from
15 disclosure; and

16 “(bb) submitted previously
17 by a manufacturer or processor
18 and relied on in lieu of the sub-
19 stantiation required pursuant to
20 clause (i), if the substantiation
21 has not been previously reviewed
22 by the Administrator, to deter-
23 mine if the claim warrants pro-
24 tection from disclosure;

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

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

9 “(aa) the person notifies the
10 Administrator that the person is
11 withdrawing the confidentiality
12 claim, in which case the Adminis-
13 trator shall promptly make the
14 information available to the pub-
15 lic; or

16 “(bb) the Administrator oth-
17 erwise becomes aware that the
18 need for protection from diselo-
19 sure can no longer be substan-
20 tiated, in which case the Admin-
21 istrator shall take the actions de-
22 scribed in section 14(g)(2); and

23 “(iii) encourage manufacturers or
24 processors that have previously made
25 claims to protect the specific identities of

1 chemical substances identified as inactive
2 pursuant to subsection (f)(2) to review and
3 either withdraw or substantiate the claims.

4 “(E) TIMELINE FOR COMPLETION OF RE-
5 VIEWS.—

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

13 “(ii) CONSIDERATIONS.—

14 “(I) IN GENERAL.—The Admin-
15 istrator may extend the deadline for
16 completion of the reviews for not more
17 than 2 additional years, after an ade-
18 quate public justification, if the Ad-
19 ministrator determines that the exten-
20 sion is necessary based on the number
21 of applicable claims needing review
22 and the available resources.

23 “(II) ANNUAL GOAL.—The Ad-
24 ministrator shall publish an annual
25 goal for the number of reviews to be

1 completed over the course of imple-
2 mentation of the plan.

3 “(5) ACTIVE AND INACTIVE SUBSTANCES.—

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

8 “(B) UPDATE.—The Administrator shall
9 update the list of chemical substances des-
10 ignated as active substances as soon as prac-
11 ticable after the date of publication of the most
12 recent data reported under—

13 “(i) part 711 of title 40, Code of Fed-
14 eral Regulations (or successor regulations);
15 and

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

18 “(C) CHANGE TO ACTIVE STATUS.—

19 “(i) IN GENERAL.—Any person that
20 intends to manufacture or process for a
21 nonexempt commercial purpose a chemical
22 substance that is designated as an inactive
23 substance shall notify the Administrator
24 before the date on which the inactive sub-
25 stance is manufactured or processed.

1 “(ii) CONFIDENTIAL CHEMICAL IDEN-
2 TITY CLAIMS.—If a person submitting a
3 notice under clause (i) for an inactive sub-
4 stance on the confidential portion of the
5 list published under paragraph (1) seeks to
6 maintain an existing claim for protection
7 against disclosure of the specific identity of
8 the inactive substance as confidential, the
9 person shall—

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

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

15 “(iii) ACTIVE STATUS.—On receiving
16 a notification under clause (i), the Admin-
17 istrator shall—

18 “(I) designate the applicable
19 chemical substance as an active sub-
20 stance;

21 “(II) pursuant to section 14,
22 promptly review any claim and associ-
23 ated substantiation submitted pursu-
24 ant to clause (ii) for protection
25 against disclosure of the specific iden-

1 tivity of the chemical substance and ap-
2 prove, modify, or deny the claim;

3 “(III) except as provided in this
4 section and section 14, protect from
5 disclosure the specific identity of the
6 chemical substance for which the Ad-
7 ministrator approves a claim under
8 subclause (II) for a period of not less
9 than 10 years, unless, prior to the ex-
10 piration of the period—

11 “(aa) the person notifies the
12 Administrator that the person is
13 withdrawing the confidentiality
14 claim, in which case the Adminis-
15 trator shall promptly make the
16 information available to the pub-
17 lic; or

18 “(bb) the Administrator oth-
19 erwise becomes aware that the
20 need for protection from disclo-
21 sure can no longer be substan-
22 tiated, in which case the Admin-
23 istrator shall take the actions de-
24 scribed in section 14(g)(2); and

1 “(IV) pursuant to section 4A, re-
2 view the priority of the chemical sub-
3 stance as the Administrator deter-
4 mines to be necessary.

5 “(D) CATEGORY STATUS.—The list of in-
6 active substances shall not be considered to be
7 a category for purposes of section 26(c).

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

18 “(7) PUBLIC PARTICIPATION.—Subject to this
19 subsection, the Administrator shall make available to
20 the public—

21 “(A) the specific identity of each chemical
22 substance on the nonconfidential portion of the
23 list published under paragraph (1) that the Ad-
24 ministrators has designated as—

25 “(i) an active substance; or

1 “(ii) an inactive substance;

2 “(B) the accession number, generic name,
3 and, if applicable, premanufacture notice case
4 number for each chemical substance on the con-
5 fidential portion of the list published under
6 paragraph (1) for which a claim of confiden-
7 tiality was received and approved by the Admin-
8 istrator pursuant to section 14; and

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

11 “(i) no claim of protection against dis-
12 closure of the specific identity of the active
13 substance pursuant to this subsection was
14 received;

15 “(ii) a claim for protection against
16 disclosure of the specific identity of the ac-
17 tive substance has been denied by the Ad-
18 ministrator; or

19 “(iii) the time period for protection
20 against disclosure of the specific identity of
21 the active substance has expired.

22 “(8) LIMITATION.—No person may assert a
23 new claim under this subsection for protection from
24 disclosure of a specific identity of any active or inac-
25 tive chemical substance for which a notice is received

1 under paragraph (4)(A)(i) or (5)(C)(i) that is not on
2 the confidential portion of the list published under
3 paragraph (1).

4 “(9) CERTIFICATION.—Under the rule promul-
5 gated under this subsection, manufacturers and
6 processors shall be required—

7 “(A) to certify that each report the manu-
8 facturer or processor submits complies with the
9 requirements of the rule, and that any confiden-
10 tiality claims are true and correct; and

11 “(B) to retain a record supporting the cer-
12 tification for a period of 5 years beginning on
13 the last day of the submission period.”;

14 (3) in subsection (e)—

15 (A) by striking “Any person” and inserting
16 the following:

17 “(1) IN GENERAL.—Any person”; and

18 (B) by adding at the end the following:

19 “(2) APPLICABILITY.—Any person may submit
20 to the Administrator information reasonably sup-
21 porting the conclusion that a chemical substance or
22 mixture presents, will present, or does not present a
23 substantial risk of harm to health and the environ-
24 ment.”; and

1 (4) in subsection (f), by striking “For purposes
2 of this section, the” and inserting the following: “In
3 this section:

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

6 “(A) that has been manufactured or proc-
7 essed for a nonexempt commercial purpose at
8 any point during the 10-year period ending on
9 the date of enactment of the Frank R. Lauten-
10 berg Chemical Safety for the 21st Century Act;

11 “(B) that is added to the list published
12 under subsection (b)(1) after that date of en-
13 actment; or

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

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

20 “(3) MANUFACTURE; PROCESS.—The”.

21 **SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.**

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

24 (1) in subsection (a)—

1 (A) in paragraph (1), in the first sen-
2 tence—

3 (i) by striking “presents or will
4 present an unreasonable risk to health or
5 the environment” and inserting “does not
6 meet the safety standard”; and

7 (ii) by striking “such risk” the first
8 place it appears and inserting “the risk
9 posed by the substance or mixture”;

10 (B) in paragraph (2), in the matter fol-
11 lowing subparagraph (B), by striking “section 6
12 or 7” and inserting “section 6(d) or section 7”;
13 and

14 (C) in paragraph (3), by striking “section
15 6 or 7” and inserting “section 6(d) or 7”;

16 (2) in subsection (d), in the first sentence, by
17 striking “Health, Education, and Welfare” and in-
18 serting “Health and Human Services”; and

19 (3) by adding at the end the following:

20 “(e) EXPOSURE INFORMATION.—If the Adminis-
21 trator obtains information related to exposures or releases
22 of a chemical substance that may be prevented or reduced
23 under another Federal law, including laws not adminis-
24 tered by the Administrator, the Administrator shall make

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

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

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

9 **SEC. 13. EXPORTS.**

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

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

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

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

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

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

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

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

4 “(4) TESTING.—The Administrator may re-
5 quire testing under section 4 of any chemical sub-
6 stance or mixture exempted from this Act under
7 paragraph (1) for the purpose of determining wheth-
8 er the chemical substance or mixture meets the safe-
9 ty standard within the United States.”;

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

12 “(b) NOTICE.—

13 “(1) IN GENERAL.—A person shall notify the
14 Administrator that the person is exporting or in-
15 tends to export to a foreign country—

16 “(A) a chemical substance or a mixture
17 containing a chemical substance that the Ad-
18 ministrator has determined under section 5 is
19 not likely to meet the safety standard and for
20 which a prohibition or other restriction has
21 been proposed or established under that section;

22 “(B) a chemical substance or a mixture
23 containing a chemical substance that the Ad-
24 ministrator has determined under section 6
25 does not meet the safety standard and for

1 which a prohibition or other restriction has
2 been proposed or established under that section;

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

6 “(D) a chemical substance or mixture sub-
7 ject to a prohibition or other restriction pursu-
8 ant to a rule, order, or consent agreement in ef-
9 fect under this Act; or

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

13 “(2) RULES.—

14 “(A) IN GENERAL.—The Administrator
15 shall promulgate rules to carry out paragraph
16 (1).

17 “(B) CONTENTS.—The rules promulgated
18 pursuant to subparagraph (A) shall—

19 “(i) include such exemptions as the
20 Administrator determines to be appro-
21 priate, which may include exemptions iden-
22 tified under section 5(h); and

23 “(ii) indicate whether, or to what ex-
24 tent, the rules apply to articles containing

1 a chemical substance or mixture described
2 in paragraph (1).

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

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

11 “(B) for a chemical substance described in
12 paragraph (1)(C), a notice that satisfies the ob-
13 ligation of the United States under the applica-
14 ble treaty; and

15 “(C) for a chemical substance or mixture
16 described in paragraph (1)(E), a notice of avail-
17 ability of the information on the chemical sub-
18 stance or mixture submitted to the Adminis-
19 trator.”; and

20 (3) in subsection (c)—

21 (A) by striking paragraph (3); and

22 (B) by redesignating paragraphs (4)
23 through (6) as paragraphs (3) through (5), re-
24 spectively.

1 **SEC. 14. IMPORTS.**

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

4 **“SEC. 13. IMPORTS.**

5 “(a) REFUSAL OF ENTRY.—

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

13 “(A) the Administrator—

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

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

21 “(B) the chemical substance—

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

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

1 title or a rule promulgated by the Adminis-
2 trator pursuant to this title; or

3 “(C) the chemical substance, mixture, or
4 any article containing the chemical substance or
5 mixture is offered for entry in violation of—

6 “(i) a rule, consent agreement, or
7 order in effect under this Act; or

8 “(ii) an order issued in a civil action
9 brought under section 7 or title IV.

10 “(2) PROCEDURE.—

11 “(A) IN GENERAL.—Subject to subpara-
12 graph (B), if a chemical substance, mixture, or
13 article containing a chemical substance or mix-
14 ture is refused entry under paragraph (1), the
15 Secretary of Homeland Security—

16 “(i) shall notify the consignee of the
17 entry of the refusal;

18 “(ii) shall not release the chemical
19 substance or mixture to the consignee; and

20 “(iii) shall cause the disposal or stor-
21 age of the chemical substance or mixture
22 under such rules as the Secretary may pre-
23 scribe, if the chemical substance or mix-
24 ture has not been exported by the con-
25 signee during the 90-day period beginning

1 on the date of receipt of the notice of the
2 refused entry.

3 “(B) EXCEPTION.—

4 “(i) IN GENERAL.—The Secretary of
5 Homeland Security, pending a review by
6 the Administrator, may release to the con-
7 signee the chemical substance or mixture if
8 the consignee—

9 “(I) executes a bond for the
10 amount of the full invoice of the
11 chemical substance or mixture (as set
12 forth in the customs entry); and

13 “(II) pays a duty on the chemical
14 substance or mixture.

15 “(ii) ADMINISTRATION.—If a con-
16 signee fails to return a chemical substance
17 or mixture released to that consignee
18 under clause (i) for any cause to the cus-
19 tody of the Secretary of Homeland Secu-
20 rity on demand, the consignee shall be lia-
21 ble to the United States for liquidated
22 damages equal to the full amount of the
23 bond executed under clause (i)(I).

24 “(C) STORAGE.—All charges for storage,
25 cartage, and labor on or for the disposal of a

1 chemical substance or mixture that is refused
2 entry or released under this subsection shall be
3 paid by the owner or consignee, and a default
4 on that payment shall constitute a lien against
5 any future entry made by the owner or con-
6 signee.

7 “(b) CERTIFICATION.—

8 “(1) IN GENERAL.—A person offering a chem-
9 ical substance or mixture subject to this Act for
10 entry into the customs territory of the United States
11 shall certify to the Secretary of Homeland Security
12 that—

13 “(A) after reasonable inquiry and to the
14 best knowledge and belief of the person, the
15 chemical substance or mixture is in compliance
16 with any applicable rule, consent agreement, or
17 order under section 5 or 6; and

18 “(B) the chemical substance—

19 “(i) is included on the list under sec-
20 tion 8(b)(1); or

21 “(ii) is exempt from any requirement
22 to be included on that list by this title or
23 a rule promulgated by the Administrator
24 pursuant to this title.

25 “(2) ARTICLES.—

1 “(A) IN GENERAL.—The Administrator, by
2 rule, may require certification under paragraph
3 (1) for an article containing a chemical sub-
4 stance or mixture that is subject to rule under
5 section 5 or 6.

6 “(B) REQUIREMENT.—The rule under sub-
7 paragraph (A) shall identify, with reasonable
8 specificity, the types of articles, including parts
9 or components of articles, that will be subject to
10 the certification requirement.

11 “(C) FACTORS FOR CONSIDERATION.—In
12 determining the need for and content of a cer-
13 tification rule under this paragraph, the Admin-
14 istrator shall take into consideration—

15 “(i) the utility of the certification to
16 enforcement of the applicable rule, consent
17 agreement, or order under section 5 or 6;

18 “(ii) the contribution of imported arti-
19 cles to the potential risk presented by ex-
20 posure to the chemical substance or mix-
21 ture subject to rule under section 5 or 6;

22 “(iii) the impact on commerce and po-
23 tential for the certification to impede or
24 disrupt import of articles;

1 “(iv) the frequency or duration of the
2 certification requirement; and

3 “(v) specification of the concentration
4 of a chemical substance in an article that
5 would subject the article to the certifi-
6 cation requirement.

7 “(3) REASONABLE INQUIRY.—

8 “(A) IN GENERAL.—For purposes of a cer-
9 tification under paragraph (1), reasonable in-
10 quiry shall include good faith reliance by an im-
11 porter on—

12 “(i) a safety data sheet or similar dec-
13 laration provided by a supplier that docu-
14 ments the specific identity of the chemical
15 substance or the specific identities of all
16 chemical substances in a mixture; or

17 “(ii) for chemical substances or mix-
18 tures claimed by the supplier as confiden-
19 tial, or not otherwise disclosed by the sup-
20 plier, a certification by the supplier that
21 the imported chemical substance or mix-
22 ture satisfies the applicable certification re-
23 quirements under paragraph (1).

24 “(B) ARTICLES.—For purposes of a cer-
25 tification under paragraph (2), reasonable in-

1 quiry shall include good faith reliance by an im-
2 porter on a certification by the supplier that the
3 imported article satisfies the applicable certifi-
4 cation requirements in a rule promulgated pur-
5 suant to paragraph (2).

6 “(4) INFORMATION REGARDING IDENTITY.—
7 For purposes of this subsection, the Administrator
8 shall provide publicly accessible information regard-
9 ing the identity of a chemical substance or mixture
10 subject to rule under this Act that would be readily
11 understood in import transactions.

12 “(c) NOTICE.—A person offering a chemical sub-
13 stance for entry into the customs territory of the United
14 States shall notify the Secretary of Homeland Security
15 if—

16 “(1) the chemical substance or chemical sub-
17 stance in a mixture is a high-priority substance;

18 “(2) the chemical substance or chemical sub-
19 stance in a mixture is 1 for which the United States
20 is obligated to provide export notification by treaty;
21 or

22 “(3) the chemical substance or chemical sub-
23 stance in a mixture—

1 “(A) is the subject of a safety assessment
2 and safety determination conducted pursuant to
3 section 6; and

4 “(B) has been found not to meet the safety
5 standard.

6 “(d) RULES.—

7 “(1) IN GENERAL.—The Secretary of Homeland
8 Security, after consultation with the Administrator,
9 shall promulgate rules to carry out this section.

10 “(2) APPLICATION.—The rules under para-
11 graph (1) may modify the application of any require-
12 ment of this section, as appropriate for the efficient
13 and effective implementation of this Act.”.

14 **SEC. 15. CONFIDENTIAL INFORMATION.**

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

17 **“SEC. 14. CONFIDENTIAL INFORMATION.**

18 “(a) IN GENERAL.—Except as otherwise provided in
19 this section, the Administrator shall not disclose informa-
20 tion that is exempt from disclosure pursuant to subsection
21 (a) of section 552 of title 5, United States Code, under
22 subsection (b)(4) of that section—

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

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

3 “(b) INFORMATION GENERALLY PROTECTED FROM
4 DISCLOSURE.—The following information specific to, and
5 submitted by, a manufacturer, processor, or distributor
6 that meets the requirements of subsections (a) and (d)
7 shall be presumed to be protected from disclosure, subject
8 to the condition that nothing in this Act prohibits the dis-
9 closure of any such information through discovery, sub-
10 poena, other court order, or any other judicial process oth-
11 erwise allowed under applicable Federal or State law:

12 “(1) Specific information describing the proc-
13 esses used in manufacture or processing of a chem-
14 ical substance, mixture, or article.

15 “(2) Marketing and sales information.

16 “(3) Information identifying a supplier or cus-
17 tomer.

18 “(4) Details of the full composition of a mixture
19 and the respective percentages of constituents.

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

23 “(6) Specific production or import volumes of
24 the manufacturer and specific aggregated volumes
25 across manufacturers, if the Administrator deter-

1 mines that disclosure of the specific aggregated vol-
2 umes would reveal confidential information.

3 “(7) Except as otherwise provided in this sec-
4 tion, the specific identity of a chemical substance
5 prior to the date on which the chemical substance is
6 first offered for commercial distribution, including
7 the chemical name, molecular formula, Chemical Ab-
8 stracts Service number, and other information that
9 would identify a specific chemical substance, if—

10 “(A) the specific identity was claimed as
11 confidential information at the time it was sub-
12 mitted in a notice under section 5; and

13 “(B) the claim—

14 “(i) is not subject to an exception
15 under subsection (e); or

16 “(ii) has not subsequently been with-
17 drawn or found by the Administrator not
18 to warrant protection as confidential infor-
19 mation under subsection (f)(2) or (g).

20 “(c) INFORMATION NOT PROTECTED FROM DISCLO-
21 SURE.—Notwithstanding subsections (a) and (b), the fol-
22 lowing information shall not be protected from disclosure:

23 “(1) INFORMATION FROM HEALTH AND SAFETY
24 STUDIES.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graph (B), subsection (a) does not prohibit the
3 disclosure of—

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

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

11 “(II) any chemical substance or
12 mixture for which—

13 “(aa) testing is required
14 under section 4; or

15 “(bb) a notification is re-
16 quired under section 5; or

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

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

1 “(i) a process used in the manufac-
2 turing or processing of a chemical sub-
3 stance or mixture; or

4 “(ii) in the case of a mixture, the por-
5 tion of the mixture comprised by any
6 chemical substance in the mixture.

7 “(2) CERTAIN REQUESTS.—If a request is made
8 to the Administrator under section 552(a) of title 5,
9 United States Code, for information that is de-
10 scribed in paragraph (1) that is not described in
11 paragraph (1)(B), the Administrator may not deny
12 the request on the basis of section 552(b)(4) of title
13 5, United States Code.

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

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

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

3 “(C) Any general information describing
4 the manufacturing volumes, expressed as spe-
5 cific aggregated volumes or, if the Adminis-
6 trator determines that disclosure of specific ag-
7 gregated volumes would reveal confidential in-
8 formation, expressed in ranges.

9 “(D) A general description of a process
10 used in the manufacture or processing and in-
11 dustrial, commercial, or consumer functions and
12 uses of a chemical substance, mixture, or article
13 containing a chemical substance or mixture, in-
14 cluding information specific to an industry or
15 industry sector that customarily would be
16 shared with the general public or within an in-
17 dustry or industry sector.

18 “(4) MIXED CONFIDENTIAL AND NONCON-
19 FIDENTIAL INFORMATION.—Any information that is
20 otherwise eligible for protection under this section
21 and contained in a submission of information de-
22 scribed in this subsection shall be protected from
23 disclosure, if the submitter complies with subsection
24 (d), subject to the condition that information in the

1 submission that is not eligible for protection against
2 disclosure shall be disclosed.

3 “(5) BAN OR PHASE-OUT.—If the Adminis-
4 trator promulgates a rule pursuant to section 6(d)
5 that establishes a ban or phase-out of the manufac-
6 ture, processing, or distribution in commerce of a
7 chemical substance—

8 “(A) any protection from disclosure pro-
9 vided under this section with respect to infor-
10 mation relating to the chemical substance shall
11 no longer apply; and

12 “(B) the Administrator promptly shall
13 make the information public.

14 “(d) REQUIREMENTS FOR CONFIDENTIALITY
15 CLAIMS.—

16 “(1) ASSERTION OF CLAIMS.—

17 “(A) IN GENERAL.—A person seeking to
18 protect any information submitted under this
19 Act from disclosure (including information de-
20 scribed in subsection (b)) shall assert to the Ad-
21 ministrator a claim for protection concurrent
22 with submission of the information, in accord-
23 ance with such rules regarding a claim for pro-
24 tection from disclosure as the Administrator

1 has promulgated or may promulgate pursuant
2 to this title.

3 “(B) INCLUSION.—An assertion of a claim
4 under subparagraph (A) shall include a state-
5 ment that the person has—

6 “(i) taken reasonable measures to pro-
7 tect the confidentiality of the information;

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

12 “(iii) a reasonable basis to conclude
13 that disclosure of the information is likely
14 to cause substantial harm to the competi-
15 tive position of the person; and

16 “(iv) a reasonable basis to believe that
17 the information is not readily discoverable
18 through reverse engineering.

19 “(C) SPECIFIC CHEMICAL IDENTITY.—In
20 the case of a claim under subparagraph (A) for
21 protection against disclosure of a specific chem-
22 ical identity, the claim shall include a struc-
23 turally descriptive generic name for the chem-
24 ical substance that the Administrator may dis-

1 close to the public, subject to the condition that
2 the generic name shall—

3 “(i) conform with guidance prescribed
4 by the Administrator under paragraph
5 (3)(A); and

6 “(ii) describe the chemical structure
7 of the substance as specifically as prac-
8 ticable while protecting those features of
9 the chemical structure—

10 “(I) that are considered to be
11 confidential; and

12 “(II) the disclosure of which
13 would be likely to harm the competi-
14 tive position of the person.

15 “(D) PUBLIC INFORMATION.—No person
16 may assert a claim under this section for pro-
17 tection from disclosure of information that is al-
18 ready publicly available.

19 “(2) ADDITIONAL REQUIREMENTS FOR CON-
20 FIDENTIALITY CLAIMS.—Except for information de-
21 scribed in paragraphs (1) through (7) of subsection
22 (b), a person asserting a claim to protect informa-
23 tion from disclosure under this Act shall substan-
24 tiate the claim, in accordance with the rules promul-
25 gated and guidance issued by the Administrator.

1 “(3) GUIDANCE.—The Administrator shall de-
2 velop guidance regarding—

3 “(A) the determination of structurally de-
4 scriptive generic names, in the case of claims
5 for the protection against disclosure of specific
6 chemical identity; and

7 “(B) the content and form of the state-
8 ments of need and agreements required under
9 paragraphs (4), (5), and (6) of subsection (e).

10 “(4) CERTIFICATION.—An authorized official of
11 a person described in paragraph (1)(A) shall certify
12 that the information that has been submitted is true
13 and correct.

14 “(e) EXCEPTIONS TO PROTECTION FROM DISCLO-
15 SURE.—Information described in subsection (a) shall be
16 disclosed if—

17 “(1) the information is to be disclosed to an of-
18 ficer or employee of the United States in connection
19 with the official duties of the officer or employee—

20 “(A) under any law for the protection of
21 health or the environment; or

22 “(B) for a specific law enforcement pur-
23 pose;

1 “(2) the information is to be disclosed to a con-
2 tractor of the United States and employees of that
3 contractor—

4 “(A) if, in the opinion of the Adminis-
5 trator, the disclosure is necessary for the satis-
6 factory performance by the contractor of a con-
7 tract with the United States for the perform-
8 ance of work in connection with this Act; and

9 “(B) subject to such conditions as the Ad-
10 ministrators may specify;

11 “(3) the Administrator determines that disclo-
12 sure is necessary to protect health or the environ-
13 ment;

14 “(4) the information is to be disclosed to a
15 State or political subdivision of a State, on written
16 request, for the purpose of development, administra-
17 tion, or enforcement of a law, if—

18 “(A) 1 or more applicable agreements with
19 the Administrator that conform with the guid-
20 ance issued under subsection (d)(3)(B) ensure
21 that the recipient will take appropriate meas-
22 ures, and has adequate authority, to maintain
23 the confidentiality of the information in accord-
24 ance with procedures comparable to the proce-

1 dures used by the Administrator to safeguard
2 the information; and

3 “(B) the Administrator notifies the person
4 that submitted the information that the infor-
5 mation has been disclosed to the State or polit-
6 ical subdivision of a State;

7 “(5) a health or environmental professional em-
8 ployed by a Federal or State agency or a treating
9 physician or nurse in a nonemergency situation pro-
10 vides a written statement of need and agrees to sign
11 a written confidentiality agreement with the Admin-
12 istrator, subject to the conditions that—

13 “(A) the statement of need and confiden-
14 tiality agreement shall conform with the guid-
15 ance issued under subsection (d)(3)(B);

16 “(B) the written statement of need shall be
17 a statement that the person has a reasonable
18 basis to suspect that—

19 “(i) the information is necessary for,
20 or will assist in—

21 “(I) the diagnosis or treatment of
22 1 or more individuals; or

23 “(II) responding to an environ-
24 mental release or exposure; and

1 “(ii) 1 or more individuals being diag-
2 nosed or treated have been exposed to the
3 chemical substance concerned, or an envi-
4 ronmental release or exposure has oc-
5 curred; and

6 “(C) the confidentiality agreement shall
7 provide that the person will not use the infor-
8 mation for any purpose other than the health or
9 environmental needs asserted in the statement
10 of need, except as otherwise may be authorized
11 by the terms of the agreement or by the person
12 submitting the information to the Adminis-
13 trator, except that nothing in this Act prohibits
14 the disclosure of any such information through
15 discovery, subpoena, other court order, or any
16 other judicial process otherwise allowed under
17 applicable Federal or State law;

18 “(6) in the event of an emergency, a treating
19 physician, nurse, agent of a poison control center,
20 public health or environmental official of a State or
21 political subdivision of a State, or first responder
22 (including any individual duly authorized by a Fed-
23 eral agency, State, or political subdivision of a State
24 who is trained in urgent medical care or other emer-
25 gency procedures, including a police officer, fire-

1 fighter, or emergency medical technician) requests
2 the information, subject to the conditions that—

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

8 “(i) a medical or public health or en-
9 vironmental emergency exists;

10 “(ii) the information is necessary for,
11 or will assist in, emergency or first-aid di-
12 agnosis or treatment; or

13 “(iii) 1 or more individuals being di-
14 agnosed or treated have likely been ex-
15 posed to the chemical substance concerned,
16 or a serious environmental release of or ex-
17 posure to the chemical substance con-
18 cerned has occurred;

19 “(B) if requested by the person submitting
20 the information to the Administrator, the treat-
21 ing physician, nurse, agent, public health or en-
22 vironmental official of a State or a political sub-
23 division of a State, or first responder shall, as
24 described in paragraph (5)—

1 “(i) provide a written statement of
2 need; and

3 “(ii) agree to sign a confidentiality
4 agreement; and

5 “(C) the written confidentiality agreement
6 or statement of need shall be submitted as soon
7 as practicable, but not necessarily before the in-
8 formation is disclosed;

9 “(7) the Administrator determines that disclo-
10 sure is relevant in a proceeding under this Act, sub-
11 ject to the condition that the disclosure shall be
12 made in such a manner as to preserve confidentiality
13 to the maximum extent practicable without impair-
14 ing the proceeding;

15 “(8) the information is to be disclosed, on writ-
16 ten request of any duly authorized congressional
17 committee, to that committee; or

18 “(9) the information is required to be disclosed
19 or otherwise made public under any other provision
20 of Federal law.

21 “(f) DURATION OF PROTECTION FROM DISCLO-
22 SURE.—

23 “(1) IN GENERAL.—

24 “(A) INFORMATION PROTECTED FROM DIS-
25 CLOSURE.—Subject to paragraph (2), the Ad-

1 administrator shall protect from disclosure infor-
2 mation that meets the requirements of sub-
3 section (d) for a period of 10 years, unless,
4 prior to the expiration of the period—

5 “(i) an affected person notifies the
6 Administrator that the person is with-
7 drawing the confidentiality claim, in which
8 case the Administrator shall promptly
9 make the information available to the pub-
10 lic; or

11 “(ii) the Administrator otherwise be-
12 comes aware that the need for protection
13 from disclosure can no longer be substan-
14 tiated, in which case the Administrator
15 shall take the actions described in sub-
16 section (g)(2).

17 “(B) EXTENSIONS.—

18 “(i) IN GENERAL.—Not later than the
19 date that is 60 days before the expiration
20 of the period described in subparagraph
21 (A), the Administrator shall provide to the
22 person that asserted the claim a notice of
23 the impending expiration of the period.

24 “(ii) STATEMENT.—

1 “(I) IN GENERAL.—Not later
2 than the date that is 30 days before
3 the expiration of the period described
4 in subparagraph (A), a person re-
5 asserting the relevant claim shall sub-
6 mit to the Administrator a statement
7 substantiating, in accordance with
8 subsection (d)(2), the need to extend
9 the period.

10 “(II) ACTION BY ADMINIS-
11 TRATOR.—Not later than the date
12 that is 30 days after the date of re-
13 ceipt of a statement under subclause
14 (I), the Administrator shall—

15 “(aa) review the request;

16 “(bb) make a determination
17 regarding whether the informa-
18 tion for which the request is
19 made continues to meet the rel-
20 evant criteria established under
21 this section; and

22 “(cc)(AA) grant an exten-
23 sion of not more than 10 years;
24 or

25 “(BB) deny the claim.

1 “(C) NO LIMIT ON NUMBER OF EXTEN-
2 SIONS.—There shall be no limit on the number
3 of extensions granted under subparagraph (B),
4 if the Administrator determines that the rel-
5 evant statement under subparagraph
6 (B)(ii)(I)—

7 “(i) establishes the need to extend the
8 period; and

9 “(ii) meets the requirements estab-
10 lished by the Administrator.

11 “(2) REVIEW AND RESUBSTANTIATION.—

12 “(A) DISCRETION OF ADMINISTRATOR.—

13 The Administrator may review, at any time, a
14 claim for protection against disclosure under
15 subsection (a) for information submitted to the
16 Administrator regarding a chemical substance
17 and require any person that has claimed protec-
18 tion for that information, whether before, on, or
19 after the date of enactment of the Frank R.
20 Lautenberg Chemical Safety for the 21st Cen-
21 tury Act, to withdraw or reassert and substan-
22 tiate or resubstantiate the claim in accordance
23 with this section—

1 “(i) after the chemical substance is
2 identified as a high-priority substance
3 under section 4A;

4 “(ii) for any chemical substance for
5 which the Administrator has made a deter-
6 mination under section 6(c)(1)(C);

7 “(iii) for any inactive chemical sub-
8 stance identified under section 8(b)(5); or

9 “(iv) in limited circumstances, if the
10 Administrator determines that disclosure
11 of certain information currently protected
12 from disclosure would assist the Adminis-
13 trator in conducting safety assessments
14 and safety determinations under sub-
15 sections (b) and (c) of section 6 or promul-
16 gating rules pursuant to section 6(d), sub-
17 ject to the condition that the information
18 shall not be disclosed unless the claimant
19 withdraws the claim or the Administrator
20 determines that the information does not
21 meet the requirements of subsection (d).

22 “(B) REVIEW REQUIRED.—The Adminis-
23 trator shall review a claim for protection from
24 disclosure under subsection (a) for information
25 submitted to the Administrator regarding a

1 chemical substance and require any person that
2 has claimed protection for that information,
3 whether before, on, or after the date of enact-
4 ment of the Frank R. Lautenberg Chemical
5 Safety for the 21st Century Act, to withdraw or
6 reassert and substantiate or resubstantiate the
7 claim in accordance with this section—

8 “(i) as necessary to comply with a re-
9 quest for information received by the Ad-
10 ministrator under section 552 of title 5,
11 United States Code;

12 “(ii) if information available to the
13 Administrator provides a basis that the re-
14 quirements of section 552(b)(4) of title 5,
15 United States Code, are no longer met; or

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

19 “(C) ACTION BY RECIPIENT.—If the Ad-
20 ministrator makes a request under subpara-
21 graph (A) or (B), the recipient of the request
22 shall—

23 “(i) reassert and substantiate or re-
24 substantiate the claim; or

25 “(ii) withdraw the claim.

1 “(D) PERIOD OF PROTECTION.—Protec-
2 tion from disclosure of information subject to a
3 claim that is reviewed and approved by the Ad-
4 ministrator under this paragraph shall be ex-
5 tended for a period of 10 years from the date
6 of approval, subject to any subsequent request
7 by the Administrator under this paragraph.

8 “(3) UNIQUE IDENTIFIER.—The Administrator
9 shall—

10 “(A)(i) develop a system to assign a
11 unique identifier to each specific chemical iden-
12 tity for which the Administrator approves a re-
13 quest for protection from disclosure, other than
14 a specific chemical identity or structurally de-
15 scriptive generic term; and

16 “(ii) apply that identifier consistently to all
17 information relevant to the applicable chemical
18 substance;

19 “(B) annually publish and update a list of
20 chemical substances, referred to by unique iden-
21 tifier, for which claims to protect the specific
22 chemical identity from disclosure have been ap-
23 proved, including the expiration date for each
24 such claim;

1 “(C) ensure that any nonconfidential infor-
2 mation received by the Administrator with re-
3 spect to such a chemical substance during the
4 period of protection from disclosure—

5 “(i) is made public; and

6 “(ii) identifies the chemical substance
7 using the unique identifier; and

8 “(D) for each claim for protection of spe-
9 cific chemical identity that has been denied by
10 the Administrator on expiration of the period
11 for appeal under subsection (g)(3), that has ex-
12 pired, or that has been withdrawn by the sub-
13 mitter, provide public access to the specific
14 chemical identity clearly linked to all noncon-
15 fidential information received by the Adminis-
16 trator with respect to the chemical substance.

17 “(g) DUTIES OF ADMINISTRATOR.—

18 “(1) DETERMINATION.—

19 “(A) IN GENERAL.—Except as provided in
20 subsection (b), the Administrator shall, subject
21 to subparagraph (C), not later than 90 days
22 after the receipt of a claim under subsection
23 (d), and not later than 30 days after the receipt
24 of a request for extension of a claim under sub-

1 section (f), review and approve, modify, or deny
2 the claim or request.

3 “(B) DENIAL OR MODIFICATION.—

4 “(i) IN GENERAL.—Except as pro-
5 vided in subsections (e) and (f), the Ad-
6 ministrator shall deny a claim to protect a
7 chemical identity from disclosure only if
8 the person that has submitted the claim
9 fails to meet the requirements of sub-
10 sections (a) and (d).

11 “(ii) REASONS FOR DENIAL OR MODI-
12 FICATION.—The Administrator shall pro-
13 vide to a person that has submitted a
14 claim described in clause (i) a written
15 statement of the reasons for the denial or
16 modification of the claim.

17 “(C) SUBSETS.—The Administrator
18 shall—

19 “(i) except for claims described in
20 subsection (b)(7), review all claims under
21 this section for the protection against dis-
22 closure of the specific identity of a chem-
23 ical substance; and

1 “(ii) review a representative subset,
2 comprising at least 25 percent, of all other
3 claims for protection against disclosure.

4 “(D) EFFECT OF FAILURE TO ACT.—The
5 failure of the Administrator to make a decision
6 regarding a claim for protection against disclo-
7 sure or extension under this section shall not be
8 the basis for denial or elimination of a claim for
9 protection against disclosure.

10 “(2) NOTIFICATION.—

11 “(A) IN GENERAL.—Except as provided in
12 subparagraph (B) and subsections (c), (e), and
13 (f), if the Administrator denies or modifies a
14 claim under paragraph (1), the Administrator
15 shall notify, in writing and by certified mail, the
16 person that submitted the claim of the intent of
17 the Administrator to release the information.

18 “(B) RELEASE OF INFORMATION.—

19 “(i) IN GENERAL.—Except as pro-
20 vided in clause (ii), the Administrator shall
21 not release information under this sub-
22 section until the date that is 30 days after
23 the date on which the person that sub-
24 mitted the request receives notification
25 under subparagraph (A).

1 “(ii) EXCEPTIONS.—

2 “(I) IN GENERAL.—For informa-
3 tion under paragraph (3) or (8) of
4 subsection (e), the Administrator shall
5 not release that information until the
6 date that is 15 days after the date on
7 which the person that submitted the
8 claim receives a notification, unless
9 the Administrator determines that re-
10 lease of the information is necessary
11 to protect against an imminent and
12 substantial harm to health or the en-
13 vironment, in which case no prior no-
14 tification shall be necessary.

15 “(II) NO NOTIFICATION.—For
16 information under paragraph (1), (2),
17 (6), (7), or (9) of subsection (e), no
18 prior notification shall be necessary.

19 “(3) APPEALS.—

20 “(A) IN GENERAL.—If a person receives a
21 notification under paragraph (2) and believes
22 disclosure of the information is prohibited
23 under subsection (a), before the date on which
24 the information is to be released, the person

1 may bring an action to restrain disclosure of
2 the information in—

3 “(i) the United States district court of
4 the district in which the complainant re-
5 sides or has the principal place of business;
6 or

7 “(ii) the United States District Court
8 for the District of Columbia.

9 “(B) NO DISCLOSURE.—The Adminis-
10 trator shall not disclose any information that is
11 the subject of an appeal under this section be-
12 fore the date on which the applicable court
13 rules on an action under subparagraph (A).

14 “(4) ADMINISTRATION.—In carrying out this
15 subsection, the Administrator shall use the proce-
16 dures described in part 2 of title 40, Code of Fed-
17 eral Regulations (or successor regulations).

18 “(h) CRIMINAL PENALTY FOR WRONGFUL DISCLO-
19 SURE.—

20 “(1) OFFICERS AND EMPLOYEES OF UNITED
21 STATES.—

22 “(A) IN GENERAL.—Subject to paragraph
23 (2), a current or former officer or employee of
24 the United States described in subparagraph
25 (B) shall be guilty of a misdemeanor and fined

1 under title 18, United States Code, or impris-
2 oned for not more than 1 year, or both.

3 “(B) DESCRIPTION.—A current or former
4 officer or employee of the United States re-
5 ferred to in subparagraph (A) is a current or
6 former officer or employee of the United States
7 who—

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

12 “(ii) knowing that disclosure of that
13 material is prohibited by subsection (a),
14 willfully discloses the material in any man-
15 ner to any person not entitled to receive
16 that material.

17 “(2) OTHER LAWS.—Section 1905 of title 18,
18 United States Code, shall not apply with respect to
19 the publishing, divulging, disclosure, making known
20 of, or making available, information reported or oth-
21 erwise obtained under this Act.

22 “(3) CONTRACTORS.—For purposes of this sub-
23 section, any contractor of the United States that is
24 provided information in accordance with subsection
25 (e)(2), including any employee of that contractor,

1 shall be considered to be an employee of the United
2 States.

3 “(i) APPLICABILITY.—

4 “(1) IN GENERAL.—Except as otherwise pro-
5 vided in this section, section 8, or any other applica-
6 ble Federal law, the Administrator shall have no au-
7 thority—

8 “(A) to require the substantiation or re-
9 substantiation of a claim for the protection
10 from disclosure of information submitted to the
11 Administrator under this Act before the date of
12 enactment of the Frank R. Lautenberg Chem-
13 ical Safety for the 21st Century Act; or

14 “(B) to impose substantiation or re-
15 substantiation requirements under this Act that
16 are more extensive than those required under
17 this section.

18 “(2) PRIOR ACTIONS.—Nothing in this Act pre-
19 vents the Administrator from reviewing, requiring
20 substantiation or resubstantiation for, or approving,
21 modifying or denying any claim for the protection
22 from disclosure of information before the effective
23 date of such rules applicable to those claims as the
24 Administrator may promulgate after the date of en-

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

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

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

7 “(1) fail or refuse to comply with—

8 “(A) any rule promulgated, consent agree-
9 ment entered into, or order issued under section
10 4;

11 “(B) any requirement under section 5 or 6;

12 “(C) any rule promulgated, consent agree-
13 ment entered into, or order issued under section
14 5 or 6; or

15 “(D) any requirement of, or any rule pro-
16 mulgated or order issued pursuant to title II;”.

17 **SEC. 17. PENALTIES.**

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

20 (1) in subsection (a)(1)—

21 (A) in the first sentence—

22 (i) by inserting “this Act or a rule or
23 order promulgated or issued pursuant to
24 this Act, including” after “a provision of”;

25 and

1 (ii) by striking “\$25,000” and insert-
2 ing “\$37,500”; and

3 (B) in the second sentence, by striking“
4 violation of section 15 or 409” and inserting
5 “violation of this Act”; and

6 (2) in subsection (b)—

7 (A) by striking “Any person who” and in-
8 serting the following:

9 “(1) IN GENERAL.—Any person that”;

10 (B) by striking “section 15 or 409” and
11 inserting “this Act”;

12 (C) by striking “\$25,000” and inserting
13 “\$50,000”; and

14 (D) by adding at the end the following:

15 “(2) IMMINENT DANGER OF DEATH OR SERIOUS
16 BODILY INJURY.—

17 “(A) IN GENERAL.—Any person that
18 knowingly or willfully violates any provision of
19 this Act, and that knows at the time of the vio-
20 lation that the violation places an individual in
21 imminent danger of death or serious bodily in-
22 jury, shall be subject on conviction to a fine of
23 not more than \$250,000, or imprisonment for
24 not more than 15 years, or both.

1 “(B) ORGANIZATIONS.—An organization
2 that commits a violation described in subpara-
3 graph (A) shall be subject on conviction to a
4 fine of not more than \$1,000,000 for each vio-
5 lation.

6 “(3) KNOWLEDGE OF IMMINENT DANGER OR
7 INJURY.—For purposes of determining whether a
8 defendant knew that the violation placed another in-
9 dividual in imminent danger of death or serious bod-
10 ily injury—

11 “(A) the defendant shall be responsible
12 only for actual awareness or actual belief pos-
13 sessed; and

14 “(B) knowledge possessed by an individual
15 may not be attributed to the defendant.”.

16 **SEC. 18. STATE-FEDERAL RELATIONSHIP.**

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

20 “(a) IN GENERAL.—

21 “(1) ESTABLISHMENT OR ENFORCEMENT.—Ex-
22 cept as provided in subsections (c), (d), (e), (f), and
23 (g), and subject to paragraph (2), no State or polit-
24 ical subdivision of a State may establish or continue
25 to enforce any of the following:

1 “(A) TESTING AND INFORMATION COLLEC-
2 TION.—A statute or administrative action to re-
3 quire the development of information on a
4 chemical substance or category of substances
5 that is reasonably likely to produce the same in-
6 formation required under section 4, 5, or 6 in—

7 “(i) a rule promulgated by the Admin-
8 istrator;

9 “(ii) a testing consent agreement en-
10 tered into by the Administrator; or

11 “(iii) an order issued by the Adminis-
12 trator.

13 “(B) CHEMICAL SUBSTANCES FOUND TO
14 MEET THE SAFETY STANDARD OR RE-
15 STRICTED.—A statute or administrative action
16 to prohibit or otherwise restrict the manufac-
17 ture, processing, or distribution in commerce or
18 use of a chemical substance—

19 “(i) found to meet the safety standard
20 and consistent with the scope of the deter-
21 mination made under section 6; or

22 “(ii) found not to meet the safety
23 standard, after the effective date of the
24 rule issued under section 6(d) for the sub-

1 stance, consistent with the scope of the de-
2 termination made by the Administrator.

3 “(C) SIGNIFICANT NEW USE.—A statute or
4 administrative action requiring the notification
5 of a use of a chemical substance that the Ad-
6 ministrator has specified as a significant new
7 use and for which the Administrator has re-
8 quired notification pursuant to a rule promul-
9 gated under section 5.

10 “(2) EFFECTIVE DATE OF PREEMPTION.—
11 Under this subsection, Federal preemption of State
12 statutes and administrative actions applicable to spe-
13 cific substances shall not occur until the effective
14 date of the applicable action described in paragraph
15 (1) taken by the Administrator.

16 “(b) NEW STATUTES OR ADMINISTRATIVE ACTIONS
17 CREATING PROHIBITIONS OR OTHER RESTRICTIONS.—
18 Except as provided in subsections (c), (d), and (e), no
19 State or political subdivision of a State may establish
20 (after the date of enactment of the Frank R. Lautenberg
21 Chemical Safety for the 21st Century Act) a statute or
22 administrative action prohibiting or restricting the manu-
23 facture, processing, distribution in commerce or use of a
24 chemical substance that is a high-priority substance des-
25 ignated under section 4A, as of the date on which the Ad-

1 administrator commences a safety assessment under section
2 6.

3 “(c) SCOPE OF PREEMPTION.—Federal preemption
4 under subsections (a) and (b) of State statutes and admin-
5 istrative actions applicable to specific substances shall
6 apply only to—

7 “(1) the chemical substances or category of
8 substances subject to a rule, order, or consent agree-
9 ment under section 4;

10 “(2) the uses or conditions of use of such sub-
11 stances that are identified by the Administrator as
12 subject to review in a safety assessment and in-
13 cluded in the scope of the safety determination made
14 by the Administrator for the substance, or of any
15 rule the Administrator promulgates pursuant to sec-
16 tion 6(d); or

17 “(3) the uses of such substances that the Ad-
18 ministrator has specified as significant new uses and
19 for which the Administrator has required notifica-
20 tion pursuant to a rule promulgated under section 5.

21 “(d) EXCEPTIONS.—

22 “(1) IN GENERAL.—Subsections (a) and (b)
23 shall not apply to a statute or administrative action
24 of a State or a political subdivision of a State appli-
25 cable to a specific chemical substance that—

1 “(A) is adopted under the authority of, or
2 authorized to comply with, any other Federal
3 law;

4 “(B) implements a reporting, monitoring,
5 or other information collection obligation for
6 the chemical substance not otherwise required
7 by the Administrator under this Act or required
8 under any other Federal law; or

9 “(C) is adopted pursuant to authority
10 under a law of the State or political subdivision
11 of the State related to water quality, air qual-
12 ity, or waste treatment or disposal, unless the
13 action taken by the State or political subdivi-
14 sion of a State—

15 “(i) imposes a restriction on the man-
16 ufacture, processing, distribution in com-
17 merce, or use of a chemical substance; and

18 “(ii)(I) is already required by a deci-
19 sion by the Administrator under section 5
20 or 6;

21 “(II) is taken to address a health or
22 environmental concern that applies to the
23 uses or conditions of use that are included
24 in the scope of a safety determination pur-
25 suant to section 6 or the scope of a signifi-

1 cant new use rule promulgated pursuant to
2 section 5, but is inconsistent with the ac-
3 tion of the Administrator; or

4 “(III) would cause a violation of the
5 applicable action by the Administrator
6 under section 5 or 6.

7 “(2) NO PREEMPTION OF STATE STATUTES
8 AND ADMINISTRATIVE ACTIONS.—Nothing in this
9 Act, nor any amendment made by this Act, nor any
10 rule, standard of performance, safety determination,
11 or scientific assessment implemented pursuant to
12 this Act, shall affect the right of a State or a polit-
13 ical subdivision of a State to adopt or enforce any
14 rule, standard of performance, safety determination,
15 scientific assessment, or any protection for public
16 health or the environment that—

17 “(A) is adopted under the authority of, or
18 authorized to comply with, any other Federal
19 law;

20 “(B) implements a reporting, monitoring,
21 or other information collection obligation for
22 the chemical substance not otherwise required
23 by the Administrator under this Act or required
24 under any other Federal law; or

1 “(C) is adopted pursuant to authority
2 under a law of the State or political subdivision
3 of the State related to water quality, air qual-
4 ity, or waste treatment or disposal, unless the
5 action taken by the State or political subdivi-
6 sion of a State—

7 “(i) imposes a restriction on the man-
8 ufacture, processing, distribution in com-
9 merce, or use of a chemical substance; and

10 “(ii)(I) is already required by a deci-
11 sion by the Administrator under section 5
12 or 6;

13 “(II) is taken to address a health or
14 environmental concern that applies to the
15 uses or conditions of use that are included
16 in the scope of a safety determination pur-
17 suant to section 6 or the scope of a signifi-
18 cant new use rule promulgated pursuant to
19 section 5, but is inconsistent with the ac-
20 tion of the Administrator; or

21 “(III) would cause a violation of the
22 applicable action by the Administrator
23 under section 5 or 6.

24 “(3) APPLICABILITY TO CERTAIN RULES OR OR-
25 DERS.—Notwithstanding subsection (e)—

1 “(A) nothing in this section shall be con-
2 strued as modifying the effect under this sec-
3 tion, as in effect on the day before the effective
4 date of the Frank R. Lautenberg Chemical
5 Safety for the 21st Century Act, of any rule or
6 order promulgated or issued under this Act
7 prior to that effective date; and

8 “(B) with respect to a chemical substance
9 or mixture for which any rule or order was pro-
10 mulgated or issued under section 6 prior to the
11 effective date of the Frank R. Lautenberg
12 Chemical Safety for the 21st Century Act with
13 regards to manufacturing, processing, distribu-
14 tion in commerce, use, or disposal of a chemical
15 substance, this section (as in effect on the day
16 before the effective date of the Frank R. Lau-
17 tenberg Chemical Safety for the 21st Century
18 Act) shall govern the preemptive effect of any
19 rule or order that is promulgated or issued re-
20 specting such chemical substance or mixture
21 under section 6 of this Act after that effective
22 date, unless the latter rule or order is with re-
23 spect to a chemical substance or mixture con-
24 taining a chemical substance and follows a des-
25 ignation of that chemical substance as a high-

1 priority substance under subsection (b) or (c) of
2 section 4A or as an additional priority for safe-
3 ty assessment and safety determination under
4 section 4A(d).

5 “(e) PRESERVATION OF CERTAIN STATE LAW.—

6 “(1) IN GENERAL.—Nothing in this Act, sub-
7 ject to subsection (g) of this section, shall—

8 “(A) be construed to preempt or otherwise
9 affect any action taken before January 1, 2015,
10 under the authority of a State law that pro-
11 hibits or otherwise restricts manufacturing,
12 processing, distribution in commerce, use, or
13 disposal of a chemical substance; or

14 “(B) be construed to preempt or otherwise
15 affect any action taken pursuant to a State law
16 that was in effect on August 31, 2003.

17 “(2) EFFECT OF SUBSECTION.—This sub-
18 section does not affect, modify, or alter the relation-
19 ship between State and Federal law pursuant to any
20 other Federal law.

21 “(f) STATE WAIVERS.—

22 “(1) IN GENERAL.—Upon application of a State
23 or political subdivision of a State, the Administrator
24 may—

1 “(A) by rule, exempt from subsection (a),
2 under such conditions as may be prescribed in
3 the rule, a statute or administrative action of
4 that State or political subdivision of the State
5 that relates to the effects of, or exposure to, a
6 chemical substance under the conditions of use
7 if the Administrator determines that—

8 “(i) compelling State or local condi-
9 tions warrant granting the waiver to pro-
10 tect health or the environment;

11 “(ii) compliance with the proposed re-
12 quirement of the State or political subdivi-
13 sion of the State would not unduly burden
14 interstate commerce in the manufacture,
15 processing, distribution in commerce, or
16 use of a chemical substance;

17 “(iii) compliance with the proposed re-
18 quirement of the State or political subdivi-
19 sion of the State would not cause a viola-
20 tion of any applicable Federal law, rule, or
21 order; and

22 “(iv) based on the judgment of the
23 Administrator, the proposed requirement
24 of the State or political subdivision of the
25 State is consistent with sound objective sci-

1 entific practices, the weight of the evi-
2 dence, and the best available science; or

3 “(B) exempt from subsection (b) a statute
4 or administrative action of a State or political
5 subdivision of a State that relates to the effects
6 of exposure to a chemical substance under the
7 conditions of use if the Administrator deter-
8 mines that—

9 “(i) the State has a compelling local
10 interest that warrants granting the waiver
11 to protect health or the environment;

12 “(ii) compliance with the proposed re-
13 quirement of the State will not unduly bur-
14 den interstate commerce in the manufac-
15 ture, processing, distribution in commerce,
16 or use of a chemical substance;

17 “(iii) compliance with the proposed re-
18 quirement would not cause a violation of
19 any applicable Federal law, rule, or order;
20 and

21 “(iv) the proposed requirement is
22 grounded in reasonable scientific concern.

23 “(2) APPROVAL OF A STATE WAIVER RE-
24 QUEST.—The Administrator shall grant or deny a
25 waiver application—

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

4 “(B) not later than 90 days after the date
5 on which an application under paragraph
6 (1)(B) is submitted.

7 “(3) NOTICE AND COMMENT.—The application
8 of a State or political subdivision of the State shall
9 be subject to public notice and comment.

10 “(4) FINAL AGENCY ACTION.—The decision of
11 the Administrator on the application of a State or
12 political subdivision of the State shall be—

13 “(A) considered to be a final agency ac-
14 tion; and

15 “(B) subject to judicial review.

16 “(5) DURATION OF WAIVERS.—A waiver grant-
17 ed under paragraph (1)(B) shall remain in effect
18 until the later of—

19 “(A) such time as the safety assessment
20 and safety determination is completed; and

21 “(B) the date on which compliance with an
22 applicable rule issued under section 6(d) is re-
23 quired.

24 “(6) JUDICIAL REVIEW OF WAIVERS.—Not later
25 than 60 days after the date on which the Adminis-

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

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

21 “(g) SAVINGS.—

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

1 “(A) IN GENERAL.—Nothing in this Act,
2 nor any amendment made by this Act, nor any
3 safety standard, rule, requirement, standard of
4 performance, safety determination, or scientific
5 assessment implemented pursuant to this Act,
6 shall be construed to preempt, displace, or sup-
7 plant any state or Federal common law rights
8 or any state or Federal statute creating a rem-
9 edy for civil relief, including those for civil dam-
10 age, or a penalty for a criminal conduct.

11 “(B) CLARIFICATION OF NO PREEMP-
12 TION.—Notwithstanding any other provision of
13 this Act, nothing in this Act, nor any amend-
14 ments made by this Act, shall preempt or pre-
15 clude any cause of action for personal injury,
16 wrongful death, property damage, or other in-
17 jury based on negligence, strict liability, prod-
18 ucts liability, failure to warn, or any other legal
19 theory of liability under any State law, mari-
20 time law, or Federal common law or statutory
21 theory.

22 “(2) NO EFFECT ON PRIVATE REMEDIES.—

23 “(A) Nothing in this Act, nor any amend-
24 ments made by this Act, nor any rules, regula-
25 tions, requirements, safety assessments, safety

1 determinations, scientific assessments, or orders
2 issued pursuant to this Act shall be interpreted
3 as, in either the plaintiff’s or defendant’s favor,
4 dispositive in any civil action.

5 “(B) This Act does not affect the authority
6 of any court to make a determination in an ad-
7 judicatory proceeding under applicable State or
8 Federal law with respect to the admission into
9 evidence or any other use of this Act or rules,
10 regulations, requirements, standards of per-
11 formance, safety assessments, scientific assess-
12 ments, or orders issued pursuant to this Act.”.

13 **SEC. 19. JUDICIAL REVIEW.**

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

16 (1) in subsection (a)—

17 (A) in paragraph (1)—

18 (i) in subparagraph (A), by striking
19 “section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e),
20 or 8, or under title II or IV” and inserting
21 “section 4(a), 5(d), 6(c), 6(d), 6(g), or 8,
22 or title II or IV”; and

23 (ii) in subparagraph (B), by striking
24 “an order issued under subparagraph (A)

1 or (B) of section 6(b)(1)” and inserting
2 “an order issued under this title”; and

3 (B) in paragraph (2), in the first sentence,
4 by striking “paragraph (1)(A)” and inserting
5 “paragraph (1)”; and

6 (C) by striking paragraph (3); and

7 (2) in subsection (c)(1)(B)—

8 (A) in clause (i)—

9 (i) by striking “section 4(a), 5(b)(4),
10 6(a), or 6(e)” and inserting “section 4(a),
11 5(d), 6(d), or 6(g)”; and

12 (ii) by striking “evidence in the rule-
13 making record (as defined in subsection
14 (a)(3)) taken as a whole;” and inserting
15 “evidence (including any matter) in the
16 rulemaking record, taken as a whole; and”;
17 and

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

21 “(ii) the court may not review the
22 contents and adequacy of any statement of
23 basis and purpose required by section
24 553(e) of title 5, United States Code, to be

1 incorporated in the rule, except as part of
2 the rulemaking record, taken as a whole.”.

3 **SEC. 20. CITIZENS’ PETITIONS.**

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

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

9 (2) in subsection (b)—

10 (A) in paragraph (1), by striking “an
11 order under section 5(e), 6(b)(1)(A), or
12 6(b)(1)(B)” and inserting “an order under sec-
13 tion 4 or 5(d)”; and

14 (B) in paragraph (4), by striking subpara-
15 graph (B) and inserting the following:

16 “(B) DE NOVO PROCEEDING.—

17 “(i) IN GENERAL.—In an action
18 under subparagraph (A) to initiate a pro-
19 ceeding to promulgate a rule pursuant to
20 section 4, 5, 6, or 8 or an order issued
21 under section 4 or 5, the petitioner shall be
22 provided an opportunity to have the peti-
23 tion considered by the court in a de novo
24 proceeding.

25 “(ii) DEMONSTRATION.—

1 “(I) IN GENERAL.—The court in
2 a de novo proceeding under this sub-
3 paragraph shall order the Adminis-
4 trator to initiate the action requested
5 by the petitioner if the petitioner dem-
6 onstrates to the satisfaction of the
7 court by a preponderance of the evi-
8 dence that—

9 “(aa) in the case of a peti-
10 tion to initiate a proceeding for
11 the issuance of a rule or order
12 under section 4, the information
13 available to the Administrator is
14 insufficient for the Administrator
15 to perform an action described in
16 section 4, 4A, 5, or 6(d);

17 “(bb) in the case of a peti-
18 tion to issue an order under sec-
19 tion 5(d), there is a reasonable
20 basis to conclude that the chem-
21 ical substance is not likely to
22 meet the safety standard;

23 “(cc) in the case of a peti-
24 tion to initiate a proceeding for
25 the issuance of a rule under sec-

1 tion 6(d), there is a reasonable
2 basis to conclude that the chem-
3 ical substance will not meet the
4 safety standard; or

5 “(dd) in the case of a peti-
6 tion to initiate a proceeding for
7 the issuance of a rule under sec-
8 tion 8, there is a reasonable basis
9 to conclude that the rule is nec-
10 essary to protect health or the
11 environment or ensure that the
12 chemical substance meets the
13 safety standard.

14 “(II) DEFERMENT.—The court
15 in a de novo proceeding under this
16 subparagraph may permit the Admin-
17 istrator to defer initiating the action
18 requested by the petitioner until such
19 time as the court prescribes, if the
20 court finds that—

21 “(aa) the extent of the risk
22 to health or the environment al-
23 leged by the petitioner is less
24 than the extent of risks to health
25 or the environment with respect

1 to which the Administrator is
2 taking action under this Act; and

3 “(bb) there are insufficient
4 resources available to the Admin-
5 istrator to take the action re-
6 quested by the petitioner.”.

7 **SEC. 21. EMPLOYMENT EFFECTS.**

8 Section 24(b)(2)(B)(ii) of the Toxic Substances Con-
9 trol Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by
10 striking “section 6(c)(3),” and inserting “the applicable
11 requirements of this Act;”.

12 **SEC. 22. STUDIES.**

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

15 **SEC. 23. ADMINISTRATION.**

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

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

20 “(b) FEES.—

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

1 “(A) the payment of 1 or more reasonable
2 fees as a condition of submitting a notice or re-
3 questing an exemption under section 5; and

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

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

10 “(ii) is required to submit a notice
11 pursuant to section 8(b)(5)(B)(i) changing
12 the status of a chemical substance from in-
13 active to active;

14 “(iii) is required to report information
15 pursuant to the rules promulgated under
16 section 8(a)(4); and

17 “(iv) manufactures or processes a
18 chemical substance subject to a safety as-
19 sessment and safety determination pursu-
20 ant to section 6.

21 “(2) UTILIZATION AND COLLECTION OF
22 FEES.—The Administrator shall—

23 “(A) utilize the fees collected under para-
24 graph (1) only to defray costs associated with
25 the actions of the Administrator—

1 “(i) to collect, process, review, provide
2 access to, and protect from disclosure
3 (where appropriate) information on chem-
4 ical substances under this Act;

5 “(ii) to review notices and make de-
6 terminations for chemical substances under
7 paragraphs (1) and (3) of section 5(d) and
8 impose any necessary restrictions under
9 section 5(d)(4);

10 “(iii) to make prioritization decisions
11 under section 4A;

12 “(iv) to conduct and complete safety
13 assessments and determinations under sec-
14 tion 6; and

15 “(v) to conduct any necessary rule-
16 making pursuant to section 6(d);

17 “(B) insofar as possible, collect the fees
18 described in paragraph (1) in advance of con-
19 ducting any fee-supported activity;

20 “(C) deposit the fees in the Fund estab-
21 lished by paragraph (4)(A); and

22 “(D) not collect excess fees or retain a sig-
23 nificant amount of unused fees.

1 “(3) AMOUNT AND ADJUSTMENT OF FEES; RE-
2 FUNDS.—In setting fees under this section, the Ad-
3 ministrator shall—

4 “(A) take into account the cost to the Ad-
5 ministrator of conducting the activities de-
6 scribed in paragraph (2);

7 “(B) prescribe lower fees for small busi-
8 ness concerns, after consultation with the Ad-
9 ministrator of the Small Business Administra-
10 tion;

11 “(C) set the fees established under para-
12 graph (1) at levels such that the fees will, in
13 aggregate, provide a sustainable source of funds
14 to defray approximately 25 percent of the costs
15 of conducting the activities identified in para-
16 graph (2)(A), not to exceed \$18,000,000, not
17 including fees under subparagraph (E) of this
18 paragraph;

19 “(D) reflect an appropriate balance in the
20 assessment of fees between manufacturers and
21 processors, and allow the payment of fees by
22 consortia of manufacturers or processors;

23 “(E) for substances designated as addi-
24 tional priorities pursuant to section 4A(c), es-
25 tablish the fee at a level sufficient to defray the

1 full costs to the Administrator of conducting
2 the safety assessment and safety determination
3 under section 6;

4 “(F) 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 “(G) 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, in-
19 crease or decrease the fees established under
20 paragraph (1) as necessary—

21 “(i) to ensure that funds deposited in
22 the Fund are sufficient to conduct the ac-
23 tivities identified in paragraph (2)(A) and
24 the full costs of safety assessments and

1 safety determinations pursuant to subpara-
2 graph (E); and

3 “(ii) to account for inflation;

4 “(H) adjust fees established under para-
5 graph (1) as necessary to vary on account of
6 differing circumstances, including reduced fees
7 or waivers in appropriate circumstances, to re-
8 duce the burden on manufacturing or proc-
9 essing, remove barriers to innovation, or where
10 the costs to the Administrator of collecting the
11 fees exceed the fee revenue anticipated to be
12 collected; and

13 “(I) if a notice submitted under section 5
14 is refused or subsequently withdrawn, refund
15 the fee or a portion of the fee if no substantial
16 work was performed on the notice.

17 “(4) TSCA IMPLEMENTATION FUND.—

18 “(A) ESTABLISHMENT.—There is estab-
19 lished in the Treasury of the United States a
20 fund, to be known as the ‘TSCA Implementa-
21 tion Fund’ (referred to in this subsection as the
22 ‘Fund’), consisting of—

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

1 “(ii) any interest earned on the in-
2 vestment of amounts in the Fund; and

3 “(iii) any proceeds from the sale or
4 redemption of investments held in the
5 Fund.

6 “(B) CREDITING AND AVAILABILITY OF
7 FEES.—

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

14 “(ii) REQUIREMENTS.—Fees collected
15 under this section shall not—

16 “(I) be made available or obli-
17 gated for any purpose other than to
18 defray the costs of conducting the ac-
19 tivities identified in paragraph (2)(A);

20 “(II) otherwise be available for
21 any purpose other than implementa-
22 tion of this Act; and

23 “(III) so long as amounts in the
24 Fund remain available, be subject to

1 restrictions on expenditures applicable
2 to the Federal government as a whole.

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

6 “(i) maintained readily available or on
7 deposit;

8 “(ii) invested in obligations of the
9 United States or guaranteed by the United
10 States; or

11 “(iii) invested in obligations, partici-
12 pations, or other instruments that are law-
13 ful investments for fiduciary, trust, or pub-
14 lic funds.

15 “(D) MINIMUM AMOUNT OF APPROPRIA-
16 TIONS.—Fees may not be assessed for a fiscal
17 year under this section unless the amount of
18 appropriations for salaries, contracts, and ex-
19 penses for the functions (as in existence in fis-
20 cal year 2015) of the Office of Pollution Pre-
21 vention and Toxics of the Environmental Pro-
22 tection Agency for the fiscal year (excluding the
23 amount of any fees appropriated for the fiscal
24 year) are equal to or greater than the amount
25 of appropriations for covered functions for fiscal

1 year 2015 (excluding the amount of any fees
2 appropriated for the fiscal year).

3 “(5) AUDITING.—

4 “(A) FINANCIAL STATEMENTS OF AGEN-
5 CIES.—For the purpose of section 3515(c) of
6 title 31, United States Code, the Fund shall be
7 considered a component of an executive agency.

8 “(B) COMPONENTS.—The annual audit re-
9 quired under sections 3515(b) and 3521 of that
10 title of the financial statements of activities
11 under this subsection shall include an analysis
12 of—

13 “(i) the fees collected under para-
14 graph (1) and disbursed;

15 “(ii) compliance with the deadlines es-
16 tablished in section 6 of this Act;

17 “(iii) the amounts budgeted, appro-
18 priated, collected from fees, and disbursed
19 to meet the requirements of sections 4, 4A,
20 5, 6, 8, and 14, including the allocation of
21 full time equivalent employees to each such
22 section or activity; and

23 “(iv) the reasonableness of the alloca-
24 tion of the overhead associated with the

1 conduct of the activities described in para-
2 graph (2)(A).

3 “(C) INSPECTOR GENERAL.—The Inspec-
4 tor General of the Environmental Protection
5 Agency shall—

6 “(i) conduct the annual audit required
7 under this subsection; and

8 “(ii) report the findings and rec-
9 ommendations of the audit to the Adminis-
10 trator and to the appropriate committees
11 of Congress.

12 “(6) TERMINATION.—The authority provided by
13 this section shall terminate at the conclusion of the
14 fiscal year that is 10 years after the date of enact-
15 ment of the Frank R. Lautenberg Chemical Safety
16 for the 21st Century Act, unless otherwise reauthor-
17 ized or modified by Congress.”;

18 (2) in subsection (e), by striking “Health, Edu-
19 cation, and Welfare” each place it appears and in-
20 serting “Health and Human Services”; and

21 (3) adding at the end the following:

22 “(h) PRIOR ACTIONS.—Nothing in this Act elimi-
23 nates, modifies, or withdraws any rule promulgated, order
24 issued, or exemption established pursuant to this Act be-

1 fore the date of enactment of the Frank R. Lautenberg
2 Chemical Safety for the 21st Century Act.”.

3 **SEC. 24. DEVELOPMENT AND EVALUATION OF TEST METH-**
4 **ODS AND SUSTAINABLE CHEMISTRY.**

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

7 (1) in subsection (a), in the first sentence by
8 striking “Health, Education, and Welfare” and in-
9 serting “Health and Human Services”; and

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

11 “(c) SUSTAINABLE CHEMISTRY PROGRAM.—The
12 President shall establish an interagency Sustainable
13 Chemistry Program to promote and coordinate Federal
14 sustainable chemistry research, development, demonstra-
15 tion, technology transfer, commercialization, education,
16 and training activities.

17 “(d) PROGRAM ACTIVITIES.—The activities of the
18 Program shall be designed to—

19 “(1) provide sustained support for sustainable
20 chemistry research, development, demonstration,
21 technology transfer, commercialization, education,
22 and training through—

23 “(A) coordination of sustainable chemistry
24 research, development, demonstration, and tech-

1 nology transfer conducted at Federal labora-
2 tories and agencies; and

3 “(B) to the extent practicable, encourage-
4 ment of consideration of sustainable chemistry
5 in, as appropriate—

6 “(i) the conduct of Federal and State
7 science and engineering research and de-
8 velopment; and

9 “(ii) the solicitation and evaluation of
10 applicable proposals for science and engi-
11 neering research and development;

12 “(2) examine methods by which the Federal
13 Government can create incentives for consideration
14 and use of sustainable chemistry processes and prod-
15 ucts, including innovative financing mechanisms;

16 “(3) expand the education and training of un-
17 dergraduate and graduate students and professional
18 scientists and engineers, including through partner-
19 ships with industry, in sustainable chemistry science
20 and engineering;

21 “(4) collect and disseminate information on sus-
22 tainable chemistry research, development, and tech-
23 nology transfer including information on—

24 “(A) incentives and impediments to devel-
25 opment, manufacturing, and commercialization;

1 “(B) accomplishments;

2 “(C) best practices; and

3 “(D) costs and benefits; and

4 “(5) support (including through technical as-
5 sistance, participation, financial support, or other
6 forms of support) economic, legal, and other appro-
7 priate social science research to identify barriers to
8 commercialization and methods to advance commer-
9 cialization of sustainable chemistry.

10 “(e) INTERAGENCY WORKING GROUP.—

11 “(1) ESTABLISHMENT.—Not later than 180
12 days after the date of enactment of the Frank R.
13 Lautenberg Chemical Safety for the 21st Century
14 Act, the President, in consultation with the Office of
15 Science and Technology Policy, shall establish an
16 Interagency Working Group that shall include rep-
17 resentatives from the National Science Foundation,
18 the National Institute of Standards and Technology,
19 the Department of Energy, the Environmental Pro-
20 tection Agency, the Department of Agriculture, the
21 Department of Defense, the National Institutes of
22 Health, and any other agency that the President
23 may designate to oversee the planning, management,
24 and coordination of the Program.

1 “(2) GOVERNANCE.—The Director of the Na-
2 tional Science Foundation and the Assistant Admin-
3 istrator for Research and Development of the Envi-
4 ronmental Protection Agency, or their designees,
5 shall serve as co-chairs of the Interagency Working
6 Group.

7 “(3) RESPONSIBILITIES.—In overseeing the
8 planning, management, and coordination of the Pro-
9 gram, the Interagency Working Group shall—

10 “(A) establish goals and priorities for the
11 Program, in consultation with the Advisory
12 Council;

13 “(B) provide for interagency coordination,
14 including budget coordination, of activities
15 under the Program;

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

18 “(D) establish and consult with an Advi-
19 sory Council on a regular basis.

20 “(4) MEMBERSHIP.—The Advisory Council
21 members shall not be employees of the Federal Gov-
22 ernment and shall include a diverse representation of
23 knowledgeable individuals from the private sector
24 (including small- and medium-sized enterprises from
25 across the value chain), academia, State and tribal

1 governments, and nongovernmental organizations
2 and others who are in a position to provide exper-
3 tise.

4 “(f) AGENCY BUDGET REQUESTS.—

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

10 “(A) identifies the activities of the agency
11 or department that contribute directly to the
12 Program; and

13 “(B) states the portion of the agency or
14 department’s request for appropriations that is
15 allocated to those activities.

16 “(2) ANNUAL BUDGET REQUEST TO CON-
17 GRESS.—The President shall include in the annual
18 budget request to Congress a statement of the por-
19 tion of the annual budget request for each agency or
20 department that will be allocated to activities under-
21 taken pursuant to the Program.

22 “(g) REPORT TO CONGRESS.—

23 “(1) IN GENERAL.—Not later than 2 years
24 after the date of enactment of the Frank R. Lauten-
25 berg Chemical Safety for the 21st Century Act, the

1 Interagency Working Group shall submit a report to
2 the Committee on Science, Space, and Technology
3 and Committee on Energy and Commerce of the
4 House of Representatives and the Committee on En-
5 vironment and Public Works and the Committee on
6 Commerce, Science, and Transportation of the Sen-
7 ate that shall include—

8 “(A) a summary of federally funded sus-
9 tainable chemistry research, development, dem-
10 onstration, technology transfer, commercializa-
11 tion, education, and training activities;

12 “(B) a summary of the financial resources
13 allocated to sustainable chemistry initiatives;

14 “(C) an analysis of the progress made to-
15 ward achieving the goals and priorities of this
16 Act, and recommendations for future program
17 activities;

18 “(D) an assessment of the benefits of ex-
19 panding existing, federally supported regional
20 innovation and manufacturing hubs to include
21 sustainable chemistry and the value of directing
22 the creation of 1 or more dedicated sustainable
23 chemistry centers of excellence or hubs; and

24 “(E) an evaluation of steps taken and fu-
25 ture strategies to avoid duplication of efforts,

1 streamline interagency coordination, facilitate
2 information sharing, and spread best practices
3 between participating agencies in the Program.

4 “(2) SUBMISSION TO GAO.—The Interagency
5 Working Group shall also submit the report de-
6 scribed in paragraph (1) to the Government Ac-
7 countability Office for consideration in future Con-
8 gressional inquiries.”.

9 **SEC. 25. STATE PROGRAMS.**

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

12 (1) in subsection (b)(1)—

13 (A) in subparagraphs (A) through (D), by
14 striking the comma at the end of each subpara-
15 graph and inserting a semicolon; and

16 (B) in subparagraph (E), by striking “,
17 and” and inserting “; and”; and

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

19 **SEC. 26. AUTHORIZATION OF APPROPRIATIONS.**

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

22 **SEC. 27. ANNUAL REPORT.**

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

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

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

7 **SEC. 28. EFFECTIVE DATE.**

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

10 (1) by striking “Except as provided in section
11 4(f), this” and inserting the following:

12 “(a) **IN GENERAL.**—This”; and

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

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

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