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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, Mr. PORTMAN, Mr. WARNER, Mr. PETERS, Mr. ROUNDS, Mr. BROWN, Mr. THUNE, Mr. BARRASSO, Mr. BOOKER, Mr. CORNYN, Mr. COTTON, Mr. ISAKSON, Mr. KAINE, Mrs. MCCASKILL, Mr. MERKLEY, Ms. MURKOWSKI, Mr. MURPHY, Mr. RUBIO, Mr. SCOTT, Mrs. SHAHEEN, Mr. WHITEHOUSE, Mr. CASEY, Mr. PERDUE, Ms. KLOBUCHAR, Mr. COATS, and Mr. TOOMEY) introduced the following bill; which was read twice and referred to the Committee on Environment and Public Works

JUNE 17, 2015

Reported by Mr. INHOFE, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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,*

1 **SECTION 1. SHORT TITLE.**

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

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

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

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

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

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

13 (3) by adding at the following:

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

18 “(A) shall be administered in a manner
19 that—

20 “(i) protects the health of children,
21 pregnant women, the elderly, workers, con-
22 sumers, the general public, and the envi-
23 ronment from the risks of harmful expo-
24 sures to chemical substances and mixtures;
25 and

1 “(ii) ensures that appropriate infor-
2 mation on chemical substances and mix-
3 tures is available to public health officials
4 and first responders in the event of an
5 emergency; and

6 “(B) shall not displace or supplant com-
7 mon law rights of action or remedies for civil
8 relief.”.

9 **SEC. 3. DEFINITIONS.**

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

12 (1) by redesignating paragraphs (4), (5), (6),
13 (7), (8), (9), (10), (11), (12), (13), and (14) as
14 paragraphs (5), (6), (7), (8), (9), (10), (12), (13),
15 (17), (18), and (19), respectively;

16 (2) by inserting after paragraph (3) the fol-
17 lowing:

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

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

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

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

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

8 “(ii) susceptible to greater adverse
9 health consequences from chemical expo-
10 sures than the general population; and

11 “(B) that when identified by the Adminis-
12 trator may include such groups as infants, chil-
13 dren, pregnant women, workers, and the elder-
14 ly.”; and

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

17 “(14) SAFETY ASSESSMENT.—The term ‘safety
18 assessment’ means an assessment of the risk posed
19 by a chemical substance under the conditions of use,
20 integrating hazard, use, and exposure information
21 regarding the chemical substance.

22 “(15) SAFETY DETERMINATION.—The term
23 ‘safety determination’ means a determination by the
24 Administrator as to whether a chemical substance

1 meets the safety standard under the conditions of
2 use.

3 “(16) SAFETY STANDARD.—The term ‘safety
4 standard’ means a standard that ensures, without
5 taking into consideration cost or other nonrisk fac-
6 tors, that no unreasonable risk of harm to health or
7 the environment will result from exposure to a chem-
8 ical substance under the conditions of use, including
9 no unreasonable risk of harm to—

10 “(A) the general population; or

11 “(B) any potentially exposed or susceptible
12 population that the Administrator has identified
13 as relevant to the safety assessment and safety
14 determination for a chemical substance.”.

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

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

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

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

22 “(b) DEADLINE.—Not later than 2 years after the
23 date of enactment of the Frank R. Lautenberg Chemical
24 Safety for the 21st Century Act, the Administrator shall
25 develop, after providing public notice and an opportunity

1 for comment, any policies, procedures, and guidance the
 2 Administrator determines to be necessary to carry out sec-
 3 tions 4, 4A, 5, and 6, including the policies, procedures,
 4 and guidance required by this section.

5 “(e) USE OF SCIENCE.—

6 “(1) IN GENERAL.—The Administrator shall es-
 7 tablish policies, procedures, and guidance on the use
 8 of science in making decisions under sections 4, 4A,
 9 5, and 6.

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

13 “(3) REQUIREMENTS.—The policies, proce-
 14 dures, and guidance issued under this section shall
 15 describe the manner in which the Administrator
 16 shall ensure that—

17 “(A) decisions made by the Adminis-
 18 trator—

19 “(i) are based on information, proce-
 20 dures, measures, methods, and models em-
 21 ployed in a manner consistent with the
 22 best available science;

23 “(ii) take into account the extent to
 24 which—

1 “(I) assumptions and methods
2 are clearly and completely described
3 and documented;

4 “(II) variability and uncertainty
5 are evaluated and characterized; and

6 “(III) the information has been
7 subject to independent verification
8 and peer review; and

9 “(iii) are based on the weight of the
10 scientific evidence, by which the Adminis-
11 trator considers all information in a sys-
12 tematic and integrative framework to con-
13 sider the relevance of different informa-
14 tion;

15 “(B) to the extent practicable and if ap-
16 propriate, the use of peer review, standardized
17 test design and methods, consistent data eval-
18 uation procedures, and good laboratory prac-
19 tices will be encouraged;

20 “(C) a clear description of each individual
21 and entity that funded the generation or assess-
22 ment of information, and the degree of control
23 those individuals and entities had over the gen-
24 eration, assessment, and dissemination of infor-
25 mation (including control over the design of the

1 work and the publication of information) is
2 made available; and

3 “(D) if appropriate, the recommendations
4 in reports of the National Academy of Sciences
5 that provide advice regarding assessing the haz-
6 ards, exposures, and risks of chemical sub-
7 stances are considered.

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

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

18 “(1) review the adequacy of any policies, proce-
19 dures, and guidance developed under this section, in-
20 cluding animal, nonanimal, and epidemiological test
21 methods and procedures for assessing and deter-
22 mining risk under this Act; and

23 “(2) after providing public notice and an oppor-
24 tunity for comment, revise the policies, procedures,

1 and guidance if necessary to reflect new scientific
2 developments or understandings.

3 “(f) SOURCES OF INFORMATION.—In making any de-
4 cision with respect to a chemical substance under section
5 4, 4A, 5, or 6, the Administrator shall take into consider-
6 ation information relating to the hazards and exposures
7 of a chemical substance under the conditions of use that
8 is reasonably available to the Administrator, including in-
9 formation that is—

10 “(1) submitted to the Administrator pursuant
11 to any rule, consent agreement, order, or other re-
12 quirement of this Act, or on a voluntary basis, in-
13 cluding pursuant to any request made under this
14 Act, by—

15 “(A) manufacturers or processors of a sub-
16 stance;

17 “(B) the public;

18 “(C) other Federal departments or agen-
19 cies; or

20 “(D) the Governor of a State or a State
21 agency with responsibility for protecting health
22 or the environment;

23 “(2) submitted to a governmental entity in any
24 jurisdiction pursuant to a governmental requirement

1 relating to the protection of health or the environ-
2 ment; or

3 ~~“(3) identified through an active search by the~~
4 Administrator of information sources that are pub-
5 licly available or otherwise accessible by the Admin-
6 istrator.

7 ~~“(g) TESTING OF CHEMICAL SUBSTANCES AND MIX-~~
8 ~~TURES.—~~

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

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

15 ~~“(3) CONTENTS.—The policies and procedures~~
16 ~~established under paragraph (1) shall—~~

17 ~~“(A) address how and when the exposure~~
18 ~~level or exposure potential of a chemical sub-~~
19 ~~stance would factor into decisions to require~~
20 ~~new testing, subject to the condition that the~~
21 ~~Administrator shall not interpret the lack of ex-~~
22 ~~posure information as a lack of exposure or ex-~~
23 ~~posure potential;~~

24 ~~“(B) describe the manner in which the Ad-~~
25 ~~ministrator will determine that additional infor-~~

1 mation is necessary to carry out this Act, in-
2 cluding information relating to potentially ex-
3 posed or susceptible populations;

4 “(C) require the Administrator to consult
5 with the Director of the National Institute for
6 Occupational Safety and Health prior to pre-
7 scribing epidemiologic studies of employees; and

8 “(D) prior to adopting a requirement for
9 testing using vertebrate animals, require the
10 Administrator to take into consideration, as ap-
11 propriate and to the extent practicable, reason-
12 ably available—

13 “(i) toxicity information;

14 “(ii) computational toxicology and
15 bioinformatics;

16 “(iii) high-throughput screening meth-
17 ods and the prediction models of those
18 methods; and

19 “(iv) scientifically reliable and rel-
20 evant alternatives to tests on animals that
21 would provide equivalent information.

22 “(4) TIERED TESTING.—

23 “(A) IN GENERAL.—Except as provided in
24 subparagraph (D), the Administrator shall em-
25 ploy a tiered screening and testing process;

1 under which the results of screening-level tests
2 or assessments of available information inform
3 the decision as to whether 1 or more additional
4 tests are necessary.

5 “(B) SCREENING-LEVEL TESTS.—

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

14 “(ii) USE.—Screening-level tests shall
15 be used—

16 “(I) to screen chemical sub-
17 stances or mixtures for potential ad-
18 verse effects; and

19 “(II) to inform a decision of the
20 Administrator regarding whether
21 more complex or targeted additional
22 testing is necessary.

23 “(C) ADDITIONAL TESTING.—If the Ad-
24 ministrator determines under subparagraph (B)
25 that additional testing is necessary to provide

1 more definitive information for safety assess-
2 ments or safety determinations, the Adminis-
3 trator may require more advanced tests for po-
4 tential health or environmental effects or expo-
5 sure potential.

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

13 “(h) SAFETY ASSESSMENTS AND SAFETY DETER-
14 MINATIONS.—

15 “(1) SCHEDULE.—

16 “(A) IN GENERAL.—The Administrator
17 shall inform the public regarding the schedule
18 for the completion of each safety assessment
19 and safety determination as soon as practicable
20 after designation as a high-priority substance
21 pursuant to section 4A.

22 “(B) DIFFERING TIMES.—The Adminis-
23 trator may allot different times for different
24 chemical substances in the schedules under this
25 paragraph, subject to the condition that all

1 schedules shall comply with the deadlines estab-
 2 lished under section 6.

3 ~~“(C) ANNUAL PLAN.—At the beginning of~~
 4 ~~each calendar year, the Administrator shall~~
 5 ~~identify the substances subject to safety assess-~~
 6 ~~ments and safety determinations to be com-~~
 7 ~~pleted that year.~~

8 ~~“(2) POLICIES AND PROCEDURES FOR SAFETY~~
 9 ~~ASSESSMENTS AND SAFETY DETERMINATIONS.—~~

10 ~~“(A) IN GENERAL.—The Administrator~~
 11 ~~shall establish, by rule, policies and procedures~~
 12 ~~regarding the manner in which the Adminis-~~
 13 ~~trator shall carry out section 6.~~

14 ~~“(B) GOAL.—A goal of the policies and~~
 15 ~~procedures under this paragraph shall be to~~
 16 ~~make the basis of decisions of the Adminis-~~
 17 ~~trator clear to the public.~~

18 ~~“(C) MINIMUM REQUIREMENTS.—At a~~
 19 ~~minimum, the policies and procedures under~~
 20 ~~this paragraph shall—~~

21 ~~“(i) describe—~~

22 ~~“(I) the manner in which the Ad-~~
 23 ~~ministrator will identify informational~~
 24 ~~needs and seek that information from~~
 25 ~~the public;~~

1 “(II) the information (including
2 draft safety assessments) that may be
3 submitted by interested individuals or
4 entities, including States; and

5 “(III) the criteria by which that
6 information will be evaluated;

7 “(ii) require the Administrator—

8 “(I)(aa) to define the scope of
9 the safety assessment and safety de-
10 termination to be conducted under
11 section 6, including the hazards, expo-
12 sures, conditions of use, and poten-
13 tially exposed and susceptible popu-
14 lations that the Administrator expects
15 to consider in a safety assessment;

16 “(bb) to explain the basis for the
17 scope of the safety assessment and
18 safety determination; and

19 “(cc) to accept comments regard-
20 ing the scope of the safety assessment
21 and safety determination; and

22 “(II)(aa) to identify the items de-
23 scribed in subclause (I) that the Ad-
24 ministrator has considered in the final
25 safety assessment; and

1 “(bb) to explain the basis for the
2 consideration of those items;

3 “(iii) describe the manner in which
4 aggregate exposures, or significant subsets
5 of exposures, to a chemical substance
6 under the conditions of use will be consid-
7 ered, and explain the basis for that consid-
8 eration in the final safety assessment;

9 “(iv) require that each safety assess-
10 ment and safety determination shall in-
11 clude—

12 “(I) a description of the weight
13 of the scientific evidence of risk; and

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

21 “(v) establish a timely and trans-
22 parent process for evaluating whether new
23 information submitted or obtained after
24 the date of a final safety assessment or
25 safety determination warrants reconsider-

1 ation of the safety assessment or safety de-
2 termination; and

3 “~~(vi)~~ when relevant information is
4 provided or otherwise made available to the
5 Administrator, shall consider the extent of
6 Federal regulation under other Federal
7 laws.

8 “~~(D)~~ GUIDANCE.—

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

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

1 “(3) ARTICLES.—If the Administrator intends
2 to prohibit or otherwise restrict an article on the
3 basis of a chemical substance contained in that arti-
4 cle, the Administrator shall have evidence of signifi-
5 cant exposure to the chemical substance from such
6 article.

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

9 “(1) make publicly available a nontechnical
10 summary, and the final version, of each safety as-
11 sessment and safety determination;

12 “(2) provide public notice and an opportunity
13 for comment on each proposed safety assessment
14 and safety determination; and

15 “(3) make public in a final safety assessment
16 and safety determination—

17 “(A) the list of studies considered by the
18 Administrator in carrying out the safety assess-
19 ment or safety determination; and

20 “(B) the list of policies, procedures, and
21 guidance that were followed in carrying out the
22 safety assessment or safety determination.

23 “(j) CONSULTATION WITH SCIENCE ADVISORY COM-
24 MITTEE ON CHEMICALS.—

1 “(1) ESTABLISHMENT.—Not later than 1 year
2 after the date of enactment of this section, the Ad-
3 ministrator shall establish an advisory committee, to
4 be known as the ‘Science Advisory Committee on
5 Chemicals’ (referred to in this subsection as the
6 ‘Committee’).

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

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

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

1 “(5) RELATIONSHIP TO OTHER LAW.—All pro-
 2 ceedings and meetings of the Committee shall be
 3 subject to the Federal Advisory Committee Act (5
 4 U.S.C. App.).”

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

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

8 (1) by striking subsections (a), (b), (c), (d), and
 9 (g);

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

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

13 (A) by striking “rule” each place it ap-
 14 pears and inserting “rule, testing consent
 15 agreement, or order”;

16 (B) by striking “under subsection (a)”
 17 each place it appears and inserting “under this
 18 subsection”; and

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

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

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

24 (B) by striking the last sentence; and

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

3 “(a) DEVELOPMENT OF NEW INFORMATION ON
4 CHEMICAL SUBSTANCES AND MIXTURES.—

5 “(1) IN GENERAL.—The Administrator may re-
6 quire the development of new information relating to
7 a chemical substance or mixture in accordance with
8 this section if the Administrator determines that the
9 information is necessary—

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

13 “(B) to implement a requirement imposed
14 in a consent agreement or order issued under
15 section 5(d)(4) or under a rule promulgated
16 under section 6(d)(3);

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

18 “(D) at the request of the implementing
19 authority under another Federal law, to meet
20 the regulatory testing needs of that authority.

21 “(2) LIMITED TESTING FOR PRIORITIZATION
22 PURPOSES.—

23 “(A) IN GENERAL.—Except as provided in
24 subparagraph (B), the Administrator may re-

1 quire the development of new information for
2 the purposes of section 4A.

3 “(B) PROHIBITION.—Testing required
4 under subparagraph (A) shall not be required
5 for the purpose of establishing or implementing
6 a minimum information requirement.

7 “(C) LIMITATION.—The Administrator
8 may require the development of new informa-
9 tion pursuant to subparagraph (A) only if the
10 Administrator determines that additional infor-
11 mation is necessary to establish the priority of
12 a chemical substance.

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

16 “(A) promulgating a rule;

17 “(B) entering into a testing consent agree-
18 ment; or

19 “(C) issuing an order.

20 “(4) CONTENTS.—

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

1 “(i) identification of the chemical sub-
2 stance or mixture for which testing is re-
3 quired;

4 “(ii) identification of the persons re-
5 quired to conduct the testing;

6 “(iii) test protocols and methodologies
7 for the development of test data and infor-
8 mation for the chemical substance or mix-
9 ture, including specific reference to reliable
10 nonanimal test procedures; and

11 “(iv) specification of the period within
12 which individuals and entities required to
13 conduct the testing shall submit to the Ad-
14 ministrator the information developed in
15 accordance with the procedures described
16 in clause (iii).

17 “(B) CONSIDERATIONS.—In determining
18 the procedures and period to be required under
19 subparagraph (A), the Administrator shall take
20 into consideration—

21 “(i) the relative costs of the various
22 test protocols and methodologies that may
23 be required; and

1 “(ii) the reasonably foreseeable avail-
2 ability of facilities and personnel required
3 to perform the testing.

4 “(b) STATEMENT OF NEED.—

5 “(1) IN GENERAL.—In promulgating a rule, en-
6 tering into a testing consent agreement, or issuing
7 an order for the development of additional informa-
8 tion (including information on exposure or exposure
9 potential) pursuant to this section, the Adminis-
10 trator shall—

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

13 “(B) explain why information reasonably
14 available to the Administrator at that time is
15 inadequate to meet that need, including a ref-
16 erence, as appropriate, to the information iden-
17 tified in paragraph (2)(B); and

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

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

21 “(A) IN GENERAL.—If the Administrator
22 issues an order under this section, the Adminis-
23 trator shall issue a statement providing a jus-
24 tification for why issuance of an order is war-

1 ranted instead of promulgating a rule or enter-
2 ing into a testing consent agreement.

3 “(B) CONTENTS.—A statement described
4 in subparagraph (A) shall contain a description
5 of—

6 “(i) information that is readily acces-
7 sible to the Administrator, including infor-
8 mation submitted under any other provi-
9 sion of law;

10 “(ii) the extent to which the Adminis-
11 trator has obtained or attempted to obtain
12 the information through voluntary submis-
13 sions; and

14 “(iii) any information relied on in
15 safety assessments for other chemical sub-
16 stances relevant to the chemical substances
17 that would be the subject of the order.

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

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

23 “(A) encouraging and facilitating—

24 “(i) the use of integrated and tiered
25 testing and assessment strategies;

1 “(ii) the use of best available science
2 in existence on the date on which the test
3 is conducted;

4 “(iii) the use of test methods that
5 eliminate or reduce the use of animals
6 while providing information of high sci-
7 entific quality;

8 “(iv) the grouping of 2 or more chem-
9 ical substances into scientifically appro-
10 priate categories in cases in which testing
11 of a chemical substance would provide reli-
12 able and useful information on other chem-
13 ical substances in the category;

14 “(v) the formation of industry con-
15 sortia to jointly conduct testing to avoid
16 unnecessary duplication of tests; and

17 “(vi) the submission of information
18 from—

19 “(I) animal-based studies; and

20 “(II) emerging methods and
21 models; and

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

1 “(2) IMPLEMENTATION OF ALTERNATIVE TEST-
2 ING METHODS.—To promote the development and
3 timely incorporation of new testing methods that are
4 not based on vertebrate animals, the Administrator
5 shall—

6 “(A) after providing an opportunity for
7 public comment, develop a strategic plan to pro-
8 mote the development and implementation of al-
9 ternative test methods and testing strategies to
10 generate information under this title that can
11 reduce, refine, or replace the use of vertebrate
12 animals, including toxicity pathway-based risk
13 assessment, in vitro studies, systems biology,
14 computational toxicology, bioinformatics, and
15 high-throughput screening;

16 “(B) as practicable, ensure that the stra-
17 tegic plan developed under subparagraph (A) is
18 reflected in the development of requirements for
19 testing under this section;

20 “(C) beginning on the date that is 5 years
21 after the date of enactment of the Frank R.
22 Lautenberg Chemical Safety for the 21st Cen-
23 tury Act and every 5 years thereafter, submit to
24 Congress a report that describes the progress
25 made in implementing this subsection and goals

1 for future alternative test methods implementa-
2 tion; and

3 “(D) fund and carry out research, develop-
4 ment, performance assessment, and
5 translational studies to accelerate the develop-
6 ment of test methods and testing strategies that
7 reduce, refine, or replace the use of vertebrate
8 animals in any testing under this title.

9 “(3) CRITERIA FOR ADAPTING OR WAIVING ANI-
10 MAL TESTING REQUIREMENTS.—On request from a
11 manufacturer or processor that is required to con-
12 duct testing of a chemical substance or mixture on
13 vertebrate animals under this section, the Adminis-
14 trator may adapt or waive the requirement, if the
15 Administrator determines that—

16 “(A) there is sufficient evidence from sev-
17 eral independent sources of information to sup-
18 port a conclusion that a chemical substance or
19 mixture has, or does not have, a particular
20 property if the information from each individual
21 source alone is insufficient to support the con-
22 clusion;

23 “(B) as a result of 1 or more physical or
24 chemical properties of the chemical substance

1 or mixture or other toxicokinetic consider-
2 ations—

3 “(i) the substance cannot be absorbed;

4 or

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

7 “(C) a chemical substance or mixture can-
8 not be tested in vertebrate animals at con-
9 centrations that do not result in significant
10 pain or distress, because of physical or chemical
11 properties of the chemical substance or mixture,
12 such as a potential to cause severe corrosion or
13 severe irritation to the tissues of the animal.

14 “(d) TESTING REQUIREMENTS.—

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

17 “(A) manufacturers and processors of the
18 chemical substance or mixture; and

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

21 “(i) after the effective date of the
22 rule, testing consent agreement, or order;
23 but

24 “(ii) subject to paragraph (3), before
25 the period ending on the date that is 180

1 days after the end of the period described
2 in this section.

3 “(2) DESIGNATION.—The Administrator may
4 permit 2 or more persons identified in subparagraph
5 (A) or (B) of paragraph (1) to designate 1 of the
6 persons or a qualified third party—

7 “(A) to develop the information; and

8 “(B) to submit the information on behalf
9 of the persons making the designation.

10 “(3) EXEMPTIONS.—

11 “(A) IN GENERAL.—A person otherwise
12 subject to a rule, testing consent agreement, or
13 order under this section may submit to the Ad-
14 ministrators an application for an exemption on
15 the basis that the information is being devel-
16 oped by a person designated under paragraph
17 (2).

18 “(B) FAIR AND EQUITABLE REIMBURSE-
19 MENT TO DESIGNEE.—

20 “(i) IN GENERAL.—If the Adminis-
21 trator accepts an application submitted
22 under subparagraph (A), the Adminis-
23 trator shall direct the applicant to provide
24 to the person designated under paragraph
25 (2) fair and equitable reimbursement, as

1 agreed to between the applicant and the
2 designee.

3 “(ii) ARBITRATION.—If the applicant
4 and a person designated under paragraph
5 (2) cannot reach agreement on the amount
6 of fair and equitable reimbursement, the
7 amount shall be determined by arbitration.

8 “(C) TERMINATION.—If, after granting an
9 exemption under this paragraph, the Adminis-
10 trator determines that a person covered by the
11 exemption has failed to comply with the rule,
12 testing consent agreement, or order, the Admin-
13 istrator shall—

14 “(i) by order, terminate the exemp-
15 tion; and

16 “(ii) notify in writing each person
17 that received an exemption of the require-
18 ments with respect to which the exemption
19 was granted.

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

24 (b) CONFORMING AMENDMENT.—Section
25 104(i)(5)(A) of the Comprehensive Environmental Re-

1 spouse, Compensation, and Liability Act of 1980 (42
 2 U.S.C. 9604(i)(5)(A)) is amended in the third sentence
 3 by striking “section 4(e)” and inserting “section 4(f)”.

4 **SEC. 6. PRIORITIZATION SCREENING.**

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

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

8 **“(a) ESTABLISHMENT AND LIST OF SUBSTANCES.—**

9 **“(1) IN GENERAL.—**Not later than 1 year after
 10 the date of enactment of this section, the Adminis-
 11 trator shall establish, by rule, a risk-based screening
 12 process and explicit criteria for identifying existing
 13 chemical substances that are—

14 **“(A)** a high priority for a safety assess-
 15 ment and safety determination under section 6
 16 (referred to in this Act as ‘high-priority sub-
 17 stances’); and

18 **“(B)** a low priority for a safety assessment
 19 and safety determination (referred to in this
 20 Act as ‘low-priority substances’).

21 **“(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY**
 22 **SUBSTANCES.—**

23 **“(A) IN GENERAL.—**Before the date of
 24 promulgation of the rule under paragraph (1)

1 and not later than 180 days after the date of
2 enactment of this section, the Administrator—

3 “(i) shall take into consideration and
4 publish an initial list of high-priority sub-
5 stances and low-priority substances; and

6 “(ii) pursuant to section 6(b), may
7 initiate or continue safety assessments and
8 safety determinations for those high-pri-
9 ority substances.

10 “(B) REQUIREMENTS.—

11 “(i) IN GENERAL.—The initial list of
12 chemical substances shall contain at least
13 10 high-priority substances, at least 5 of
14 which are drawn from the list of chemical
15 substances identified by the Administrator
16 in the October, 2014 TSCA Work Plan
17 and subsequent updates, and at least 10
18 low-priority substances.

19 “(ii) SUBSEQUENTLY IDENTIFIED
20 SUBSTANCES.—Insofar as possible, at least
21 50 percent of all substances subsequently
22 identified by the Administrator as high-pri-
23 ority substances shall be drawn from the
24 list of chemical substances identified by the
25 Administrator in the October, 2014 TSCA

1 Work Plan and subsequent updates, until
2 all Work Plan chemicals have been des-
3 ignated under this subsection.

4 “(C) ADDITIONAL CHEMICAL REVIEWS.—

5 The Administrator shall—

6 “(i) 3 years after the date of enact-
7 ment of the Frank R. Lautenberg Chem-
8 ical Safety for the 21st Century Act, add
9 additional high-priority substances suffi-
10 cient to ensure that at least a total of 20
11 high-priority substances have undergone or
12 are undergoing the process established in
13 section 6(a); and additional low-priority
14 substances sufficient to ensure that at
15 least a total of 20 low-priority substances
16 have been designated; and

17 “(ii) as soon as practicable and not
18 later than 5 years after the date of enact-
19 ment of the Frank R. Lautenberg Chem-
20 ical Safety for the 21st Century Act, add
21 additional high-priority substances suffi-
22 cient to ensure that at least a total of 25
23 high-priority substances have undergone or
24 are undergoing the process established in
25 section 6(a); and additional low-priority

1 substances sufficient to ensure that at
2 least a total of 25 low-priority substances
3 have been designated.

4 “(3) IMPLEMENTATION.—

5 “(A) CONSIDERATION OF ACTIVE AND IN-
6 ACTIVE SUBSTANCES.—

7 “(i) ACTIVE SUBSTANCES.—In ear-
8 rying out paragraph (1), the Administrator
9 shall take into consideration active sub-
10 stances, as determined under section 8,
11 which may include chemical substances on
12 the interim list of active substances estab-
13 lished under that section.

14 “(ii) INACTIVE SUBSTANCES.—In ear-
15 rying out paragraph (1), the Administrator
16 may take into consideration inactive sub-
17 stances, as determined under section 8,
18 that the Administrator determines—

19 “(I)(aa) have not been subject to
20 a regulatory or other enforceable ac-
21 tion by the Administrator to ban or
22 phase out the substances; and

23 “(bb) have the potential for high
24 hazard and widespread exposure; or

1 “(H)(aa) have been subject to a
2 regulatory or other enforceable action
3 by the Administrator to ban or phase
4 out the substances; and

5 “(bb) with respect to which there
6 exists the potential for residual high
7 hazards or widespread exposures not
8 otherwise addressed by the regulatory
9 or other action.

10 “(iii) REPOPULATION.—

11 “(I) IN GENERAL.—On the com-
12 pletion of a safety determination
13 under section 6 for a chemical sub-
14 stance, the Administrator shall re-
15 move the chemical substance from the
16 list of high-priority substances estab-
17 lished under this subsection.

18 “(II) ADDITIONS.—The Adminis-
19 trator shall add at least 1 chemical
20 substance to the list of high-priority
21 substances for each chemical sub-
22 stance removed from the list of high-
23 priority substances established under
24 this subsection, until a safety assess-

1 ment and safety determination is com-
2 pleted for all high-priority substances.

3 ~~“(III) LOW-PRIORITY SUB-~~
4 ~~STANCES.—~~If a low-priority substance
5 is subsequently designated as a high-
6 priority substance, the Administrator
7 shall remove that substance from the
8 list of low-priority substances.

9 ~~“(B) TIMELY COMPLETION OF~~
10 ~~PRIORITIZATION SCREENING PROCESS.—~~

11 ~~“(i) IN GENERAL.—~~The Administrator
12 shall—

13 ~~“(I) not later than 180 days~~
14 ~~after the effective date of the final~~
15 ~~rule under paragraph (1), begin the~~
16 ~~prioritization screening process; and~~

17 ~~“(II) make every effort to com-~~
18 ~~plete the designation of all active sub-~~
19 ~~stances as high-priority substances or~~
20 ~~low-priority substances in a timely~~
21 ~~manner.~~

22 ~~“(ii) DECISIONS ON SUBSTANCES SUB-~~
23 ~~JECT TO TESTING FOR PRIORITIZATION~~
24 ~~PURPOSES.—~~Not later than 90 days after
25 the date of receipt of information regard-

1 ing a chemical substance complying with a
2 rule, testing consent agreement, or order
3 issued under section 4(a)(2), the Adminis-
4 trator shall designate the chemical sub-
5 stance as a high-priority substance or low-
6 priority substance.

7 “(iii) CONSIDERATION.—

8 “(I) IN GENERAL.—The Admin-
9 istrator shall screen substances and
10 designate high-priority substances
11 taking into consideration the ability of
12 the Administrator to schedule and
13 complete safety assessments and safe-
14 ty determinations under section 6 in a
15 timely manner.

16 “(II) ANNUAL GOAL.—The Ad-
17 ministrator shall publish an annual
18 goal for the number of chemical sub-
19 stances to be subject to the
20 prioritization screening process.

21 “(C) SCREENING OF CATEGORIES OF SUB-
22 STANCES.—The Administrator may screen cat-
23 egories of chemical substances to ensure an effi-
24 cient prioritization screening process to allow
25 for timely and adequate designations of high-

1 priority substances and low-priority substances
2 and safety assessments and safety determina-
3 tions for high-priority substances.

4 “(D) PUBLICATION OF LIST OF CHEMICAL
5 SUBSTANCES.—Not less frequently than once
6 each year, the Administrator shall publish a list
7 of chemical substances that—

8 “(i) are being considered in the
9 prioritization screening process and the
10 status of the chemical substances in the
11 prioritization process, including those
12 chemical substances for which
13 prioritization decisions have been deferred;
14 and

15 “(ii) are designated as high-priority
16 substances or low-priority substances, in-
17 cluding the bases for such designations.

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

20 “(A) the recommendation of the Governor
21 of a State or a State agency with responsibility
22 for protecting health or the environment from
23 chemical substances appropriate for
24 prioritization screening;

1 “(B) the hazard and exposure potential of
2 the chemical substance (or category of sub-
3 stances); including specific scientific classifica-
4 tions and designations by authoritative govern-
5 mental entities;

6 “(C) the conditions of use or significant
7 changes in the conditions of use of the chemical
8 substance;

9 “(D) evidence and indicators of exposure
10 potential to humans or the environment from
11 the chemical substance; including potentially ex-
12 posed or susceptible populations;

13 “(E) the volume of a chemical substance
14 manufactured or processed;

15 “(F) whether the volume of a chemical
16 substance as reported under a rule promulgated
17 pursuant to section 8(a) has significantly in-
18 creased or decreased during the period begin-
19 ning on the date of a previous report or the
20 date on which a notice has been submitted
21 under section 5(b) for that chemical substance;

22 “(G) the availability of information regard-
23 ing potential hazards and exposures required
24 for conducting a safety assessment or safety de-
25 termination; with limited availability of relevant

1 information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

2
3
4
5
6 “(H) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a low-priority substance.

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14 “(b) PRIORITIZATION SCREENING PROCESS AND DECISIONS.—

15
16 “(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall include a requirement that the Administrator shall—

17
18
19 “(A) identify the chemical substances being considered for prioritization;

20
21 “(B) request interested persons to supply information regarding the chemical substances being considered;

22
23
24 “(C) apply the criteria identified in subsection (a)(4); and

25

1 “(D) subject to paragraph (5) and using
2 the information available to the Administrator
3 at the time of the decision, identify a chemical
4 substance as a high-priority substance or a low-
5 priority substance.

6 “(2) INTEGRATION OF INFORMATION.—The
7 prioritization screening decision regarding a chem-
8 ical substance shall integrate any hazard and expo-
9 sure information relating to the chemical substance
10 that is available to the Administrator.

11 “(3) IDENTIFICATION OF HIGH-PRIORITY SUB-
12 STANCES.—The Administrator—

13 “(A) shall identify as a high-priority sub-
14 stance a chemical substance that, relative to
15 other chemical substances, the Administrator
16 determines has the potential for high hazard
17 and widespread exposure;

18 “(B) may identify as a high-priority sub-
19 stance a chemical substance that, relative to
20 other chemical substances, the Administrator
21 determines has the potential for high hazard or
22 widespread exposure; and

23 “(C) may identify as a high-priority sub-
24 stance an inactive substance, as determined
25 under subsection (a)(3)(A)(ii) and section 8(b);

1 that the Administrator determines warrants a
2 safety assessment and safety determination
3 under section 6.

4 “(4) IDENTIFICATION OF LOW-PRIORITY SUB-
5 STANCES.—The Administrator shall identify as a
6 low-priority substance a chemical substance that the
7 Administrator concludes has information sufficient
8 to establish that the chemical substance is likely to
9 meet the applicable safety standard.

10 “(5) DEFERRING A DECISION.—If the Adminis-
11 trator determines that additional information is re-
12 quired to establish the priority of a chemical sub-
13 stance under this section, the Administrator may
14 defer the prioritization screening decision for a rea-
15 sonable period—

16 “(A) to allow for the submission of addi-
17 tional information by an interested person and
18 for the Administrator to evaluate the additional
19 information; or

20 “(B) to require the development of infor-
21 mation pursuant to a rule, testing consent
22 agreement, or order issued under section
23 4(a)(2).

24 “(6) DEADLINES FOR SUBMISSION OF INFOR-
25 MATION.—If the Administrator requests the develop-

1 ment or submission of information under this sec-
2 tion, the Administrator shall establish a deadline for
3 submission of the information.

4 “(7) NOTICE AND COMMENT.—The Adminis-
5 trator shall—

6 “(A) publish the proposed decisions made
7 under paragraphs (3), (4), and (5) and the
8 basis for the decisions; and

9 “(B) provide an opportunity for public
10 comment.

11 “(8) REVISIONS OF PRIOR DESIGNATIONS.—

12 “(A) IN GENERAL.—At any time, and at
13 the discretion of the Administrator, the Admin-
14 istrator may revise the designation of a chem-
15 ical substance as a high-priority substance or a
16 low-priority substance based on information
17 available to the Administrator after the date of
18 the determination under paragraph (3) or (4).

19 “(B) LIMITED AVAILABILITY.—If limited
20 availability of relevant information was a basis
21 in the designation of a chemical substance as a
22 high-priority substance, the Administrator shall
23 reevaluate the prioritization screening of the
24 chemical substance on receiving the relevant in-
25 formation.

1 “(9) OTHER INFORMATION RELEVANT TO
2 PRIORITIZATION.—

3 “(A) IN GENERAL.—If, after the date of
4 enactment of the Frank R. Lautenberg Chem-
5 ical Safety for the 21st Century Act, a State
6 proposes an administrative action or enacts a
7 statute or takes an administrative action to pro-
8 hibit or otherwise restrict the manufacturing,
9 processing, distribution in commerce, or use of
10 a chemical substance that the Administrator
11 has not as designated a high-priority substance,
12 the Governor or State agency with responsi-
13 bility for implementing the statute or adminis-
14 trative action shall notify the Administrator.

15 “(B) REQUESTS FOR INFORMATION.—Fol-
16 lowing receipt of a notification provided under
17 subparagraph (A), the Administrator may re-
18 quest any available information from the Gov-
19 ernor or the State agency with respect to—

20 “(i) scientific evidence related to the
21 hazards, exposures and risks of the chem-
22 ical substance under the conditions of use
23 which the statute or administrative action
24 is intended to address;

1 “(ii) any State or local conditions
2 which warranted the statute or administra-
3 tive action;

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

6 “(iv) any other available information
7 relevant to the prohibition or other restric-
8 tion, including information on any alter-
9 natives considered and their hazards, expo-
10 sures, and risks.

11 “(C) **PRIORITIZATION SCREENING.**—The
12 Administrator shall conduct a prioritization
13 screening under this subsection for all sub-
14 stances that—

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

17 “(ii) the Administrator determines—

18 “(I) are likely to have significant
19 health or environmental impacts;

20 “(II) are likely to have signifi-
21 cant impact on interstate commerce;

22 or

23 “(III) have been subject to a pro-
24 hibition or other restriction under a

1 statute or administrative action in 2
2 or more States.

3 “(D) AVAILABILITY TO PUBLIC.—Subject
4 to section 14 and any applicable State law re-
5 garding the protection of confidential informa-
6 tion provided to the State or to the Adminis-
7 trator, the Administrator shall make informa-
8 tion received from a Governor or State agency
9 under subparagraph (A) publicly available.

10 “(E) EFFECT OF PARAGRAPH.—Nothing
11 in this paragraph shall preempt a State statute
12 or administrative action, require approval of a
13 State statute or administrative action, or apply
14 section 15 to a State.

15 “(10) REVIEW.—Not less frequently than once
16 every 5 years after the date on which the process
17 under this subsection is established, the Adminis-
18 trator shall—

19 “(A) review the process on the basis of ex-
20 perience and taking into consideration resources
21 available to efficiently and effectively screen and
22 prioritize chemical substances; and

23 “(B) if necessary, modify the prioritization
24 screening process.

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

5 “(A) the manufacture, processing, distribu-
6 tion in commerce, use, or disposal of the chem-
7 ical substance; or

8 “(B) the regulation of those activities.

9 “(e) ADDITIONAL PRIORITIES FOR SAFETY ASSESS-
10 MENTS AND DETERMINATIONS.—

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

13 “(A) include a process by which a manu-
14 facturer or processor of an active chemical sub-
15 stance that has not been designated a high-pri-
16 ority substance, or that has not been subject to
17 or is not in the process of a prioritization
18 screening by the Administrator, may request
19 that the Administrator designate the substance
20 for a safety assessment and safety determina-
21 tion, subject to the payment of fees pursuant to
22 section 26(b)(3)(E); and

23 “(B) provide guidance to submitters on the
24 information to be provided in such requests,
25 and specify the criteria the Administrator shall

1 use to determine whether or not to grant such
2 a request, which shall include whether the sub-
3 stance is subject to restrictions imposed by stat-
4 utes enacted or administrative actions taken by
5 1 or more States on the manufacture, proe-
6 cessing, distribution in commerce, or use of the
7 substance.

8 “(2) PREFERENCE.—Subject to paragraph (3),
9 in deciding whether to grant requests under this
10 subsection the Administrator shall give a preference
11 to requests concerning substances for which the Ad-
12 ministrator determines that restrictions imposed by
13 1 or more States have the potential to have a signifi-
14 cant impact on interstate commerce or health or the
15 environment.

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

19 “(A) not more than 15 percent of the total
20 number of substances designated to undergo
21 safety assessments and safety determinations
22 under this section are substances designated
23 under the process and criteria pursuant to
24 paragraph (1); and

1 “(B) the resources allocated to conducting
2 safety assessments and safety determinations
3 for additional priorities designated under this
4 subsection are proportionate to the number of
5 such substances relative to the total number of
6 substances designated to undergo safety assess-
7 ments and safety determinations under this sec-
8 tion.

9 “(4) REQUIREMENTS.—

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

13 “(B) DECISION BY ADMINISTRATOR.—Not
14 later than 180 days after the date on which the
15 Administrator receives a request under this
16 subsection, the Administrator shall decide
17 whether or not to grant the request.

18 “(C) ASSESSMENT AND DETERMINA-
19 TION.—If the Administrator grants a request
20 under this subsection, the safety assessment
21 and safety determination—

22 “(i) shall be conducted in accordance
23 with the deadlines and other requirements
24 of sections 3A(i) and 6; and

1 “(ii) shall not be expedited or other-
2 wise subject to special treatment relative to
3 high-priority substances designated pursu-
4 ant to subsection (b)(3) that are under-
5 going safety assessments and safety deter-
6 minations.

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

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

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

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

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

16 (2) by striking subsection (b);

17 (3) by redesignating subsection (a) as sub-
18 section (b);

19 (4) by redesignating subsection (i) as subsection
20 (a) and moving the subsection so as to appear at the
21 beginning of the section;

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

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

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

3 (i) by striking “subsection (d)” and
4 inserting “subsection (b)”; and

5 (ii) by striking “and such person com-
6 plies with any applicable requirement of
7 subsection (b)”; and

8 (6) by redesignating subsections (e) and (d) as
9 subsection (d) and (e), respectively, and moving sub-
10 section (e) (as so redesigned) so as appear after sub-
11 section (b) (as redesignated by paragraph (3));

12 (7) in subsection (e) (as so redesignated)—

13 (A) by striking paragraph (1) and insert-
14 ing the following:

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

18 “(A) the information required by sections
19 720.45 and 720.50 of title 40, Code of Federal
20 Regulations (or successor regulations); and

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

23 (B) in paragraph (2)—

1 (i) in the matter preceding subpara-
2 graph (A), by striking “or of data under
3 subsection (b)”;

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

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

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

9 (C) in paragraph (3), by striking “sub-
10 section (a) and for which the notification period
11 prescribed by subsection (a), (b), or (c)” and
12 inserting “subsection (b) and for which the no-
13 tification period prescribed by subsection (b) or
14 (d)”;

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

17 “(d) REVIEW OF NOTICE.—

18 “(1) INITIAL REVIEW.—

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

23 “(i) conduct an initial review of the
24 notice;

1 “(ii) as needed, develop a profile of
2 the relevant chemical substance and the
3 potential for exposure to humans and the
4 environment; and

5 “(iii) make any necessary determina-
6 tion under paragraph (3).

7 “(B) EXTENSION.—Except as provided in
8 paragraph (5), the Administrator may extend
9 the period described in subparagraph (A) for
10 good cause for 1 or more periods, the total of
11 which shall be not more than 90 days.

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

15 “(A) any relevant information identified in
16 subsection (c)(1); and

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

19 “(3) DETERMINATIONS.—Before the end of the
20 applicable period for review under paragraph (1),
21 based on the information described in paragraph (2),
22 and subject to section 18(g), the Administrator shall
23 determine that—

24 “(A) the relevant chemical substance or
25 significant new use is not likely to meet the

1 safety standard, in which case the Adminis-
2 trator shall take appropriate action under para-
3 graph (4);

4 “(B) the relevant chemical substance or
5 significant new use is likely to meet the safety
6 standard, in which case the Administrator shall
7 allow the review period to expire without addi-
8 tional restrictions; or

9 “(C) additional information is necessary in
10 order to make a determination under subpara-
11 graph (A) or (B), in which case the Adminis-
12 trator shall take appropriate action under para-
13 graph (5).

14 “(4) RESTRICTIONS.—

15 “(A) DETERMINATION BY ADMINIS-
16 TRATOR.—

17 “(i) IN GENERAL.—If the Adminis-
18 trator makes a determination under sub-
19 paragraph (A) or (C) of paragraph (3)
20 with respect to a notice submitted under
21 subsection (b)—

22 “(I) the Administrator, before
23 the end of the applicable period for re-
24 view under paragraph (1) and by con-
25 sent agreement or order, as appro-

1 prate, shall prohibit or otherwise re-
2 strict the manufacture, processing,
3 use, distribution in commerce, or dis-
4 posal (as applicable) of the chemical
5 substance, or of the chemical sub-
6 stance for a significant new use, with-
7 out compliance with the restrictions
8 specified in the consent agreement or
9 order that the Administrator deter-
10 mines are sufficient to ensure that the
11 chemical substance or significant new
12 use is likely to meet the safety stand-
13 ard; and

14 “(H) no person may commence
15 manufacture of the chemical sub-
16 stance, or manufacture or processing
17 of the chemical substance for a sig-
18 nificant new use, except in compliance
19 with the restrictions specified in the
20 consent agreement or order.

21 “(ii) LIKELY TO MEET STANDARD.—If
22 the Administrator makes a determination
23 under subparagraph (B) of paragraph (3)
24 with respect to a chemical substance or
25 significant new use for which a notice was

1 submitted under subsection (b); at the end
2 of the applicable period for review under
3 paragraph (1), the submitter of the notice
4 may commence manufacture for commer-
5 cial purposes of the chemical substance or
6 manufacture or processing of the chemical
7 substance for a significant new use.

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

12 “(i) take into consideration whether to
13 promulgate a rule pursuant to subsection
14 (b)(2) that identifies as a significant new
15 use any manufacturing, processing, use,
16 distribution in commerce, or disposal of
17 the chemical substance, or of the chemical
18 substance for a new use, that is not in
19 compliance with the restrictions imposed
20 by the consent agreement or order; and

21 “(ii)(I) initiate a rulemaking described
22 in clause (i); or

23 “(II) publish a statement describing
24 the reasons of the Administrator for not
25 initiating a rulemaking.

1 “(C) INCLUSIONS.—A prohibition or other
2 restriction under subparagraph (A) may in-
3 clude, as appropriate—

4 “(i) subject to section 18(g), a re-
5 quirement that a chemical substance shall
6 be marked with, or accompanied by, clear
7 and adequate minimum warnings and in-
8 structions with respect to use, distribution
9 in commerce, or disposal, or any combina-
10 tion of those activities, with the form and
11 content of the minimum warnings and in-
12 structions to be prescribed by the Adminis-
13 trator;

14 “(ii) a requirement that manufactur-
15 ers or processors of the chemical substance
16 shall—

17 “(I) make and retain records of
18 the processes used to manufacture or
19 process, as applicable, the chemical
20 substance; or

21 “(II) monitor or conduct such
22 additional tests as are reasonably nec-
23 essary to address potential risks from
24 the manufacture, processing, distribu-
25 tion in commerce, use, or disposal, as

1 applicable; of the chemical substance;
2 subject to section 4;

3 “(iii) a restriction on the quantity of
4 the chemical substance that may be manu-
5 factured, processed, or distributed in com-
6 merce—

7 “(I) in general; or

8 “(II) for a particular use;

9 “(iv) a prohibition or other restriction
10 of—

11 “(I) the manufacture, processing,
12 or distribution in commerce of the
13 chemical substance for a significant
14 new use;

15 “(II) any method of commercial
16 use of the chemical substance; or

17 “(III) any method of disposal of
18 the chemical substance; or

19 “(v) a prohibition or other restriction
20 on the manufacture, processing, or dis-
21 tribution in commerce of the chemical sub-
22 stance—

23 “(I) in general; or

24 “(II) for a particular use.

1 “(D) WORKPLACE EXPOSURES.—The Ad-
2 ministrators shall consult with the Assistant Sec-
3 retary of Labor for Occupational Safety and
4 Health prior to adopting any prohibition or
5 other restriction under this subsection to ad-
6 dress workplace exposures.

7 “(E) DEFINITION OF REQUIREMENT.—For
8 purposes of this Act, the term ‘requirement’ as
9 used in this section does not displace common
10 law.

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

15 “(A) shall provide an opportunity for the
16 submitter of the notice to submit the additional
17 information;

18 “(B) may, by agreement with the sub-
19 mitter, extend the review period for a reason-
20 able time to allow the development and submis-
21 sion of the additional information;

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

1 “(D) on receipt of information the Admin-
2 istrator finds supports the determination under
3 paragraph (3); shall promptly make the deter-
4 mination.”;

5 (9) by striking subsections (e) through (g) and
6 inserting the following:

7 “(e) NOTICE OF COMMENCEMENT.—

8 “(1) IN GENERAL.—Not later than 30 days
9 after the date on which a manufacturer that has
10 submitted a notice under subsection (b) commences
11 nonexempt commercial manufacture of a chemical
12 substance, the manufacturer shall submit to the Ad-
13 ministrator a notice of commencement that identi-
14 fies—

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

16 “(B) the initial date of nonexempt com-
17 mercial manufacture.

18 “(2) WITHDRAWAL.—A manufacturer or proc-
19 essor that has submitted a notice under subsection
20 (b), but that has not commenced nonexempt com-
21 mercial manufacture or processing of the chemical
22 substance, may withdraw the notice.

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

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

3 ~~“(2) new information regarding the chemical~~
 4 ~~substance.~~

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

7 ~~“(1) all notices, determinations, consent agree-~~
 8 ~~ments, rules, and orders of the Administrator; and~~

9 ~~“(2) all information submitted or issued under~~
 10 ~~this section.”; and~~

11 ~~(10) in subsection (h)—~~

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

14 ~~(B) by striking paragraph (2);~~

15 ~~(C) by redesignating paragraphs (3)~~
 16 ~~through (6) as paragraphs (2) through (5), re-~~
 17 ~~spectively;~~

18 ~~(D) in paragraph (2) (as so redesignated),~~
 19 ~~in the matter preceding subparagraph (A), by~~
 20 ~~striking “subsections (a) and (b)” and inserting~~
 21 ~~“subsection (b)”;~~

22 ~~(E) in paragraph (3) (as so redesign-~~
 23 ~~ated)—~~

24 ~~(i) in the first sentence, by striking~~
 25 ~~“will not present an unreasonable risk of~~

1 injury to health or the environment” and
 2 inserting “will meet the safety standard”;
 3 and

4 (ii) by striking the second sentence;
 5 (F) in paragraph (4) (as so redesignated),
 6 by striking “subsections (a) and (b)” and in-
 7 serting “subsection (b)”; and

8 (G) in paragraph (5) (as so redesignated),
 9 in the first sentence, by striking “paragraph (1)
 10 or (5)” and inserting “paragraph (1) or (4)”.

11 **SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINA-**
 12 **TIONS.**

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

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

17 **“SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINA-**
 18 **TIONS.”;**

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

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

23 **“(a) IN GENERAL.—**The Administrator—

24 **“(1) shall conduct a safety assessment and**
 25 **make a safety determination of each high-priority**

1 substance in accordance with subsections (b) and
2 (c);

3 “(2) shall, as soon as practicable and not later
4 than 6 months after the date on which a chemical
5 substance is designated as a high-priority substance,
6 define the scope of the safety assessment and safety
7 determination to be conducted pursuant to this sec-
8 tion, including the hazards, exposures, conditions of
9 use, and potentially exposed or susceptible popu-
10 lations that the Administrator expects to consider;

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

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

18 “(5) shall promulgate a final rule pursuant to
19 subsection (d) by not later than 2 years after the
20 date on which the safety determination is completed;
21 and

22 “(6) may extend any deadline under this sub-
23 section for a reasonable period of time after an ade-
24 quate public justification, subject to the condition
25 that the aggregate length of all extensions of dead-

1 lines under paragraphs (4) and (5) and any deferral
2 under subsection (c)(2) does not exceed 2 years.

3 “(b) PRIOR ACTIONS.—

4 “(1) PRIOR-INITIATED ASSESSMENTS.—

5 “(A) IN GENERAL.—Nothing in this Act
6 prevents the Administrator from initiating a
7 safety assessment or safety determination re-
8 garding a chemical substance, or from con-
9 tinuing or completing such a safety assessment
10 or safety determination that was initiated be-
11 fore the date of enactment of the Frank R.
12 Lautenberg Chemical Safety for the 21st Cen-
13 tury Act, prior to the effective date of the poli-
14 cies and procedures required to be established
15 by the Administrator under section 3A or 4A.

16 “(B) INTEGRATION OF PRIOR POLICIES
17 AND PROCEDURES.—As policies and procedures
18 under section 3A and 4A are established, to the
19 maximum extent practicable, the Administrator
20 shall integrate the policies and procedures into
21 ongoing safety assessments and safety deter-
22 minations.

23 “(2) ACTIONS COMPLETED PRIOR TO COMPLE-
24 TION OF POLICIES AND PROCEDURES.—Nothing in
25 this Act requires the Administrator to revise or with-

1 draw a completed safety assessment, safety deter-
2 mination, or rule solely because the action was com-
3 pleted prior to the completion of a policy or proce-
4 dure established under section 3A or 4A, and the va-
5 lidity of a completed assessment, determination, or
6 rule shall not be determined based on the content of
7 such a policy or procedure.

8 “(e) SAFETY DETERMINATIONS.—

9 “(1) IN GENERAL.—Based on a review of the
10 information available to the Administrator, including
11 draft safety assessments submitted by interested
12 persons, and subject to section 18, the Adminis-
13 trator shall determine that—

14 “(A) the relevant chemical substance meets
15 the safety standard;

16 “(B) the relevant chemical substance does
17 not meet the safety standard, in which case the
18 Administrator shall, by rule under subsection

19 (d)—

20 “(i) impose restrictions necessary to
21 ensure that the chemical substance meets
22 the safety standard under the conditions of
23 use; or

24 “(ii) if the safety standard cannot be
25 met with the application of restrictions;

1 ban or phase out the chemical substance,
2 as appropriate; or

3 “(C) additional information is necessary in
4 order to make a determination under subpara-
5 graph (A) or (B), in which case the Adminis-
6 trator shall take appropriate action under para-
7 graph (2).

8 “(2) ADDITIONAL INFORMATION.—If the Ad-
9 ministratoꝛ determines that additional information is
10 necessary to make a safety assessment or safety de-
11 termination for a high-priority substance, the Ad-
12 ministratoꝛ—

13 “(A) shall provide an opportunity for inter-
14 ested persons to submit the additional informa-
15 tion;

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

20 “(C) may defer, for a reasonable period
21 consistent with the deadlines described in sub-
22 section (a), a safety assessment and safety de-
23 termination until after receipt of the informa-
24 tion; and

1 “(D) consistent with the deadlines de-
2 scribed in subsection (a), on receipt of informa-
3 tion the Administrator finds supports the safety
4 assessment and safety determination, shall
5 make a determination under paragraph (1).

6 “(3) ESTABLISHMENT OF DEADLINE.—In re-
7 questing the development or submission of informa-
8 tion under this section, the Administrator shall es-
9 tablish a deadline for the submission of the informa-
10 tion.

11 “(d) RULE.—

12 “(1) IMPLEMENTATION.—If the Administrator
13 makes a determination under subsection (c)(1)(B)
14 with respect to a chemical substance, the Adminis-
15 trator shall promulgate a rule establishing restric-
16 tions necessary to ensure that the chemical sub-
17 stance meets the safety standard.

18 “(2) SCOPE.—The rule promulgated pursuant
19 to this subsection—

20 “(A) may—

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

23 “(ii) exempt replacement parts for ar-
24 ticles manufactured prior to the applicable
25 compliance deadline; and

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

3 “(i) shall be as soon as practicable;

4 and

5 “(ii) as determined by the Adminis-
6 trator, may vary for different affected per-
7 sons.

8 “(C) WORKPLACE EXPOSURES.—The Ad-
9 ministratoꝛ shall consult with the Assistant Sec-
10 retary of Labor for Occupational Safety and
11 Health before adopting any prohibition or other
12 restriction under this subsection to address
13 workplace exposures.

14 “(D) DEFINITION OF REQUIREMENT.—For
15 the purposes of this Act, the term ‘requirement’
16 as used in this section does not displace com-
17 mon law.

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

20 “(A) subject to section 18, a requirement
21 that a chemical substance shall be marked with,
22 or accompanied by, clear and adequate min-
23 imum warnings and instructions with respect to
24 use, distribution in commerce, or disposal, or
25 any combination of those activities, with the

1 form and content of the minimum warnings and
2 instructions to be prescribed by the Adminis-
3 trator;

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

6 “(i) make and retain records of the
7 processes used to manufacture or process
8 the chemical substance;

9 “(ii) describe and apply the relevant
10 quality control procedures followed in the
11 manufacturing or processing of the sub-
12 stance; or

13 “(iii) monitor or conduct tests that
14 are reasonably necessary to ensure compli-
15 ance with the requirements of any rule
16 under this subsection;

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

20 “(D) a requirement to ban or phase out, or
21 any other rule regarding, the manufacture,
22 processing, or distribution in commerce of the
23 chemical substance for—

24 “(i) a particular use;

1 “(ii) a particular use at a concentra-
2 tion in excess of a level specified by the
3 Administrator; or

4 “(iii) all uses;

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

8 “(i) a particular use; or

9 “(ii) a particular use at a concentra-
10 tion in excess of a level specified by the
11 Administrator;

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

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

19 “(H) a requirement directing manufactur-
20 ers or processors of the chemical substance to
21 give notice of the Administrator’s determination
22 under subsection (c)(1)(B) to distributors in
23 commerce of the chemical substance and, to the
24 extent reasonably ascertainable, to other per-

1 sons in the chain of commerce in possession of
2 the chemical substance.

3 “(4) ANALYSIS FOR RULEMAKING.—

4 “(A) CONSIDERATIONS.—In deciding
5 which restrictions to impose under paragraph
6 (3) as part of developing a rule under para-
7 graph (1), the Administrator shall take into
8 consideration, to the extent practicable based on
9 reasonably available information, the quantifi-
10 able and nonquantifiable costs and benefits of
11 the proposed regulatory action and of the 1 or
12 more primary alternative regulatory actions
13 considered by the Administrator.

14 “(B) ALTERNATIVES.—As part of the
15 analysis, the Administrator shall review any 1
16 or more technically and economically feasible al-
17 ternatives to the chemical substance that the
18 Administrator determines are relevant to the
19 rulemaking.

20 “(C) PUBLIC AVAILABILITY.—In proposing
21 a rule under paragraph (1), the Administrator
22 shall make publicly available any analysis con-
23 ducted under this paragraph.

24 “(D) STATEMENT REQUIRED.—In making
25 final a rule under paragraph (1), the Adminis-

1 trator shall include a statement describing how
2 the analysis considered under subparagraph (A)
3 was taken into account.

4 “(5) EXEMPTIONS.—

5 “(A) IN GENERAL.—The Administrator
6 may exempt 1 or more uses of a chemical sub-
7 stance from any restriction in a rule promul-
8 gated under paragraph (1) if the Administrator
9 determines that—

10 “(i) the rule cannot be complied with,
11 without—

12 “(I) harming national security;

13 “(II) causing significant interrup-
14 tion in the national economy due to
15 the lack of availability of a chemical
16 substance; or

17 “(III) interfering with a critical
18 or essential use for which no tech-
19 nically and economically feasible safer
20 alternative is available, taking into
21 consideration hazard and exposure; or

22 “(ii) the use of the chemical sub-
23 stance, as compared to reasonably available
24 alternatives, provides a substantial benefit

1 to health, the environment, or public safe-
2 ty.

3 “(B) EXEMPTION ANALYSIS.—In pro-
4 posing a rule under paragraph (1) that includes
5 an exemption under this paragraph, the Admin-
6 istrator shall make publicly available any anal-
7 ysis conducted under this paragraph to assess
8 the need for the exemption.

9 “(C) STATEMENT REQUIRED.—In making
10 final a rule under paragraph (1) that includes
11 an exemption under this paragraph, the Admin-
12 istrator shall include a statement describing
13 how the analysis considered under subpara-
14 graph (B) was taken into account.

15 “(D) ANALYSIS IN CASE OF BAN OR
16 PHASE-OUT.—In determining whether an ex-
17 emption should be granted under this para-
18 graph for a chemical substance for which a ban
19 or phase-out is proposed, the Administrator
20 shall take into consideration, to the extent prac-
21 ticable based on reasonably available informa-
22 tion, the quantifiable and nonquantifiable costs
23 and benefits of the 1 or more technically and
24 economically feasible alternatives to the chem-
25 ical substance most likely to be used in place of

1 the chemical substance under the conditions of
2 use if the rule is promulgated.

3 “(E) CONDITIONS.—As part of a rule pro-
4 mulgated under paragraph (1), the Adminis-
5 trator shall include conditions in any exemption
6 established under this paragraph, including rea-
7 sonable recordkeeping, monitoring, and report-
8 ing requirements, to the extent that the Admin-
9 istrator determines the conditions are necessary
10 to protect health and the environment while
11 achieving the purposes of the exemption.

12 “(F) DURATION.—

13 “(i) IN GENERAL.—The Administrator
14 shall establish, as part of a rule under
15 paragraph (1) that contains an exemption
16 under this paragraph, a time limit on any
17 exemption for a time to be determined by
18 the Administrator as reasonable on a case-
19 by-case basis.

20 “(ii) AUTHORITY OF ADMINIS-
21 TRATOR.—The Administrator, by rule, may
22 extend, modify, or eliminate the exemption
23 if the Administrator determines, on the
24 basis of reasonably available information
25 and after adequate public justification, the

1 exemption warrants extension or is no
2 longer necessary.

3 “(iii) CONSIDERATIONS.—

4 “(I) IN GENERAL.—Subject to
5 subclause (II), the Administrator shall
6 issue exemptions and establish time
7 periods by considering factors deter-
8 mined by the Administrator to be rel-
9 evant to the goals of fostering innova-
10 tion and the development of alter-
11 natives that meet the safety standard.

12 “(II) LIMITATION.—Any renewal
13 of an exemption in the case of a rule
14 requiring the ban or phase-out of a
15 chemical substance shall not exceed 5
16 years.

17 “(e) IMMEDIATE EFFECT.—The Administrator may
18 declare a proposed rule under subsection (d) to be effective
19 on publication of the rule in the Federal Register and until
20 the effective date of final action taken respecting the rule,
21 if—

22 “(1) the Administrator determines that—

23 “(A) the manufacture, processing, distribu-
24 tion in commerce, use, or disposal of the chem-
25 ical substance or mixture subject to the pro-

1 posed rule or any combination of those activi-
2 ties is likely to result in an unreasonable risk
3 of serious or widespread harm to health or the
4 environment before the effective date; and

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

7 “(2) in the case of a proposed rule to prohibit
8 the manufacture, processing, or distribution of a
9 chemical substance or mixture because of the risk
10 determined under paragraph (1)(A), a court has
11 granted relief in an action under section 7 with re-
12 spect to that risk associated with the chemical sub-
13 stance or mixture.

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

16 “(1) a safety determination; and the associated
17 safety assessment; for a chemical substance that the
18 Administrator determines under subsection (c) meets
19 the safety standard; shall be considered to be a final
20 agency action; effective beginning on the date of
21 issuance of the final safety determination; and

22 “(2) a final rule promulgated under subsection
23 (d); and the associated safety assessment and safety
24 determination that a chemical substance does not
25 meet the safety standard; shall be considered to be

1 a final agency action, effective beginning on the date
2 of promulgation of the final rule.”; and

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

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

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

8 **SEC. 9. IMMINENT HAZARDS.**

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

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

13 “(a) CIVIL ACTIONS.—

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

17 “(A) seizure of an imminently hazardous
18 chemical substance or mixture or any article
19 containing the chemical substance or mixture;

20 “(B) relief (as authorized by subsection
21 (b)) against any person that manufactures,
22 processes, distributes in commerce, uses, or dis-
23 poses of, an imminently hazardous chemical
24 substance or mixture or any article containing
25 the chemical substance or mixture; or

1 “(C) both seizure described in subpara-
2 graph (A) and relief described in subparagraph
3 (B).”

4 “(2) ~~RULE, ORDER, OR OTHER PROCEEDING.—~~
5 A civil action may be commenced under this para-
6 graph, notwithstanding—

7 “(A) the existence of—

8 “(i) a decision by the Administrator
9 under section 4A, 5(d)(3), or 6(e)(1); or

10 “(ii) a rule, testing consent agree-
11 ment, or order under section 4, 5(d)(4),
12 6(d), or 6(h); or

13 “(B) the pendency of any administrative or
14 judicial proceeding under any provision of this
15 Act.”;

16 (2) in subsection (d), by striking “section 6(a)”
17 and inserting “section 6(e)”; and

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

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

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

23 (1) in subsection (a)—

24 (A) in paragraph (3)(A)(ii)(I)—

1 (i) by striking “5(b)(4)” and inserting
2 “5”;

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

5 (iii) by striking “5(e),” and inserting
6 “5(d)(4);”; and

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

8 “(4) RULES.—

9 “(A) DEADLINE.—

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

22 “(ii) MODIFICATION OF PRIOR
23 RULES.—In carrying out this subpara-
24 graph, the Administrator may modify, as
25 appropriate, rules promulgated before the

1 date of enactment of the Frank R. Lauten-
2 berg Chemical Safety for the 21st Century
3 Act.

4 “(B) CONTENTS.—The rules promulgated
5 pursuant to subparagraph (A)—

6 “(i) may impose different reporting
7 and recordkeeping requirements on manu-
8 facturers and processors; and

9 “(ii) shall include the level of detail
10 necessary to be reported, including the
11 manner by which use and exposure infor-
12 mation may be reported.

13 “(C) ADMINISTRATION.—In implementing
14 the reporting and recordkeeping requirements
15 under this paragraph, the Administrator shall
16 take measures—

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

19 “(ii) to minimize the impact of the
20 rules on small manufacturers and pro-
21 cessors; and

22 “(iii) to apply any reporting obliga-
23 tions to those persons likely to have infor-
24 mation relevant to the effective implemen-
25 tation of this title.

1 “(5) GUIDANCE.—The Administrator shall de-
2 velop guidance relating to the information required
3 to be reported under the rules promulgated under
4 this subsection.”;

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

7 “(3) NOMENCLATURE.—

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

10 “(i) maintain the use of Class 2 no-
11 menclature in use on the date of enact-
12 ment of the Frank R. Lautenberg Chem-
13 ical Safety for the 21st Century Act;

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

24 “(iii) treat all components of cat-
25 egories that are considered to be statutory

1 mixtures under this Act as being included
2 on the list published under paragraph (1)
3 under the Chemical Abstracts Service
4 numbers for the respective categories, in-
5 cluding, without limitation—

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

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

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

12 “(IV) frits, chemicals, CAS No.
13 65997-18-4;

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

16 “(VI) ceramic materials and
17 wares, chemicals, CAS No. 66402-
18 68-4.

19 “(B) MULTIPLE NOMENCLATURE CONVEN-
20 TIONS.—

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

24 “(I) maintain the nomenclature
25 conventions for substances; and

1 “(H) develop new guidance
2 that—

3 “(aa) establishes equivalency
4 between the nomenclature con-
5 ventions for chemical substances
6 on the list published under para-
7 graph (1); and

8 “(bb) permits persons to
9 rely on the new guidance for pur-
10 poses of determining whether a
11 chemical substance is on the list
12 published under paragraph (1).

13 “(ii) MULTIPLE CAS NUMBERS.—For
14 any chemical substance appearing multiple
15 times on the list under different Chemical
16 Abstracts Service numbers, the Adminis-
17 trator shall develop guidance recognizing
18 the multiple listings as a single chemical
19 substance.

20 “(4) CHEMICAL SUBSTANCES IN COMMERCE.—

21 “(A) RULES.—

22 “(i) IN GENERAL.—Not later than 1
23 year after the date of enactment of the
24 Frank R. Lautenberg Chemical Safety for
25 the 21st Century Act, the Administrator,

1 by rule, shall require manufacturers and
2 processors to notify the Administrator, by
3 not later than 180 days after the date of
4 promulgation of the rule, of each chemical
5 substance on the list published under para-
6 graph (1) that the manufacturer or proc-
7 essor, as applicable, has manufactured or
8 processed for a nonexempt commercial pur-
9 pose during the 10-year period ending on
10 the day before the date of enactment of the
11 Frank R. Lautenberg Chemical Safety for
12 the 21st Century Act.

13 “(ii) ACTIVE SUBSTANCES.—The Ad-
14 ministrator shall, pursuant to paragraph
15 (5)(A), designate chemical substances for
16 which notices are received under clause (i)
17 to be active substances on the list pub-
18 lished under paragraph (1).

19 “(B) CONFIDENTIAL CHEMICAL SUB-
20 STANCES.—The rule promulgated by the Ad-
21 ministrator pursuant to subparagraph (A) shall
22 require—

23 “(i) the Administrator to maintain the
24 list under paragraph (1), which shall in-
25 clude a confidential portion and a noncon-

1 confidential portion consistent with this sec-
2 tion and section 14;

3 “(ii) a manufacturer or processor that
4 is submitting a notice pursuant to sub-
5 paragraph (A) for a chemical substance on
6 the confidential portion of the list pub-
7 lished under paragraph (1) to indicate in
8 the notice whether the manufacturer or
9 processor seeks to maintain any existing
10 claim for protection against disclosure of
11 the specific identity of the substance as
12 confidential pursuant to section 14; and

13 “(iii) the substantiation of those
14 claims pursuant to section 14 and in ac-
15 cordance with the review plan described in
16 subparagraph (C).

17 “(C) REVIEW PLAN.—Not later than 1
18 year after the date on which the Administrator
19 compiles the initial list of active substances pur-
20 suant to subparagraph (A), the Administrator
21 shall promulgate a rule that establishes a plan
22 to review all claims to protect the specific iden-
23 tities of chemical substances on the confidential
24 portion of the list published under paragraph
25 (1) that are notified pursuant to subparagraph

1 (A) or identified as active substances under
2 subsection (f)(1).

3 “(D) REQUIREMENTS OF REVIEW PLAN.—

4 The review plan under subparagraph (C)
5 shall—

6 “(i) require, at the time requested by
7 the Administrator, all manufacturers or
8 processors asserting claims under subpara-
9 graph (B) to substantiate the claim unless
10 the manufacturer or processor has sub-
11 stantiated the claim in a submission made
12 to the Administrator during the 5-year pe-
13 riod ending on the date of the request by
14 the Administrator;

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

17 “(I) to review each substan-
18 tiation—

19 “(aa) submitted pursuant to
20 clause (i) to determine if the
21 claim warrants protection from
22 disclosure; and

23 “(bb) submitted previously
24 by a manufacturer or processor
25 and relied on in lieu of the sub-

1 stantiation required pursuant to
2 clause (i), if the substantiation
3 has not been previously reviewed
4 by the Administrator, to deter-
5 mine if the claim warrants pro-
6 tection from disclosure;

7 “(II) approve, modify, or deny
8 each claim; and

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

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

22 “(bb) the Administrator oth-
23 erwise becomes aware that the
24 need for protection from disclo-
25 sure can no longer be substan-

1 tiated, in which case the Admin-
2 istrator shall take the actions de-
3 scribed in section 14(g)(2); and

4 “(iii) encourage manufacturers or
5 processors that have previously made
6 claims to protect the specific identities of
7 chemical substances identified as inactive
8 pursuant to subsection (f)(2) to review and
9 either withdraw or substantiate the claims.

10 “(E) TIMELINE FOR COMPLETION OF RE-
11 VIEWS.—

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

19 “(ii) CONSIDERATIONS.—

20 “(I) IN GENERAL.—The Admin-
21 istrator may extend the deadline for
22 completion of the reviews for not more
23 than 2 additional years, after an ade-
24 quate public justification, if the Ad-
25 ministrator determines that the exten-

1 sion is necessary based on the number
2 of applicable claims needing review
3 and the available resources.

4 “(H) ANNUAL GOAL.—The Ad-
5 ministrators shall publish an annual
6 goal for the number of reviews to be
7 completed over the course of imple-
8 mentation of the plan.

9 “(5) ACTIVE AND INACTIVE SUBSTANCES.—

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

14 “(B) UPDATE.—The Administrator shall
15 update the list of chemical substances des-
16 ignated as active substances as soon as prac-
17 ticable after the date of publication of the most
18 recent data reported under—

19 “(i) part 711 of title 40, Code of Fed-
20 eral Regulations (or successor regulations);
21 and

22 “(ii) the rules promulgated pursuant
23 to subsection (a)(4).

24 “(C) CHANGE TO ACTIVE STATUS.—

1 “(i) IN GENERAL.—Any person that
2 intends to manufacture or process for a
3 nonexempt commercial purpose a chemical
4 substance that is designated as an inactive
5 substance shall notify the Administrator
6 before the date on which the inactive sub-
7 stance is manufactured or processed.

8 “(ii) CONFIDENTIAL CHEMICAL IDEN-
9 TITY CLAIMS.—If a person submitting a
10 notice under clause (i) for an inactive sub-
11 stance on the confidential portion of the
12 list published under paragraph (1) seeks to
13 maintain an existing claim for protection
14 against disclosure of the specific identity of
15 the inactive substance as confidential, the
16 person shall—

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

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

22 “(iii) ACTIVE STATUS.—On receiving
23 a notification under clause (i), the Admin-
24 istrator shall—

1 “(I) designate the applicable
2 chemical substance as an active sub-
3 stance;

4 “(II) pursuant to section 14,
5 promptly review any claim and associ-
6 ated substantiation submitted pursu-
7 ant to clause (ii) for protection
8 against disclosure of the specific iden-
9 tity of the chemical substance and ap-
10 prove, modify, or deny the claim;

11 “(III) except as provided in this
12 section and section 14, protect from
13 disclosure the specific identity of the
14 chemical substance for which the Ad-
15 ministrator approves a claim under
16 subclause (II) for a period of not less
17 than 10 years; unless, prior to the ex-
18 piration of the period—

19 “(aa) the person notifies the
20 Administrator that the person is
21 withdrawing the confidentiality
22 claim; in which case the Adminis-
23 trator shall promptly make the
24 information available to the pub-
25 lic; or

1 “(bb) the Administrator oth-
2 erwise becomes aware that the
3 need for protection from disclo-
4 sure can no longer be substan-
5 tiated, in which case the Admin-
6 istrator shall take the actions de-
7 scribed in section 14(g)(2); and

8 “(IV) pursuant to section 4A, re-
9 view the priority of the chemical sub-
10 stance as the Administrator deter-
11 mines to be necessary.

12 “(D) CATEGORY STATUS.—The list of in-
13 active substances shall not be considered to be
14 a category for purposes of section 26(e).

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

1 “(7) PUBLIC PARTICIPATION.—Subject to this
2 subsection, the Administrator shall make available to
3 the public—

4 “(A) the specific identity of each chemical
5 substance on the nonconfidential portion of the
6 list published under paragraph (1) that the Ad-
7 ministrator has designated as—

8 “(i) an active substance; or

9 “(ii) an inactive substance;

10 “(B) the accession number, generic name,
11 and, if applicable, premanufacture notice case
12 number for each chemical substance on the con-
13 fidential portion of the list published under
14 paragraph (1) for which a claim of confiden-
15 tiality was received and approved by the Admin-
16 istrator pursuant to section 14; and

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

19 “(i) no claim of protection against dis-
20 closure of the specific identity of the active
21 substance pursuant to this subsection was
22 received;

23 “(ii) a claim for protection against
24 disclosure of the specific identity of the ac-

1 tive substance has been denied by the Ad-
2 ministrator; or

3 “~~(iii)~~ the time period for protection
4 against disclosure of the specific identity of
5 the active substance has expired.

6 “~~(8)~~ LIMITATION.—No person may assert a
7 new claim under this subsection for protection from
8 disclosure of a specific identity of any active or inae-
9 tive chemical substance for which a notice is received
10 under paragraph ~~(4)(A)(i)~~ or ~~(5)(C)(i)~~ that is not on
11 the confidential portion of the list published under
12 paragraph ~~(1)~~.

13 “~~(9)~~ CERTIFICATION.—Under the rule promul-
14 gated under this subsection, manufacturers and
15 processors shall be required—

16 “~~(A)~~ to certify that each report the manu-
17 facturer or processor submits complies with the
18 requirements of the rule, and that any confiden-
19 tiality claims are true and correct; and

20 “~~(B)~~ to retain a record supporting the cer-
21 tification for a period of 5 years beginning on
22 the last day of the submission period.”;

23 ~~(3)~~ in subsection ~~(c)~~—

24 ~~(A)~~ by striking “Any person” and inserting
25 the following:

1 “(1) IN GENERAL.—Any person”;

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

3 “(2) APPLICABILITY.—Any person may submit
4 to the Administrator information reasonably sup-
5 porting the conclusion that a chemical substance or
6 mixture presents, will present, or does not present a
7 substantial risk of harm to health and the environ-
8 ment.”; and

9 (4) in subsection (f), by striking “For purposes
10 of this section, the” and inserting the following: “In
11 this section:

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

14 “(A) that has been manufactured or proe-
15 cessed for a nonexempt commercial purpose at
16 any point during the 10-year period ending on
17 the date of enactment of the Frank R. Lauten-
18 berg Chemical Safety for the 21st Century Act;

19 “(B) that is added to the list published
20 under subsection (b)(1) after that date of en-
21 actment; or

22 “(C) for which a notice is received under
23 subsection (b)(5)(C).

24 “(2) INACTIVE SUBSTANCE.—The term ‘inactive
25 substance’ means a chemical substance on the list

1 published under subsection (b)(1) that does not meet
2 any of the criteria described in paragraph (1).

3 ~~“(3) MANUFACTURE; PROCESS.—The”.~~

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

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

7 (1) in subsection (a)—

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

10 (i) by striking “presents or will
11 present an unreasonable risk to health or
12 the environment” and inserting “does not
13 meet the safety standard”; and

14 (ii) by striking “such risk” the first
15 place it appears and inserting “the risk
16 posed by the substance or mixture”;

17 (B) in paragraph (2), in the matter fol-
18 lowing subparagraph (B), by striking “section 6
19 or 7” and inserting “section 6(d) or section 7”;
20 and

21 (C) in paragraph (3), by striking “section
22 6 or 7” and inserting “section 6(d) or 7”;

23 (2) in subsection (d), in the first sentence, by
24 striking “Health, Education, and Welfare” and in-
25 serting “Health and Human Services”; and

1 ~~(3)~~ by adding at the end the following:

2 ~~“(e) EXPOSURE INFORMATION.—If the Adminis-~~
 3 ~~trator obtains information related to exposures or releases~~
 4 ~~of a chemical substance that may be prevented or reduced~~
 5 ~~under another Federal law, including laws not adminis-~~
 6 ~~tered by the Administrator, the Administrator shall make~~
 7 ~~such information available to the relevant Federal agency~~
 8 ~~or office of the Environmental Protection Agency.”.~~

9 **SEC. 12. RESEARCH, DEVELOPMENT, COLLECTION, DIS-**
 10 **SEMINATION, AND UTILIZATION OF DATA.**

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

15 **SEC. 13. EXPORTS.**

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

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

20 ~~“(2) EXCEPTION.—Paragraph (1) shall not~~
 21 ~~apply to any chemical substance that the Adminis-~~
 22 ~~trator determines—~~

23 ~~“(A) under section 5 is not likely to meet~~
 24 ~~the safety standard; or~~

1 “(B) under section 6 does not meet the
2 safety standard.

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

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

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

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

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

19 “(b) NOTICE.—

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

23 “(A) a chemical substance or a mixture
24 containing a chemical substance that the Ad-
25 ministrator has determined under section 5 is

1 not likely to meet the safety standard and for
2 which a prohibition or other restriction has
3 been proposed or established under that section;

4 “(B) a chemical substance or a mixture
5 containing a chemical substance that the Ad-
6 ministrator has determined under section 6
7 does not meet the safety standard and for
8 which a prohibition or other restriction has
9 been proposed or established under that section;

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

13 “(D) a chemical substance or mixture sub-
14 ject to a prohibition or other restriction pursu-
15 ant to a rule, order, or consent agreement in ef-
16 fect under this Act; or

17 “(E) a chemical substance or mixture for
18 which the submission of information is required
19 under section 4.

20 “(2) RULES.—

21 “(A) IN GENERAL.—The Administrator
22 shall promulgate rules to carry out paragraph
23 (1).

24 “(B) CONTENTS.—The rules promulgated
25 pursuant to subparagraph (A) shall—

1 “(i) include such exemptions as the
2 Administrator determines to be appro-
3 priate, which may include exemptions iden-
4 tified under section 5(h); and

5 “(ii) indicate whether, or to what ex-
6 tent, the rules apply to articles containing
7 a chemical substance or mixture described
8 in paragraph (1).

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

12 “(A) for a chemical substance or mixture
13 described in subparagraph (A), (B), or (D) of
14 paragraph (1), a notice of the determination,
15 rule, order, consent agreement, requirement, or
16 designation;

17 “(B) for a chemical substance described in
18 paragraph (1)(C), a notice that satisfies the ob-
19 ligation of the United States under the applica-
20 ble treaty; and

21 “(C) for a chemical substance or mixture
22 described in paragraph (1)(E), a notice of avail-
23 ability of the information on the chemical sub-
24 stance or mixture submitted to the Adminis-
25 trator.”; and

1 (3) in subsection (c)—
2 (A) by striking paragraph (3); and
3 (B) by redesignating paragraphs (4)
4 through (6) as paragraphs (3) through (5), re-
5 spectively.

6 **SEC. 14. IMPORTS.**

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

9 **“SEC. 13. IMPORTS.**

10 “(a) REFUSAL OF ENTRY.—

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

18 “(A) the Administrator—

19 “(i) has determined under section 6(e)
20 that the chemical substance or mixture
21 does not meet the safety standard; and

22 “(ii) has promulgated a rule pursuant
23 to section 6(d) banning the chemical sub-
24 stance or mixture, as of the effective date
25 of the rule;

1 “(B) the chemical substance—

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

4 “(ii) is not exempt from any require-
5 ment to be included on that list by this
6 title or a rule promulgated by the Adminis-
7 trator pursuant to this title; or

8 “(C) the chemical substance, mixture, or
9 any article containing the chemical substance or
10 mixture is offered for entry in violation of—

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

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

15 “(2) PROCEDURE.—

16 “(A) IN GENERAL.—Subject to subpara-
17 graph (B), if a chemical substance, mixture, or
18 article containing a chemical substance or mix-
19 ture is refused entry under paragraph (1), the
20 Secretary of Homeland Security—

21 “(i) shall notify the consignee of the
22 entry of the refusal;

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

1 “(iii) shall cause the disposal or stor-
2 age of the chemical substance or mixture
3 under such rules as the Secretary may pre-
4 scribe, if the chemical substance or mix-
5 ture has not been exported by the con-
6 signee during the 90-day period beginning
7 on the date of receipt of the notice of the
8 refused entry.

9 “(B) EXCEPTION.—

10 “(i) IN GENERAL.—The Secretary of
11 Homeland Security, pending a review by
12 the Administrator, may release to the con-
13 signee the chemical substance or mixture if
14 the consignee—

15 “(I) executes a bond for the
16 amount of the full invoice of the
17 chemical substance or mixture (as set
18 forth in the customs entry); and

19 “(II) pays a duty on the chemical
20 substance or mixture.

21 “(ii) ADMINISTRATION.—If a con-
22 signee fails to return a chemical substance
23 or mixture released to that consignee
24 under clause (i) for any cause to the cus-
25 tody of the Secretary of Homeland Secu-

1 rity on demand, the consignee shall be lia-
2 ble to the United States for liquidated
3 damages equal to the full amount of the
4 bond executed under clause (i)(I).

5 “(C) STORAGE.—All charges for storage,
6 cartage, and labor on or for the disposal of a
7 chemical substance or mixture that is refused
8 entry or released under this subsection shall be
9 paid by the owner or consignee, and a default
10 on that payment shall constitute a lien against
11 any future entry made by the owner or con-
12 signee.

13 “(b) CERTIFICATION.—

14 “(1) IN GENERAL.—A person offering a chem-
15 ical substance or mixture subject to this Act for
16 entry into the customs territory of the United States
17 shall certify to the Secretary of Homeland Security
18 that—

19 “(A) after reasonable inquiry and to the
20 best knowledge and belief of the person, the
21 chemical substance or mixture is in compliance
22 with any applicable rule, consent agreement, or
23 order under section 5 or 6; and

24 “(B) the chemical substance—

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

3 “(ii) is exempt from any requirement
4 to be included on that list by this title or
5 a rule promulgated by the Administrator
6 pursuant to this title.

7 “(2) ARTICLES.—

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

13 “(B) REQUIREMENT.—The rule under sub-
14 paragraph (A) shall identify, with reasonable
15 specificity, the types of articles, including parts
16 or components of articles, that will be subject to
17 the certification requirement.

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

22 “(i) the utility of the certification to
23 enforcement of the applicable rule, consent
24 agreement, or order under section 5 or 6;

1 “(ii) the contribution of imported arti-
2 cles to the potential risk presented by ex-
3 posure to the chemical substance or mix-
4 ture subject to rule under section 5 or 6;

5 “(iii) the impact on commerce and po-
6 tential for the certification to impede or
7 disrupt import of articles;

8 “(iv) the frequency or duration of the
9 certification requirement; and

10 “(v) specification of the concentration
11 of a chemical substance in an article that
12 would subject the article to the certifi-
13 cation requirement.

14 “(3) REASONABLE INQUIRY.—

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

19 “(i) a safety data sheet or similar dec-
20 laration provided by a supplier that docu-
21 ments the specific identity of the chemical
22 substance or the specific identities of all
23 chemical substances in a mixture; or

24 “(ii) for chemical substances or mix-
25 tures claimed by the supplier as confiden-

1 tial, or not otherwise disclosed by the sup-
2 plier, a certification by the supplier that
3 the imported chemical substance or mix-
4 ture satisfies the applicable certification re-
5 quirements under paragraph (1).

6 “(B) ARTICLES.—For purposes of a cer-
7 tification under paragraph (2), reasonable in-
8 quiry shall include good faith reliance by an im-
9 porter on a certification by the supplier that the
10 imported article satisfies the applicable certifi-
11 cation requirements in a rule promulgated pur-
12 suant to paragraph (2).

13 “(4) INFORMATION REGARDING IDENTITY.—
14 For purposes of this subsection, the Administrator
15 shall provide publicly accessible information regard-
16 ing the identity of a chemical substance or mixture
17 subject to rule under this Act that would be readily
18 understood in import transactions.

19 “(e) NOTICE.—A person offering a chemical sub-
20 stance for entry into the customs territory of the United
21 States shall notify the Secretary of Homeland Security
22 if—

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

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

5 “(3) the chemical substance or chemical sub-
 6 stance in a mixture—

7 “(A) is the subject of a safety assessment
 8 and safety determination conducted pursuant to
 9 section 6; and

10 “(B) has been found not to meet the safety
 11 standard.

12 “(d) RULES.—

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

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

20 **SEC. 15. CONFIDENTIAL INFORMATION.**

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

23 **“SEC. 14. CONFIDENTIAL INFORMATION.**

24 “(a) IN GENERAL.—Except as otherwise provided in
 25 this section, the Administrator shall not disclose informa-

1 tion that is exempt from disclosure pursuant to subsection
2 (a) of section 552 of title 5, United States Code, under
3 subsection (b)(4) of that section—

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

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

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

17 “(1) Specific information describing the proce-
18 sses used in manufacture or processing of a chem-
19 ical substance, mixture, or article.

20 “(2) Marketing and sales information.

21 “(3) Information identifying a supplier or cus-
22 tomer.

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

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

4 “(6) Specific production or import volumes of
5 the manufacturer and specific aggregated volumes
6 across manufacturers, if the Administrator deter-
7 mines that disclosure of the specific aggregated vol-
8 umes would reveal confidential information.

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

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

19 “(B) the claim—

20 “(i) is not subject to an exception
21 under subsection (e); or

22 “(ii) has not subsequently been with-
23 drawn or found by the Administrator not
24 to warrant protection as confidential infor-
25 mation under subsection (f)(2) or (g).

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

4 “(1) INFORMATION FROM HEALTH AND SAFETY
5 STUDIES.—

6 “(A) IN GENERAL.—Subject to subpara-
7 graph (B), subsection (a) does not prohibit the
8 disclosure of—

9 “(i) any health and safety study that
10 is submitted under this Act with respect
11 to—

12 “(I) any chemical substance or
13 mixture that, on the date on which
14 the study is to be disclosed, has been
15 offered for commercial distribution; or

16 “(II) any chemical substance or
17 mixture for which—

18 “(aa) testing is required
19 under section 4; or

20 “(bb) a notification is re-
21 quired under section 5; or

22 “(ii) any information reported to, or
23 otherwise obtained by, the Administrator
24 from a health and safety study relating to

1 a chemical substance or mixture described
2 in subclause (I) or (II) of clause (i).

3 “(B) EFFECT OF PARAGRAPH.—Nothing
4 in this paragraph authorizes the release of any
5 information that discloses—

6 “(i) a process used in the manufac-
7 turing or processing of a chemical sub-
8 stance or mixture; or

9 “(ii) in the case of a mixture, the por-
10 tion of the mixture comprised by any
11 chemical substance in the mixture.

12 “(2) CERTAIN REQUESTS.—If a request is made
13 to the Administrator under section 552(a) of title 5,
14 United States Code, for information that is de-
15 scribed in paragraph (1) that is not described in
16 paragraph (1)(B), the Administrator may not deny
17 the request on the basis of section 552(b)(4) of title
18 5, United States Code.

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

22 “(A) For information submitted after the
23 date of enactment of the Frank R. Lautenberg
24 Chemical Safety for the 21st Century Act, the
25 specific identity of a chemical substance as of

1 the date on which the chemical substance is
2 first offered for commercial distribution, if the
3 person submitting the information does not
4 meet the requirements of subsection (d).

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

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

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

22 “(4) MIXED CONFIDENTIAL AND NONCON-
23 FIDENTIAL INFORMATION.—Any information that is
24 otherwise eligible for protection under this section
25 and contained in a submission of information de-

1 scribed in this subsection shall be protected from
2 disclosure, if the submitter complies with subsection
3 (d), subject to the condition that information in the
4 submission that is not eligible for protection against
5 disclosure shall be disclosed.

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

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

15 ~~“(B) the Administrator promptly shall~~
16 ~~make the information public.~~

17 ~~“(d) REQUIREMENTS FOR CONFIDENTIALITY~~
18 ~~CLAIMS.—~~

19 ~~“(1) ASSERTION OF CLAIMS.—~~

20 ~~“(A) IN GENERAL.—A person seeking to~~
21 ~~protect any information submitted under this~~
22 ~~Act from disclosure (including information de-~~
23 ~~scribed in subsection (b)) shall assert to the Ad-~~
24 ~~ministrator a claim for protection concurrent~~
25 ~~with submission of the information, in accord-~~

1 ance with such rules regarding a claim for pro-
2 tection from disclosure as the Administrator
3 has promulgated or may promulgate pursuant
4 to this title.

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

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

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

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

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

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

1 ical substance that the Administrator may dis-
2 close to the public, subject to the condition that
3 the generic name shall—

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

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

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

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

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

20 “(2) ADDITIONAL REQUIREMENTS FOR CON-
21 FIDENTIALITY CLAIMS.—Except for information de-
22 scribed in paragraphs (1) through (7) of subsection
23 (b), a person asserting a claim to protect informa-
24 tion from disclosure under this Act shall substan-

1 tiate the claim, in accordance with the rules promul-
2 gated and guidance issued by the Administrator.

3 ~~“(3) GUIDANCE.—~~The Administrator shall de-
4 velop guidance regarding—

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

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

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

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

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

22 ~~“(A) under any law for the protection of~~
23 health or the environment; or

24 ~~“(B) for a specific law enforcement pur-~~
25 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(e)(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(e)(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 noneon-
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 “(e) 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 (c)—

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(e), 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(e), 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 proe-
 9 cessing, 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(e) 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 Inspee-
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 “(e) 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”;

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.”.~~

19 **SECTION 1. SHORT TITLE.**

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

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

23 Section 2(c) of the Toxic Substances Control Act (15
24 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 in-
5 serting “, as provided under this Act” before the pe-
6 riod at the end; and

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

8 “(2) REFORM.—This Act, including reforms in
9 accordance with the amendments made by the Frank
10 R. Lautenberg Chemical Safety for the 21st Century
11 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 environ-
17 ment from the risks of harmful exposures to
18 chemical substances and mixtures; and

19 “(ii) ensures that appropriate informa-
20 tion on chemical substances and mixtures is
21 available to public health officials and first
22 responders in the event of an emergency;
23 and

24 “(B) shall not displace or supplant common
25 law rights of action or remedies for civil relief.”.

1 **SEC. 3. DEFINITIONS.**

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

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

8 *(2) by inserting after paragraph (3) the fol-*
9 *lowing:*

10 *“(4) CONDITIONS OF USE.—The term ‘conditions*
11 *of use’ means the intended, known, or reasonably fore-*
12 *seeable circumstances the Administrator determines a*
13 *chemical substance is manufactured, processed, dis-*
14 *tributed in commerce, used, or disposed of.”;*

15 *(3) by inserting after paragraph (10) (as so re-*
16 *designated) the following:*

17 *“(11) POTENTIALLY EXPOSED OR SUSCEPTIBLE*
18 *POPULATION.—The term ‘potentially exposed or sus-*
19 *ceptible population’ means 1 or more groups—*

20 *“(A) of individuals within the general pop-*
21 *ulation who may be—*

22 *“(i) differentially exposed to chemical*
23 *substances under the conditions of use; or*

24 *“(ii) susceptible to greater adverse*
25 *health consequences from chemical exposures*
26 *than the general population; and*

1 “(B) that when identified by the Adminis-
2 trator may include such groups as infants, chil-
3 dren, pregnant women, workers, and the elder-
4 ly.”; and

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

7 “(14) SAFETY ASSESSMENT.—The term ‘safety
8 assessment’ means an assessment of the risk posed by
9 a chemical substance under the conditions of use, in-
10 tegrating hazard, use, and exposure information re-
11 garding the chemical substance.

12 “(15) SAFETY DETERMINATION.—The term ‘safe-
13 ty determination’ means a determination by the Ad-
14 ministrator as to whether a chemical substance meets
15 the safety standard under the conditions of use.

16 “(16) SAFETY STANDARD.—The term ‘safety
17 standard’ means a standard that ensures, without
18 taking into consideration cost or other nonrisk fac-
19 tors, that no unreasonable risk of injury to health or
20 the environment will result from exposure to a chem-
21 ical substance under the conditions of use, including
22 no unreasonable risk of injury to—

23 “(A) the general population; or

24 “(B) any potentially exposed or susceptible
25 population that the Administrator has identified

1 *as relevant to the safety assessment and safety*
2 *determination for a chemical substance.”.*

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

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

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

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

10 “(b) *DEADLINE.*—*Not later than 2 years after the date*
11 *of enactment of the Frank R. Lautenberg Chemical Safety*
12 *for the 21st Century Act, the Administrator shall develop,*
13 *after providing public notice and an opportunity for com-*
14 *ment, any policies, procedures, and guidance the Adminis-*
15 *trator determines to be necessary to carry out sections 4,*
16 *4A, 5, and 6, including the policies, procedures, and guid-*
17 *ance required by this section.*

18 “(c) *USE OF SCIENCE.*—

19 “(1) *IN GENERAL.*—*The Administrator shall es-*
20 *tablish policies, procedures, and guidance on the use*
21 *of science in making decisions under sections 4, 4A,*
22 *5, and 6.*

23 “(2) *GOAL.*—*A goal of the policies, procedures,*
24 *and guidance described in paragraph (1) shall be to*
25 *make the basis of decisions clear to the public.*

1 “(3) *REQUIREMENTS.*—*The policies, procedures,*
2 *and guidance issued under this section shall describe*
3 *the manner in which the Administrator shall ensure*
4 *that —*

5 “(A) *decisions made by the Adminis-*
6 *trator—*

7 “(i) *are based on information, proce-*
8 *dures, measures, methods, and models em-*
9 *ployed in a manner consistent with the best*
10 *available science;*

11 “(ii) *take into account the extent to*
12 *which—*

13 “(I) *assumptions and methods are*
14 *clearly and completely described and*
15 *documented;*

16 “(II) *variability and uncertainty*
17 *are evaluated and characterized; and*

18 “(III) *the information has been*
19 *subject to independent verification and*
20 *peer review; and*

21 “(iii) *are based on the weight of the*
22 *scientific evidence, by which the Adminis-*
23 *trator considers all information in a sys-*
24 *tematic and integrative framework to con-*
25 *sider the relevance of different information;*

1 “(B) to the extent practicable and if appro-
2 priate, the use of peer review, standardized test
3 design and methods, consistent data evaluation
4 procedures, and good laboratory practices will be
5 encouraged;

6 “(C) a clear description of each individual
7 and entity that funded the generation or assess-
8 ment of information, and the degree of control
9 those individuals and entities had over the gen-
10 eration, assessment, and dissemination of infor-
11 mation (including control over the design of the
12 work and the publication of information) is
13 made available; and

14 “(D) if appropriate, the recommendations
15 in reports of the National Academy of Sciences
16 that provide advice regarding assessing the haz-
17 ards, exposures, and risks of chemical substances
18 are considered.

19 “(d) *EXISTING EPA POLICIES, PROCEDURES, AND*
20 *GUIDANCE.*—The policies, procedures, and guidance de-
21 scribed in subsection (b) shall incorporate, as appropriate,
22 existing relevant hazard, exposure, and risk assessment
23 guidelines and methodologies, data evaluation and quality
24 criteria, testing methodologies, and other relevant guidelines
25 and policies of the Environmental Protection Agency.

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

5 “(1) review the adequacy of any policies, proce-
6 dures, and guidance developed under this section, in-
7 cluding animal, nonanimal, and epidemiological test
8 methods and procedures for assessing and deter-
9 mining risk under this Act; and

10 “(2) after providing public notice and an oppor-
11 tunity for comment, revise the policies, procedures,
12 and guidance if necessary to reflect new scientific de-
13 velopments or understandings.

14 “(f) *SOURCES OF INFORMATION.*—In carrying out sec-
15 tions 4, 4A, 5, and 6, the Administrator shall take into con-
16 sideration information relating to a chemical substance, in-
17 cluding hazard and exposure information, under the condi-
18 tions of use that is reasonably available to the Adminis-
19 trator, including information that is—

20 “(1) submitted to the Administrator pursuant to
21 any rule, consent agreement, order, or other require-
22 ment of this Act, or on a voluntary basis, including
23 pursuant to any request made under this Act, by—

24 “(A) manufacturers or processors of a sub-
25 stance;

1 “(B) *the public;*

2 “(C) *other Federal departments or agencies;*

3 *or*

4 “(D) *the Governor of a State or a State*
5 *agency with responsibility for protecting health*
6 *or the environment;*

7 “(2) *submitted to a governmental entity in any*
8 *jurisdiction pursuant to a governmental requirement*
9 *relating to the protection of health or the environ-*
10 *ment; or*

11 “(3) *identified through an active search by the*
12 *Administrator of information sources that are pub-*
13 *licly available or otherwise accessible by the Adminis-*
14 *trator.*

15 “(g) *TESTING OF CHEMICAL SUBSTANCES AND MIX-*
16 *TURES.—*

17 “(1) *IN GENERAL.—The Administrator shall es-*
18 *tablish policies and procedures for the testing of chem-*
19 *ical substances or mixtures under section 4.*

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

23 “(3) *CONTENTS.—The policies and procedures es-*
24 *tablished under paragraph (1) shall—*

1 “(A) address how and when the exposure
2 level or exposure potential of a chemical sub-
3 stance would factor into decisions to require new
4 testing, subject to the condition that the Admin-
5 istrator shall not interpret the lack of exposure
6 information as a lack of exposure or exposure po-
7 tential;

8 “(B) describe the manner in which the Ad-
9 ministrator will determine that additional infor-
10 mation is necessary to carry out this Act, includ-
11 ing information relating to potentially exposed
12 or susceptible populations;

13 “(C) require the Administrator to consult
14 with the Director of the National Institute for
15 Occupational Safety and Health prior to pre-
16 scribing epidemiologic studies of employees; and

17 “(D) require that prior to making a request
18 or adopting a requirement for testing using
19 vertebrate animals, the Administrator shall take
20 into consideration, as appropriate and to the ex-
21 tent practicable, reasonably available—

22 “(i) toxicity information;

23 “(ii) computational toxicology and
24 bioinformatics;

1 “(iii) *high-throughput screening meth-*
2 *ods and the prediction models of those meth-*
3 *ods; and*

4 “(iv) *scientifically reliable and rel-*
5 *evant alternatives to tests on animals that*
6 *would provide equivalent information.*

7 “(h) *SAFETY ASSESSMENTS AND SAFETY DETERMINA-*
8 *TIONS.—*

9 “(1) *SCHEDULE.—*

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

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

22 “(C) *ANNUAL PLAN.—At the beginning of*
23 *each calendar year, the Administrator shall iden-*
24 *tify the substances subject to safety assessments*

1 *and safety determinations to be completed that*
2 *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 pro-*
10 *cedures under this paragraph shall be to make*
11 *the basis of decisions of the Administrator clear*
12 *to the public.*

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

16 “(i) *describe—*

17 “(I) *the manner in which the Ad-*
18 *ministrator 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 the
5 safety assessment and safety deter-
6 mination to be conducted under section
7 6, including the hazards, exposures,
8 conditions of use, and potentially ex-
9 posed and susceptible populations that
10 the Administrator expects to consider
11 in a safety assessment;

12 “(bb) to explain the basis for the
13 scope of the safety assessment and safe-
14 ty 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 ag-
25 gregate exposures, or significant subsets of

1 *exposures, to a chemical substance under the*
2 *conditions of use will be considered, and ex-*
3 *plain the basis for that consideration in the*
4 *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 of*
9 *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 transparent*
18 *process for evaluating whether new informa-*
19 *tion submitted or obtained after the date of*
20 *a final safety assessment or safety deter-*
21 *mination warrants reconsideration of the*
22 *safety assessment or safety determination;*
23 *and*

24 *“(vi) when relevant information is pro-*
25 *vided 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 their own draft safety*
11 *assessments and other information for sub-*
12 *mission to the Administrator, which may be*
13 *considered at the discretion of the Adminis-*
14 *trator.*

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 safety*
19 *assessment for consideration by the Admin-*
20 *istrator.*

21 *“(i) PUBLICLY AVAILABLE INFORMATION.—Subject to*
22 *section 14, the Administrator shall—*

23 *“(1) make publicly available a nontechnical*
24 *summary, and the final version, of each safety assess-*
25 *ment and safety determination;*

1 “(2) *provide public notice and an opportunity*
2 *for comment on each proposed safety assessment and*
3 *safety determination; and*

4 “(3) *make public in a final safety assessment*
5 *and safety determination—*

6 “(A) *the list of studies considered by the Ad-*
7 *ministrator in carrying out the safety assessment*
8 *or safety determination; and*

9 “(B) *the list of policies, procedures, and*
10 *guidance that were followed in carrying out the*
11 *safety assessment or safety determination.*

12 “(j) *CONSULTATION WITH SCIENCE ADVISORY COM-*
13 *MITTEE ON CHEMICALS.—*

14 “(1) *ESTABLISHMENT.—Not later than 1 year*
15 *after the date of enactment of this section, the Admin-*
16 *istrator shall establish an advisory committee, to be*
17 *known as the ‘Science Advisory Committee on Chemi-*
18 *cals’ (referred to in this subsection as the ‘Com-*
19 *mittee’).*

20 “(2) *PURPOSE.—The purpose of the Committee*
21 *shall be to provide independent advice and expert*
22 *consultation, on the request of the Administrator,*
23 *with respect to the scientific and technical aspects of*
24 *issues relating to the implementation of this title.*

1 “(3) *COMPOSITION.*—*The Committee shall be*
2 *composed of representatives of such science, govern-*
3 *ment, labor, public health, public interest, animal*
4 *protection, industry, and other groups as the Admin-*
5 *istrator determines to be advisable, including, at a*
6 *minimum, representatives that have specific scientific*
7 *expertise in the relationship of chemical exposures to*
8 *women, children, and other potentially exposed or*
9 *susceptible populations.*

10 “(4) *SCHEDULE.*—*The Administrator shall con-*
11 *vene the Committee in accordance with such schedule*
12 *as the Administrator determines to be appropriate,*
13 *but not less frequently than once every 2 years.*

14 “(5) *RELATIONSHIP TO OTHER LAW.*—*All pro-*
15 *ceedings and meetings of the Committee shall be sub-*
16 *ject to the Federal Advisory Committee Act (5 U.S.C.*
17 *App.).”.*

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

19 “(a) *IN GENERAL.*—*Section 4 of the Toxic Substances*
20 *Control Act (15 U.S.C. 2603) is amended—*

21 (1) *by striking subsections (a), (b), (c), (d), and*
22 (1);

23 (2) *by redesignating subsections (e) and (f) as*
24 *subsections (f) and (g), respectively;*

25 (3) *in subsection (f) (as so redesignated)—*

1 (A) by striking “rule” each place it appears
2 and inserting “rule, testing consent agreement,
3 or order”;

4 (B) by striking “under subsection (a)” each
5 place it appears and inserting “under this sub-
6 section”; and

7 (C) in paragraph (1)—

8 (i) in subparagraph (A)(v), by insert-
9 ing “, without taking into account cost or
10 other nonrisk factors” after “the environ-
11 ment”; and

12 (ii) in subparagraph (B), in the last
13 sentence, by striking “rulemaking”;

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

15 (A) in the first sentence—

16 (i) by striking “from cancer, gene
17 mutations, or birth defects”; and

18 (ii) by inserting “, without taking into
19 account cost or other nonrisk factors” before
20 the period at the end; and

21 (B) by striking the last sentence; and

22 (5) by inserting before subsection (f) (as so redesi-
23 gnated) the following:

24 “(a) DEVELOPMENT OF NEW INFORMATION ON CHEM-
25 ICAL SUBSTANCES AND MIXTURES.—

1 “(1) *IN GENERAL.*—*The Administrator may re-*
2 *quire the development of new information relating to*
3 *a chemical substance or mixture in accordance with*
4 *this section if the Administrator determines that the*
5 *information is necessary—*

6 “(A) *to review a notice under section 5(d)*
7 *or to perform a safety assessment or safety deter-*
8 *mination under section 6;*

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

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

14 “(D) *at the request of the implementing au-*
15 *thority under another Federal law, to meet the*
16 *regulatory testing needs of that authority.*

17 “(2) *LIMITED TESTING FOR PRIORITIZATION*
18 *PURPOSES.—*

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

23 “(B) *PROHIBITION.*—*Testing required*
24 *under subparagraph (A) shall not be required for*

1 *the purpose of establishing or implementing a*
2 *minimum information requirement.*

3 “(C) *LIMITATION.*—*The Administrator may*
4 *require the development of new information pur-*
5 *suant to subparagraph (A) only if the Adminis-*
6 *trator determines that additional information is*
7 *necessary to establish the priority of a chemical*
8 *substance.*

9 “(3) *FORM.*—*The Administrator may require the*
10 *development of information described in paragraph*
11 *(1) or (2) by—*

12 “(A) *promulgating a rule;*

13 “(B) *entering into a testing consent agree-*
14 *ment; or*

15 “(C) *issuing an order.*

16 “(4) *CONTENTS.*—

17 “(A) *IN GENERAL.*—*A rule, testing consent*
18 *agreement, or order issued under this subsection*
19 *shall include—*

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

23 “(ii) *identification of the persons re-*
24 *quired to conduct the testing;*

1 “(iii) test protocols and methodologies
2 for the development of information for the
3 chemical substance or mixture, including
4 specific reference to any reliable nonanimal
5 test procedures; and

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

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

16 “(i) the relative costs of the various test
17 protocols and methodologies that may be re-
18 quired; and

19 “(ii) the reasonably foreseeable avail-
20 ability of facilities and personnel required
21 to perform the testing.

22 “(b) STATEMENT OF NEED.—

23 “(1) IN GENERAL.—In promulgating a rule, en-
24 tering into a testing consent agreement, or issuing an
25 order for the development of additional information

1 *(including information on exposure or exposure po-*
2 *tential) pursuant to this section, the Administrator*
3 *shall—*

4 “(A) *identify the need intended to be met by*
5 *the rule, agreement, or order;*

6 “(B) *explain why information reasonably*
7 *available to the Administrator at that time is in-*
8 *adequate to meet that need, including a ref-*
9 *erence, as appropriate, to the information identi-*
10 *fied in paragraph (2)(B); and*

11 “(C) *explain the basis for any decision that*
12 *requires the use of vertebrate animals.*

13 “(2) *EXPLANATION IN CASE OF ORDER.—*

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

20 “(B) *CONTENTS.—A statement described in*
21 *subparagraph (A) shall contain a description*
22 *of—*

23 “(i) *information that is readily acces-*
24 *sible to the Administrator, including infor-*

1 *mation submitted under any other provi-*
2 *sion of law;*

3 *“(ii) the extent to which the Adminis-*
4 *trator has obtained or attempted to obtain*
5 *the information through voluntary submis-*
6 *sions; and*

7 *“(iii) any information relied on in*
8 *safety assessments for other chemical sub-*
9 *stances relevant to the chemical substances*
10 *that would be the subject of the order.*

11 *“(c) REDUCTION OF TESTING ON VERTEBRATES.—*

12 *“(1) IN GENERAL.—The Administrator shall*
13 *minimize, to the extent practicable, the use of*
14 *vertebrate animals in testing of chemical substances*
15 *or mixtures, by—*

16 *“(A) encouraging and facilitating—*

17 *“(i) the use of integrated and tiered*
18 *testing and assessment strategies;*

19 *“(ii) the use of best available science in*
20 *existence on the date on which the test is*
21 *conducted;*

22 *“(iii) the use of test methods that*
23 *eliminate or reduce the use of animals while*
24 *providing information of high scientific*
25 *quality;*

1 “(iv) the grouping of 2 or more chem-
2 ical substances into scientifically appro-
3 priate categories in cases in which testing of
4 a chemical substance would provide reliable
5 and useful information on other chemical
6 substances in the category;

7 “(v) the formation of industry con-
8 sortia to jointly conduct testing to avoid
9 unnecessary duplication of tests; and

10 “(vi) the submission of information
11 from—

12 “(I) animal-based studies; and

13 “(II) emerging methods and mod-
14 els; and

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

18 “(2) IMPLEMENTATION OF ALTERNATIVE TESTING
19 METHODS.—To promote the development and timely
20 incorporation of new testing methods that are not
21 based on vertebrate animals, the Administrator
22 shall—

23 “(A) not later than 2 years after the date
24 of enactment of the Frank R. Lautenberg Chem-
25 ical Safety for the 21st Century Act, develop a

1 *strategic plan to promote the development and*
2 *implementation of alternative test methods and*
3 *testing strategies to generate information under*
4 *this title that can reduce, refine, or replace the*
5 *use of vertebrate animals, including toxicity*
6 *pathway-based risk assessment, in vitro studies,*
7 *systems biology, computational toxicology,*
8 *bioinformatics, and high-throughput screening;*

9 “(B) as practicable, ensure that the stra-
10 *tegic plan developed under subparagraph (A) is*
11 *reflected in the development of requirements for*
12 *testing under this section;*

13 “(C) identify in the strategic plan developed
14 *under subparagraph (A) particular alternative*
15 *test methods or testing strategies that do not re-*
16 *quire new vertebrate animal testing and are sci-*
17 *entifically reliable, relevant, and capable of pro-*
18 *viding information of equivalent scientific reli-*
19 *ability and quality to that which would be ob-*
20 *tained from vertebrate animal testing;*

21 “(D) provide an opportunity for public no-
22 *tice and comment on the contents of the plan de-*
23 *veloped under subparagraph (A), including the*
24 *criteria for considering scientific reliability, rel-*
25 *evance, and equivalent information and the test*

1 *methods and strategies identified in subpara-*
2 *graph (C);*

3 “(E) *beginning on the date that is 5 years*
4 *after the date of enactment of the Frank R. Lau-*
5 *tenberg Chemical Safety for the 21st Century Act*
6 *and every 5 years thereafter, submit to Congress*
7 *a report that describes the progress made in im-*
8 *plementing this subsection and goals for future*
9 *alternative test methods implementation;*

10 “(F) *fund and carry out research, develop-*
11 *ment, performance assessment, and translational*
12 *studies to accelerate the development of test meth-*
13 *ods and testing strategies that reduce, refine, or*
14 *replace the use of vertebrate animals in any test-*
15 *ing under this title; and*

16 “(G) *identify synergies with the related in-*
17 *formation requirements of other jurisdictions to*
18 *minimize the potential for additional or duplica-*
19 *tive testing.*

20 “(3) *CRITERIA FOR ADAPTING OR WAIVING ANI-*
21 *MAL TESTING REQUIREMENTS.—On request from a*
22 *manufacturer or processor that is required to conduct*
23 *testing of a chemical substance or mixture on*
24 *vertebrate animals under this section, the Adminis-*

1 *trator may adapt or waive the requirement, if the Ad-*
2 *ministrators determine that—*

3 *“(A) there is sufficient evidence from several*
4 *independent sources of information to support a*
5 *conclusion that a chemical substance or mixture*
6 *has, or does not have, a particular property if*
7 *the information from each individual source*
8 *alone is insufficient to support the conclusion;*

9 *“(B) as a result of 1 or more physical or*
10 *chemical properties of the chemical substance or*
11 *mixture or other toxicokinetic considerations—*

12 *“(i) the substance cannot be absorbed;*

13 *or*

14 *“(ii) testing for a specific endpoint is*
15 *technically not practicable to conduct; or*

16 *“(C) a chemical substance or mixture can-*
17 *not be tested in vertebrate animals at concentra-*
18 *tions that do not result in significant pain or*
19 *distress, because of physical or chemical prop-*
20 *erties of the chemical substance or mixture, such*
21 *as a potential to cause severe corrosion or severe*
22 *irritation to the tissues of the animal.*

23 *“(4) VOLUNTARY TESTING.—*

24 *“(A) IN GENERAL.—Any person developing*
25 *information for submission under this title on a*

1 *voluntary basis and not pursuant to any request*
2 *or requirement by the Administrator shall first*
3 *attempt to develop the information by means of*
4 *an alternative or nonanimal test method or test-*
5 *ing strategy that the Administrator has deter-*
6 *mined under paragraph (2)(C) to be scientif-*
7 *ically reliable, relevant, and capable of providing*
8 *equivalent information, before conducting new*
9 *animal testing.*

10 “(B) *EFFECT OF PARAGRAPH.—Nothing in*
11 *this paragraph—*

12 “(i) *requires the Administrator to re-*
13 *view the basis on which the person is con-*
14 *ducting testing described in subparagraph*
15 *(A);*

16 “(ii) *prohibits the use of other test*
17 *methods or testing strategies by any person*
18 *for purposes other than developing informa-*
19 *tion for submission under this title on a*
20 *voluntary basis; or*

21 “(iii) *prohibits the use of other test*
22 *methods or testing strategies by any person,*
23 *subsequent to the attempt to develop infor-*
24 *mation using the test methods and testing*

1 *strategies identified by the Administrator*
2 *under paragraph (2)(C).*

3 “(d) *TESTING REQUIREMENTS.*—

4 “(1) *IN GENERAL.*—*The Administrator may re-*
5 *quire the development of information by—*

6 “(A) *manufacturers and processors of the*
7 *chemical substance or mixture; and*

8 “(B) *subject to paragraph (3), persons that*
9 *begin to manufacture or process the chemical*
10 *substance or mixture—*

11 “(i) *after the effective date of the rule,*
12 *testing consent agreement, or order; but*

13 “(ii) *before the period ending on the*
14 *later of—*

15 “(I) *5 years after the date referred*
16 *to in clause (i); or*

17 “(II) *the last day of the period*
18 *that begins on the date referred to in*
19 *clause (i) and that is equal to the pe-*
20 *riod that the Administrator determines*
21 *was necessary to develop the informa-*
22 *tion.*

23 “(2) *DESIGNATION.*—*The Administrator may*
24 *permit 2 or more persons identified in subparagraph*

1 (A) or (B) of paragraph (1) to designate 1 of the per-
2 sons or a qualified third party—

3 “(A) to develop the information; and

4 “(B) to submit the information on behalf of
5 the persons making the designation.

6 “(3) EXEMPTIONS.—

7 “(A) IN GENERAL.—A person otherwise sub-
8 ject to a rule, testing consent agreement, or order
9 under this section may submit to the Adminis-
10 trator an application for an exemption on the
11 basis that the information is being developed by
12 a person designated under paragraph (2).

13 “(B) FAIR AND EQUITABLE REIMBURSE-
14 MENT TO DESIGNEE.—

15 “(i) IN GENERAL.—If the Adminis-
16 trator accepts an application submitted
17 under subparagraph (A), the Administrator
18 shall direct the applicant to provide to the
19 person designated under paragraph (2) fair
20 and equitable reimbursement, as agreed to
21 between the applicant and the designee.

22 “(ii) ARBITRATION.—If the applicant
23 and a person designated under paragraph
24 (2) cannot reach agreement on the amount

1 *of fair and equitable reimbursement, the*
2 *amount shall be determined by arbitration.*

3 “(C) *TERMINATION.*—*If, after granting an*
4 *exemption under this paragraph, the Adminis-*
5 *trator determines that no person designated*
6 *under paragraph (2) has complied with the rule,*
7 *testing consent agreement, or order, the Adminis-*
8 *trator shall—*

9 “(i) *by order, terminate the exemption;*
10 *and*

11 “(ii) *notify in writing each person that*
12 *received an exemption of the requirements*
13 *with respect to which the exemption was*
14 *granted.*

15 “(4) *TIERED TESTING.*—

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

23 “(B) *SCREENING-LEVEL TESTS.*—

24 “(i) *IN GENERAL.*—*The screening-level*
25 *tests required for a chemical substance or*

1 *mixture may include tests for hazard*
2 *(which may include in silico, in vitro, and*
3 *in vivo tests), environmental and biological*
4 *fate and transport, and measurements or*
5 *modeling of exposure or exposure potential,*
6 *as appropriate.*

7 “(ii) *USE.—Screening-level tests shall*
8 *be used—*

9 “(I) *to screen chemical substances*
10 *or mixtures for potential adverse ef-*
11 *fects; and*

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

16 “(C) *ADDITIONAL TESTING.—If the Admin-*
17 *istrator determines under subparagraph (B) that*
18 *additional testing is necessary to provide more*
19 *definitive information for safety assessments or*
20 *safety determinations, the Administrator may*
21 *require more advanced tests for potential health*
22 *or environmental effects or exposure potential.*

23 “(D) *ADVANCED TESTING WITHOUT*
24 *SCREENING.—The Administrator may require*
25 *more advanced testing without conducting*

1 *screening-level testing when other information*
 2 *available to the Administrator justifies the ad-*
 3 *vanced testing, pursuant to guidance developed*
 4 *by the Administrator under this section.*

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

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

14 **SEC. 6. PRIORITIZATION SCREENING.**

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

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

18 “(a) *PRIORITIZATION SCREENING PROCESS AND LIST*
 19 *OF SUBSTANCES.*—

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

1 “(A) a high priority for a safety assessment
2 and safety determination under section 6 (re-
3 ferred 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 Act
7 as ‘low-priority substances’).

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

10 “(A) IN GENERAL.—Before the date of pro-
11 mulgation of the rule under paragraph (1) and
12 not later than 180 days after the date of enact-
13 ment 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-priority
20 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 and*
3 *subsequent updates, and at least 10 low-pri-*
4 *ority substances.*

5 “(ii) *SUBSEQUENTLY IDENTIFIED SUB-*
6 *STANCES.—Insofar as possible, at least 50*
7 *percent of all substances subsequently iden-*
8 *tified by the Administrator as high-priority*
9 *substances shall be drawn from the list of*
10 *chemical substances identified by the Ad-*
11 *ministrator 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 “(iii) *PERSISTENCE AND BIOACCUMU-*
16 *LATION.—In developing the initial list and*
17 *in identifying additional high-priority sub-*
18 *stances, the Administrator shall give pref-*
19 *erence to chemical substances scored as high*
20 *for persistence and bioaccumulation in the*
21 *October 2014 TSCA Work Plan and subse-*
22 *quent updates.*

23 “(C) *ADDITIONAL CHEMICAL REVIEWS.—*
24 *The Administrator shall, as soon as practicable*
25 *and not later than—*

1 “(i) 3 years after the date of enactment
2 of the Frank R. Lautenberg Chemical Safe-
3 ty for the 21st Century Act, add additional
4 high-priority substances sufficient to ensure
5 that at least a total of 20 high-priority sub-
6 stances have undergone or are undergoing
7 the process established in section 6(a), and
8 additional low-priority substances sufficient
9 to ensure that at least a total of 20 low-pri-
10 ority substances have been designated; and

11 “(ii) 5 years after the date of enact-
12 ment of the Frank R. Lautenberg Chemical
13 Safety for the 21st Century Act, add addi-
14 tional high-priority substances sufficient to
15 ensure that at least a total of 25 high-pri-
16 ority substances have undergone or are un-
17 dergoing the process established in section
18 6(a), and additional low-priority substances
19 sufficient to ensure that at least a total of
20 25 low-priority substances have been des-
21 ignated.

22 “(3) IMPLEMENTATION.—

23 “(A) CONSIDERATION OF ACTIVE AND INAC-
24 TIVE SUBSTANCES.—

1 “(i) *ACTIVE SUBSTANCES.*—*In carrying out paragraph (1), the Administrator*
2 *shall take into consideration active sub-*
3 *stances, as determined under section 8,*
4 *which may include chemical substances on*
5 *the interim list of active substances estab-*
6 *lished under that section.*

8 “(ii) *INACTIVE SUBSTANCES.*—*In carrying out paragraph (1), the Administrator*
9 *may take into consideration inactive sub-*
10 *stances, as determined under section 8, that*
11 *the Administrator determines—*

12 “(I)(aa) *have not 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) *have the potential for high*
17 *hazard and widespread exposure; or*

18 “(II)(aa) *have been subject to a*
19 *regulatory or other enforceable action*
20 *by the Administrator to ban or phase*
21 *out the substances; and*

22 “(bb) *with respect to which there*
23 *exists the potential for residual high*
24 *hazards or widespread exposures not*
25

1 otherwise addressed by the regulatory
2 or other action.

3 “(iii) REPOPULATION.—

4 “(I) IN GENERAL.—On the com-
5 pletion of a safety determination under
6 section 6 for a chemical substance, the
7 Administrator shall remove the chem-
8 ical substance from the list of high-pri-
9 ority substances established under this
10 subsection.

11 “(II) ADDITIONS.—The Adminis-
12 trator shall add at least 1 chemical
13 substance to the list of high-priority
14 substances for each chemical substance
15 removed from the list of high-priority
16 substances established under this sub-
17 section, until a safety assessment and
18 safety determination is completed for
19 all high-priority substances.

20 “(III) LOW-PRIORITY SUB-
21 STANCES.—If a low-priority substance
22 is subsequently designated as a high-
23 priority substance, the Administrator
24 shall remove that substance from the
25 list of low-priority substances.

1 “(B) *TIMELY COMPLETION OF*
2 *PRIORITIZATION SCREENING PROCESS.—*

3 “(i) *IN GENERAL.—The Administrator*
4 *shall—*

5 “(I) *except as provided under*
6 *paragraph (2), not later than 180 days*
7 *after the effective date of the final rule*
8 *under paragraph (1), begin the*
9 *prioritization screening process; and*

10 “(II) *make every effort to complete*
11 *the designation of all active substances*
12 *as high-priority substances or low-pri-*
13 *ority substances in a timely manner.*

14 “(ii) *DECISIONS ON SUBSTANCES SUB-*
15 *JECT TO TESTING FOR PRIORITIZATION*
16 *PURPOSES.—Not later than 90 days after*
17 *the date of receipt of information regarding*
18 *a chemical substance complying with a rule,*
19 *testing consent agreement, or order issued*
20 *under section 4(a)(2), the Administrator*
21 *shall designate the chemical substance as a*
22 *high-priority substance or low-priority sub-*
23 *stance.*

24 “(iii) *CONSIDERATION.—*

1 “(I) *IN GENERAL.*—*The Administrator shall screen substances and designate high-priority substances taking into consideration the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in a timely manner.*

9 “(II) *ANNUAL GOAL.*—*The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.*

14 “(C) *SCREENING OF CATEGORIES OF SUBSTANCES.*—*The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate designations of high-priority substances and low-priority substances and safety assessments and safety determinations for high-priority substances.*

22 “(D) *PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.*—*The Administrator shall keep current and publish a list of chemical substances that—*

1 “(i) are being considered in the
2 prioritization screening process and the sta-
3 tus of the chemical substances in the
4 prioritization process, including those chem-
5 ical substances for which prioritization de-
6 cisions have been deferred; and

7 “(ii) are designated as high-priority
8 substances or low-priority substances, in-
9 cluding the bases for such designations.

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

12 “(A) the recommendation of the Governor of
13 a State or a State agency with responsibility for
14 protecting health or the environment from chem-
15 ical substances appropriate for prioritization
16 screening;

17 “(B) the hazard and exposure potential of
18 the chemical substance (or category of sub-
19 stances), including persistence, bioaccumulation,
20 and specific scientific classifications and des-
21 ignations by authoritative governmental entities;

22 “(C) the conditions of use or significant
23 changes in the conditions of use of the chemical
24 substance;

1 “(D) evidence and indicators of exposure
2 potential to humans or the environment from the
3 chemical substance, including potentially exposed
4 or susceptible populations;

5 “(E) the volume of a chemical substance
6 manufactured or processed;

7 “(F) whether the volume of a chemical sub-
8 stance as reported under a rule promulgated
9 pursuant to section 8(a) has significantly in-
10 creased or decreased during the period beginning
11 on the date of a previous report or the date on
12 which a notice has been submitted under section
13 5(b) for that chemical substance;

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

23 “(H) the extent of Federal or State regula-
24 tion of the chemical substance or the extent of the
25 impact of State regulation of the chemical sub-

1 *stance on the United States, with existing Fed-*
2 *eral or State regulation of any uses evaluated in*
3 *the prioritization screening process as a factor in*
4 *designating a chemical substance to be a high-*
5 *priority or a low-priority substance.*

6 “(b) *PRIORITIZATION SCREENING PROCESS AND DECI-*
7 *SIONS.—*

8 “(1) *IN GENERAL.—The prioritization screening*
9 *process developed under subsection (a) shall include a*
10 *requirement that the Administrator shall—*

11 “(A) *identify the chemical substances being*
12 *considered for prioritization;*

13 “(B) *request interested persons to supply*
14 *information regarding the chemical substances*
15 *being considered;*

16 “(C) *apply the criteria identified in sub-*
17 *section (a)(4); and*

18 “(D) *subject to paragraph (5) and using the*
19 *information available to the Administrator at*
20 *the time of the decision, identify a chemical sub-*
21 *stance as a high-priority substance or a low-pri-*
22 *ority substance.*

23 “(2) *INTEGRATION OF INFORMATION.—The*
24 *prioritization screening decision regarding a chemical*
25 *substance shall integrate any hazard and exposure in-*

1 *formation relating to the chemical substance that is*
2 *available to the Administrator.*

3 “(3) *IDENTIFICATION OF HIGH-PRIORITY SUB-*
4 *STANCES.—The Administrator—*

5 “(A) *shall identify as a high-priority sub-*
6 *stance a chemical substance that, relative to*
7 *other active chemical substances, the Adminis-*
8 *trator determines has the potential for signifi-*
9 *cant hazard and significant exposure;*

10 “(B) *may identify as a high-priority sub-*
11 *stance a chemical substance that, relative to*
12 *other active chemical substances, the Adminis-*
13 *trator determines has the potential for signifi-*
14 *cant hazard or significant exposure; and*

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

21 “(4) *IDENTIFICATION OF LOW-PRIORITY SUB-*
22 *STANCES.—The Administrator shall identify as a low-*
23 *priority substance a chemical substance that the Ad-*
24 *ministrator concludes has information sufficient to es-*

1 *tablish that the chemical substance is likely to meet*
2 *the safety standard.*

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

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

13 “(B) *to require the development of informa-*
14 *tion pursuant to a rule, testing consent agree-*
15 *ment, or order issued under section 4(a)(2).*

16 “(6) *DEADLINES FOR SUBMISSION OF INFORMA-*
17 *TION.*—*If the Administrator requests the development*
18 *or submission of information under this section, the*
19 *Administrator shall establish a deadline for submis-*
20 *sion of the information.*

21 “(7) *NOTICE AND COMMENT.*—*The Administrator*
22 *shall—*

23 “(A) *publish, including in the Federal Reg-*
24 *ister, the proposed decisions made under para-*

1 *graphs (3), (4), and (5) and the basis for the de-*
2 *isions; and*

3 *“(B) provide 90 days for public comment.*

4 *“(8) REVISIONS OF PRIOR DESIGNATIONS.—*

5 *“(A) IN GENERAL.—At any time, and at the*
6 *discretion of the Administrator, the Adminis-*
7 *trator may revise the designation of a chemical*
8 *substance as a high-priority substance or a low-*
9 *priority substance based on information avail-*
10 *able to the Administrator after the date of the de-*
11 *termination under paragraph (3) or (4).*

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

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

21 *“(A) IN GENERAL.—If, after the date of en-*
22 *actment of the Frank R. Lautenberg Chemical*
23 *Safety for the 21st Century Act, a State proposes*
24 *an administrative action or enacts a statute or*
25 *takes an administrative action to prohibit or*

1 *otherwise restrict the manufacturing, processing,*
2 *distribution in commerce, or use of a chemical*
3 *substance that the Administrator has not des-*
4 *ignated as a high-priority substance, the Gov-*
5 *ernor or State agency with responsibility for im-*
6 *plementing the statute or administrative action*
7 *shall notify the Administrator.*

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

13 “(i) *scientific evidence related to the*
14 *hazards, exposures and risks of the chemical*
15 *substance under the conditions of use which*
16 *the statute or administrative action is in-*
17 *tended to address;*

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

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

23 “(iv) *any other available information*
24 *relevant to the prohibition or other restric-*
25 *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 substances*
6 *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 significant*
13 *impact on interstate commerce; or*

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

18 “(D) *AVAILABILITY TO PUBLIC.—Subject to*
19 *section 14 and any applicable State law regard-*
20 *ing the protection of confidential information*
21 *provided to the State or to the Administrator,*
22 *the Administrator shall make information re-*
23 *ceived from a Governor or State agency under*
24 *subparagraph (A) publicly available.*

1 “(E) *EFFECT OF PARAGRAPH.*—Nothing in
2 this paragraph shall preempt a State statute or
3 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 Administrator
9 shall—

10 “(A) review the process on the basis of expe-
11 rience 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 designa-
17 tion by the Administrator under this section with re-
18 spect to a chemical substance shall not affect—

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

22 “(B) the regulation of those activities.

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

25 “(1) *REQUIREMENTS.*—

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

4 “(i) *include a process by which a man-*
5 *ufacturer or processor of an active chemical*
6 *substance that has not been designated a*
7 *high-priority substance or is not in the*
8 *process of a prioritization screening by the*
9 *Administrator, may request that the Ad-*
10 *ministrator designate the substance as an*
11 *additional priority for a safety assessment*
12 *and safety determination, subject to the*
13 *payment of fees pursuant to section*
14 *26(b)(3)(E);*

15 “(ii) *specify the information to be pro-*
16 *vided in such requests; and*

17 “(iii) *specify the criteria the Adminis-*
18 *trator shall use to determine whether or not*
19 *to grant such a request, which shall include*
20 *whether the substance is subject to restric-*
21 *tions imposed by statutes enacted or admin-*
22 *istrative actions taken by 1 or more States*
23 *on the manufacture, processing, distribution*
24 *in commerce, or use of the substance.*

1 “(B) *PREFERENCE.*—Subject to paragraph
2 (2), in deciding whether to grant requests under
3 this subsection the Administrator shall give a
4 preference to requests concerning substances for
5 which the Administrator determines that restric-
6 tions imposed by 1 or more States have the po-
7 tential to have a significant impact on interstate
8 commerce or health or the environment.

9 “(C) *EXCEPTIONS.*—Chemical substances
10 for which requests have been granted under this
11 subsection shall not be subject to subsection
12 (a)(3)(A)(iii) or section 18(b).

13 “(2) *LIMITATIONS.*—In considering whether to
14 grant a request submitted under paragraph (1), the
15 Administrator shall ensure that—

16 “(A) if a sufficient number of additional
17 priority requests meet the requirements of para-
18 graph (1), not less than 25 percent, or more than
19 30 percent, of the cumulative number of sub-
20 stances designated to undergo safety assessments
21 and safety determinations under subsections
22 (a)(2) and (b)(3) are substances designated
23 under the process and criteria pursuant to para-
24 graph (1);

1 “(B) the resources allocated to conducting
2 safety assessments and safety determinations for
3 additional priorities designated under this sub-
4 section are proportionate to the number of such
5 substances relative to the total number of sub-
6 stances designated to undergo safety assessments
7 and safety determinations under this section;
8 and

9 “(C) the number of additional priority re-
10 quests stipulated under subparagraph (A) is in
11 addition to the total number of high-priority
12 substances identified under subsections (a)(2)
13 and (b)(3).

14 “(3) *ADDITIONAL REVIEW OF WORK PLAN CHEMI-*
15 *CALS FOR SAFETY ASSESSMENT AND SAFETY DETER-*
16 *MINATION.—In the case of a request under paragraph*
17 *(1) with respect to a chemical substance identified by*
18 *the Administrator in the October 2014 Work Plan—*

19 “(A) the 30-percent cap specified in para-
20 graph (2)(A) shall not apply and the addition of
21 Work Plan chemicals shall be at the discretion of
22 the Administrator; and

23 “(B) notwithstanding paragraph (1)(C), re-
24 quests for additional Work Plan chemicals under
25 this subsection shall be considered high-priority

1 *chemicals subject to section 18(b) but not sub-*
2 *section (a)(3)(A)(iii).*

3 “(4) *REQUIREMENTS.*—

4 “(A) *IN GENERAL.*—*The public shall be pro-*
5 *vided notice and an opportunity to comment on*
6 *requests submitted under this subsection.*

7 “(B) *DECISION BY ADMINISTRATOR.*—*Not*
8 *later than 180 days after the date on which the*
9 *Administrator receives a request under this sub-*
10 *section, the Administrator shall decide whether*
11 *or not to grant the request.*

12 “(C) *ASSESSMENT AND DETERMINATION.*—
13 *If the Administrator grants a request under this*
14 *subsection, the safety assessment and safety de-*
15 *termination—*

16 “(i) *shall be conducted in accordance*
17 *with the deadlines and other requirements*
18 *of sections 3A(i) and 6; and*

19 “(ii) *shall not be expedited or otherwise*
20 *subject to special treatment relative to high-*
21 *priority substances designated pursuant to*
22 *subsection (b)(3) that are undergoing safety*
23 *assessments and safety determinations.”.*

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 head-*
5 *ing 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 subsection*
9 *(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”;*

16 *(B) in paragraph (1)—*

17 *(i) in the matter preceding subpara-*
18 *graph (A), by striking “subsection (h)” and*
19 *inserting “paragraph (3) and subsection*
20 *(h)”;* and

21 *(ii) in the matter following subpara-*
22 *graph (B)—*

23 *(I) by striking “subsection (d)”*
24 *and inserting “subsection (c)”;* and

1 (II) by striking “and such person
2 complies with any applicable require-
3 ment of subsection (b)”; and

4 (C) by adding at the end the following:

5 “(3) *ARTICLE CONSIDERATION.*—*The Adminis-*
6 *trator may require the notification for the import or*
7 *processing of a chemical substance as part of an arti-*
8 *cle or category of articles under paragraph (1)(B) if*
9 *the Administrator makes an affirmative finding in a*
10 *rule under paragraph (2) that the reasonable poten-*
11 *tial for exposure to the chemical substance through the*
12 *article or category of articles subject to the rule war-*
13 *rants notification.”;*

14 (6) by redesignating subsections (c) and (d) as
15 subsections (d) and (c), respectively, and moving sub-
16 section (c) (as so redesigned) so as appear after sub-
17 section (b) (as redesignated by paragraph (3));

18 (7) in subsection (c) (as so redesigned)—

19 (A) by striking paragraph (1) and inserting
20 the following:

21 “(1) *IN GENERAL.*—*The notice required by sub-*
22 *section (b) shall include, with respect to a chemical*
23 *substance—*

1 “(A) the information required by sections
2 720.45 and 720.50 of title 40, Code of Federal
3 Regulations (or successor regulations); and

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

6 (B) in paragraph (2)—

7 (i) in the matter preceding subpara-
8 graph (A)—

9 (I) by striking “subsection (a)”
10 and inserting “subsection (b)”; and

11 (II) by striking “or of data under
12 subsection (b)”;

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

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

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

18 (C) in paragraph (3), by striking “sub-
19 section (a) and for which the notification period
20 prescribed by subsection (a), (b), or (c)” and in-
21 serting “subsection (b) and for which the notifi-
22 cation period prescribed by subsection (b) or
23 (d)”;

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

1 “(d) *REVIEW OF NOTICE.*—

2 “(1) *INITIAL REVIEW.*—

3 “(A) *IN GENERAL.*—*Subject to subpara-*
4 *graph (B), not later than 90 days after the date*
5 *of receipt of a notice submitted under subsection*
6 *(b), the Administrator shall—*

7 “(i) *conduct an initial review of the*
8 *notice;*

9 “(ii) *as needed, develop a profile of the*
10 *relevant chemical substance and the poten-*
11 *tial for exposure to humans and the envi-*
12 *ronment; and*

13 “(iii) *make any necessary determina-*
14 *tion under paragraph (3).*

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

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

23 “(A) *any relevant information identified in*
24 *subsection (c)(1); and*

1 “(B) any other relevant additional informa-
2 tion available to the Administrator.

3 “(3) DETERMINATIONS.—Before the end of the
4 applicable period for review under paragraph (1),
5 based on the information described in paragraph (2),
6 and subject to section 18(g), the Administrator shall
7 determine that—

8 “(A) the relevant chemical substance or sig-
9 nificant new use is not likely to meet the safety
10 standard, in which case the Administrator shall
11 take appropriate action under paragraph (4);

12 “(B) the relevant chemical substance or sig-
13 nificant new use is likely to meet the safety
14 standard, in which case the Administrator shall
15 allow the review period to expire without addi-
16 tional restrictions; or

17 “(C) additional information is necessary in
18 order to make a determination under subpara-
19 graph (A) or (B), in which case the Adminis-
20 trator shall take appropriate action under para-
21 graphs (4) and (5).

22 “(4) RESTRICTIONS.—

23 “(A) DETERMINATION BY ADMINIS-
24 TRATOR.—

1 “(i) *IN GENERAL.*—*If the Adminis-*
2 *trator makes a determination under sub-*
3 *paragraph (A) or (C) of paragraph (3) with*
4 *respect to a notice submitted under sub-*
5 *section (b)—*

6 “(I) *the Administrator, before the*
7 *end of the applicable period for review*
8 *under paragraph (1) and by consent*
9 *agreement or order, as appropriate,*
10 *shall prohibit or otherwise restrict the*
11 *manufacture, processing, use, distribu-*
12 *tion in commerce, or disposal (as ap-*
13 *plicable) of the chemical substance, or*
14 *of the chemical substance for a signifi-*
15 *cant new use, without compliance with*
16 *the restrictions specified in the consent*
17 *agreement or order that the Adminis-*
18 *trator determines are sufficient to en-*
19 *sure that the chemical substance or sig-*
20 *nificant new use is likely to meet the*
21 *safety standard; and*

22 “(II) *no person may commence*
23 *manufacture of the chemical substance,*
24 *or manufacture or processing of the*
25 *chemical substance for a significant*

1 *new use, except in compliance with the*
2 *restrictions specified in the consent*
3 *agreement or order.*

4 “(i) *LIKELY TO MEET STANDARD.—If*
5 *the Administrator makes a determination*
6 *under subparagraph (B) of paragraph (3)*
7 *with respect to a chemical substance or sig-*
8 *nificant new use for which a notice was*
9 *submitted under subsection (b), at the end*
10 *of the applicable period for review under*
11 *paragraph (1), the submitter of the notice*
12 *may commence manufacture for commercial*
13 *purposes of the chemical substance or man-*
14 *ufacture or processing of the chemical sub-*
15 *stance for a significant new use.*

16 “(B) *REQUIREMENTS.—Not later than 90*
17 *days after issuing a consent agreement or order*
18 *under subparagraph (A), the Administrator*
19 *shall—*

20 “(i) *take into consideration whether to*
21 *promulgate a rule pursuant to subsection*
22 *(b)(2) that identifies as a significant new*
23 *use any manufacturing, processing, use, dis-*
24 *tribution in commerce, or disposal of the*
25 *chemical substance, or of the chemical sub-*

1 *stance for a new use, that is not in compli-*
2 *ance with the restrictions imposed by the*
3 *consent agreement or order; and*

4 *“(i)(I) initiate a rulemaking described*
5 *in clause (i); or*

6 *“(II) publish a statement describing*
7 *the reasons of the Administrator for not ini-*
8 *tiating a rulemaking.*

9 *“(C) INCLUSIONS.—A prohibition or other*
10 *restriction under subparagraph (A) may include,*
11 *as appropriate—*

12 *“(i) subject to section 18(g), a require-*
13 *ment that a chemical substance shall be*
14 *marked with, or accompanied by, clear and*
15 *adequate minimum warnings and instruc-*
16 *tions with respect to use, distribution in*
17 *commerce, or disposal, or any combination*
18 *of those activities, with the form and con-*
19 *tent of the minimum warnings and instruc-*
20 *tions to be prescribed by the Administrator*

21 *“(ii) a requirement that manufacturers*
22 *or processors of the chemical substance*
23 *shall—*

24 *“(I) make and retain records of*
25 *the processes used to manufacture or*

1 *process, as applicable, the chemical*
2 *substance; or*

3 *“(II) monitor or conduct such ad-*
4 *ditional tests as are reasonably nec-*
5 *essary to address potential risks from*
6 *the manufacture, processing, distribu-*
7 *tion in commerce, use, or disposal, as*
8 *applicable, of the chemical substance,*
9 *subject to section 4;*

10 *“(iii) a restriction on the quantity of*
11 *the chemical substance that may be manu-*
12 *factured, processed, or distributed in com-*
13 *merce—*

14 *“(I) in general; or*

15 *“(II) for a particular use;*

16 *“(iv) a prohibition or other restriction*
17 *of—*

18 *“(I) the manufacture, processing,*
19 *or distribution in commerce of the*
20 *chemical substance for a significant*
21 *new use;*

22 *“(II) any method of commercial*
23 *use of the chemical substance; or*

24 *“(III) any method of disposal of*
25 *the chemical substance; or*

1 “(v) a prohibition or other restriction
2 on the manufacture, processing, or distribu-
3 tion in commerce of the chemical sub-
4 stance—

5 “(I) in general; or

6 “(II) for a particular use.

7 “(D) *PERSISTENT AND BIOACCUMULATIVE*
8 *SUBSTANCES.—For a chemical substance the Ad-*
9 *ministrator determines ranks high for persistence*
10 *and bioaccumulation, the Administrator shall, in*
11 *selecting among prohibitions and other restric-*
12 *tions that the Administrator determines are suf-*
13 *ficient to ensure that the chemical substance is*
14 *likely to meet the safety standard, reduce poten-*
15 *tial exposure to the substance to the maximum*
16 *extent practicable.*

17 “(E) *WORKPLACE EXPOSURES.—The Ad-*
18 *ministrator shall consult with the Assistant Sec-*
19 *retary of Labor for Occupational Safety and*
20 *Health prior to adopting any prohibition or*
21 *other restriction under this subsection to address*
22 *workplace exposures.*

23 “(F) *DEFINITION OF REQUIREMENT.—For*
24 *purposes of this Act, the term ‘requirement’ as*

1 *used in this section does not displace common*
2 *law.*

3 “(5) *ADDITIONAL INFORMATION.—If the Admin-*
4 *istrator determines under paragraph (3)(C) that ad-*
5 *ditional information is necessary to conduct a review*
6 *under this subsection, the Administrator—*

7 “(A) *shall provide an opportunity for the*
8 *submitter of the notice to submit the additional*
9 *information;*

10 “(B) *may, by agreement with the submitter,*
11 *extend the review period for a reasonable time to*
12 *allow the development and submission of the ad-*
13 *ditional information;*

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

18 “(D) *on receipt of information the Adminis-*
19 *trator finds supports the determination under*
20 *paragraph (3), shall promptly make the deter-*
21 *mination.”;*

22 (9) *by striking subsections (e) through (g) and*
23 *inserting the following:*

24 “(e) *NOTICE OF COMMENCEMENT.—*

1 “(1) *IN GENERAL.*—Not later than 30 days after
2 the date on which a manufacturer that has submitted
3 a notice under subsection (b) commences nonexempt
4 commercial manufacture of a chemical substance, the
5 manufacturer shall submit to the Administrator a no-
6 tice of commencement that identifies—

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

8 “(B) the initial date of nonexempt commer-
9 cial manufacture.

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

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

18 “(1) a notice of commencement for a chemical
19 substance under subsection (e); or

20 “(2) new information regarding the chemical
21 substance.

22 “(g) *TRANSPARENCY.*—Subject to section 14, the Ad-
23 ministrators shall make available to the public—

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

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

3 (10) in subsection (h)—

4 (A) in paragraph (1)—

5 (i) in the matter preceding subpara-
6 graph (A), by striking “(a) or”; and

7 (ii) in subparagraph (A), by inserting
8 “, without taking into account cost or other
9 nonrisk factors” after “the environment”;

10 (B) by striking paragraph (2);

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

14 (D) in paragraph (2) (as so redesignated),
15 in the matter preceding subparagraph (A), by
16 striking “subsections (a) and (b)” and inserting
17 “subsection (b)”;

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

19 (i) in the first sentence, by striking
20 “will not present an unreasonable risk of
21 injury to health or the environment” and
22 inserting “will meet the safety standard”;
23 and

24 (ii) by striking the second sentence;

1 (F) in paragraph (4) (as so redesignated),
2 by striking “subsections (a) and (b)” and insert-
3 ing “subsection (b)”; and

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

7 **SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINA-**
8 **TIONS.**

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

11 (1) by striking the section designation and head-
12 ing and inserting the following:

13 **“SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINA-**
14 **TIONS.”;**

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

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

19 “(a) *IN GENERAL.*—The Administrator—

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

23 “(2) shall, as soon as practicable and not later
24 than 6 months after the date on which a chemical
25 substance is designated as a high-priority substance,

1 *define and publish the scope of the safety assessment*
2 *and safety determination to be conducted pursuant to*
3 *this section, including the hazards, exposures, condi-*
4 *tions of use, and potentially exposed or susceptible*
5 *populations that the Administrator expects to con-*
6 *sider;*

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

10 *“(4) shall complete a safety assessment and safe-*
11 *ty determination not later than 3 years after the date*
12 *on which a chemical substance is designated as a*
13 *high-priority substance;*

14 *“(5) shall promulgate a final rule pursuant to*
15 *subsection (d) by not later than 2 years after the date*
16 *on which the safety determination is completed; and*

17 *“(6) may extend any deadline under paragraph*
18 *(4) or (5) for a reasonable period of time after an*
19 *adequate public justification, subject to the condition*
20 *that the aggregate length of all extensions of deadlines*
21 *under this subsection, plus any deferral under sub-*
22 *section (c)(2), does not exceed 2 years.*

23 *“(b) PRIOR ACTIONS AND NOTICE OF EXISTING INFOR-*
24 *MATION.—*

25 *“(1) PRIOR-INITIATED ASSESSMENTS.—*

1 “(A) *IN GENERAL.*—*Nothing in this Act*
2 *prevents the Administrator from initiating a*
3 *safety assessment or safety determination regard-*
4 *ing a chemical substance, or from continuing or*
5 *completing such a safety assessment or safety de-*
6 *termination that was initiated before the date of*
7 *enactment of the Frank R. Lautenberg Chemical*
8 *Safety for the 21st Century Act, prior to the ef-*
9 *fective date of the policies and procedures re-*
10 *quired to be established by the Administrator*
11 *under section 3A or 4A.*

12 “(B) *INTEGRATION OF PRIOR POLICIES AND*
13 *PROCEDURES.*—*As policies and procedures under*
14 *section 3A and 4A are established, to the max-*
15 *imum extent practicable, the Administrator shall*
16 *integrate the policies and procedures into ongo-*
17 *ing safety assessments and safety determinations.*

18 “(2) *ACTIONS COMPLETED PRIOR TO COMPLE-*
19 *TION OF POLICIES AND PROCEDURES.*—*Nothing in*
20 *this Act requires the Administrator to revise or with-*
21 *draw a completed safety assessment, safety determina-*
22 *tion, or rule solely because the action was completed*
23 *prior to the completion of a policy or procedure estab-*
24 *lished under section 3A or 4A, and the validity of a*
25 *completed assessment, determination, or rule shall not*

1 *be determined based on the content of such a policy*
2 *or procedure.*

3 “(3) *NOTICE OF EXISTING INFORMATION.*—

4 “(A) *IN GENERAL.*—*The Administrator*
5 *shall, where such information is available, take*
6 *notice of existing information regarding hazard*
7 *and exposure published by other Federal agencies*
8 *and the National Academies and incorporate the*
9 *information in safety assessments and safety de-*
10 *terminations with the objective of increasing the*
11 *efficiency of the safety assessments and safety de-*
12 *terminations.*

13 “(B) *INCLUSION OF INFORMATION.*—*Exist-*
14 *ing information described in subparagraph (A)*
15 *should be included to the extent practicable and*
16 *where the Administrator determines the informa-*
17 *tion is relevant and scientifically reliable.*

18 “(c) *SAFETY DETERMINATIONS.*—

19 “(1) *IN GENERAL.*—*Based on a review of the in-*
20 *formation available to the Administrator, including*
21 *draft safety assessments submitted by interested per-*
22 *sons, and subject to section 18, the Administrator*
23 *shall determine that—*

24 “(A) *the relevant chemical substance meets*
25 *the safety standard;*

1 “(B) the relevant chemical substance does
2 not meet the safety standard, in which case the
3 Administrator shall, by rule under subsection
4 (d)—

5 “(i) impose restrictions necessary to
6 ensure that the chemical substance meets the
7 safety standard under the conditions of use;
8 or

9 “(ii) if the safety standard cannot be
10 met with the application of restrictions, ban
11 or phase out the chemical substance, as ap-
12 propriate; or

13 “(C) additional information is necessary in
14 order to make a determination under subpara-
15 graph (A) or (B), in which case the Adminis-
16 trator shall take appropriate action under para-
17 graph (2).

18 “(2) *ADDITIONAL INFORMATION.*—If the Admin-
19 istrator determines that additional information is
20 necessary to make a safety assessment or safety deter-
21 mination for a high-priority substance, the Adminis-
22 trator—

23 “(A) shall provide an opportunity for inter-
24 ested persons to submit the additional informa-
25 tion;

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

5 “(C) may defer, for a reasonable period con-
6 sistent with the deadlines described in subsection
7 (a), a safety assessment and safety determination
8 until after receipt of the information; and

9 “(D) consistent with the deadlines described
10 in subsection (a), on receipt of information the
11 Administrator finds supports the safety assess-
12 ment and safety determination, shall make a de-
13 termination under paragraph (1).

14 “(3) *ESTABLISHMENT OF DEADLINE.*—In re-
15 questing the development or submission of informa-
16 tion under this section, the Administrator shall estab-
17 lish a deadline for the submission of the information.

18 “(d) *RULE.*—

19 “(1) *IMPLEMENTATION.*—If the Administrator
20 makes a determination under subsection (c)(1)(B)
21 with respect to a chemical substance, the Adminis-
22 trator shall promulgate a rule establishing restrictions
23 necessary to ensure that the chemical substance meets
24 the safety standard.

25 “(2) *SCOPE.*—

1 “(A) *IN GENERAL.*—*The rule promulgated*
2 *pursuant to this subsection—*

3 “(i) *may apply to mixtures containing*
4 *the chemical substance, as appropriate;*

5 “(ii) *shall include dates by which com-*
6 *pliance is mandatory, which—*

7 “(I) *shall be as soon as prac-*
8 *ticable;*

9 “(II) *in the case of a ban or*
10 *phase-out of the chemical substance,*
11 *shall implement the ban or phase-out*
12 *in as short a period as practicable;*
13 *and*

14 “(III) *as determined by the Ad-*
15 *ministrator, may vary for different af-*
16 *ected persons; and*

17 “(iii) *shall exempt replacement parts*
18 *that are manufactured prior to the effective*
19 *date of the rule for articles that are first*
20 *manufactured prior to the effective date of*
21 *the rule unless the Administrator finds the*
22 *replacement parts contribute significantly*
23 *to the identified risk; and*

24 “(iv) *shall, in selecting among prohibi-*
25 *tions and other restrictions, apply such pro-*

1 *hibitions or other restrictions to articles*
2 *containing the chemical substance only to*
3 *the extent necessary to address the identified*
4 *risks in order to determine that the chem-*
5 *ical substance meets the safety standard.*

6 *“(B) PERSISTENT AND BIOACCUMULATIVE*
7 *SUBSTANCES.—For a chemical substance the Ad-*
8 *ministrator determines ranks high for persistence*
9 *and bioaccumulation, the Administrator shall, in*
10 *selecting among prohibitions and other restric-*
11 *tions that the Administrator determines are suf-*
12 *ficient to ensure that the chemical substance*
13 *meets the safety standard, reduce exposure to the*
14 *substance to the maximum extent practicable.*

15 *“(C) WORKPLACE EXPOSURES.—The Ad-*
16 *ministrator shall consult with the Assistant Sec-*
17 *retary of Labor for Occupational Safety and*
18 *Health before adopting any prohibition or other*
19 *restriction under this subsection to address work-*
20 *place exposures.*

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

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

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

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

14 “(i) make and retain records of the
15 processes used to manufacture or process the
16 chemical substance;

17 “(ii) describe and apply the relevant
18 quality control procedures followed in the
19 manufacturing or processing of the sub-
20 stance; or

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

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

4 “(D) a requirement to ban or phase out, or
5 any other rule regarding, the manufacture, proc-
6 essing, or distribution in commerce of the chem-
7 ical substance for—

8 “(i) a particular use;

9 “(ii) a particular use at a concentra-
10 tion in excess of a level specified by the Ad-
11 ministrator; or

12 “(iii) all uses;

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

16 “(i) a particular use; or

17 “(ii) a particular use at a concentra-
18 tion in excess of a level specified by the Ad-
19 ministrator;

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

23 “(G) a requirement to ban, phase out, or
24 otherwise restrict any method of disposal of the

1 *chemical substance or any article containing the*
2 *chemical substance; and*

3 “(H) *a requirement directing manufactur-*
4 *ers or processors of the chemical substance to give*
5 *notice of the Administrator’s determination*
6 *under subsection (c)(1)(B) to distributors in*
7 *commerce of the chemical substance and, to the*
8 *extent reasonably ascertainable, to other persons*
9 *in the chain of commerce in possession of the*
10 *chemical substance.*

11 “(4) *ANALYSIS FOR RULEMAKING.—*

12 “(A) *CONSIDERATIONS.—In deciding which*
13 *restrictions to impose under paragraph (3) as*
14 *part of developing a rule under paragraph (1),*
15 *the Administrator shall take into consideration,*
16 *to the extent practicable based on reasonably*
17 *available information, the quantifiable and non-*
18 *quantifiable costs and benefits of the proposed*
19 *regulatory action and of the 1 or more primary*
20 *alternative regulatory actions considered by the*
21 *Administrator.*

22 “(B) *ALTERNATIVES.—As part of the anal-*
23 *ysis, the Administrator shall review any 1 or*
24 *more technically and economically feasible alter-*
25 *natives to the chemical substance that the Ad-*

1 *administrator determines are relevant to the rule-*
2 *making.*

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

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

12 “(5) *EXEMPTIONS.*—

13 “(A) *IN GENERAL.*—*The Administrator*
14 *may exempt 1 or more uses of a chemical sub-*
15 *stance from any restriction in a rule promul-*
16 *gated under paragraph (1) if the Administrator*
17 *determines that—*

18 “(i) *the rule cannot be complied with,*
19 *without—*

20 “(I) *harming national security;*

21 “(II) *causing significant disrup-*
22 *tion in the national economy due to*
23 *the lack of availability of a chemical*
24 *substance; or*

1 “(III) interfering with a critical
2 or essential use for which no tech-
3 nically and economically feasible safer
4 alternative is available, taking into
5 consideration hazard and exposure; or

6 “(ii) the use of the chemical substance,
7 as compared to reasonably available alter-
8 natives, provides a substantial benefit to
9 health, the environment, or public safety.

10 “(B) EXEMPTION ANALYSIS.—In proposing
11 a rule under paragraph (1) that includes an ex-
12 emption under this paragraph, the Adminis-
13 trator shall make publicly available any analysis
14 conducted under this paragraph to assess the
15 need for the exemption.

16 “(C) STATEMENT REQUIRED.—In making
17 final a rule under paragraph (1) that includes
18 an exemption under this paragraph, the Admin-
19 istrator shall include a statement describing how
20 the analysis considered under subparagraph (B)
21 was taken into account.

22 “(D) ANALYSIS IN CASE OF BAN OR PHASE-
23 OUT.—In determining whether an exemption
24 should be granted under this paragraph for a
25 chemical substance for which a ban or phase-out

1 *is proposed, the Administrator shall take into*
2 *consideration, to the extent practicable based on*
3 *reasonably available information, the quantifi-*
4 *able and nonquantifiable costs and benefits of the*
5 *1 or more technically and economically feasible*
6 *alternatives to the chemical substance most likely*
7 *to be used in place of the chemical substance*
8 *under the conditions of use if the rule is promul-*
9 *gated.*

10 “(E) *CONDITIONS.*—*As part of a rule pro-*
11 *mulgated under paragraph (1), the Adminis-*
12 *trator shall include conditions in any exemption*
13 *established under this paragraph, including rea-*
14 *sonable recordkeeping, monitoring, and reporting*
15 *requirements, to the extent that the Adminis-*
16 *trator determines the conditions are necessary to*
17 *protect health and the environment while achiev-*
18 *ing the purposes of the exemption.*

19 “(F) *DURATION.*—

20 “(i) *IN GENERAL.*—*The Administrator*
21 *shall establish, as part of a rule under*
22 *paragraph (1) that contains an exemption*
23 *under this paragraph, a time limit on any*
24 *exemption for a time to be determined by*

1 *the Administrator as reasonable on a case-*
2 *by-case basis.*

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

11 “(iii) *CONSIDERATIONS.—*

12 “(I) *IN GENERAL.—Subject to*
13 *subclause (II), the Administrator shall*
14 *issue exemptions and establish time pe-*
15 *riods by considering factors determined*
16 *by the Administrator to be relevant to*
17 *the goals of fostering innovation and*
18 *the development of alternatives that*
19 *meet the safety standard.*

20 “(II) *LIMITATION.—Any renewal*
21 *of an exemption in the case of a rule*
22 *requiring the ban or phase-out of a*
23 *chemical substance shall not exceed 5*
24 *years.*

1 “(e) *IMMEDIATE EFFECT.*—*The Administrator may*
2 *declare a proposed rule under subsection (d)(1) to be effec-*
3 *tive on publication of the rule in the Federal Register and*
4 *until the effective date of final action taken respecting the*
5 *rule, if—*

6 “(1) *the Administrator determines that—*

7 “(A) *the manufacture, processing, distribu-*
8 *tion in commerce, use, or disposal of the chem-*
9 *ical substance or mixture subject to the proposed*
10 *rule or any combination of those activities is*
11 *likely to result in a risk of serious or widespread*
12 *injury to health or the environment before the ef-*
13 *fective date; and*

14 “(B) *making the proposed rule so effective is*
15 *necessary to protect the public interest; and*

16 “(2) *in the case of a proposed rule to prohibit the*
17 *manufacture, processing, or distribution in commerce*
18 *of a chemical substance or mixture because of the risk*
19 *determined under paragraph (1)(A), a court has*
20 *granted relief in an action under section 7 with re-*
21 *spect to that risk associated with the chemical sub-*
22 *stance or mixture.*

23 “(f) *FINAL AGENCY ACTION.*—*Under this section and*
24 *subject to section 18—*

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

7 “(2) a final rule promulgated under subsection
8 (d)(1), and the associated safety assessment and safe-
9 ty determination that a chemical substance does not
10 meet the safety standard, shall be considered to be a
11 final agency action, effective beginning on the date of
12 promulgation of the final rule.”; and

13 (4) in subsection (g) (as redesignated by para-
14 graph (2))—

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

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

18 **SEC. 9. IMMINENT HAZARDS.**

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

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

23 “(a) CIVIL ACTIONS.—

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

4 “(A) *seizure of an imminently hazardous*
5 *chemical substance or mixture or any article*
6 *containing the chemical substance or mixture;*

7 “(B) *relief (as authorized by subsection (b))*
8 *against any person that manufactures, processes,*
9 *distributes in commerce, uses, or disposes of, an*
10 *imminently hazardous chemical substance or*
11 *mixture or any article containing the chemical*
12 *substance or mixture; or*

13 “(C) *both seizure described in subparagraph*
14 *(A) and relief described in subparagraph (B).*

15 “(2) *RULE, ORDER, OR OTHER PROCEEDING.*—*A*
16 *civil action may be commenced under this paragraph,*
17 *notwithstanding—*

18 “(A) *the existence of a decision, rule, con-*
19 *sent agreement, or order by the Administrator*
20 *under section 4, 4A, 5, or 6 or title IV or VI; or*

21 “(B) *the pendency of any administrative or*
22 *judicial proceeding under any provision of this*
23 *Act.”;*

24 (2) *in subsection (b)(1), by striking “unreason-*
25 *able”;*

1 (3) *in subsection (d), by striking “section 6(a)”*
2 *and inserting “section 6(d)”*; and

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

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

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

8 (1) *in subsection (a)—*

9 (A) *in paragraph (3)(A)(i)(I)—*

10 (i) *by striking “5(b)(4)” and inserting*
11 *“5”*;

12 (ii) *by inserting “section 4 or” after*
13 *“in effect under”*; and

14 (iii) *by striking “5(e),” and inserting*
15 *“5(d)(4);”*; and

16 (B) *by adding at the end the following:*

17 “(4) *RULES.—*

18 “(A) *DEADLINE.—*

19 “(i) *IN GENERAL.—Not later than 2*
20 *years after the date of enactment of the*
21 *Frank R. Lautenberg Chemical Safety for*
22 *the 21st Century Act, the Administrator*
23 *shall promulgate rules requiring the main-*
24 *tenance of records and the reporting of in-*
25 *formation known or reasonably ascertain-*

1 able by the person making the report, in-
2 cluding rules requiring processors to report
3 information, so that the Administrator has
4 the information necessary to carry out sec-
5 tions 4 and 6.

6 “(ii) *MODIFICATION OF PRIOR*
7 *RULES.*—In carrying out this subpara-
8 graph, the Administrator may modify, as
9 appropriate, rules promulgated before the
10 date of enactment of the Frank R. Lauten-
11 berg Chemical Safety for the 21st Century
12 Act.

13 “(B) *CONTENTS.*—The rules promulgated
14 pursuant to subparagraph (A)—

15 “(i) may impose different reporting
16 and recordkeeping requirements on manu-
17 facturers and processors; and

18 “(ii) shall include the level of detail
19 necessary to be reported, including the man-
20 ner by which use and exposure information
21 may be reported.

22 “(C) *ADMINISTRATION.*—In implementing
23 the reporting and recordkeeping requirements
24 under this paragraph, the Administrator shall
25 take measures—

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

3 “(ii) to minimize the impact of the
4 rules on small manufacturers and proc-
5 essors; and

6 “(iii) to apply any reporting obliga-
7 tions to those persons likely to have infor-
8 mation relevant to the effective implementa-
9 tion of this title.

10 “(5) GUIDANCE.—The Administrator shall de-
11 velop guidance relating to the information required to
12 be reported under the rules promulgated under this
13 subsection.”;

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

16 “(3) NOMENCLATURE.—

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

19 “(i) maintain the use of Class 2 no-
20 menclature in use on the date of enactment
21 of the Frank R. Lautenberg Chemical Safe-
22 ty for the 21st Century Act;

23 “(ii) maintain the use of the Soap and
24 Detergent Association Nomenclature Sys-
25 tem, published in March 1978 by the Ad-

1 *ministrator in section 1 of addendum III of*
2 *the document entitled ‘Candidate List of*
3 *Chemical Substances’, and further described*
4 *in the appendix A of volume I of the 1985*
5 *edition of the Toxic Substances Control Act*
6 *Substances Inventory (EPA Document No.*
7 *EPA-560/7-85-002a); and*

8 *“(iii) treat all components of categories*
9 *that are considered to be statutory mixtures*
10 *under this Act as being included on the list*
11 *published under paragraph (1) under the*
12 *Chemical Abstracts Service numbers for the*
13 *respective categories, including, without*
14 *limitation—*

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

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

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

21 *“(IV) frits, chemicals, CAS No.*
22 *65997-18-4;*

23 *“(V) steel manufacture, chemicals,*
24 *CAS No. 65997-19-5; and*

1 “(VI) *ceramic materials and*
2 *wares, chemicals, CAS No. 66402–68–*
3 *4.*

4 “(B) *MULTIPLE NOMENCLATURE CONVEN-*
5 *TIONS.—*

6 “(i) *IN GENERAL.—If an existing guid-*
7 *ance allows for multiple nomenclature con-*
8 *ventions, the Administrator shall—*

9 “(I) *maintain the nomenclature*
10 *conventions for substances; and*

11 “(II) *develop new guidance that—*

12 “(aa) *establishes equivalency*
13 *between the nomenclature conven-*
14 *tions for chemical substances on*
15 *the list published under para-*
16 *graph (1); and*

17 “(bb) *permits persons to rely*
18 *on the new guidance for purposes*
19 *of determining whether a chemical*
20 *substance is on the list published*
21 *under paragraph (1).*

22 “(ii) *MULTIPLE CAS NUMBERS.—For*
23 *any chemical substance appearing multiple*
24 *times on the list under different Chemical*
25 *Abstracts Service numbers, the Adminis-*

1 *trator shall develop guidance recognizing*
2 *the multiple listings as a single chemical*
3 *substance.*

4 “(4) *CHEMICAL SUBSTANCES IN COMMERCE.—*

5 “(A) *RULES.—*

6 “(i) *IN GENERAL.—Not later than 1*
7 *year after the date of enactment of the*
8 *Frank R. Lautenberg Chemical Safety for*
9 *the 21st Century Act, the Administrator, by*
10 *rule, shall require manufacturers and proc-*
11 *essors to notify the Administrator, by not*
12 *later than 180 days after the date of pro-*
13 *mulgation of the rule, of each chemical sub-*
14 *stance on the list published under para-*
15 *graph (1) that the manufacturer or proc-*
16 *essor, as applicable, has manufactured or*
17 *processed for a nonexempt commercial pur-*
18 *pose during the 10-year period ending on*
19 *the day before the date of enactment of the*
20 *Frank R. Lautenberg Chemical Safety for*
21 *the 21st Century Act.*

22 “(ii) *ACTIVE SUBSTANCES.—The Ad-*
23 *ministrator shall, pursuant to paragraph*
24 *(5)(A), designate chemical substances for*
25 *which notices are received under clause (i)*

1 to be active substances on the list published
2 under paragraph (1).

3 “(B) CONFIDENTIAL CHEMICAL SUB-
4 STANCES.—The rule promulgated by the Admin-
5 istrator pursuant to subparagraph (A) shall re-
6 quire—

7 “(i) the Administrator to maintain the
8 list under paragraph (1), which shall in-
9 clude a confidential portion and a noncon-
10 fidential portion consistent with this section
11 and section 14;

12 “(ii) a manufacturer or processor that
13 is submitting a notice pursuant to subpara-
14 graph (A) for a chemical substance on the
15 confidential portion of the list published
16 under paragraph (1) to indicate in the no-
17 tice whether the manufacturer or processor
18 seeks to maintain any existing claim for
19 protection against disclosure of the specific
20 identity of the substance as confidential
21 pursuant to section 14; and

22 “(iii) the substantiation of those claims
23 pursuant to section 14 and in accordance
24 with the review plan described in subpara-
25 graph (C).

1 “(C) *REVIEW PLAN.*—Not later than 1 year
2 after the date on which the Administrator com-
3 piles the initial list of active substances pursuant
4 to subparagraph (A), the Administrator shall
5 promulgate a rule that establishes a plan to re-
6 view all claims to protect the specific identities
7 of chemical substances on the confidential por-
8 tion of the list published under paragraph (1)
9 that are notified pursuant to subparagraph (A)
10 or identified as active substances under sub-
11 section (f)(1).

12 “(D) *REQUIREMENTS OF REVIEW PLAN.*—
13 The review plan under subparagraph (C) shall—

14 “(i) require, at the time requested by
15 the Administrator, all manufacturers or
16 processors asserting claims under subpara-
17 graph (B) to substantiate the claim unless
18 the manufacturer or processor has substan-
19 tiated the claim in a submission made to
20 the Administrator during the 5-year period
21 ending on the date of the request by the Ad-
22 ministratoꝛ;

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

1 “(I) to review each substan-
2 tiation—

3 “(aa) submitted pursuant to
4 clause (i) to determine if the
5 claim warrants protection from
6 disclosure; and

7 “(bb) submitted previously
8 by a manufacturer or processor
9 and relied on in lieu of the sub-
10 stantiation required pursuant to
11 clause (i), if the substantiation
12 has not been previously reviewed
13 by the Administrator, to deter-
14 mine if the claim warrants pro-
15 tection from disclosure;

16 “(II) approve, modify, or deny
17 each claim; and

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

24 “(aa) the person notifies the
25 Administrator that the person is

1 *withdrawing the confidentiality*
2 *claim, in which case the Adminis-*
3 *trator shall promptly make the*
4 *information available to the pub-*
5 *lic; or*

6 *“(bb) the Administrator oth-*
7 *erwise becomes aware that the*
8 *need for protection from disclosure*
9 *can no longer be substantiated, in*
10 *which case the Administrator*
11 *shall take the actions described in*
12 *section 14(g)(2); and*

13 *“(iii) encourage manufacturers or*
14 *processors that have previously made claims*
15 *to protect the specific identities of chemical*
16 *substances identified as inactive pursuant*
17 *to subsection (f)(2) to review and either*
18 *withdraw or substantiate the claims.*

19 *“(E) TIMELINE FOR COMPLETION OF RE-*
20 *VIEWS.—*

21 *“(i) IN GENERAL.—The Administrator*
22 *shall implement the review plan so as to*
23 *complete reviews of all claims specified in*
24 *subparagraph (C) not later than 5 years*
25 *after the date on which the Administrator*

1 *compiles the initial list of active substances*
2 *pursuant to subparagraph (A).*

3 “(ii) *CONSIDERATIONS.*—

4 “(I) *IN GENERAL.*—*The Adminis-*
5 *trator may extend the deadline for*
6 *completion of the reviews for not more*
7 *than 2 additional years, after an ade-*
8 *quate public justification, if the Ad-*
9 *ministrator determines that the exten-*
10 *sion is necessary based on the number*
11 *of applicable claims needing review*
12 *and the available resources.*

13 “(II) *ANNUAL GOAL.*—*The Ad-*
14 *ministrator shall publish an annual*
15 *goal for the number of reviews to be*
16 *completed over the course of implemen-*
17 *tation of the plan.*

18 “(5) *ACTIVE AND INACTIVE SUBSTANCES.*—

19 “(A) *IN GENERAL.*—*The Administrator*
20 *shall maintain and keep current designations of*
21 *active substances and inactive substances on the*
22 *list published under paragraph (1).*

23 “(B) *UPDATE.*—*The Administrator shall*
24 *update the list of chemical substances designated*
25 *as active substances as soon as practicable after*

1 *the date of publication of the most recent data*
2 *reported under—*

3 “(i) *part 711 of title 40, Code of Fed-*
4 *eral Regulations (or successor regulations);*
5 *and*

6 “(ii) *the rules promulgated pursuant to*
7 *subsection (a)(4).*

8 “(C) *CHANGE TO ACTIVE STATUS.—*

9 “(i) *IN GENERAL.—Any person that*
10 *intends to manufacture or process for a*
11 *nonexempt commercial purpose a chemical*
12 *substance that is designated as an inactive*
13 *substance shall notify the Administrator be-*
14 *fore the date on which the inactive sub-*
15 *stance is manufactured or processed.*

16 “(ii) *CONFIDENTIAL CHEMICAL IDEN-*
17 *TITY CLAIMS.—If a person submitting a no-*
18 *tice under clause (i) for an inactive sub-*
19 *stance on the confidential portion of the list*
20 *published under paragraph (1) seeks to*
21 *maintain an existing claim for protection*
22 *against disclosure of the specific identity of*
23 *the inactive substance as confidential, the*
24 *person shall—*

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

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

6 “(iii) *ACTIVE STATUS*.—On receiving a
7 notification under clause (i), the Adminis-
8 trator shall—

9 “(I) designate the applicable
10 chemical substance as an active sub-
11 stance;

12 “(II) pursuant to section 14,
13 promptly review any claim and associ-
14 ated substantiation submitted pursu-
15 ant to clause (ii) for protection against
16 disclosure of the specific identity of the
17 chemical substance and approve, mod-
18 ify, or deny the claim;

19 “(III) except as provided in this
20 section and section 14, protect from
21 disclosure the specific identity of the
22 chemical substance for which the Ad-
23 ministrator approves a claim under
24 subclause (II) for a period of not less

1 *than 10 years, unless, prior to the ex-*
2 *piration of the period—*

3 “(aa) *the person notifies the*
4 *Administrator that the person is*
5 *withdrawing the confidentiality*
6 *claim, in which case the Adminis-*
7 *trator shall promptly make the*
8 *information available to the pub-*
9 *lic; or*

10 “(bb) *the Administrator oth-*
11 *erwise becomes aware that the*
12 *need for protection from disclosure*
13 *can no longer be substantiated, in*
14 *which case the Administrator*
15 *shall take the actions described in*
16 *section 14(g)(2); and*

17 “(IV) *pursuant to section 4A, re-*
18 *view the priority of the chemical sub-*
19 *stance as the Administrator determines*
20 *to be necessary.*

21 “(D) *CATEGORY STATUS.—The list of inac-*
22 *tive substances shall not be considered to be a*
23 *category for purposes of section 26(c).*

24 “(6) *INTERIM LIST OF ACTIVE SUBSTANCES.—*
25 *Prior to the promulgation of the rule required under*

1 paragraph (4)(A), the Administrator shall designate
2 the chemical substances reported under part 711 of
3 title 40, Code of Federal Regulations (or successor reg-
4 ulations), during the reporting period that most close-
5 ly preceded the date of enactment of the Frank R.
6 Lautenberg Chemical Safety for the 21st Century Act,
7 as the interim list of active substances for the pur-
8 poses of section 4A.

9 “(7) PUBLIC PARTICIPATION.—Subject to this
10 subsection, the Administrator shall make available to
11 the public—

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

16 “(i) an active substance; or

17 “(ii) an inactive substance;

18 “(B) the accession number, generic name,
19 and, if applicable, premanufacture notice case
20 number for each chemical substance on the con-
21 fidential portion of the list published under
22 paragraph (1) for which a claim of confiden-
23 tiality was received and approved by the Admin-
24 istrator pursuant to section 14; and

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

3 “(i) no claim of protection against dis-
4 closure of the specific identity of the active
5 substance pursuant to this subsection was
6 received;

7 “(ii) a claim for protection against
8 disclosure of the specific identity of the ac-
9 tive substance has been denied by the Ad-
10 ministrators; or

11 “(iii) the time period for protection
12 against disclosure of the specific identity of
13 the active substance has expired.

14 “(8) *LIMITATION.*—No person may assert a new
15 claim under this subsection for protection from disclo-
16 sure of a specific identity of any active or inactive
17 chemical substance for which a notice is received
18 under paragraph (4)(A)(i) or (5)(C)(i) that is not on
19 the confidential portion of the list published under
20 paragraph (1).

21 “(9) *CERTIFICATION.*—Under the rules promul-
22 gated under this subsection, manufacturers and proc-
23 essors shall be required—

24 “(A) to certify that each report the manu-
25 facturer or processor submits complies with the

1 *requirements of the rule, and that any confiden-*
2 *tiality claims are true and correct; and*

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

6 *(3) in subsection (e)—*

7 *(A) by striking “Any person” and inserting*
8 *the following:*

9 *“(1) IN GENERAL.—Any person”;* and

10 *(B) by adding at the end the following:*

11 *“(2) APPLICABILITY.—Any person may submit*
12 *to the Administrator information reasonably sup-*
13 *porting the conclusion that a chemical substance or*
14 *mixture presents, will present, or does not present a*
15 *substantial risk of injury to health and the environ-*
16 *ment.”;* and

17 *(4) in subsection (f), by striking “For purposes*
18 *of this section, the” and inserting the following: “In*
19 *this section:*

20 *“(1) ACTIVE SUBSTANCE.—The term ‘active sub-*
21 *stance’ means a chemical substance—*

22 *“(A) that has been manufactured or proc-*
23 *essed for a nonexempt commercial purpose at*
24 *any point during the 10-year period ending on*

1 *the date of enactment of the Frank R. Lauten-*
2 *berg Chemical Safety for the 21st Century Act;*

3 *“(B) that is added to the list published*
4 *under subsection (b)(1) after that date of enact-*
5 *ment; or*

6 *“(C) for which a notice is received under*
7 *subsection (b)(5)(C).*

8 *“(2) INACTIVE SUBSTANCE.—The term ‘inactive*
9 *substance’ means a chemical substance on the list*
10 *published under subsection (b)(1) that does not meet*
11 *any of the criteria described in paragraph (1).*

12 *“(3) MANUFACTURE; PROCESS.—The”.*

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

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

16 *(1) in subsection (a)—*

17 *(A) in paragraph (1), in the first sen-*
18 *tence—*

19 *(i) by striking “presents or will present*
20 *an unreasonable risk to health or the envi-*
21 *ronment” and inserting “does not meet the*
22 *safety standard”; and*

23 *(ii) by striking “such risk” the first*
24 *place it appears and inserting “the risk*
25 *posed by the substance or mixture”;*

1 **SEC. 13. EXPORTS.**

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

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

6 *“(2) EXCEPTION.—Paragraph (1) shall not*
7 *apply to any chemical substance that the Adminis-*
8 *trator determines—*

9 *“(A) under section 5 is not likely to meet*
10 *the safety standard; or*

11 *“(B) under section 6 does not meet the safe-*
12 *ty standard.*

13 *“(3) WAIVERS.—For a mixture or article con-*
14 *taining a chemical substance described in paragraph*
15 *(2), the Administrator may—*

16 *“(A) determine that paragraph (1) shall not*
17 *apply to the mixture or article; or*

18 *“(B) establish a threshold concentration in*
19 *a mixture or article at which paragraph (1)*
20 *shall not apply.*

21 *“(4) TESTING.—The Administrator may require*
22 *testing under section 4 of any chemical substance or*
23 *mixture exempted from this Act under paragraph (1)*
24 *for the purpose of determining whether the chemical*
25 *substance or mixture meets the safety standard within*
26 *the United States.”;*

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

3 “(b) *NOTICE.—*

4 “(1) *IN GENERAL.—A person shall notify the Ad-*
5 *ministrator that the person is exporting or intends to*
6 *export to a foreign country—*

7 “(A) *a chemical substance or a mixture con-*
8 *taining a chemical substance that the Adminis-*
9 *trator has determined under section 5 is not like-*
10 *ly to meet the safety standard and for which a*
11 *prohibition or other restriction has been proposed*
12 *or established under that section;*

13 “(B) *a chemical substance or a mixture*
14 *containing a chemical substance that the Admin-*
15 *istrator has determined under section 6 does not*
16 *meet the safety standard and for which a prohi-*
17 *bition or other restriction has been proposed or*
18 *established under that section;*

19 “(C) *a chemical substance for which the*
20 *United States is obligated by treaty to provide*
21 *export notification;*

22 “(D) *a chemical substance or mixture sub-*
23 *ject to a significant new use rule, or a prohibi-*
24 *tion or other restriction pursuant to a rule,*

1 *order, or consent agreement in effect under this*
2 *Act; or*

3 “(E) *a chemical substance or mixture for*
4 *which the submission of information is required*
5 *under section 4.*

6 “(2) *RULES.—*

7 “(A) *IN GENERAL.—The Administrator*
8 *shall promulgate rules to carry out paragraph*
9 *(1).*

10 “(B) *CONTENTS.—The rules promulgated*
11 *pursuant to subparagraph (A) shall—*

12 “(i) *include such exemptions as the*
13 *Administrator determines to be appropriate,*
14 *which may include exemptions identified*
15 *under section 5(h); and*

16 “(ii) *indicate whether, or to what ex-*
17 *tent, the rules apply to articles containing*
18 *a chemical substance or mixture described*
19 *in paragraph (1).*

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

23 “(A) *for a chemical substance or mixture*
24 *described in subparagraph (A), (B), or (D) of*
25 *paragraph (1), a notice of the determination,*

1 *rule, order, consent agreement, requirement, or*
2 *designation;*

3 “(B) *for a chemical substance described in*
4 *paragraph (1)(C), a notice that satisfies the obli-*
5 *gation of the United States under the applicable*
6 *treaty; and*

7 “(C) *for a chemical substance or mixture*
8 *described in paragraph (1)(E), a notice of avail-*
9 *ability of the information on the chemical sub-*
10 *stance or mixture submitted to the Adminis-*
11 *trator.”; and*

12 (3) *in subsection (c)—*

13 (A) *by striking paragraph (3); and*

14 (B) *by redesignating paragraphs (4)*
15 *through (6) as paragraphs (3) through (5), re-*
16 *spectively.*

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

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

20 **“SEC. 14. CONFIDENTIAL INFORMATION.**

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

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

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

5 “(b) *INFORMATION GENERALLY PROTECTED FROM*
6 *DISCLOSURE.*—The following information specific to, and
7 submitted by, a manufacturer, processor, or distributor that
8 meets the requirements of subsections (a) and (d) shall be
9 presumed to be protected from disclosure, subject to the con-
10 dition that nothing in this Act prohibits the disclosure of
11 any such information, or information that is the subject
12 of subsection (g)(3), through discovery, subpoena, other
13 court order, or any other judicial process otherwise allowed
14 under applicable Federal or State law:

15 “(1) Specific information describing the proc-
16 esses used in manufacture or processing of a chemical
17 substance, mixture, or article.

18 “(2) Marketing and sales information.

19 “(3) Information identifying a supplier or cus-
20 tomer.

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

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

1 “(6) *Specific production or import volumes of*
2 *the manufacturer and specific aggregated volumes*
3 *across manufacturers, if the Administrator determines*
4 *that disclosure of the specific aggregated volumes*
5 *would reveal confidential information.*

6 “(7) *Except as otherwise provided in this section,*
7 *the specific identity of a chemical substance prior to*
8 *the date on which the chemical substance is first of-*
9 *fered for commercial distribution, including the chem-*
10 *ical name, molecular formula, Chemical Abstracts*
11 *Service number, and other information that would*
12 *identify a specific chemical substance, if—*

13 “(A) *the specific identity was claimed as*
14 *confidential information at the time it was sub-*
15 *mitted in a notice under section 5; and*

16 “(B) *the claim—*

17 “(i) *is not subject to an exception*
18 *under subsection (e); or*

19 “(ii) *has not subsequently been with-*
20 *drawn or found by the Administrator not to*
21 *warrant protection as confidential informa-*
22 *tion under subsection (f)(2) or (g).*

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

1 “(1) *INFORMATION FROM HEALTH AND SAFETY*
2 *STUDIES.—*

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

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

9 “(I) *any chemical substance or*
10 *mixture that, on the date on which the*
11 *study is to be disclosed, has been of-*
12 *fered for commercial distribution; or*

13 “(II) *any chemical substance or*
14 *mixture for which—*

15 “(aa) *testing is required*
16 *under section 4; or*

17 “(bb) *a notification is re-*
18 *quired under section 5; or*

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

1 “(B) *EFFECT OF PARAGRAPH.*—*Nothing in*
2 *this paragraph authorizes the release of any in-*
3 *formation that discloses—*

4 “(i) *a process used in the manufac-*
5 *turing or processing of a chemical substance*
6 *or mixture; or*

7 “(ii) *in the case of a mixture, the por-*
8 *tion of the mixture comprised by any chem-*
9 *ical substance in the mixture.*

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

17 “(3) *OTHER INFORMATION NOT PROTECTED*
18 *FROM DISCLOSURE.*—*The following information is not*
19 *protected from disclosure under this section:*

20 “(A) *For information submitted after the*
21 *date of enactment of the Frank R. Lautenberg*
22 *Chemical Safety for the 21st Century Act, the*
23 *specific identity of a chemical substance as of the*
24 *date on which the chemical substance is first of-*
25 *fered for commercial distribution, if the person*

1 submitting the information does not meet the re-
2 quirements of subsection (d).

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

5 “(C) Any general information describing
6 the manufacturing volumes, expressed as specific
7 aggregated volumes or, if the Administrator de-
8 termines that disclosure of specific aggregated
9 volumes would reveal confidential information,
10 expressed in ranges.

11 “(D) A general description of a process used
12 in the manufacture or processing and industrial,
13 commercial, or consumer functions and uses of a
14 chemical substance, mixture, or article con-
15 taining a chemical substance or mixture, includ-
16 ing information specific to an industry or indus-
17 try sector that customarily would be shared with
18 the general public or within an industry or in-
19 dustry sector.

20 “(4) MIXED CONFIDENTIAL AND NONCONFIDEN-
21 TIAL INFORMATION.—Any information that is other-
22 wise eligible for protection under this section and con-
23 tained in a submission of information described in
24 this subsection shall be protected from disclosure, if
25 the submitter complies with subsection (d), subject to

1 *the condition that information in the submission that*
2 *is not eligible for protection against disclosure shall*
3 *be disclosed.*

4 “(5) *BAN OR PHASE-OUT.*—*If the Administrator*
5 *promulgates a rule pursuant to section 6(d) that es-*
6 *tablishes a ban or phase-out of the manufacture, proc-*
7 *essing, or distribution in commerce of a chemical sub-*
8 *stance, subject to paragraphs (2), (3), and (4) of sub-*
9 *section (g), any protection from disclosure provided*
10 *under this section with respect to the specific identity*
11 *of the chemical substance and other information relat-*
12 *ing to the chemical substance shall no longer apply.*

13 “(d) *REQUIREMENTS FOR CONFIDENTIALITY*
14 *CLAIMS.*—

15 “(1) *ASSERTION OF CLAIMS.*—

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

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

4 “(i) *taken reasonable measures to pro-*
5 *tect the confidentiality of the information;*

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

10 “(iii) *a reasonable basis to conclude*
11 *that disclosure of the information is likely*
12 *to cause substantial harm to the competitive*
13 *position of the person; and*

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

17 “(C) *SPECIFIC CHEMICAL IDENTITY.*—*In*
18 *the case of a claim under subparagraph (A) for*
19 *protection against disclosure of a specific chem-*
20 *ical identity, the claim shall include a struc-*
21 *turally descriptive generic name for the chemical*
22 *substance that the Administrator may disclose to*
23 *the public, subject to the condition that the ge-*
24 *neric name shall—*

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

4 “(ii) describe the chemical structure of
5 the substance as specifically as practicable
6 while protecting those features of the chem-
7 ical structure—

8 “(I) that are considered to be con-
9 fidential; and

10 “(II) the disclosure of which
11 would be likely to harm the competitive
12 position of the person.

13 “(D) PUBLIC INFORMATION.—No person
14 may assert a claim under this section for protec-
15 tion from disclosure of information that is al-
16 ready publicly available.

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

24 “(3) GUIDANCE.—The Administrator shall de-
25 velop guidance regarding—

1 “(A) the determination of structurally de-
2 scriptive generic names, in the case of claims for
3 the protection against disclosure of specific chem-
4 ical identity; and

5 “(B) the content and form of the statements
6 of need and agreements required under para-
7 graphs (4), (5), and (6) of subsection (e).

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

12 “(e) EXCEPTIONS TO PROTECTION FROM DISCLO-
13 SURE.—Information described in subsection (a)—

14 “(1) shall be disclosed if the information is to be
15 disclosed to an officer or employee of the United
16 States in connection with the official duties of the of-
17 ficer or employee—

18 “(A) under any law for the protection of
19 health or the environment; or

20 “(B) for a specific law enforcement purpose;

21 “(2) shall be disclosed if the information is to be
22 disclosed to a contractor of the United States and em-
23 ployees of that contractor—

24 “(A) if, in the opinion of the Administrator,
25 the disclosure is necessary for the satisfactory

1 *performance by the contractor of a contract with*
2 *the United States for the performance of work in*
3 *connection with this Act; and*

4 *“(B) subject to such conditions as the Ad-*
5 *ministrator may specify;*

6 *“(3) shall be disclosed if the Administrator deter-*
7 *mines that disclosure is necessary to protect health or*
8 *the environment;*

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

13 *“(A) 1 or more applicable agreements with*
14 *the Administrator that conform with the guid-*
15 *ance issued under subsection (d)(3)(B) ensure*
16 *that the recipient will take appropriate meas-*
17 *ures, and has adequate authority, to maintain*
18 *the confidentiality of the information in accord-*
19 *ance with procedures comparable to the proce-*
20 *dures used by the Administrator to safeguard the*
21 *information; and*

22 *“(B) the Administrator notifies the person*
23 *that submitted the information that the informa-*
24 *tion has been disclosed to the State or political*
25 *subdivision of a State;*

1 “(5) shall be disclosed if a health or environ-
2 mental professional employed by a Federal or State
3 agency or a treating physician or nurse in a non-
4 emergency situation provides a written statement of
5 need and agrees to sign a written confidentiality
6 agreement with the Administrator, subject to the con-
7 ditions that—

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

11 “(B) the written statement of need shall be
12 a statement that the person has a reasonable
13 basis to suspect that—

14 “(i) the information is necessary for,
15 or will assist in—

16 “(I) the diagnosis or treatment of
17 1 or more individuals; or

18 “(II) responding to an environ-
19 mental release or exposure; and

20 “(ii) 1 or more individuals being diag-
21 nosed or treated have been exposed to the
22 chemical substance concerned, or an envi-
23 ronmental release or exposure has occurred;
24 and

1 “(C) the confidentiality agreement shall
2 provide that the person will not use the informa-
3 tion for any purpose other than the health or en-
4 vironmental needs asserted in the statement of
5 need, except as otherwise may be authorized by
6 the terms of the agreement or by the person sub-
7 mitting the information to the Administrator,
8 except that nothing in this Act prohibits the dis-
9 closure of any such information through dis-
10 covery, subpoena, other court order, or any other
11 judicial process otherwise allowed under applica-
12 ble Federal or State law;

13 “(6) shall be disclosed if in the event of an emer-
14 gency, a treating physician, nurse, agent of a poison
15 control center, public health or environmental official
16 of a State or political subdivision of a State, or first
17 responder (including any individual duly authorized
18 by a Federal agency, State, or political subdivision of
19 a State who is trained in urgent medical care or
20 other emergency procedures, including a police officer,
21 firefighter, or emergency medical technician) requests
22 the information, subject to the conditions that—

23 “(A) the treating physician, nurse, agent,
24 public health or environmental official of a State
25 or a political subdivision of a State, or first re-

1 *sponder shall have a reasonable basis to suspect*
2 *that—*

3 *“(i) a medical or public health or envi-*
4 *ronmental emergency exists;*

5 *“(ii) the information is necessary for,*
6 *or will assist in, emergency or first-aid di-*
7 *agnosis or treatment; or*

8 *“(iii) 1 or more individuals being di-*
9 *agnosed or treated have likely been exposed*
10 *to the chemical substance concerned, or a se-*
11 *rious environmental release of or exposure*
12 *to the chemical substance concerned has oc-*
13 *curred;*

14 *“(B) if requested by the person submitting*
15 *the information to the Administrator, the treat-*
16 *ing physician, nurse, agent, public health or en-*
17 *vironmental official of a State or a political sub-*
18 *division of a State, or first responder shall, as*
19 *described in paragraph (5)—*

20 *“(i) provide a written statement of*
21 *need; and*

22 *“(ii) agree to sign a confidentiality*
23 *agreement; and*

24 *“(C) the written confidentiality agreement*
25 *or statement of need shall be submitted as soon*

1 *as practicable, but not necessarily before the in-*
2 *formation is disclosed;*

3 “(7) *may be disclosed if the Administrator deter-*
4 *mines that disclosure is relevant in a proceeding*
5 *under this Act, subject to the condition that the disclo-*
6 *sure shall be made in such a manner as to preserve*
7 *confidentiality to the maximum extent practicable*
8 *without impairing the proceeding;*

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

12 “(9) *shall be disclosed if the information is re-*
13 *quired to be disclosed or otherwise made public under*
14 *any other provision of Federal law.*

15 “(f) *DURATION OF PROTECTION FROM DISCLOSURE.—*

16 “(1) *IN GENERAL.—*

17 “(A) *INFORMATION PROTECTED FROM DIS-*
18 *CLOSURE.—Subject to paragraph (2), the Ad-*
19 *ministrator shall protect from disclosure infor-*
20 *mation that meets the requirements of subsection*
21 *(d) for a period of 10 years, unless, prior to the*
22 *expiration of the period—*

23 “(i) *an affected person notifies the Ad-*
24 *ministrator that the person is withdrawing*
25 *the confidentiality claim, in which case the*

1 *Administrator shall promptly make the in-*
2 *formation available to the public; or*

3 *“(ii) the Administrator otherwise be-*
4 *comes aware that the need for protection*
5 *from disclosure can no longer be substan-*
6 *tiated, in which case the Administrator*
7 *shall take the actions described in subsection*
8 *(g)(2).*

9 *“(B) EXTENSIONS.—*

10 *“(i) IN GENERAL.—Not later than the*
11 *date that is 60 days before the expiration of*
12 *the period described in subparagraph (A),*
13 *the Administrator shall provide to the per-*
14 *son that asserted the claim a notice of the*
15 *impending expiration of the period.*

16 *“(ii) STATEMENT.—*

17 *“(I) IN GENERAL.—Not later than*
18 *the date that is 30 days before the expi-*
19 *ration of the period described in sub-*
20 *paragraph (A), a person reasserting*
21 *the relevant claim shall submit to the*
22 *Administrator a statement substan-*
23 *tiating, in accordance with subsection*
24 *(d)(2), the need to extend the period.*

1 “(II) ACTION BY ADMINIS-
 2 TRATOR.—Not later than the date that
 3 is 30 days after the date of receipt of
 4 a statement under subclause (I), the
 5 Administrator shall—

6 “(aa) review the request;

7 “(bb) make a determination
 8 regarding whether the information
 9 for which the request is made con-
 10 tinues to meet the relevant cri-
 11 teria established under this sec-
 12 tion; and

13 “(cc)(AA) grant an extension
 14 of not more than 10 years; or

15 “(BB) deny the claim.

16 “(C) NO LIMIT ON NUMBER OF EXTEN-
 17 SIONS.—There shall be no limit on the number
 18 of extensions granted under subparagraph (B), if
 19 the Administrator determines that the relevant
 20 statement under subparagraph (B)(i)(I)—

21 “(i) establishes the need to extend the
 22 period; and

23 “(ii) meets the requirements established
 24 by the Administrator.

25 “(2) REVIEW AND RESUBSTANTIATION.—

1 “(A) *DISCRETION OF ADMINISTRATOR.*—*The*
2 *Administrator may review, at any time, a claim*
3 *for protection against disclosure under subsection*
4 *(a) for information submitted to the Adminis-*
5 *trator regarding a chemical substance and re-*
6 *quire any person that has claimed protection for*
7 *that information, whether before, on, or after the*
8 *date of enactment of the Frank R. Lautenberg*
9 *Chemical Safety for the 21st Century Act, to*
10 *withdraw or reassert and substantiate or re-*
11 *substantiate the claim in accordance with this*
12 *section—*

13 “(i) *after the chemical substance is*
14 *identified as a high-priority substance*
15 *under section 4A;*

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

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

21 “(iv) *in limited circumstances, if the*
22 *Administrator determines that disclosure of*
23 *certain information currently protected*
24 *from disclosure would assist the Adminis-*
25 *trator in conducting safety assessments and*

1 *safety determinations under subsections (b)*
2 *and (c) of section 6 or promulgating rules*
3 *pursuant to section 6(d), subject to the con-*
4 *dition that the information shall not be dis-*
5 *closed unless the claimant withdraws the*
6 *claim or the Administrator determines that*
7 *the information does not meet the require-*
8 *ments of subsection (d).*

9 “(B) *REVIEW REQUIRED.—The Adminis-*
10 *trator shall review a claim for protection from*
11 *disclosure under subsection (a) for information*
12 *submitted to the Administrator regarding a*
13 *chemical substance and require any person that*
14 *has claimed protection for that information,*
15 *whether before, on, or after the date of enactment*
16 *of the Frank R. Lautenberg Chemical Safety for*
17 *the 21st Century Act, to withdraw or reassert*
18 *and substantiate or resubstantiate the claim in*
19 *accordance with this section—*

20 “(i) *as necessary to comply with a re-*
21 *quest for information received by the Ad-*
22 *ministrator under section 552 of title 5,*
23 *United States Code;*

24 “(ii) *if information available to the*
25 *Administrator provides a basis that the re-*

1 *quirements of section 552(b)(4) of title 5,*
2 *United States Code, are no longer met; or*

3 *“(iii) for any substance for which the*
4 *Administrator has made a determination*
5 *under section 6(c)(1)(B).*

6 *“(C) ACTION BY RECIPIENT.—If the Admin-*
7 *istrator makes a request under subparagraph (A)*
8 *or (B), the recipient of the request shall—*

9 *“(i) reassert and substantiate or re-*
10 *substantiate the claim; or*

11 *“(ii) withdraw the claim.*

12 *“(D) PERIOD OF PROTECTION.—Protection*
13 *from disclosure of information subject to a claim*
14 *that is reviewed and approved by the Adminis-*
15 *trator under this paragraph shall be extended for*
16 *a period of 10 years from the date of approval,*
17 *subject to any subsequent request by the Admin-*
18 *istrator under this paragraph.*

19 *“(3) UNIQUE IDENTIFIER.—The Administrator*
20 *shall—*

21 *“(A)(i) develop a system to assign a unique*
22 *identifier to each specific chemical identity for*
23 *which the Administrator approves a request for*
24 *protection from disclosure, other than a specific*

1 *chemical identity or structurally descriptive ge-*
2 *neric term; and*

3 “(i) *apply that identifier consistently to all*
4 *information relevant to the applicable chemical*
5 *substance;*

6 “(B) *annually publish and update a list of*
7 *chemical substances, referred to by unique identi-*
8 *fier, for which claims to protect the specific*
9 *chemical identity from disclosure have been ap-*
10 *proved, including the expiration date for each*
11 *such claim;*

12 “(C) *ensure that any nonconfidential infor-*
13 *mation received by the Administrator with re-*
14 *spect to such a chemical substance during the pe-*
15 *riod of protection from disclosure—*

16 “(i) *is made public; and*

17 “(ii) *identifies the chemical substance*
18 *using the unique identifier; and*

19 “(D) *for each claim for protection of specific*
20 *chemical identity that has been denied by the*
21 *Administrator on expiration of the period for*
22 *appeal under subsection (g)(4), that has expired,*
23 *or that has been withdrawn by the submitter,*
24 *provide public access to the specific chemical*
25 *identity clearly linked to all nonconfidential in-*

1 *formation received by the Administrator with re-*
2 *spect to the chemical substance.*

3 “(g) *DUTIES OF ADMINISTRATOR.—*

4 “(1) *DETERMINATION.—*

5 “(A) *IN GENERAL.—Except as provided in*
6 *subsection (b), the Administrator shall, subject to*
7 *subparagraph (C), not later than 90 days after*
8 *the receipt of a claim under subsection (d), and*
9 *not later than 30 days after the receipt of a re-*
10 *quest for extension of a claim under subsection*
11 *(f), review and approve, modify, or deny the*
12 *claim or request.*

13 “(B) *DENIAL OR MODIFICATION.—*

14 “(i) *IN GENERAL.—Except as provided*
15 *in subsections (c) and (f), the Administrator*
16 *shall deny a claim to protect a chemical*
17 *identity from disclosure only if the person*
18 *that has submitted the claim fails to meet*
19 *the requirements of subsections (a) and (d).*

20 “(ii) *REASONS FOR DENIAL OR MODI-*
21 *FICATION.—The Administrator shall pro-*
22 *vide to a person that has submitted a claim*
23 *described in clause (i) a written statement*
24 *of the reasons for the denial or modification*
25 *of the claim.*

1 “(C) *SUBSETS.*—*The Administrator shall—*

2 “(i) *except for claims described in sub-*
3 *section (b)(7), review all claims under this*
4 *section for the protection against disclosure*
5 *of the specific identity of a chemical sub-*
6 *stance; and*

7 “(ii) *review a representative subset,*
8 *comprising at least 25 percent, of all other*
9 *claims for protection against disclosure.*

10 “(D) *EFFECT OF FAILURE TO ACT.*—*The*
11 *failure of the Administrator to make a decision*
12 *regarding a claim for protection against disclo-*
13 *sure or extension under this section shall not be*
14 *the basis for denial or elimination of a claim for*
15 *protection against disclosure.*

16 “(2) *NOTIFICATION.*—

17 “(A) *IN GENERAL.*—*Except as provided in*
18 *subparagraph (B) and subsections (c), (e), and*
19 *(f), if the Administrator denies or modifies a*
20 *claim under paragraph (1), or promulgates a*
21 *rule under section 6(d) establishing a ban or*
22 *phase-out of a chemical substance, the Adminis-*
23 *trator shall notify, in writing and by certified*
24 *mail, the person that submitted the claim of the*

1 *intent of the Administrator to release the infor-*
2 *mation.*

3 “(B) *RELEASE OF INFORMATION.*—

4 “(i) *IN GENERAL.*—*Except as provided*
5 *in clause (ii), the Administrator shall not*
6 *release information under this subsection*
7 *until the date that is 30 days after the date*
8 *on which the person that submitted the re-*
9 *quest receives notification under subpara-*
10 *graph (A).*

11 “(ii) *EXCEPTIONS.*—

12 “(I) *IN GENERAL.*—*For informa-*
13 *tion under paragraph (3) or (8) of sub-*
14 *section (e), the Administrator shall not*
15 *release that information until the date*
16 *that is 15 days after the date on which*
17 *the person that submitted the claim re-*
18 *ceives a notification, unless the Admin-*
19 *istrator determines that release of the*
20 *information is necessary to protect*
21 *against an imminent and substantial*
22 *harm to health or the environment, in*
23 *which case no prior notification shall*
24 *be necessary.*

1 “(II) *NO NOTIFICATION.*—*For in-*
2 *formation under paragraph (1), (2),*
3 *(6), (7), or (9) of subsection (e), no*
4 *prior notification shall be necessary.*

5 “(3) *REBUTTABLE PRESUMPTION.*—

6 “(A) *IN GENERAL.*—*With respect to notifi-*
7 *cations provided by the Administrator pursuant*
8 *to subsection (c)(5), there shall be a rebuttable*
9 *presumption that the public interest in dis-*
10 *closing confidential information related to a*
11 *chemical substance subject to a rule promulgated*
12 *under section 6(d) that establishes a ban or*
13 *phase-out of the manufacture, processing, or dis-*
14 *tribution in commerce of the substance outweighs*
15 *the proprietary interest in maintaining the pro-*
16 *tection from disclosure of that information.*

17 “(B) *REQUEST FOR NONDISCLOSURE.*—*A*
18 *person that receives a notification under para-*
19 *graph (2) with respect to the information de-*
20 *scribed in subparagraph (A) may submit to the*
21 *Administrator, before the date on which the in-*
22 *formation is to be released, a request with sup-*
23 *porting documentation describing why the per-*
24 *son believes some or all of that information*
25 *should not be disclosed.*

1 “(C) DETERMINATION BY ADMINIS-
2 TRATOR.—

3 “(i) IN GENERAL.—Not later than 30
4 days after the Administrator receives a re-
5 quest under subparagraph (B), the Admin-
6 istrator shall determine, at the discretion of
7 the Administrator, whether the documenta-
8 tion provided by the person making the re-
9 quest rebuts or does not rebut the presump-
10 tion described in subparagraph (A), for all
11 or a portion of the information that the per-
12 son has requested not be disclosed.

13 “(ii) OBJECTIVE.—The Administrator
14 shall make the determination with the objec-
15 tive of ensuring that information relevant to
16 protection of health and the environment is
17 disclosed to the maximum extent prac-
18 ticable.

19 “(D) TIMING.—Not later than 30 days after
20 making the determination described in subpara-
21 graph (C), the Administrator shall make public
22 the information the Administrator has deter-
23 mined is not to be protected from disclosure.

24 “(E) NO TIMELY REQUEST RECEIVED.—If
25 the Administrator does not receive, before the

1 *date on which the information described in sub-*
2 *paragraph (A) is to be released, a request pursu-*
3 *ant to subparagraph (B), the Administrator*
4 *shall promptly make public all of the informa-*
5 *tion.*

6 “(4) *APPEALS.*—

7 “(A) *IN GENERAL.*—*If a person receives a*
8 *notification under paragraph (2) and believes*
9 *disclosure of the information is prohibited under*
10 *subsection (a), before the date on which the infor-*
11 *mation is to be released, the person may bring*
12 *an action to restrain disclosure of the informa-*
13 *tion in—*

14 “(i) *the United States district court of*
15 *the district in which the complainant re-*
16 *sides or has the principal place of business;*
17 *or*

18 “(ii) *the United States District Court*
19 *for the District of Columbia.*

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

1 “(5) *ADMINISTRATION.*—*In carrying out this*
2 *subsection, the Administrator shall use the procedures*
3 *described in part 2 of title 40, Code of Federal Regu-*
4 *lations (or successor regulations).*

5 “(h) *CRIMINAL PENALTY FOR WRONGFUL DISCLO-*
6 *SURE.*—

7 “(1) *OFFICERS AND EMPLOYEES OF UNITED*
8 *STATES.*—

9 “(A) *IN GENERAL.*—*Subject to paragraph*
10 *(2), a current or former officer or employee of the*
11 *United States described in subparagraph (B)*
12 *shall be guilty of a misdemeanor and fined*
13 *under title 18, United States Code, or impris-*
14 *oned for not more than 1 year, or both.*

15 “(B) *DESCRIPTION.*—*A current or former*
16 *officer or employee of the United States referred*
17 *to in subparagraph (A) is a current or former*
18 *officer or employee of the United States who—*

19 “(i) *by virtue of that employment or*
20 *official position has obtained possession of,*
21 *or has access to, material the disclosure of*
22 *which is prohibited by subsection (a); and*

23 “(ii) *knowing that disclosure of that*
24 *material is prohibited by subsection (a),*
25 *willfully discloses the material in any man-*

1 ner to any person not entitled to receive
2 that material.

3 “(2) *OTHER LAWS.*—Section 1905 of title 18,
4 *United States Code, shall not apply with respect to*
5 *the publishing, divulging, disclosure, making known*
6 *of, or making available, information reported or oth-*
7 *erwise obtained under this Act.*

8 “(3) *CONTRACTORS.*—For purposes of this sub-
9 section, any contractor of the United States that is
10 provided information in accordance with subsection
11 (e)(2), including any employee of that contractor,
12 shall be considered to be an employee of the United
13 States.

14 “(i) *APPLICABILITY.*—

15 “(1) *IN GENERAL.*—Except as otherwise provided
16 in this section, section 8, or any other applicable Fed-
17 eral law, the Administrator shall have no authority—

18 “(A) to require the substantiation or re-
19 substantiation of a claim for the protection from
20 disclosure of information submitted to the Ad-
21 ministrators under this Act before the date of en-
22 actment of the Frank R. Lautenberg Chemical
23 Safety for the 21st Century Act; or

24 “(B) to impose substantiation or resubstan-
25 tiation requirements under this Act that are

1 *more extensive than those required under this*
2 *section.*

3 “(2) *PRIOR ACTIONS.*—*Nothing in this Act pre-*
4 *vents the Administrator from reviewing, requiring*
5 *substantiation or resubstantiation for, or approving,*
6 *modifying or denying any claim for the protection*
7 *from disclosure of information before the effective date*
8 *of such rules applicable to those claims as the Admin-*
9 *istrator may promulgate after the date of enactment*
10 *of the Frank R. Lautenberg Chemical Safety for the*
11 *21st Century Act.”.*

12 **SEC. 15. PROHIBITED ACTS.**

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

16 “(1) *fail or refuse to comply with—*

17 “(A) *any rule promulgated, consent agree-*
18 *ment entered into, or order issued under section*
19 4;

20 “(B) *any requirement under section 5 or 6;*

21 “(C) *any rule promulgated, consent agree-*
22 *ment entered into, or order issued under section*
23 5 or 6; or

24 “(D) *any requirement of, or any rule pro-*
25 *mulgated or order issued pursuant to title II;”.*

1 **SEC. 16. PENALTIES.**

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

4 *(1) in subsection (a)(1)—*

5 *(A) in the first sentence—*

6 *(i) by inserting “this Act or a rule or*
 7 *order promulgated or issued pursuant to*
 8 *this Act, including” after “a provision of”;*
 9 *and*

10 *(ii) by striking “\$25,000” and insert-*
 11 *ing “\$37,500”; and*

12 *(B) in the second sentence, by striking “ vio-*
 13 *lation of section 15 or 409” and inserting “viola-*
 14 *tion of this Act”; and*

15 *(2) in subsection (b)—*

16 *(A) by striking “Any person who” and in-*
 17 *serting the following:*

18 *“(1) IN GENERAL.—Any person that”;*

19 *(B) by striking “section 15 or 409” and in-*
 20 *serting “this Act”;*

21 *(C) by striking “\$25,000” and inserting*
 22 *“\$50,000”; and*

23 *(D) by adding at the end the following:*

24 *“(2) IMMINENT DANGER OF DEATH OR SERIOUS*
 25 *BODILY INJURY.—*

1 “(A) *IN GENERAL.*—Any person that know-
2 ingly or willfully violates any provision of this
3 Act, and that knows at the time of the violation
4 that the violation places an individual in immi-
5 nent danger of death or serious bodily injury,
6 shall be subject on conviction to a fine of not
7 more than \$250,000, or imprisonment for not
8 more than 15 years, or both.

9 “(B) *ORGANIZATIONS.*—An organization
10 that commits a violation described in subpara-
11 graph (A) shall be subject on conviction to a fine
12 of not more than \$1,000,000 for each violation.

13 “(3) *KNOWLEDGE OF IMMINENT DANGER OR IN-*
14 *JURY.*—For purposes of determining whether a de-
15 fendant knew that the violation placed another indi-
16 vidual in imminent danger of death or serious bodily
17 injury—

18 “(A) the defendant shall be responsible only
19 for actual awareness or actual belief possessed;
20 and

21 “(B) knowledge possessed by an individual
22 may not be attributed to the defendant.”.

1 **SEC. 17. STATE-FEDERAL RELATIONSHIP.**

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

5 “(a) *IN GENERAL.*—

6 “(1) *ESTABLISHMENT OR ENFORCEMENT.*—*Ex-*
7 *cept as provided in subsections (c), (d), (e), (f), and*
8 *(g), and subject to paragraph (2), no State or polit-*
9 *ical subdivision of a State may establish or continue*
10 *to enforce any of the following:*

11 “(A) *TESTING AND INFORMATION COLLEC-*
12 *TION.*—*A statute or administrative action to re-*
13 *quire the development of information on a chem-*
14 *ical substance or category of substances that is*
15 *reasonably likely to produce the same informa-*
16 *tion required under section 4, 5, or 6 in—*

17 “(i) *a rule promulgated by the Admin-*
18 *istrator;*

19 “(ii) *a testing consent agreement en-*
20 *tered into by the Administrator; or*

21 “(iii) *an order issued by the Adminis-*
22 *trator.*

23 “(B) *CHEMICAL SUBSTANCES FOUND TO*
24 *MEET THE SAFETY STANDARD OR RE-*
25 *STRICTED.*—*A statute or administrative action*
26 *to prohibit or otherwise restrict the manufacture,*

1 *processing, or distribution in commerce or use of*
2 *a chemical substance—*

3 “(i) *found to meet the safety standard*
4 *and consistent with the scope of the deter-*
5 *mination made under section 6; or*

6 “(ii) *found not to meet the safety*
7 *standard, after the effective date of the rule*
8 *issued under section 6(d) for the substance,*
9 *consistent with the scope of the determina-*
10 *tion made by the Administrator.*

11 “(C) *SIGNIFICANT NEW USE.—A statute or*
12 *administrative action requiring the notification*
13 *of a use of a chemical substance that the Admin-*
14 *istrator has specified as a significant new use*
15 *and for which the Administrator has required*
16 *notification pursuant to a rule promulgated*
17 *under section 5.*

18 “(2) *EFFECTIVE DATE OF PREEMPTION.—Under*
19 *this subsection, Federal preemption of State statutes*
20 *and administrative actions applicable to specific sub-*
21 *stances shall not occur until the effective date of the*
22 *applicable action described in paragraph (1) taken by*
23 *the Administrator.*

24 “(b) *NEW STATUTES OR ADMINISTRATIVE ACTIONS*
25 *CREATING PROHIBITIONS OR OTHER RESTRICTIONS.—*

1 “(1) *IN GENERAL.*—*Except as provided in sub-*
2 *sections (c), (d), and (e), beginning on the date on*
3 *which the Administrator defines the scope of a safety*
4 *assessment and safety determination under section*
5 *6(a)(2) and ending on the date on which the Admin-*
6 *istrator publishes the safety determination, no State*
7 *or political subdivision of a State may establish a*
8 *statute or administrative action prohibiting or re-*
9 *stricting the manufacture, processing, distribution in*
10 *commerce or use of a chemical substance that is a*
11 *high-priority substance designated under section 4A.*

12 “(2) *EFFECT OF SUBSECTION.*—

13 “(A) *IN GENERAL.*—*This subsection does*
14 *not restrict the authority of a State or political*
15 *subdivision of a State to continue to enforce any*
16 *State statute enacted, or administrative action*
17 *taken, prior to the date on which the Adminis-*
18 *trator defines the scope of a safety assessment*
19 *and safety determination under section 6(a)(2).*

20 “(B) *LIMITATION.*—*Subparagraph (A) does*
21 *not allow a State or political subdivision of a*
22 *State to enforce any new prohibition or restric-*
23 *tion under a State statute or administrative ac-*
24 *tion described in that subparagraph, if the pro-*

1 *hibition or restriction is established after the*
2 *date described in that subparagraph.*

3 “(c) *SCOPE OF PREEMPTION.—Federal preemption*
4 *under subsections (a) and (b) of State statutes and adminis-*
5 *trative actions applicable to specific substances shall apply*
6 *only to—*

7 “(1) *the chemical substances or category of sub-*
8 *stances subject to a rule, order, or consent agreement*
9 *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 included*
13 *in the scope of the safety determination made by the*
14 *Administrator for the substance, or of any rule the*
15 *Administrator promulgates pursuant to section 6(d);*
16 *or*

17 “(3) *the uses of such substances that the Admin-*
18 *istrator has specified as significant new uses and for*
19 *which the Administrator has required notification*
20 *pursuant to a rule promulgated under section 5.*

21 “(d) *EXCEPTIONS.—*

22 “(1) *NO PREEMPTION OF STATE STATUTES AND*
23 *ADMINISTRATIVE ACTIONS.—*

24 “(A) *IN GENERAL.—Nothing in this Act,*
25 *nor any amendment made by this Act, nor any*

1 *rule, standard of performance, safety determina-*
2 *tion, or scientific assessment implemented pursu-*
3 *ant to this Act, shall affect the right of a State*
4 *or a political subdivision of a State to adopt or*
5 *enforce any rule, standard of performance, safety*
6 *determination, scientific assessment, or any pro-*
7 *tection for public health or the environment*
8 *that—*

9 *“(i) is adopted or authorized under the*
10 *authority of any other Federal law or*
11 *adopted to satisfy or obtain authorization*
12 *or approval under any other Federal law;*

13 *“(ii) implements a reporting, moni-*
14 *toring, disclosure, or other information obli-*
15 *gation for the chemical substance not other-*
16 *wise required by the Administrator under*
17 *this Act or required under any other Fed-*
18 *eral law;*

19 *“(iii) is adopted pursuant to authority*
20 *under a law of the State or political sub-*
21 *division of the State related to water qual-*
22 *ity, air quality, or waste treatment or dis-*
23 *posal, except to the extent that the action—*

24 *“(I) imposes a restriction on the*
25 *manufacture, processing, distribution*

1 *in commerce, or use of a chemical sub-*
2 *stance; and*

3 *“(II)(aa) addresses the same haz-*
4 *ards and exposures, with respect to the*
5 *same conditions of use as are included*
6 *in the scope of the safety determination*
7 *pursuant to section 6, but is incon-*
8 *sistent with the action of the Adminis-*
9 *trator; or*

10 *“(bb) would cause a violation of*
11 *the applicable action by the Adminis-*
12 *trator under section 5 or 6; or*

13 *“(iv) subject to subparagraph (B), is*
14 *identical to a requirement prescribed by the*
15 *Administrator.*

16 *“(B) IDENTICAL REQUIREMENTS.—*

17 *“(i) IN GENERAL.—The penalties and*
18 *other sanctions applicable under State law*
19 *in the event of noncompliance with the*
20 *identical requirement shall be no more*
21 *stringent than the penalties and other sanc-*
22 *tions available to the Administrator under*
23 *section 16 of this Act.*

24 *“(ii) PENALTIES.—In the case of an*
25 *identical requirement, no State may assess*

1 *a penalty for a specific violation for which*
2 *the Administrator has already assessed a*
3 *penalty under section 16, and the Adminis-*
4 *trator may not assess a penalty under sec-*
5 *tion 16 for a specific violation for which a*
6 *State has already assessed a penalty.*

7 “(2) *APPLICABILITY TO CERTAIN RULES OR OR-*
8 *DERS.—Notwithstanding subsection (e)—*

9 “(A) *nothing in this section shall be con-*
10 *strued as modifying the effect under this section,*
11 *as in effect on the day before the effective date of*
12 *the Frank R. Lautenberg Chemical Safety for the*
13 *21st Century Act, of any rule or order promul-*
14 *gated or issued under this Act prior to that effec-*
15 *tive date; and*

16 “(B) *with respect to a chemical substance or*
17 *mixture for which any rule or order was promul-*
18 *gated or issued under section 6 prior to the effec-*
19 *tive date of the Frank R. Lautenberg Chemical*
20 *Safety for the 21st Century Act with regards to*
21 *manufacturing, processing, distribution in com-*
22 *merce, use, or disposal of a chemical substance,*
23 *this section (as in effect on the day before the ef-*
24 *fective date of the Frank R. Lautenberg Chemical*
25 *Safety for the 21st Century Act) shall govern the*

1 *preemptive effect of any rule or order that is pro-*
2 *mulgated or issued respecting such chemical sub-*
3 *stance or mixture under section 6 of this Act*
4 *after that effective date, unless the latter rule or*
5 *order is with respect to a chemical substance or*
6 *mixture containing a chemical substance and fol-*
7 *lows a designation of that chemical substance as*
8 *a high-priority substance under section 4A(b) or*
9 *as an additional priority for safety assessment*
10 *and safety determination under section 4A(c).*

11 “(e) *PRESERVATION OF CERTAIN STATE LAW.—*

12 “(1) *IN GENERAL.—Nothing in this Act, subject*
13 *to subsection (g) of this section, shall—*

14 “(A) *be construed to preempt or otherwise*
15 *affect the authority of a State or political sub-*
16 *division of a State to continue to enforce any ac-*
17 *tion taken before August 1, 2015, under the au-*
18 *thority of a State law that prohibits or otherwise*
19 *restricts manufacturing, processing, distribution*
20 *in commerce, use, or disposal of a chemical sub-*
21 *stance; or*

22 “(B) *be construed to preempt or otherwise*
23 *affect any action taken pursuant to a State law*
24 *that was in effect on August 31, 2003.*

1 “(2) *EFFECT OF SUBSECTION.*—*This subsection*
2 *does not affect, modify, or alter the relationship be-*
3 *tween State and Federal law pursuant to any other*
4 *Federal law.*

5 “(f) *STATE WAIVERS.*—

6 “(1) *DISCRETIONARY EXEMPTIONS.*—*Upon ap-*
7 *plication of a State or political subdivision of a*
8 *State, the Administrator may by rule, exempt from*
9 *subsection (a), under such conditions as may be pre-*
10 *scribed in the rule, a statute or administrative action*
11 *of that State or political subdivision of the State that*
12 *relates to the effects of, or exposure to, a chemical sub-*
13 *stance under the conditions of use if the Adminis-*
14 *trator determines that—*

15 “(A) *compelling State or local conditions*
16 *warrant granting the waiver to protect health or*
17 *the environment;*

18 “(B) *compliance with the proposed require-*
19 *ment of the State or political subdivision of the*
20 *State would not unduly burden interstate com-*
21 *merce in the manufacture, processing, distribu-*
22 *tion in commerce, or use of a chemical substance;*

23 “(C) *compliance with the proposed require-*
24 *ment of the State or political subdivision of the*

1 *State would not cause a violation of any appli-*
2 *cable Federal law, rule, or order; and*

3 “(D) based on the judgment of the Adminis-
4 trator, the proposed requirement of the State or
5 political subdivision of the State is consistent
6 with sound objective scientific practices, the
7 weight of the evidence, and the best available
8 science.

9 “(2) *REQUIRED EXEMPTIONS.*—Upon applica-
10 tion of a State or political subdivision of a State, the
11 Administrator shall exempt from subsection (b) a
12 statute or administrative action of a State or polit-
13 ical subdivision of a State that relates to the effects
14 of exposure to a chemical substance under the condi-
15 tions of use if the Administrator determines that—

16 “(A) compliance with the proposed require-
17 ment of the State will not unduly burden inter-
18 state commerce in the manufacture, processing,
19 distribution in commerce, or use of a chemical
20 substance;

21 “(B) compliance with the proposed require-
22 ment would not cause a violation of any appli-
23 cable Federal law, rule, or order; and

24 “(C) the State or political subdivision of a
25 State has a concern about the chemical substance

1 *or use of the chemical substance based in peer-*
2 *reviewed science.*

3 “(3) *DETERMINATION OF A STATE WAIVER RE-*
4 *QUEST.—The duty of the Administrator to grant or*
5 *deny a waiver application shall be nondelegable and*
6 *shall be exercised—*

7 “(A) *not later than 180 days after the date*
8 *on which an application under paragraph (1) is*
9 *submitted; and*

10 “(B) *not later than 90 days after the date*
11 *on which an application under paragraph (2) is*
12 *submitted.*

13 “(4) *FAILURE TO MAKE DETERMINATION.—If the*
14 *Administrator fails to make a determination under*
15 *paragraph (3)(B) during the 90-day period beginning*
16 *on the date on which an application under paragraph*
17 *(2) is submitted, the State statute or administrative*
18 *action that was the subject of the application shall*
19 *not be considered to be an existing statute or admin-*
20 *istrative action for purposes of subsection (b) by rea-*
21 *son of the failure of the Administrator to make a de-*
22 *termination.*

23 “(5) *NOTICE AND COMMENT.—Except in the case*
24 *of an application approved under paragraph (9), the*

1 *application of a State or political subdivision of the*
2 *State shall be subject to public notice and comment.*

3 “(6) *FINAL AGENCY ACTION.*—*The decision of the*
4 *Administrator on the application of a State or polit-*
5 *ical subdivision of the State shall be—*

6 “(A) *considered to be a final agency action;*
7 *and*

8 “(B) *subject to judicial review.*

9 “(7) *DURATION OF WAIVERS.*—

10 “(A) *IN GENERAL.*—*Except as provided in*
11 *subparagraph (B), a waiver granted under para-*
12 *graph (2) or approved under paragraph (9) shall*
13 *remain in effect—*

14 “(i) *until such time as the safety as-*
15 *essment and safety determination is com-*
16 *pleted; or*

17 “(ii) *subject to subparagraph (B),*
18 *until judicial review of the failure of the*
19 *Administrator to make a determination*
20 *under paragraph (3) is sought under para-*
21 *graph (8).*

22 “(B) *REINSTATEMENT OF WAIVER.*—*A*
23 *waiver described in subparagraph (A)(ii) shall*
24 *again take effect upon the earlier of—*

1 “(i) the date of approval by the Ad-
2 ministrators of the waiver application;

3 “(ii) the effective date of a court order
4 directing the Administrator to approve the
5 waiver application; or

6 “(iii) 90 days after the date on which
7 judicial review under paragraph (8) is
8 sought.

9 “(8) *JUDICIAL REVIEW OF WAIVERS.*—Not later
10 than 60 days after the date on which the Adminis-
11 trator makes a determination on an application of a
12 State or political subdivision of the State under para-
13 graph (1) or (2), or not later than 60 days after the
14 date on which the Administrator fails to make a de-
15 termination under paragraph (3), any person may
16 file a petition for judicial review in the United States
17 Court of Appeals for the District of Columbia Circuit,
18 which shall have exclusive jurisdiction over the deter-
19 mination.

20 “(9) *APPROVAL.*—

21 “(A) *IN GENERAL.*—If the Administrator
22 fails to meet the deadline under section 6(a)(4)
23 (including an extension granted under section
24 6(a)(6)), or the deadline established under para-
25 graph (3)(B), the application of a State or polit-

1 *ical subdivision of a State under paragraph (2)*
2 *shall be automatically approved.*

3 “(B) *REQUIREMENTS.—Notwithstanding*
4 *paragraph (6), approval of a waiver application*
5 *under subparagraph (A) for failure to meet the*
6 *deadlines under section 6(a)(4) (including an ex-*
7 *ension granted under section 6(a)(6)) shall not*
8 *be considered final agency action or be subject to*
9 *judicial review or public notice and comment.*

10 “(10) *JUDICIAL REVIEW OF LOW-PRIORITY DECI-*
11 *SIONS.—*

12 “(A) *IN GENERAL.—Not later than 60 days*
13 *after the publication of a designation under sec-*
14 *tion 4A(b)(4), any person may commence a civil*
15 *action to challenge the designation.*

16 “(B) *JURISDICTION.—The United States*
17 *Court of Appeals for the District of Columbia*
18 *Circuit shall have exclusive jurisdiction over a*
19 *civil action filed under this paragraph.*

20 “(g) *SAVINGS.—*

21 “(1) *NO PREEMPTION OF COMMON LAW OR STAT-*
22 *UTORY CAUSES OF ACTION FOR CIVIL RELIEF OR*
23 *CRIMINAL CONDUCT.—*

24 “(A) *IN GENERAL.—Nothing in this Act,*
25 *nor any amendment made by this Act, nor any*

1 *safety standard, rule, requirement, standard of*
2 *performance, safety determination, or scientific*
3 *assessment implemented pursuant to this Act,*
4 *shall be construed to preempt, displace, or sup-*
5 *plant any state or Federal common law rights or*
6 *any state or Federal statute creating a remedy*
7 *for civil relief, including those for civil damage,*
8 *or a penalty for a criminal conduct.*

9 “(B) *CLARIFICATION OF NO PREEMPTION.—*

10 *Notwithstanding any other provision of this Act,*
11 *nothing in this Act, nor any amendments made*
12 *by this Act, shall preempt or preclude any cause*
13 *of action for personal injury, wrongful death,*
14 *property damage, or other injury based on neg-*
15 *ligence, strict liability, products liability, failure*
16 *to warn, or any other legal theory of liability*
17 *under any State law, maritime law, or Federal*
18 *common law or statutory theory.*

19 “(2) *NO EFFECT ON PRIVATE REMEDIES.—*

20 “(A) *IN GENERAL.—Nothing in this Act,*
21 *nor any amendments made by this Act, nor any*
22 *rules, regulations, requirements, safety assess-*
23 *ments, safety determinations, scientific assess-*
24 *ments, or orders issued pursuant to this Act shall*

1 *be interpreted as, in either the plaintiff's or de-*
 2 *fendant's favor, dispositive in any civil action.*

3 “(B) *AUTHORITY OF COURTS.*—*This Act*
 4 *does not affect the authority of any court to*
 5 *make a determination in an adjudicatory pro-*
 6 *ceeding under applicable State or Federal law*
 7 *with respect to the admission into evidence or*
 8 *any other use of this Act or rules, regulations, re-*
 9 *quirements, standards of performance, safety as-*
 10 *sessments, scientific assessments, or orders issued*
 11 *pursuant to this Act.”.*

12 **SEC. 18. JUDICIAL REVIEW.**

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

15 *(1) in subsection (a)—*

16 *(A) in paragraph (1)—*

17 *(i) in subparagraph (A), by striking*
 18 *“section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or*
 19 *8, or under title II or IV” and inserting*
 20 *“section 4(a), 5(d), 6(c), 6(d), 6(g), or 8, or*
 21 *title II or IV”; and*

22 *(ii) in subparagraph (B), by striking*
 23 *“an order issued under subparagraph (A)*
 24 *or (B) of section 6(b)(1)” and inserting “an*
 25 *order issued under this title”; and*

1 (B) in paragraph (2), in the first sentence,
2 by striking “paragraph (1)(A)” and inserting
3 “paragraph (1)”; and

4 (C) by striking paragraph (3); and
5 (2) in subsection (c)(1)(B)—

6 (A) in clause (i)—

7 (i) by striking “section 4(a), 5(b)(4),
8 6(a), or 6(e)” and inserting “section 4(a),
9 5(d), 6(d), or 6(g)”; and

10 (ii) by striking “evidence in the rule-
11 making record (as defined in subsection
12 (a)(3)) taken as a whole;” and inserting
13 “evidence (including any matter) in the
14 rulemaking record, taken as a whole; and”;
15 and

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

19 “(ii) the court may not review the con-
20 tents and adequacy of any statement of
21 basis and purpose required by section
22 553(c) of title 5, United States Code, to be
23 incorporated in the rule, except as part of
24 the rulemaking record, taken as a whole.”.

1 **SEC. 19. CITIZENS' PETITIONS.**

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

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

7 *(2) in subsection (b)—*

8 *(A) in paragraph (1), by striking “an order*
 9 *under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)”*
 10 *and inserting “an order under section 4 or*
 11 *5(d)”;* and

12 *(B) in paragraph (4), by striking subpara-*
 13 *graph (B) and inserting the following:*

14 *“(B) DE NOVO PROCEEDING.—*

15 *“(i) IN GENERAL.—In an action under*
 16 *subparagraph (A) to initiate a proceeding*
 17 *to promulgate a rule pursuant to section 4,*
 18 *5, 6, or 8 or issue an order under section*
 19 *4 or 5(d), the petitioner shall be provided*
 20 *an opportunity to have the petition consid-*
 21 *ered by the court in a de novo proceeding.*

22 *“(ii) DEMONSTRATION.—*

23 *“(I) IN GENERAL.—The court in a*
 24 *de novo proceeding under this subpara-*
 25 *graph shall order the Administrator to*
 26 *initiate the action requested by the pe-*

1 *tioner if the petitioner demonstrates*
2 *to the satisfaction of the court by a*
3 *preponderance of the evidence that—*

4 *“(aa) in the case of a peti-*
5 *tion to initiate a proceeding for*
6 *the issuance of a rule or order*
7 *under section 4, the information*
8 *available to the Administrator is*
9 *insufficient for the Administrator*
10 *to perform an action described in*
11 *section 4, 4A, 5, or 6(d);*

12 *“(bb) in the case of a petition*
13 *to issue an order under section*
14 *5(d), there is a reasonable basis to*
15 *conclude that the chemical sub-*
16 *stance is not likely to meet the*
17 *safety standard;*

18 *“(cc) in the case of a petition*
19 *to initiate a proceeding for the*
20 *issuance of a rule under section*
21 *6(d), there is a reasonable basis to*
22 *conclude that the chemical sub-*
23 *stance will not meet the safety*
24 *standard; or*

1 “(dd) in the case of a peti-
2 tion to initiate a proceeding for
3 the issuance of a rule under sec-
4 tion 8, there is a reasonable basis
5 to conclude that the rule is nec-
6 essary to protect health or the en-
7 vironment or ensure that the
8 chemical substance meets the safe-
9 ty standard.

10 “(II) DEFERMENT.—The court in
11 a de novo proceeding under this sub-
12 paragraph may permit the Adminis-
13 trator to defer initiating the action re-
14 quested by the petitioner until such
15 time as the court prescribes, if the
16 court finds that—

17 “(aa) the extent of the risk to
18 health or the environment alleged
19 by the petitioner is less than the
20 extent of risks to health or the en-
21 vironment with respect to which
22 the Administrator is taking action
23 under this Act; and

24 “(bb) there are insufficient
25 resources available to the Admin-

1 *istrator to take the action re-*
2 *quested by the petitioner.”.*

3 **SEC. 20. EMPLOYMENT EFFECTS.**

4 *Section 24(b)(2)(B)(ii) of the Toxic Substances Control*
5 *Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by striking*
6 *“section 6(c)(3),” and inserting “the applicable require-*
7 *ments of this Act;”.*

8 **SEC. 21. STUDIES.**

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

11 **SEC. 22. ADMINISTRATION.**

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

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

16 *“(b) FEES.—*

17 *“(1) IN GENERAL.—The Administrator shall es-*
18 *tablish, not later than 1 year after the date of enact-*
19 *ment of the Frank R. Lautenberg Chemical Safety for*
20 *the 21st Century Act, by rule—*

21 *“(A) the payment of 1 or more reasonable*
22 *fees as a condition of submitting a notice or re-*
23 *questing an exemption under section 5;*

24 *“(B) the payment of 1 or more reasonable*
25 *fees by a manufacturer or processor that—*

1 “(i) is required to submit a notice pur-
2 suant to the rule promulgated under section
3 8(b)(4)(A)(i) identifying a chemical sub-
4 stance as active;

5 “(ii) is required to submit a notice
6 pursuant to section 8(b)(5)(B)(i) changing
7 the status of a chemical substance from in-
8 active to active;

9 “(iii) is required to report information
10 pursuant to the rules promulgated under
11 section 8(a)(4); and

12 “(iv) manufactures or processes a
13 chemical substance subject to a safety assess-
14 ment and safety determination pursuant to
15 section 6.

16 “(2) UTILIZATION AND COLLECTION OF FEES.—
17 The Administrator shall—

18 “(A) utilize the fees collected under para-
19 graph (1) only to defray costs associated with the
20 actions of the Administrator—

21 “(i) to collect, process, review, provide
22 access to, and protect from disclosure (where
23 appropriate) information on chemical sub-
24 stances under this Act;

1 “(ii) to review notices and make deter-
2 minations for chemical substances under
3 paragraphs (1) and (3) of section 5(d) and
4 impose any necessary restrictions under sec-
5 tion 5(d)(4);

6 “(iii) to make prioritization decisions
7 under section 4A;

8 “(iv) to conduct and complete safety
9 assessments and determinations under sec-
10 tion 6; and

11 “(v) to conduct any necessary rule-
12 making pursuant to section 6(d);

13 “(B) insofar as possible, collect the fees de-
14 scribed in paragraph (1) in advance of con-
15 ducting any fee-supported activity;

16 “(C) deposit the fees in the Fund established
17 by paragraph (4)(A); and

18 “(D) not collect excess fees or retain a sig-
19 nificant amount of unused fees.

20 “(3) AMOUNT AND ADJUSTMENT OF FEES; RE-
21 FUNDS.—In setting fees under this section, the Ad-
22 ministrator shall—

23 “(A) take into account the cost to the Ad-
24 ministrator of conducting the activities described
25 in paragraph (2);

1 “(B) prescribe lower fees for small business
2 concerns, after consultation with the Adminis-
3 trator of the Small Business Administration;

4 “(C) set the fees established under para-
5 graph (1) at levels such that the fees will, in ag-
6 gregate, provide a sustainable source of funds to
7 defray approximately 25 percent of the costs of
8 conducting the activities identified in paragraph
9 (2)(A), not to exceed \$18,000,000, not including
10 fees under subparagraph (E) of this paragraph;

11 “(D) reflect an appropriate balance in the
12 assessment of fees between manufacturers and
13 processors, and allow the payment of fees by con-
14 sortia of manufacturers or processors;

15 “(E) for substances designated as additional
16 priorities pursuant to section 4A(c), establish the
17 fee at a level sufficient to defray the full costs to
18 the Administrator of conducting the safety as-
19 sessment and safety determination under section
20 6, except that for substances subject to section
21 4A(c)(3), the Administrator shall establish the fee
22 at a level sufficient to defray 50 percent of those
23 costs;

24 “(F) prior to the establishment or amend-
25 ment of any fees under paragraph (1), consult

1 *and meet with parties potentially subject to the*
2 *fees or their representatives, subject to the condi-*
3 *tion that no obligation under the Federal Advi-*
4 *sory Committee Act (5 U.S.C. App.) or sub-*
5 *chapter III of chapter 5 of title 5, United States*
6 *Code, is applicable with respect to such meetings;*

7 “(G) beginning with the fiscal year that is
8 3 years after the date of enactment of the Frank
9 R. Lautenberg Chemical Safety for the 21st Cen-
10 *tury Act, and every 3 years thereafter, after con-*
11 *sultation with parties potentially subject to the*
12 *fees and their representatives, increase or de-*
13 *crease the fees established under paragraph (1)*
14 *as necessary—*

15 “(i) to ensure that funds deposited in
16 the Fund are sufficient to conduct the ac-
17 tivities identified in paragraph (2)(A) and
18 the full cost or 50-percent portion of the
19 costs of safety assessments and safety deter-
20 minations pursuant to subparagraph (E);
21 and

22 “(ii) to account for inflation;

23 “(H) adjust fees established under para-
24 graph (1) as necessary to vary on account of dif-
25 fering circumstances, including reduced fees or

1 *waivers in appropriate circumstances, to reduce*
 2 *the burden on manufacturing or processing, re-*
 3 *move barriers to innovation, or where the costs*
 4 *to the Administrator of collecting the fees exceed*
 5 *the fee revenue anticipated to be collected; and*

6 “(I) *if a notice submitted under section 5 is*
 7 *refused or subsequently withdrawn, refund the fee*
 8 *or a portion of the fee if no substantial work was*
 9 *performed on the notice.*

10 “(4) *TSCA IMPLEMENTATION FUND.—*

11 “(A) *ESTABLISHMENT.—There is estab-*
 12 *lished in the Treasury of the United States a*
 13 *fund, to be known as the ‘TSCA Implementation*
 14 *Fund’ (referred to in this subsection as the*
 15 *‘Fund’), consisting of—*

16 “(i) *such amounts as are deposited in*
 17 *the Fund under paragraph (2)(C); and*

18 “(ii) *any interest earned on the invest-*
 19 *ment of amounts in the Fund; and*

20 “(iii) *any proceeds from the sale or re-*
 21 *demption of investments held in the Fund.*

22 “(B) *CREDITING AND AVAILABILITY OF*
 23 *FEES.—*

24 “(i) *IN GENERAL.—Fees authorized*
 25 *under this section shall be collected and*

1 *available for obligation only to the extent*
2 *and in the amount provided in advance in*
3 *appropriations Acts, and shall be available*
4 *without fiscal year limitation.*

5 “(ii) *REQUIREMENTS.—Fees collected*
6 *under this section shall not—*

7 “(I) *be made available or obli-*
8 *gated for any purpose other than to de-*
9 *fray the costs of conducting the activi-*
10 *ties identified in paragraph (2)(A);*

11 “(II) *otherwise be available for*
12 *any purpose other than implementa-*
13 *tion of this Act; and*

14 “(III) *so long as amounts in the*
15 *Fund remain available, be subject to*
16 *restrictions on expenditures applicable*
17 *to the Federal government as a whole.*

18 “(C) *UNUSED FUNDS.—Amounts in the*
19 *Fund not currently needed to carry out this sub-*
20 *section shall be—*

21 “(i) *maintained readily available or*
22 *on deposit;*

23 “(ii) *invested in obligations of the*
24 *United States or guaranteed by the United*
25 *States; or*

1 “(iii) invested in obligations, partici-
2 pations, or other instruments that are law-
3 ful investments for fiduciary, trust, or pub-
4 lic funds.

5 “(D) *MINIMUM AMOUNT OF APPROPRIA-*
6 *TIONS.—Fees may not be assessed for a fiscal*
7 *year under this section unless the amount of ap-*
8 *propriations for salaries, contracts, and expenses*
9 *for the functions (as in existence in fiscal year*
10 *2015) of the Office of Pollution Prevention and*
11 *Toxics of the Environmental Protection Agency*
12 *for the fiscal year (excluding the amount of any*
13 *fees appropriated for the fiscal year) are equal to*
14 *or greater than the amount of appropriations for*
15 *covered functions for fiscal year 2015 (excluding*
16 *the amount of any fees appropriated for the fis-*
17 *cal year).*

18 “(5) *AUDITING.—*

19 “(A) *FINANCIAL STATEMENTS OF AGEN-*
20 *CIES.—For the purpose of section 3515(c) of title*
21 *31, United States Code, the Fund shall be con-*
22 *sidered a component of an executive agency.*

23 “(B) *COMPONENTS.—The annual audit re-*
24 *quired under sections 3515(b) and 3521 of that*
25 *title of the financial statements of activities*

1 *under this subsection shall include an analysis*
2 *of—*

3 “(i) *the fees collected under paragraph*
4 *(1) and disbursed;*

5 “(ii) *compliance with the deadlines es-*
6 *tablished in section 6 of this Act;*

7 “(iii) *the amounts budgeted, appro-*
8 *priated, collected from fees, and disbursed to*
9 *meet the requirements of sections 4, 4A, 5,*
10 *6, 8, and 14, including the allocation of full*
11 *time equivalent employees to each such sec-*
12 *tion or activity; and*

13 “(iv) *the reasonableness of the alloca-*
14 *tion of the overhead associated with the con-*
15 *duct of the activities described in paragraph*
16 *(2)(A).*

17 “(C) *INSPECTOR GENERAL.—The Inspector*
18 *General of the Environmental Protection Agency*
19 *shall—*

20 “(i) *conduct the annual audit required*
21 *under this subsection; and*

22 “(ii) *report the findings and rec-*
23 *ommendations of the audit to the Adminis-*
24 *trator and to the appropriate committees of*
25 *Congress.*

1 “(6) *TERMINATION.*—*The authority provided by*
2 *this section shall terminate at the conclusion of the*
3 *fiscal year that is 10 years after the date of enactment*
4 *of the Frank R. Lautenberg Chemical Safety for the*
5 *21st Century Act, unless otherwise reauthorized or*
6 *modified by Congress.*”;

7 (2) *in subsection (e), by striking “Health, Edu-*
8 *cation, and Welfare” each place it appears and in-*
9 *serting “Health and Human Services”; and*

10 (3) *adding at the end the following:*

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

16 **SEC. 23. DEVELOPMENT AND EVALUATION OF TEST METH-**
17 **ODS AND SUSTAINABLE CHEMISTRY.**

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

20 (1) *in subsection (a), in the first sentence by*
21 *striking “Health, Education, and Welfare” and in-*
22 *serting “Health and Human Services”; and*

23 (2) *by adding at the end the following:*

24 “(c) *SUSTAINABLE CHEMISTRY PROGRAM.*—*The Presi-*
25 *dent shall establish an interagency Sustainable Chemistry*

1 *Program to promote and coordinate Federal sustainable*
2 *chemistry research, development, demonstration, technology*
3 *transfer, commercialization, education, and training activi-*
4 *ties.*

5 “(d) *PROGRAM ACTIVITIES.*—*The activities of the Pro-*
6 *gram shall be designed to—*

7 “(1) *provide sustained support for sustainable*
8 *chemistry research, development, demonstration, tech-*
9 *nology transfer, commercialization, education, and*
10 *training through—*

11 “(A) *coordination of sustainable chemistry*
12 *research, development, demonstration, and tech-*
13 *nology transfer conducted at Federal laboratories*
14 *and agencies; and*

15 “(B) *to the extent practicable, encourage-*
16 *ment of consideration of sustainable chemistry*
17 *in, as appropriate—*

18 “(i) *the conduct of Federal and State*
19 *science and engineering research and devel-*
20 *opment; and*

21 “(ii) *the solicitation and evaluation of*
22 *applicable proposals for science and engi-*
23 *neering research and development;*

24 “(2) *examine methods by which the Federal Gov-*
25 *ernment can create incentives for consideration and*

1 *use of sustainable chemistry processes and products,*
2 *including innovative financing mechanisms;*

3 “(3) *expand the education and training of un-*
4 *dergraduate and graduate students and professional*
5 *scientists and engineers, including through partner-*
6 *ships with industry, in sustainable chemistry science*
7 *and engineering;*

8 “(4) *collect and disseminate information on sus-*
9 *tainable chemistry research, development, and tech-*
10 *nology transfer including information on—*

11 “(A) *incentives and impediments to devel-*
12 *opment, manufacturing, and commercialization;*

13 “(B) *accomplishments;*

14 “(C) *best practices; and*

15 “(D) *costs and benefits;*

16 “(5) *support (including through technical assist-*
17 *ance, participation, financial support, or other forms*
18 *of support) economic, legal, and other appropriate so-*
19 *cial science research to identify barriers to commer-*
20 *cialization and methods to advance commercialization*
21 *of sustainable chemistry.*

22 “(e) *INTERAGENCY WORKING GROUP.—*

23 “(1) *ESTABLISHMENT.—Not later than 180 days*
24 *after the date of enactment of the Frank R. Lauten-*
25 *berg Chemical Safety for the 21st Century Act, the*

1 *President, in consultation with the Office of Science*
2 *and Technology Policy, shall establish an Interagency*
3 *Working Group that shall include representatives*
4 *from the National Science Foundation, the National*
5 *Institute of Standards and Technology, the Depart-*
6 *ment of Energy, the Environmental Protection Agen-*
7 *cy, the Department of Agriculture, the Department of*
8 *Defense, the National Institutes of Health, and any*
9 *other agency that the President may designate to*
10 *oversee the planning, management, and coordination*
11 *of the Program.*

12 *“(2) GOVERNANCE.—The Director of the Na-*
13 *tional Science Foundation and the Assistant Admin-*
14 *istrator for Research and Development of the Envi-*
15 *ronmental Protection Agency, or their designees, shall*
16 *serve as co-chairs of the Interagency Working Group.*

17 *“(3) RESPONSIBILITIES.—In overseeing the*
18 *planning, management, and coordination of the Pro-*
19 *gram, the Interagency Working Group shall—*

20 *“(A) establish goals and priorities for the*
21 *Program, in consultation with the Advisory*
22 *Council;*

23 *“(B) provide for interagency coordination,*
24 *including budget coordination, of activities*
25 *under the Program;*

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

3 “(D) establish and consult with an Advisory
4 Council on a regular basis.

5 “(4) MEMBERSHIP.—The Advisory Council
6 members shall not be employees of the Federal Gov-
7 ernment and shall include a diverse representation of
8 knowledgeable individuals from the private sector (in-
9 cluding small- and medium-sized enterprises from
10 across the value chain), academia, State and tribal
11 governments, and nongovernmental organizations and
12 others who are in a position to provide expertise.

13 “(f) AGENCY BUDGET REQUESTS.—

14 “(1) IN GENERAL.—Each Federal agency and de-
15 partment participating in the Program shall, as part
16 of its annual request for appropriations to the Office
17 of Management and Budget, submit a report to the
18 Office of Management and Budget that—

19 “(A) identifies the activities of the agency
20 or department that contribute directly to the
21 Program; and

22 “(B) states the portion of the agency or de-
23 partment’s request for appropriations that is al-
24 located to those activities.

1 “(2) *ANNUAL BUDGET REQUEST TO CONGRESS.*—

2 *The President shall include in the annual budget re-*
3 *quest to Congress a statement of the portion of the an-*
4 *annual budget request for each agency or department*
5 *that will be allocated to activities undertaken pursu-*
6 *ant to the Program.*

7 “(g) *REPORT TO CONGRESS.*—

8 “(1) *IN GENERAL.*—*Not later than 2 years after*
9 *the date of enactment of the Frank R. Lautenberg*
10 *Chemical Safety for the 21st Century Act, the Inter-*
11 *agency Working Group shall submit a report to the*
12 *Committee on Science, Space, and Technology and*
13 *Committee on Energy and Commerce of the House of*
14 *Representatives and the Committee on Environment*
15 *and Public Works and the Committee on Commerce,*
16 *Science, and Transportation of the Senate that shall*
17 *include—*

18 “(A) *a summary of federally funded sus-*
19 *tainable chemistry research, development, dem-*
20 *onstration, technology transfer, commercializa-*
21 *tion, education, and training activities;*

22 “(B) *a summary of the financial resources*
23 *allocated to sustainable chemistry initiatives;*

24 “(C) *an analysis of the progress made to-*
25 *ward achieving the goals and priorities of the*

1 *program established pursuant to subsection (c),*
2 *and recommendations for future program activi-*
3 *ties;*

4 “(D) *an assessment of the benefits of ex-*
5 *anding existing, federally-supported regional*
6 *innovation and manufacturing hubs to include*
7 *sustainable chemistry and the value of directing*
8 *the creation of 1 or more dedicated sustainable*
9 *chemistry centers of excellence or hubs; and*

10 “(E) *an evaluation of steps taken and fu-*
11 *ture strategies to avoid duplication of efforts,*
12 *streamline interagency coordination, facilitate*
13 *information sharing, and spread best practices*
14 *between participating agencies in the Program.*

15 “(2) *SUBMISSION TO GAO.—The Interagency*
16 *Working Group shall also submit the report described*
17 *in paragraph (1) to the Government Accountability*
18 *Office for consideration in future Congressional in-*
19 *quiries.”.*

20 **SEC. 24. STATE PROGRAMS.**

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

23 *(1) in subsection (b)(1)—*

1 (A) in subparagraphs (A) through (D), by
2 striking the comma at the end of each subpara-
3 graph and inserting a semicolon; and

4 (B) in subparagraph (E), by striking “,
5 and” and inserting “; and”; and

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

7 **SEC. 25. AUTHORIZATION OF APPROPRIATIONS.**

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

10 **SEC. 26. ANNUAL REPORT.**

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

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

16 “(B) the number of the notices described in sub-
17 paragraph (A) for chemical substances subject to a
18 rule, testing consent agreement, or order under section
19 4;”.

20 **SEC. 27. EFFECTIVE DATE.**

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

23 (1) by striking “Except as provided in section
24 4(f), this” and inserting the following:

25 “(a) *IN GENERAL.*—This”; and

1 (2) *by adding at the end the following:*

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

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114TH CONGRESS
1ST Session

S. 697

A BILL

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

JUNE 17, 2015

Reported with an amendment