

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

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

S. 697

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

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

Viz:

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

3 **SECTION 1. SHORT TITLE.**

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

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

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

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

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

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

4 (3) by adding at the following:

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

9 “(A) shall be administered in a manner
10 that—

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

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

22 “(B) shall not displace or supplant com-
23 mon law rights of action or remedies for civil
24 relief.”.

1 **SEC. 3. DEFINITIONS.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 ical substance under the conditions of use, including
2 no unreasonable risk of injury to—

3 “(A) the general population; or

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

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

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

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

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

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

23 “(c) USE OF SCIENCE.—

24 “(1) IN GENERAL.—The Administrator shall es-
25 tablish policies, procedures, and guidance on the use

1 of science in making decisions under sections 4, 4A,
2 5, and 6.

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

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

10 “(A) decisions made by the Adminis-
11 trator—

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

16 “(ii) take into account the extent to
17 which—

18 “(I) assumptions and methods
19 are clearly and completely described
20 and documented;

21 “(II) variability and uncertainty
22 are evaluated and characterized; and

23 “(III) the information has been
24 subject to independent verification
25 and peer review; and

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

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

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

20 “(D) if appropriate, the recommendations
21 in reports of the National Academy of Sciences
22 that provide advice regarding assessing the haz-
23 ards, exposures, and risks of chemical sub-
24 stances are considered.

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

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

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

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

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

1 is reasonably available to the Administrator, including in-
2 formation that is—

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

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

10 “(B) the public;

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

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

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

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

24 “(g) TESTING OF CHEMICAL SUBSTANCES AND MIX-
25 TURES.—

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

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

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

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

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

21 “(C) require the Administrator to consult
22 with the Director of the National Institute for
23 Occupational Safety and Health prior to pre-
24 scribing epidemiologic studies of employees; and

1 “(D) prior to making a request or adopt-
2 ing a requirement for testing using vertebrate
3 animals, require the Administrator to take into
4 consideration, as appropriate and to the extent
5 practicable, reasonably available—

6 “(i) toxicity information;

7 “(ii) computational toxicology and
8 bioinformatics;

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

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

15 “(h) SAFETY ASSESSMENTS AND SAFETY DETER-
16 MINATIONS.—

17 “(1) SCHEDULE.—

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

24 “(B) DIFFERING TIMES.—The Adminis-
25 trator may allot different times for different

1 chemical substances in the schedules under this
2 paragraph, subject to the condition that all
3 schedules shall comply with the deadlines estab-
4 lished under section 6.

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

10 “(2) POLICIES AND PROCEDURES FOR SAFETY
11 ASSESSMENTS AND SAFETY DETERMINATIONS.—

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

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

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

23 “(i) describe—

24 “(I) the manner in which the Ad-
25 ministrator will identify informational

1 needs and seek that information from
2 the public;

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

7 “(III) the criteria by which that
8 information will be evaluated;

9 “(ii) require the Administrator—

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

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

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

24 “(II)(aa) to identify the items de-
25 scribed in subclause (I) that the Ad-

1 the date of a final safety assessment or
2 safety determination warrants reconsider-
3 ation of the safety assessment or safety de-
4 termination; and

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

10 “(D) GUIDANCE.—

11 “(i) IN GENERAL.—Not later than 1
12 year after the date of enactment of the
13 Frank R. Lautenberg Chemical Safety for
14 the 21st Century Act, the Administrator
15 shall develop guidance to assist interested
16 persons in developing their own draft safe-
17 ty assessments and other information for
18 submission to the Administrator, which
19 may be considered at the discretion of the
20 Administrator.

21 “(ii) REQUIREMENT.—The guidance
22 shall, at a minimum, address the quality of
23 the information submitted and the process
24 to be followed in developing a draft assess-

1 ment for consideration by the Adminis-
2 trator.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 (C) in paragraph (1)—

16 (i) in subparagraph (A)(v), by insert-
17 ing “, without taking into account cost or
18 other nonrisk factors” after “the environ-
19 ment”; and

20 (ii) in subparagraph (B), in the last
21 sentence, by striking “rulemaking”;

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

23 (A) in the first sentence—

24 (i) by striking “from cancer, gene
25 mutations, or birth defects”; and

1 (ii) by inserting “, without taking into
2 account cost or other nonrisk factors” be-
3 fore the period at the end; and

4 (B) by striking the last sentence; and

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

7 “(a) DEVELOPMENT OF NEW INFORMATION ON
8 CHEMICAL SUBSTANCES AND MIXTURES.—

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

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

17 “(B) to implement a requirement imposed
18 in a consent agreement or order issued under
19 section 5(d)(4) or under a rule promulgated
20 under section 6(d)(3);

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

22 “(D) at the request of the implementing
23 authority under another Federal law, to meet
24 the regulatory testing needs of that authority.

1 “(2) LIMITED TESTING FOR PRIORITIZATION
2 PURPOSES.—

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

7 “(B) PROHIBITION.—Testing required
8 under subparagraph (A) shall not be required
9 for the purpose of establishing or implementing
10 a minimum information requirement.

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

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

20 “(A) promulgating a rule;

21 “(B) entering into a testing consent agree-
22 ment; or

23 “(C) issuing an order.

24 “(4) CONTENTS.—

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

4 “(i) identification of the chemical sub-
5 stance or mixture for which testing is re-
6 quired;

7 “(ii) identification of the persons re-
8 quired to conduct the testing;

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

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

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

1 “(i) the relative costs of the various
2 test protocols and methodologies that may
3 be required; and

4 “(ii) the reasonably foreseeable avail-
5 ability of facilities and personnel required
6 to perform the testing.

7 “(b) STATEMENT OF NEED.—

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

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

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

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

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

24 “(A) IN GENERAL.—If the Administrator
25 issues an order under this section, the Adminis-

1 trator shall issue a statement providing a jus-
2 tification for why issuance of an order is war-
3 ranted instead of promulgating a rule or enter-
4 ing into a testing consent agreement.

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

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

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

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

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

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

25 “(A) encouraging and facilitating—

1 “(i) the use of integrated and tiered
2 testing and assessment strategies;

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

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

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

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

19 “(vi) the submission of information
20 from—

21 “(I) animal-based studies; and

22 “(II) emerging methods and
23 models; and

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

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

9 “(A) not later than 2 years after the date
10 of enactment of the Frank R. Lautenberg
11 Chemical Safety for the 21st Century Act, de-
12 velop a strategic plan to promote the develop-
13 ment and implementation of alternative test
14 methods and testing strategies to generate in-
15 formation under this title that can reduce, re-
16 fine, or replace the use of vertebrate animals,
17 including toxicity pathway-based risk assess-
18 ment, in vitro studies, systems biology, com-
19 putational toxicology, bioinformatics, and high-
20 throughput screening;

21 “(B) as practicable, ensure that the stra-
22 tegic plan developed under subparagraph (A) is
23 reflected in the development of requirements for
24 testing under this section;

1 “(C) identify in the strategic plan devel-
2 oped under subparagraph (A) particular alter-
3 native test methods or testing strategies that do
4 not require new vertebrate animal testing and
5 are scientifically reliable, relevant, and capable
6 of providing information of equivalent scientific
7 reliability and quality to that which would be
8 obtained from vertebrate animal testing;

9 “(D) provide an opportunity for public no-
10 tice and comment on the contents of the plan
11 developed under subparagraph (A), including
12 the criteria for considering scientific reliability,
13 relevance, and equivalent information and the
14 test methods and strategies identified in sub-
15 paragraph (C);

16 “(E) beginning on the date that is 5 years
17 after the date of enactment of the Frank R.
18 Lautenberg Chemical Safety for the 21st Cen-
19 tury Act and every 5 years thereafter, submit to
20 Congress a report that describes the progress
21 made in implementing this subsection and goals
22 for future alternative test methods implementa-
23 tion;

24 “(F) fund and carry out research, develop-
25 ment, performance assessment, and

1 translational studies to accelerate the develop-
2 ment of test methods and testing strategies that
3 reduce, refine, or replace the use of vertebrate
4 animals in any testing under this title; and

5 “(G) identify synergies with the related in-
6 formation requirements of other jurisdictions to
7 minimize the potential for additional or duplica-
8 tive testing.

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 “(4) VOLUNTARY TESTING.—

15 “(A) IN GENERAL.—Any person developing
16 information for submission under this title on a
17 voluntary basis and not pursuant to any request
18 or requirement by the Administrator shall first
19 attempt to develop the information by means of
20 an alternative or nonanimal test method or test-
21 ing strategy that the Administrator has deter-
22 mined under paragraph (2)(C) to be scientif-
23 ically reliable, relevant, and capable of providing
24 equivalent information, before conducting new
25 animal testing.

1 “(B) EFFECT OF PARAGRAPH.—Nothing
2 in this paragraph—

3 “(i) requires the Administrator to re-
4 view the basis on which the person is con-
5 ducting testing described in subparagraph
6 (A);

7 “(ii) prohibits the use of other test
8 methods or testing strategies by any per-
9 son for purposes other than developing in-
10 formation for submission under this title
11 on a voluntary basis; or

12 “(iii) prohibits the use of other test
13 methods or testing strategies by any per-
14 son, subsequent to the attempt to develop
15 information using the test methods and
16 testing strategies identified by the Admin-
17 istrator under paragraph (2)(C).

18 “(d) TESTING REQUIREMENTS.—

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

21 “(A) manufacturers and processors of the
22 chemical substance or mixture; and

23 “(B) subject to paragraph (3), persons
24 that begin to manufacture or process the chem-
25 ical substance or mixture—

1 “(i) after the effective date of the
2 rule, testing consent agreement, or order;
3 but

4 “(ii) before the period ending on the
5 later of—

6 “(I) 5 years after the date re-
7 ferred to in clause (i); or

8 “(II) the last day of the period
9 that begins on the date referred to in
10 clause (i) and that is equal to the pe-
11 riod that the Administrator deter-
12 mines was necessary to develop the in-
13 formation.

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

18 “(A) to develop the information; and

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

21 “(3) EXEMPTIONS.—

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

1 the basis that the information is being devel-
2 oped by a person designated under paragraph
3 (2).

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

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

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

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

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

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

7 “(4) TIERED TESTING.—

8 “(A) IN GENERAL.—Except as provided in
9 subparagraph (D), the Administrator shall em-
10 ploy a tiered screening and testing process,
11 under which the results of screening-level tests
12 or assessments of available information inform
13 the decision as to whether 1 or more additional
14 tests are necessary.

15 “(B) SCREENING-LEVEL TESTS.—

16 “(i) IN GENERAL.—The screening-
17 level tests required for a chemical sub-
18 stance or mixture may include tests for
19 hazard (which may include in silico, in
20 vitro, and in vivo tests), environmental and
21 biological fate and transport, and measure-
22 ments or modeling of exposure or exposure
23 potential, as appropriate.

24 “(ii) USE.—Screening-level tests shall
25 be used—

1 “(I) to screen chemical sub-
2 stances or mixtures for potential ad-
3 verse effects; and

4 “(II) to inform a decision of the
5 Administrator regarding whether
6 more complex or targeted additional
7 testing is necessary.

8 “(C) ADDITIONAL TESTING.—If the Ad-
9 ministrator determines under subparagraph (B)
10 that additional testing is necessary to provide
11 more definitive information for safety assess-
12 ments or safety determinations, the Adminis-
13 trator may require more advanced tests for po-
14 tential health or environmental effects or expo-
15 sure potential.

16 “(D) ADVANCED TESTING WITHOUT
17 SCREENING.—The Administrator may require
18 more advanced testing without conducting
19 screening-level testing when other information
20 available to the Administrator justifies the ad-
21 vanced testing, pursuant to guidance developed
22 by the Administrator under this section.

23 “(e) TRANSPARENCY.—Subject to section 14, the Ad-
24 ministrator shall make available to the public all testing

1 consent agreements and orders and all information sub-
2 mitted under this section.”.

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

8 **SEC. 6. PRIORITIZATION SCREENING.**

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

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

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

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

18 “(A) a high priority for a safety assess-
19 ment and safety determination under section 6
20 (referred to in this Act as ‘high-priority sub-
21 stances’); and

22 “(B) a low priority for a safety assessment
23 and safety determination (referred to in this
24 Act as ‘low-priority substances’).

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

3 “(A) IN GENERAL.—Before the date of
4 promulgation of the rule under paragraph (1)
5 and not later than 180 days after the date of
6 enactment of this section, the Administrator—

7 “(i) shall take into consideration and
8 publish an initial list of high-priority sub-
9 stances and low-priority substances; and

10 “(ii) pursuant to section 6(b), may
11 initiate or continue safety assessments and
12 safety determinations for those high-pri-
13 ority substances.

14 “(B) REQUIREMENTS.—

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

23 “(ii) SUBSEQUENTLY IDENTIFIED
24 SUBSTANCES.—Insofar as possible, at least
25 50 percent of all substances subsequently

1 identified by the Administrator as high-pri-
2 ority substances shall be drawn from the
3 list of chemical substances identified by the
4 Administrator in the October 2014 TSCA
5 Work Plan and subsequent updates, until
6 all Work Plan chemicals have been des-
7 ignated under this subsection.

8 “(iii) PERSISTENCE AND BIOACCUMU-
9 LATION.—In developing the initial list and
10 in identifying additional high-priority sub-
11 stances, the Administrator shall give pref-
12 erence to chemical substances scored as
13 high for persistence and bioaccumulation
14 in the October 2014 TSCA Work Plan and
15 subsequent updates.

16 “(C) ADDITIONAL CHEMICAL REVIEWS.—
17 The Administrator shall, as soon as practicable
18 and not later than—

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

1 section 6(a), and additional low-priority
2 substances sufficient to ensure that at
3 least a total of 20 low-priority substances
4 have been designated; and

5 “(ii) 5 years after the date of enact-
6 ment of the Frank R. Lautenberg Chem-
7 ical Safety for the 21st Century Act, add
8 additional high-priority substances suffi-
9 cient to ensure that at least a total of 25
10 high-priority substances have undergone or
11 are undergoing the process established in
12 section 6(a), and additional low-priority
13 substances sufficient to ensure that at
14 least a total of 25 low-priority substances
15 have been designated.

16 “(3) IMPLEMENTATION.—

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

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

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

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

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

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

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

21 “(iii) REPOPULATION.—

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

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

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

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

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

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

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

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

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

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

18 “(iii) CONSIDERATION.—

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

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

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

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

16 “(D) PUBLICATION OF LIST OF CHEMICAL
17 SUBSTANCES.—The Administrator shall keep
18 current and publish a list of chemical sub-
19 stances that—

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

1 prioritization decisions have been deferred;
2 and

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

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

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

13 “(B) the hazard and exposure potential of
14 the chemical substance (or category of sub-
15 stances), including persistence, bioaccumulation,
16 and specific scientific classifications and des-
17 ignations by authoritative governmental enti-
18 ties;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 “(A) publish, including in the Federal Reg-
23 ister, the proposed decisions made under para-
24 graphs (3), (4), and (5) and the basis for the
25 decisions; and

1 “(B) provide 90 days for public comment.

2 “(8) REVISIONS OF PRIOR DESIGNATIONS.—

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

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

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

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

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

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

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

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

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

21 “(iv) any other available information
22 relevant to the prohibition or other restric-
23 tion, including information on any alter-
24 natives considered and their hazards, expo-
25 sures, and risks.

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

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

7 “(ii) the Administrator determines—

8 “(I) are likely to have significant
9 health or environmental impacts;

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

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

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

24 “(E) EFFECT OF PARAGRAPH.—Nothing
25 in this paragraph shall preempt a State statute

1 or administrative action, require approval of a
2 State statute or administrative action, or apply
3 section 15 to a State.

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

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

12 “(B) if necessary, modify the prioritization
13 screening process.

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

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

21 “(B) the regulation of those activities.

22 “(c) ADDITIONAL PRIORITIES FOR SAFETY ASSESS-
23 MENTS AND DETERMINATIONS.—

24 “(1) REQUIREMENTS.—

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

4 “(i) include a process by which a
5 manufacturer or processor of an active
6 chemical substance that has not been des-
7 ignated a high-priority substance or is not
8 in the process of a prioritization screening
9 by the Administrator, may request that the
10 Administrator designate the substance as
11 an additional priority for a safety assess-
12 ment and safety determination, subject to
13 the 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
19 not to grant such a request, which shall in-
20 clude whether the substance is subject to
21 restrictions imposed by statutes enacted or
22 administrative actions taken by 1 or more
23 States on the manufacture, processing, dis-
24 tribution in commerce, or use of the sub-
25 stance.

1 “(B) PREFERENCE.—Subject to paragraph
2 (2), in deciding whether to grant requests
3 under this subsection the Administrator shall
4 give a preference to requests concerning sub-
5 stances for which the Administrator determines
6 that restrictions imposed by 1 or more States
7 have the potential to have a significant impact
8 on interstate commerce or health or the envi-
9 ronment.

10 “(C) EXCEPTIONS.—Requests granted
11 under this subsection shall not be subject to
12 subsection (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
19 than 30 percent, of the cumulative number of
20 substances designated to undergo safety assess-
21 ments and safety determinations under this sec-
22 tion are substances designated under the proc-
23 ess and criteria pursuant to paragraph (1);

24 “(B) the resources allocated to conducting
25 safety assessments and safety determinations

1 for additional priorities designated under this
2 subsection are proportionate to the number of
3 such substances relative to the total number of
4 substances designated to undergo safety assess-
5 ments and safety determinations under this sec-
6 tion; and

7 “(C) the number of additional priority re-
8 quests stipulated under subparagraph (A) is in
9 addition to the total number of high-priority
10 chemicals identified under subsection (a)(2)(B).

11 “(3) ADDITIONAL REVIEW OF WORK PLAN
12 CHEMICALS FOR SAFETY ASSESSMENT AND SAFETY
13 DETERMINATION.—In the case of a request under
14 paragraph (1) with respect to a chemical substance
15 identified by the Administrator in the October 2014
16 Work Plan—

17 “(A) the 30-percent cap specified in para-
18 graph (2)(A) shall not apply and the addition
19 of Work Plan chemicals shall be at the discre-
20 tion of the Administrator; and

21 “(B) notwithstanding paragraph (6), re-
22 quests for additional Work Plan chemicals
23 under this subsection shall be considered high-
24 priority chemicals subject to section 18(b) but
25 not subsection (a)(3)(A)(iii).

1 “(4) REQUIREMENTS.—

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

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

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

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

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

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

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

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

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

4 (2) by striking subsection (b);

5 (3) by redesignating subsection (a) as sub-
6 section (b);

7 (4) by redesignating subsection (i) as subsection
8 (a) and moving the subsection so as to appear at the
9 beginning of the section;

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

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

13 (B) in paragraph (1)—

14 (i) in the matter preceding subpara-
15 graph (A), by striking “subsection (h)”
16 and inserting “paragraph (3) and sub-
17 section (h)”;

18 (ii) in the matter following subpara-
19 graph (B)—

20 (I) by striking “subsection (d)”
21 and inserting “subsection (c)”;

22 (II) by striking “and such person
23 complies with any applicable require-
24 ment of subsection (b)”;

25 (C) by adding at the end the following:

1 “(3) ARTICLE CONSIDERATION.—The Adminis-
2 trator may require the notification for the import or
3 processing of a chemical substance as part of an ar-
4 ticle or category of articles under paragraph (1)(B)
5 if the Administrator makes an affirmative finding in
6 a rule under paragraph (2) that the reasonable po-
7 tential for exposure to the chemical substance
8 through the article or category of articles subject to
9 the rule warrants notification.”;

10 (6) by redesignating subsections (c) and (d) as
11 subsections (d) and (c), respectively, and moving
12 subsection (c) (as so redesigned) so as appear after
13 subsection (b) (as redesignated by paragraph (3));

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

15 (A) by striking paragraph (1) and insert-
16 ing the following:

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

20 “(A) the information required by sections
21 720.45 and 720.50 of title 40, Code of Federal
22 Regulations (or successor regulations); and

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

25 (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 priate, 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 “(II) 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) PERSISTENT AND BIOACCUMULATIVE
2 SUBSTANCES.—For a chemical substance the
3 Administrator determines ranks high for per-
4 sistence and bioaccumulation, the Administrator
5 shall, in selecting among prohibitions and other
6 restrictions that the Administrator determines
7 are sufficient to ensure that the chemical sub-
8 stance is likely to meet the safety standard, re-
9 duce potential exposure to the substance to the
10 maximum extent practicable.

11 “(E) WORKPLACE EXPOSURES.—The Ad-
12 ministrator shall consult with the Assistant Sec-
13 retary of Labor for Occupational Safety and
14 Health prior to adopting any prohibition or
15 other restriction under this subsection to ad-
16 dress workplace exposures.

17 “(F) DEFINITION OF REQUIREMENT.—For
18 purposes of this Act, the term ‘requirement’ as
19 used in this section does not displace common
20 law.

21 “(5) ADDITIONAL INFORMATION.—If the Ad-
22 ministrator determines under paragraph (3)(C) that
23 additional information is necessary to conduct a re-
24 view under this subsection, the Administrator—

1 “(A) shall provide an opportunity for the
2 submitter of the notice to submit the additional
3 information;

4 “(B) may, by agreement with the sub-
5 mitter, extend the review period for a reason-
6 able time to allow the development and submis-
7 sion of the additional information;

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

12 “(D) on receipt of information the Admin-
13 istrator finds supports the determination under
14 paragraph (3), shall promptly make the deter-
15 mination.”;

16 (9) by striking subsections (e) through (g) and
17 inserting the following:

18 “(e) NOTICE OF COMMENCEMENT.—

19 “(1) IN GENERAL.—Not later than 30 days
20 after the date on which a manufacturer that has
21 submitted a notice under subsection (b) commences
22 nonexempt commercial manufacture of a chemical
23 substance, the manufacturer shall submit to the Ad-
24 ministrator a notice of commencement that identi-
25 fies—

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

2 “(B) the initial date of nonexempt com-
3 mercial manufacture.

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

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

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

14 “(2) new information regarding the chemical
15 substance.

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

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

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

22 (10) in subsection (h)—

23 (A) in paragraph (1)—

24 (i) in the matter preceding subpara-
25 graph (A), by striking “(a) or”; and

1 (ii) in subparagraph (A), by inserting
2 “, without taking into account cost or
3 other nonrisk factors” after “the environ-
4 ment”;

5 (B) by striking paragraph (2);

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

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

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

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

20 (ii) by striking the second sentence;

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

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

4 **SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINA-**
5 **TIONS.**

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

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

10 **“SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINA-**
11 **TIONS.”;**

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

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

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

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

21 “(2) shall, as soon as practicable and not later
22 than 6 months after the date on which a chemical
23 substance is designated as a high-priority substance,
24 define and publish the scope of the safety assess-
25 ment and safety determination to be conducted pur-

1 suant to this section, including the hazards, expo-
2 sures, conditions of use, and potentially exposed or
3 susceptible populations that the Administrator ex-
4 pects to consider;

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

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

12 “(5) shall promulgate a final rule pursuant to
13 subsection (d) by not later than 2 years after the
14 date on which the safety determination is completed;
15 and

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

22 “(b) PRIOR ACTIONS AND NOTICE OF EXISTING IN-
23 FORMATION.—

24 “(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 re-
4 garding a chemical substance, or from con-
5 tinuing or completing such a safety assessment
6 or safety determination that was initiated be-
7 fore the date of enactment of the Frank R.
8 Lautenberg Chemical Safety for the 21st Cen-
9 tury Act, prior to the effective date of the poli-
10 cies and procedures required to be established
11 by the Administrator under section 3A or 4A.

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

19 “(2) ACTIONS COMPLETED PRIOR TO COMPLE-
20 TION OF POLICIES AND PROCEDURES.—Nothing in
21 this Act requires the Administrator to revise or with-
22 draw a completed safety assessment, safety deter-
23 mination, or rule solely because the action was com-
24 pleted prior to the completion of a policy or proce-
25 dure established under section 3A or 4A, and the va-

1 lidity of a completed assessment, determination, or
2 rule shall not be determined based on the content of
3 such a policy or procedure.

4 “(3) NOTICE OF EXISTING INFORMATION.—

5 “(A) IN GENERAL.—The Administrator
6 shall, where such information is available, take
7 notice of existing information regarding hazard
8 and exposure published by other Federal agen-
9 cies and the National Academies and incor-
10 porate the information in safety assessments
11 and safety determinations with the objective of
12 increasing the efficiency of the safety assess-
13 ments and safety determinations.

14 “(B) INCLUSION OF INFORMATION.—Ex-
15 isting information described in subparagraph
16 (A) should be included to the extent practicable
17 and where the Administrator determines the in-
18 formation is relevant and scientifically reliable.

19 “(c) SAFETY DETERMINATIONS.—

20 “(1) IN GENERAL.—Based on a review of the
21 information available to the Administrator, including
22 draft safety assessments submitted by interested
23 persons, and subject to section 18, the Adminis-
24 trator shall determine that—

1 “(A) the relevant chemical substance meets
2 the safety standard;

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

7 “(i) impose restrictions necessary to
8 ensure that the chemical substance meets
9 the safety standard under the conditions of
10 use; or

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

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

20 “(2) ADDITIONAL INFORMATION.—If the Ad-
21 ministrator determines that additional information is
22 necessary to make a safety assessment or safety de-
23 termination for a high-priority substance, the Ad-
24 ministrator—

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

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

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

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

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

23 “(d) RULE.—

24 “(1) IMPLEMENTATION.—If the Administrator
25 makes a determination under subsection (c)(1)(B)

1 with respect to a chemical substance, the Adminis-
2 trator shall promulgate a rule establishing restric-
3 tions necessary to ensure that the chemical sub-
4 stance meets the safety standard.

5 “(2) SCOPE.—

6 “(A) IN GENERAL.—The rule promulgated
7 pursuant to this subsection—

8 “(i) may apply to mixtures containing
9 the chemical substance, as appropriate;

10 “(ii) shall include dates by which com-
11 pliance is mandatory, which—

12 “(I) shall be as soon as prac-
13 ticable;

14 “(II) in the case of a ban or
15 phase-out of the chemical substance,
16 shall implement the ban or phase-out
17 in as short a period as practicable;
18 and

19 “(III) as determined by the Ad-
20 ministrator, may vary for different af-
21 fected persons; and

22 “(iii) shall exempt replacement parts
23 that are manufactured prior to the effec-
24 tive date of the rule for articles that are
25 first manufactured prior to the effective

1 date of the rule unless the Administrator
2 finds the replacement parts contribute sig-
3 nificantly to the identified risk; and

4 “(iv) shall, in selecting among prohibi-
5 tions and other restrictions, apply such
6 prohibitions or other restrictions to articles
7 containing the chemical substance only to
8 the extent necessary to address the identi-
9 fied risks in order to determine that the
10 chemical substance meets the safety stand-
11 ard.

12 “(B) PERSISTENT AND BIOACCUMULATIVE
13 SUBSTANCES.—For a chemical substance the
14 Administrator determines ranks high for per-
15 sistence and bioaccumulation, the Administrator
16 shall, in selecting among prohibitions and other
17 restrictions that the Administrator determines
18 are sufficient to ensure that the chemical sub-
19 stance meets the safety standard, reduce expo-
20 sure to the substance to the maximum extent
21 practicable.

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

1 restriction under this subsection to address
2 workplace exposures.

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

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

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

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

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

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

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

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

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

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

14 “(i) a particular use;

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

18 “(iii) all uses;

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

22 “(i) a particular use; or

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

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

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

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

16 “(4) ANALYSIS FOR RULEMAKING.—

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

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

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

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

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

18 “(5) EXEMPTIONS.—

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

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

1 “(I) harming national security;

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

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

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

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

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

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

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

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

25 “(F) DURATION.—

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

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

16 “(iii) CONSIDERATIONS.—

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

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

6 “(e) IMMEDIATE EFFECT.—The Administrator may
7 declare a proposed rule under subsection (d)(1) to be ef-
8 fective on publication of the rule in the Federal Register
9 and until the effective date of final action taken respecting
10 the rule, if—

11 “(1) the Administrator determines that—

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

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

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

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

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

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

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

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

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

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

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

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

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

3 “(a) CIVIL ACTIONS.—

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

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

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

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

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

22 “(A) the existence of a decision, rule, con-
23 sent agreement, or order by the Administrator
24 under section 4, 4A, 5, or 6 or title VI; or

1 “(B) the pendency of any administrative or
2 judicial proceeding under any provision of this
3 Act.”;

4 (2) in subsection (b)(1), by striking “unreason-
5 able”;

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

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

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

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

13 (1) in subsection (a)—

14 (A) in paragraph (3)(A)(ii)(I)—

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

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

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

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

22 “(4) RULES.—

23 “(A) DEADLINE.—

24 “(i) IN GENERAL.—Not later than 2
25 years after the date of enactment of the

1 Frank R. Lautenberg Chemical Safety for
2 the 21st Century Act, the Administrator
3 shall promulgate rules requiring the main-
4 tenance of records and the reporting of in-
5 formation known or reasonably ascertain-
6 able by the person making the report, in-
7 cluding rules requiring processors to report
8 information, so that the Administrator has
9 the information necessary to carry out sec-
10 tions 4 and 6.

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

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

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

23 “(ii) shall include the level of detail
24 necessary to be reported, including the

1 manner by which use and exposure infor-
2 mation may be reported.

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

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

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

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

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

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

22 “(3) NOMENCLATURE.—

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

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

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

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

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

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

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

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

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

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

10 “(B) MULTIPLE NOMENCLATURE CONVEN-
11 TIONS.—

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

15 “(I) maintain the nomenclature
16 conventions for substances; and

17 “(II) develop new guidance
18 that—

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

24 “(bb) permits persons to
25 rely on the new guidance for pur-

1 poses of determining whether a
2 chemical substance is on the list
3 published under paragraph (1).

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

11 “(4) CHEMICAL SUBSTANCES IN COMMERCE.—

12 “(A) RULES.—

13 “(i) IN GENERAL.—Not later than 1
14 year after the date of enactment of the
15 Frank R. Lautenberg Chemical Safety for
16 the 21st Century Act, the Administrator,
17 by rule, shall require manufacturers and
18 processors to notify the Administrator, by
19 not later than 180 days after the date of
20 promulgation of the rule, of each chemical
21 substance on the list published under para-
22 graph (1) that the manufacturer or proc-
23 essor, as applicable, has manufactured or
24 processed for a nonexempt commercial pur-
25 pose during the 10-year period ending on

1 the day before the date of enactment of the
2 Frank R. Lautenberg Chemical Safety for
3 the 21st Century Act.

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

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

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

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

1 claim for protection against disclosure of
2 the specific identity of the substance as
3 confidential pursuant to section 14; and

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

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

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

22 “(i) require, at the time requested by
23 the Administrator, all manufacturers or
24 processors asserting claims under subpara-
25 graph (B) to substantiate the claim unless

1 the manufacturer or processor has sub-
2 stantiated the claim in a submission made
3 to the Administrator during the 5-year pe-
4 riod ending on the date of the request by
5 the Administrator;

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

8 “(I) to review each substan-
9 tiation—

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

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

23 “(II) approve, modify, or deny
24 each claim; and

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

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

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

21 “(iii) encourage manufacturers or
22 processors that have previously made
23 claims to protect the specific identities of
24 chemical substances identified as inactive

1 pursuant to subsection (f)(2) to review and
2 either withdraw or substantiate the claims.

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

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

12 “(ii) CONSIDERATIONS.—

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

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

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

3 “(5) ACTIVE AND INACTIVE SUBSTANCES.—

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

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

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

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

18 “(C) CHANGE TO ACTIVE STATUS.—

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

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

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

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

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

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

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

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

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

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

25 “(i) an active substance; or

1 “(ii) an inactive substance;

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

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

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

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

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

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

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

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

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

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

14 (3) in subsection (e)—

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

17 “(1) IN GENERAL.—Any person”; and

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

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

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

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

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

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

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

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

20 “(3) MANUFACTURE; PROCESS.—The”.

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

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

24 (1) in subsection (a)—

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

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

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

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

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

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

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

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

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

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

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

9 **SEC. 13. EXPORTS.**

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

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

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

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

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

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

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

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

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

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

12 “(b) NOTICE.—

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

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

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

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

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

6 “(D) a chemical substance or mixture sub-
7 ject to a significant new use rule, or a prohibi-
8 tion or other restriction pursuant to a rule,
9 order, or consent agreement in effect under this
10 Act; or

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

14 “(2) RULES.—

15 “(A) IN GENERAL.—The Administrator
16 shall promulgate rules to carry out paragraph
17 (1).

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

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

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

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

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

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

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

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

20 (3) in subsection (c)—

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

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

1 **SEC. 14. CONFIDENTIAL INFORMATION.**

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

4 **“SEC. 14. CONFIDENTIAL INFORMATION.**

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

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

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

14 “(b) INFORMATION GENERALLY PROTECTED FROM
15 DISCLOSURE.—The following information specific to, and
16 submitted by, a manufacturer, processor, or distributor
17 that meets the requirements of subsections (a) and (d)
18 shall be presumed to be protected from disclosure, subject
19 to the condition that nothing in this Act prohibits the dis-
20 closure of any such information, or information that is the
21 subject of subsection (g)(3), through discovery, subpoena,
22 other court order, or any other judicial process otherwise
23 allowed under applicable Federal or State law:

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

1 “(2) Marketing and sales information.

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

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

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

9 “(6) Specific production or import volumes of
10 the manufacturer and specific aggregated volumes
11 across manufacturers, if the Administrator deter-
12 mines that disclosure of the specific aggregated vol-
13 umes would reveal confidential information.

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

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

24 “(B) the claim—

1 “(i) is not subject to an exception
2 under subsection (e); or

3 “(ii) has not subsequently been with-
4 drawn or found by the Administrator not
5 to warrant protection as confidential infor-
6 mation under subsection (f)(2) or (g).

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

10 “(1) INFORMATION FROM HEALTH AND SAFETY
11 STUDIES.—

12 “(A) IN GENERAL.—Subject to subpara-
13 graph (B), subsection (a) does not prohibit the
14 disclosure of—

15 “(i) any health and safety study that
16 is submitted under this Act with respect
17 to—

18 “(I) any chemical substance or
19 mixture that, on the date on which
20 the study is to be disclosed, has been
21 offered for commercial distribution; or

22 “(II) any chemical substance or
23 mixture for which—

24 “(aa) testing is required
25 under section 4; or

1 “(bb) a notification is re-
2 quired under section 5; or

3 “(ii) any information reported to, or
4 otherwise obtained by, the Administrator
5 from a health and safety study relating to
6 a chemical substance or mixture described
7 in subclause (I) or (II) of clause (i).

8 “(B) EFFECT OF PARAGRAPH.—Nothing
9 in this paragraph authorizes the release of any
10 information that discloses—

11 “(i) a process used in the manufac-
12 turing or processing of a chemical sub-
13 stance or mixture; or

14 “(ii) in the case of a mixture, the por-
15 tion of the mixture comprised by any
16 chemical substance in the mixture.

17 “(2) CERTAIN REQUESTS.—If a request is made
18 to the Administrator under section 552(a) of title 5,
19 United States Code, for information that is de-
20 scribed in paragraph (1) that is not described in
21 paragraph (1)(B), the Administrator may not deny
22 the request on the basis of section 552(b)(4) of title
23 5, United States Code.

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

4 “(A) For information submitted after the
5 date of enactment of the Frank R. Lautenberg
6 Chemical Safety for the 21st Century Act, the
7 specific identity of a chemical substance as of
8 the date on which the chemical substance is
9 first offered for commercial distribution, if the
10 person submitting the information does not
11 meet the requirements of subsection (d).

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

14 “(C) Any general information describing
15 the manufacturing volumes, expressed as spe-
16 cific aggregated volumes or, if the Adminis-
17 trator determines that disclosure of specific ag-
18 gregated volumes would reveal confidential in-
19 formation, expressed in ranges.

20 “(D) A general description of a process
21 used in the manufacture or processing and in-
22 dustrial, commercial, or consumer functions and
23 uses of a chemical substance, mixture, or article
24 containing a chemical substance or mixture, in-
25 cluding information specific to an industry or

1 industry sector that customarily would be
2 shared with the general public or within an in-
3 dustry or industry sector.

4 “(4) MIXED CONFIDENTIAL AND NONCON-
5 FIDENTIAL INFORMATION.—Any information that is
6 otherwise eligible for protection under this section
7 and contained in a submission of information de-
8 scribed in this subsection shall be protected from
9 disclosure, if the submitter complies with subsection
10 (d), subject to the condition that information in the
11 submission that is not eligible for protection against
12 disclosure shall be disclosed.

13 “(5) BAN OR PHASE-OUT.—If the Adminis-
14 trator promulgates a rule pursuant to section 6(d)
15 that establishes a ban or phase-out of the manufac-
16 ture, processing, or distribution in commerce of a
17 chemical substance, subject to paragraphs (2), (3),
18 and (4) of subsection (g), any protection from dislo-
19 sure provided under this section with respect to the
20 specific identity of the chemical substance and other
21 information relating to the chemical substance shall
22 no longer apply.

23 “(d) REQUIREMENTS FOR CONFIDENTIALITY
24 CLAIMS.—

25 “(1) ASSERTION OF CLAIMS.—

1 “(A) IN GENERAL.—A person seeking to
2 protect any information submitted under this
3 Act from disclosure (including information de-
4 scribed in subsection (b)) shall assert to the Ad-
5 ministrator a claim for protection concurrent
6 with submission of the information, in accord-
7 ance with such rules regarding a claim for pro-
8 tection from disclosure as the Administrator
9 has promulgated or may promulgate pursuant
10 to this title.

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

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

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

20 “(iii) a reasonable basis to conclude
21 that disclosure of the information is likely
22 to cause substantial harm to the competi-
23 tive position of the person; and

1 “(iv) a reasonable basis to believe that
2 the information is not readily discoverable
3 through reverse engineering.

4 “(C) SPECIFIC CHEMICAL IDENTITY.—In
5 the case of a claim under subparagraph (A) for
6 protection against disclosure of a specific chem-
7 ical identity, the claim shall include a struc-
8 turally descriptive generic name for the chem-
9 ical substance that the Administrator may dis-
10 close to the public, subject to the condition that
11 the generic name shall—

12 “(i) conform with guidance prescribed
13 by the Administrator under paragraph
14 (3)(A); and

15 “(ii) describe the chemical structure
16 of the substance as specifically as prac-
17 ticable while protecting those features of
18 the chemical structure—

19 “(I) that are considered to be
20 confidential; and

21 “(II) the disclosure of which
22 would be likely to harm the competi-
23 tive position of the person.

24 “(D) PUBLIC INFORMATION.—No person
25 may assert a claim under this section for pro-

1 tection from disclosure of information that is al-
2 ready publicly available.

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

10 “(3) GUIDANCE.—The Administrator shall de-
11 velop guidance regarding—

12 “(A) the determination of structurally de-
13 scriptive generic names, in the case of claims
14 for the protection against disclosure of specific
15 chemical identity; and

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

19 “(4) CERTIFICATION.—An authorized official of
20 a person described in paragraph (1)(A) shall certify
21 that the information that has been submitted is true
22 and correct.

23 “(e) EXCEPTIONS TO PROTECTION FROM DISCLO-
24 SURE.—Information described in subsection (a)—

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

5 “(A) under any law for the protection of
6 health or the environment; or

7 “(B) for a specific law enforcement pur-
8 pose;

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

12 “(A) if, in the opinion of the Adminis-
13 trator, the disclosure is necessary for the satis-
14 factory performance by the contractor of a con-
15 tract with the United States for the perform-
16 ance of work in connection with this Act; and

17 “(B) subject to such conditions as the Ad-
18 ministrator may specify;

19 “(3) shall be disclosed if the Administrator de-
20 termines that disclosure is necessary to protect
21 health or the environment;

22 “(4) shall be disclosed if the information is to
23 be disclosed to a State or political subdivision of a
24 State, on written request, for the purpose of develop-
25 ment, administration, or enforcement of a law, if—

1 “(A) 1 or more applicable agreements with
2 the Administrator that conform with the guid-
3 ance issued under subsection (d)(3)(B) ensure
4 that the recipient will take appropriate meas-
5 ures, and has adequate authority, to maintain
6 the confidentiality of the information in accord-
7 ance with procedures comparable to the proce-
8 dures used by the Administrator to safeguard
9 the information; and

10 “(B) the Administrator notifies the person
11 that submitted the information that the infor-
12 mation has been disclosed to the State or polit-
13 ical subdivision of a State;

14 “(5) shall be disclosed if a health or environ-
15 mental professional employed by a Federal or State
16 agency or a treating physician or nurse in a non-
17 emergency situation provides a written statement of
18 need and agrees to sign a written confidentiality
19 agreement with the Administrator, subject to the
20 conditions that—

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

1 “(B) the written statement of need shall be
2 a statement that the person has a reasonable
3 basis to suspect that—

4 “(i) the information is necessary for,
5 or will assist in—

6 “(I) the diagnosis or treatment of
7 1 or more individuals; or

8 “(II) responding to an environ-
9 mental release or exposure; and

10 “(ii) 1 or more individuals being diag-
11 nosed or treated have been exposed to the
12 chemical substance concerned, or an envi-
13 ronmental release or exposure has oc-
14 curred; and

15 “(C) the confidentiality agreement shall
16 provide that the person will not use the infor-
17 mation for any purpose other than the health or
18 environmental needs asserted in the statement
19 of need, except as otherwise may be authorized
20 by the terms of the agreement or by the person
21 submitting the information to the Adminis-
22 trator, except that nothing in this Act prohibits
23 the disclosure of any such information through
24 discovery, subpoena, other court order, or any

1 other judicial process otherwise allowed under
2 applicable Federal or State law;

3 “(6) shall be disclosed if in the event of an
4 emergency, a treating physician, nurse, agent of a
5 poison control center, public health or environmental
6 official of a State or political subdivision of a State,
7 or first responder (including any individual duly au-
8 thorized by a Federal agency, State, or political sub-
9 division of a State who is trained in urgent medical
10 care or other emergency procedures, including a po-
11 lice officer, firefighter, or emergency medical techni-
12 cian) requests the information, subject to the condi-
13 tions that—

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

19 “(i) a medical or public health or en-
20 vironmental emergency exists;

21 “(ii) the information is necessary for,
22 or will assist in, emergency or first-aid di-
23 agnosis or treatment; or

24 “(iii) 1 or more individuals being di-
25 agnosed or treated have likely been ex-

1 posed to the chemical substance concerned,
2 or a serious environmental release of or ex-
3 posure to the chemical substance con-
4 cerned has occurred;

5 “(B) if requested by the person submitting
6 the information to the Administrator, the treat-
7 ing physician, nurse, agent, public health or en-
8 vironmental official of a State or a political sub-
9 division of a State, or first responder shall, as
10 described in paragraph (5)—

11 “(i) provide a written statement of
12 need; and

13 “(ii) agree to sign a confidentiality
14 agreement; and

15 “(C) the written confidentiality agreement
16 or statement of need shall be submitted as soon
17 as practicable, but not necessarily before the in-
18 formation is disclosed;

19 “(7) may be disclosed if the Administrator de-
20 termines that disclosure is relevant in a proceeding
21 under this Act, subject to the condition that the dis-
22 closure shall be made in such a manner as to pre-
23 serve confidentiality to the maximum extent prac-
24 ticable without impairing the proceeding;

1 “(8) shall be disclosed if the information is to
2 be disclosed, on written request of any duly author-
3 ized congressional committee, to that committee; or

4 “(9) shall be disclosed if the information is re-
5 quired to be disclosed or otherwise made public
6 under any other provision of Federal law.

7 “(f) DURATION OF PROTECTION FROM DISCLO-
8 SURE.—

9 “(1) IN GENERAL.—

10 “(A) INFORMATION PROTECTED FROM DIS-
11 CLOSURE.—Subject to paragraph (2), the Ad-
12 ministrator shall protect from disclosure infor-
13 mation that meets the requirements of sub-
14 section (d) for a period of 10 years, unless,
15 prior to the expiration of the period—

16 “(i) an affected person notifies the
17 Administrator that the person is with-
18 drawing the confidentiality claim, in which
19 case the Administrator shall promptly
20 make the information available to the pub-
21 lic; or

22 “(ii) the Administrator otherwise be-
23 comes aware that the need for protection
24 from disclosure can no longer be substan-
25 tiated, in which case the Administrator

1 shall take the actions described in sub-
2 section (g)(2).

3 “(B) EXTENSIONS.—

4 “(i) IN GENERAL.—Not later than the
5 date that is 60 days before the expiration
6 of the period described in subparagraph
7 (A), the Administrator shall provide to the
8 person that asserted the claim a notice of
9 the impending expiration of the period.

10 “(ii) STATEMENT.—

11 “(I) IN GENERAL.—Not later
12 than the date that is 30 days before
13 the expiration of the period described
14 in subparagraph (A), a person re-
15 asserting the relevant claim shall sub-
16 mit to the Administrator a statement
17 substantiating, in accordance with
18 subsection (d)(2), the need to extend
19 the period.

20 “(II) ACTION BY ADMINIS-
21 TRATOR.—Not later than the date
22 that is 30 days after the date of re-
23 ceipt of a statement under subclause
24 (I), the Administrator shall—

25 “(aa) review the request;

1 “(bb) make a determination
2 regarding whether the informa-
3 tion for which the request is
4 made continues to meet the rel-
5 evant criteria established under
6 this section; and

7 “(cc)(AA) grant an exten-
8 sion of not more than 10 years;
9 or

10 “(BB) deny the claim.

11 “(C) NO LIMIT ON NUMBER OF EXTEN-
12 SIONS.—There shall be no limit on the number
13 of extensions granted under subparagraph (B),
14 if the Administrator determines that the rel-
15 evant statement under subparagraph
16 (B)(ii)(I)—

17 “(i) establishes the need to extend the
18 period; and

19 “(ii) meets the requirements estab-
20 lished by the Administrator.

21 “(2) REVIEW AND RESUBSTANTIATION.—

22 “(A) DISCRETION OF ADMINISTRATOR.—
23 The Administrator may review, at any time, a
24 claim for protection against disclosure under
25 subsection (a) for information submitted to the

1 Administrator regarding a chemical substance
2 and require any person that has claimed protec-
3 tion for that information, whether before, on, or
4 after the date of enactment of the Frank R.
5 Lautenberg Chemical Safety for the 21st Cen-
6 tury Act, to withdraw or reassert and substan-
7 tiate or resubstantiate the claim in accordance
8 with this section—

9 “(i) after the chemical substance is
10 identified as a high-priority substance
11 under section 4A;

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

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

17 “(iv) in limited circumstances, if the
18 Administrator determines that disclosure
19 of certain information currently protected
20 from disclosure would assist the Adminis-
21 trator in conducting safety assessments
22 and safety determinations under sub-
23 sections (b) and (c) of section 6 or promul-
24 gating rules pursuant to section 6(d), sub-
25 ject to the condition that the information

1 shall not be disclosed unless the claimant
2 withdraws the claim or the Administrator
3 determines that the information does not
4 meet the requirements of subsection (d).

5 “(B) REVIEW REQUIRED.—The Adminis-
6 trator shall review a claim for protection from
7 disclosure under subsection (a) for information
8 submitted to the Administrator regarding a
9 chemical substance and require any person that
10 has claimed protection for that information,
11 whether before, on, or after the date of enact-
12 ment of the Frank R. Lautenberg Chemical
13 Safety for the 21st Century Act, to withdraw or
14 reassert and substantiate or resubstantiate the
15 claim in accordance with this section—

16 “(i) as necessary to comply with a re-
17 quest for information received by the Ad-
18 ministrator under section 552 of title 5,
19 United States Code;

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

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

4 “(C) ACTION BY RECIPIENT.—If the Ad-
5 ministrator makes a request under subpara-
6 graph (A) or (B), the recipient of the request
7 shall—

8 “(i) reassert and substantiate or re-
9 substantiate the claim; or

10 “(ii) withdraw the claim.

11 “(D) PERIOD OF PROTECTION.—Protec-
12 tion from disclosure of information subject to a
13 claim that is reviewed and approved by the Ad-
14 ministrator under this paragraph shall be ex-
15 tended for a period of 10 years from the date
16 of approval, subject to any subsequent request
17 by the Administrator under this paragraph.

18 “(3) UNIQUE IDENTIFIER.—The Administrator
19 shall—

20 “(A)(i) develop a system to assign a
21 unique identifier to each specific chemical iden-
22 tity for which the Administrator approves a re-
23 quest for protection from disclosure, other than
24 a specific chemical identity or structurally de-
25 scriptive generic term; and

1 “(ii) apply that identifier consistently to all
2 information relevant to the applicable chemical
3 substance;

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

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

14 “(i) is made public; and

15 “(ii) identifies the chemical substance
16 using the unique identifier; and

17 “(D) for each claim for protection of specific
18 chemical identity that has been denied by the Administrator
19 on expiration of the period for appeal under subsection
20 (g)(4), that has expired, or that has been withdrawn by the
21 submitter, provide public access to the specific
22 chemical identity clearly linked to all nonconfidential
23 information received by the Administrator with respect to
24 the chemical substance.
25

1 “(g) DUTIES OF ADMINISTRATOR.—

2 “(1) DETERMINATION.—

3 “(A) IN GENERAL.—Except as provided in
4 subsection (b), the Administrator shall, subject
5 to subparagraph (C), not later than 90 days
6 after the receipt of a claim under subsection
7 (d), and not later than 30 days after the receipt
8 of a request for extension of a claim under sub-
9 section (f), review and approve, modify, or deny
10 the claim or request.

11 “(B) DENIAL OR MODIFICATION.—

12 “(i) IN GENERAL.—Except as pro-
13 vided in subsections (c) and (f), the Ad-
14 ministrator shall deny a claim to protect a
15 chemical identity from disclosure only if
16 the person that has submitted the claim
17 fails to meet the requirements of sub-
18 sections (a) and (d).

19 “(ii) REASONS FOR DENIAL OR MODI-
20 FICATION.—The Administrator shall pro-
21 vide to a person that has submitted a
22 claim described in clause (i) a written
23 statement of the reasons for the denial or
24 modification of the claim.

1 “(C) SUBSETS.—The Administrator
2 shall—

3 “(i) except for claims described in
4 subsection (b)(7), review all claims under
5 this section for the protection against dis-
6 closure of the specific identity of a chem-
7 ical substance; and

8 “(ii) review a representative subset,
9 comprising at least 25 percent, of all other
10 claims for protection against disclosure.

11 “(D) EFFECT OF FAILURE TO ACT.—The
12 failure of the Administrator to make a decision
13 regarding a claim for protection against disclo-
14 sure or extension under this section shall not be
15 the basis for denial or elimination of a claim for
16 protection against disclosure.

17 “(2) NOTIFICATION.—

18 “(A) IN GENERAL.—Except as provided in
19 subparagraph (B) and subsections (c), (e), and
20 (f), if the Administrator denies or modifies a
21 claim under paragraph (1), or promulgates a
22 rule under section 6(d) establishing a ban or
23 phase-out of a chemical substance, the Adminis-
24 trator shall notify, in writing and by certified
25 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 pro-
5 vided in clause (ii), the Administrator shall
6 not release information under this sub-
7 section until the date that is 30 days after
8 the date on which the person that sub-
9 mitted the request receives notification
10 under subparagraph (A).

11 “(ii) EXCEPTIONS.—

12 “(I) IN GENERAL.—For informa-
13 tion under paragraph (3) or (8) of
14 subsection (e), the Administrator shall
15 not release that information until the
16 date that is 15 days after the date on
17 which the person that submitted the
18 claim receives a notification, unless
19 the Administrator determines that re-
20 lease of the information is necessary
21 to protect against an imminent and
22 substantial harm to health or the en-
23 vironment, in which case no prior no-
24 tification shall be necessary.

1 “(II) NO NOTIFICATION.—For
2 information 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 promul-
12 gated under section 6(d) that establishes a ban
13 or phase-out of the manufacture, processing, or
14 distribution in commerce of the substance out-
15 weighs the proprietary interest in maintaining
16 the protection from disclosure of that informa-
17 tion.

18 “(B) REQUEST FOR NONDISCLOSURE.—A
19 person that receives a notification under para-
20 graph (2) with respect to the information de-
21 scribed in subparagraph (A) may submit to the
22 Administrator, before the date on which the in-
23 formation is to be released, a request with sup-
24 porting documentation describing why the per-

1 son believes some or all of that information
2 should not be disclosed.

3 “(C) DETERMINATION BY ADMINIS-
4 TRATOR.—

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

16 “(ii) OBJECTIVE.—The Administrator
17 shall make the determination with the ob-
18 jective of ensuring that information rel-
19 evant to protection of health and the envi-
20 ronment is disclosed to the maximum ex-
21 tent practicable.

22 “(D) TIMING.—Not later than 30 days
23 after making the determination described in
24 subparagraph (C), the Administrator shall
25 make public the information the Administrator

1 has determined is not to be protected from dis-
2 closure.

3 “(E) NO TIMELY REQUEST RECEIVED.—If
4 the Administrator does not receive, before the
5 date on which the information described in sub-
6 paragraph (A) is to be released, a request pur-
7 suant to subparagraph (B), the Administrator
8 shall promptly make public all of the informa-
9 tion.

10 “(4) APPEALS.—

11 “(A) IN GENERAL.—If a person receives a
12 notification under paragraph (2) and believes
13 disclosure of the information is prohibited
14 under subsection (a), before the date on which
15 the information is to be released, the person
16 may bring an action to restrain disclosure of
17 the information in—

18 “(i) the United States district court of
19 the district in which the complainant re-
20 sides or has the principal place of business;
21 or

22 “(ii) the United States District Court
23 for the District of Columbia.

24 “(B) NO DISCLOSURE.—The Adminis-
25 trator shall not disclose any information that is

1 the subject of an appeal under this section be-
2 fore the date on which the applicable court
3 rules on an action under subparagraph (A).

4 “(5) ADMINISTRATION.—In carrying out this
5 subsection, the Administrator shall use the proce-
6 dures described in part 2 of title 40, Code of Fed-
7 eral Regulations (or successor regulations).

8 “(h) CRIMINAL PENALTY FOR WRONGFUL DISCLO-
9 SURE.—

10 “(1) OFFICERS AND EMPLOYEES OF UNITED
11 STATES.—

12 “(A) IN GENERAL.—Subject to paragraph
13 (2), a current or former officer or employee of
14 the United States described in subparagraph
15 (B) shall be guilty of a misdemeanor and fined
16 under title 18, United States Code, or impris-
17 oned for not more than 1 year, or both.

18 “(B) DESCRIPTION.—A current or former
19 officer or employee of the United States re-
20 ferred to in subparagraph (A) is a current or
21 former officer or employee of the United States
22 who—

23 “(i) by virtue of that employment or
24 official position has obtained possession of,

1 or has access to, material the disclosure of
2 which is prohibited by subsection (a); and

3 “(ii) knowing that disclosure of that
4 material is prohibited by subsection (a),
5 willfully discloses the material in any man-
6 ner to any person not entitled to receive
7 that material.

8 “(2) OTHER LAWS.—Section 1905 of title 18,
9 United States Code, shall not apply with respect to
10 the publishing, divulging, disclosure, making known
11 of, or making available, information reported or oth-
12 erwise obtained under this Act.

13 “(3) CONTRACTORS.—For purposes of this sub-
14 section, any contractor of the United States that is
15 provided information in accordance with subsection
16 (e)(2), including any employee of that contractor,
17 shall be considered to be an employee of the United
18 States.

19 “(i) APPLICABILITY.—

20 “(1) IN GENERAL.—Except as otherwise pro-
21 vided in this section, section 8, or any other applica-
22 ble Federal law, the Administrator shall have no au-
23 thority—

24 “(A) to require the substantiation or re-
25 substantiation of a claim for the protection

1 from disclosure of information submitted to the
2 Administrator under this Act before the date of
3 enactment of the Frank R. Lautenberg Chem-
4 ical Safety for the 21st Century Act; or

5 “(B) to impose substantiation or re-
6 substantiation requirements under this Act that
7 are more extensive than those required under
8 this section.

9 “(2) PRIOR ACTIONS.—Nothing in this Act pre-
10 vents the Administrator from reviewing, requiring
11 substantiation or resubstantiation for, or approving,
12 modifying or denying any claim for the protection
13 from disclosure of information before the effective
14 date of such rules applicable to those claims as the
15 Administrator may promulgate after the date of en-
16 actment of the Frank R. Lautenberg Chemical Safe-
17 ty for the 21st Century Act.”.

18 **SEC. 15. PROHIBITED ACTS.**

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

22 “(1) fail or refuse to comply with—

23 “(A) any rule promulgated, consent agree-
24 ment entered into, or order issued under section
25 4;

1 “(B) any requirement under section 5 or 6;

2 “(C) any rule promulgated, consent agree-

3 ment entered into, or order issued under section

4 5 or 6; or

5 “(D) any requirement of, or any rule pro-

6 mulgated or order issued pursuant to title II;”.

7 **SEC. 16. PENALTIES.**

8 Section 16 of the Toxic Substances Control Act (15

9 U.S.C. 2615) is amended—

10 (1) in subsection (a)(1)—

11 (A) in the first sentence—

12 (i) by inserting “this Act or a rule or

13 order promulgated or issued pursuant to

14 this Act, including” after “a provision of”;

15 and

16 (ii) by striking “\$25,000” and insert-

17 ing “\$37,500”; and

18 (B) in the second sentence, by striking“

19 violation of section 15 or 409” and inserting

20 “violation of this Act”; and

21 (2) in subsection (b)—

22 (A) by striking “Any person who” and in-

23 serting the following:

24 “(1) IN GENERAL.—Any person that”;

1 (B) by striking “section 15 or 409” and
2 inserting “this Act”;

3 (C) by striking “\$25,000” and inserting
4 “\$50,000”; and

5 (D) by adding at the end the following:

6 “(2) IMMINENT DANGER OF DEATH OR SERIOUS
7 BODILY INJURY.—

8 “(A) IN GENERAL.—Any person that
9 knowingly or willfully violates any provision of
10 this Act, and that knows at the time of the vio-
11 lation that the violation places an individual in
12 imminent danger of death or serious bodily in-
13 jury, shall be subject on conviction to a fine of
14 not more than \$250,000, or imprisonment for
15 not more than 15 years, or both.

16 “(B) ORGANIZATIONS.—An organization
17 that commits a violation described in subpara-
18 graph (A) shall be subject on conviction to a
19 fine of not more than \$1,000,000 for each vio-
20 lation.

21 “(3) KNOWLEDGE OF IMMINENT DANGER OR
22 INJURY.—For purposes of determining whether a
23 defendant knew that the violation placed another in-
24 dividual in imminent danger of death or serious bod-
25 ily injury—

1 “(A) the defendant shall be responsible
2 only for actual awareness or actual belief pos-
3 sessed; and

4 “(B) knowledge possessed by an individual
5 may not be attributed to the defendant.”.

6 **SEC. 17. STATE-FEDERAL RELATIONSHIP.**

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

10 “(a) IN GENERAL.—

11 “(1) ESTABLISHMENT OR ENFORCEMENT.—Ex-
12 cept as provided in subsections (c), (d), (e), (f), and
13 (g), and subject to paragraph (2), no State or polit-
14 ical subdivision of a State may establish or continue
15 to enforce any of the following:

16 “(A) TESTING AND INFORMATION COLLEC-
17 TION.—A statute or administrative action to re-
18 quire the development of information on a
19 chemical substance or category of substances
20 that is reasonably likely to produce the same in-
21 formation required under section 4, 5, or 6 in—

22 “(i) a rule promulgated by the Admin-
23 istrator;

24 “(ii) a testing consent agreement en-
25 tered into by the Administrator; or

1 “(iii) an order issued by the Adminis-
2 trator.

3 “(B) CHEMICAL SUBSTANCES FOUND TO
4 MEET THE SAFETY STANDARD OR RE-
5 STRICTED.—A statute or administrative action
6 to prohibit or otherwise restrict the manufac-
7 ture, processing, or distribution in commerce or
8 use of a chemical substance—

9 “(i) found to meet the safety standard
10 and consistent with the scope of the deter-
11 mination made under section 6; or

12 “(ii) found not to meet the safety
13 standard, after the effective date of the
14 rule issued under section 6(d) for the sub-
15 stance, consistent with the scope of the de-
16 termination made by the Administrator.

17 “(C) SIGNIFICANT NEW USE.—A statute or
18 administrative action requiring the notification
19 of a use of a chemical substance that the Ad-
20 ministrator has specified as a significant new
21 use and for which the Administrator has re-
22 quired notification pursuant to a rule promul-
23 gated under section 5.

24 “(2) EFFECTIVE DATE OF PREEMPTION.—
25 Under this subsection, Federal preemption of State

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

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

7 “(1) IN GENERAL.—Except as provided in sub-
8 sections (c), (d), and (e), beginning on the date on
9 which the Administrator defines the scope of a safe-
10 ty assessment and safety determination under sec-
11 tion 6(a)(2) and ending on the date on which the
12 Administrator publishes the safety determination, no
13 State or political subdivision of a State may estab-
14 lish a statute or administrative action prohibiting or
15 restricting the manufacture, processing, distribution
16 in commerce or use of a chemical substance that is
17 a high-priority substance designated under section
18 4A.

19 “(2) EFFECT OF SUBSECTION.—

20 “(A) IN GENERAL.—This subsection does
21 not restrict the authority of a State or political
22 subdivision of a State to continue to enforce
23 any State statute enacted, or administrative ac-
24 tion taken, prior to the date on which the Ad-
25 ministrator defines the scope of a safety assess-

1 ment and safety determination under section
2 6(a)(2).

3 “(B) LIMITATION.—Subparagraph (A)
4 does not allow a State or political subdivision of
5 a State to enforce any new prohibition or re-
6 striction under a State statute or administrative
7 action described in that subparagraph, if the
8 prohibition or restriction is established after the
9 date described in that subparagraph.

10 “(c) SCOPE OF PREEMPTION.—Federal preemption
11 under subsections (a) and (b) of State statutes and admin-
12 istrative actions applicable to specific substances shall
13 apply only to—

14 “(1) the chemical substances or category of
15 substances subject to a rule, order, or consent agree-
16 ment under section 4;

17 “(2) the uses or conditions of use of such sub-
18 stances that are identified by the Administrator as
19 subject to review in a safety assessment and in-
20 cluded in the scope of the safety determination made
21 by the Administrator for the substance, or of any
22 rule the Administrator promulgates pursuant to sec-
23 tion 6(d); or

24 “(3) the uses of such substances that the Ad-
25 ministrator has specified as significant new uses and

1 for which the Administrator has required notifica-
2 tion pursuant to a rule promulgated under section 5.

3 “(d) EXCEPTIONS.—

4 “(1) NO PREEMPTION OF STATE STATUTES
5 AND ADMINISTRATIVE ACTIONS.—

6 “(A) IN GENERAL.—Nothing in this Act,
7 nor any amendment made by this Act, nor any
8 rule, standard of performance, safety deter-
9 mination, or scientific assessment implemented
10 pursuant to this Act, shall affect the right of a
11 State or a political subdivision of a State to
12 adopt or enforce any rule, standard of perform-
13 ance, safety determination, scientific assess-
14 ment, or any protection for public health or the
15 environment that—

16 “(i) is adopted or authorized under
17 the authority of any other Federal law or
18 adopted to satisfy or obtain authorization
19 or approval under any other Federal law;

20 “(ii) implements a reporting, moni-
21 toring, disclosure, or other information ob-
22 ligation for the chemical substance not oth-
23 erwise required by the Administrator under
24 this Act or required under any other Fed-
25 eral law;

1 “(iii) is adopted pursuant to authority
2 under a law of the State or political sub-
3 division of the State related to water qual-
4 ity, air quality, or waste treatment or dis-
5 posal, except to the extent that the ac-
6 tion—

7 “(I) imposes a restriction on the
8 manufacture, processing, distribution
9 in commerce, or use of a chemical
10 substance; and

11 “(II)(aa) addresses the same haz-
12 ards and exposures, with respect to
13 the same conditions of use as are in-
14 cluded in the scope of the safety de-
15 termination pursuant to section 6, but
16 is inconsistent with the action of the
17 Administrator; or

18 “(bb) would cause a violation of
19 the applicable action by the Adminis-
20 trator under section 5 or 6; or

21 “(iv) subject to subparagraph (B), is
22 identical to a requirement prescribed by
23 the Administrator.

24 “(B) IDENTICAL REQUIREMENTS.—

1 “(B) with respect to a chemical substance
2 or mixture for which any rule or order was pro-
3 mulgated or issued under section 6 prior to the
4 effective date of the Frank R. Lautenberg
5 Chemical Safety for the 21st Century Act with
6 regards to manufacturing, processing, distribu-
7 tion in commerce, use, or disposal of a chemical
8 substance, this section (as in effect on the day
9 before the effective date of the Frank R. Lau-
10 tenberg Chemical Safety for the 21st Century
11 Act) shall govern the preemptive effect of any
12 rule or order that is promulgated or issued re-
13 specting such chemical substance or mixture
14 under section 6 of this Act after that effective
15 date, unless the latter rule or order is with re-
16 spect to a chemical substance or mixture con-
17 taining a chemical substance and follows a des-
18 ignation of that chemical substance as a high-
19 priority substance under subsection (b) or (c) of
20 section 4A or as an additional priority for safe-
21 ty assessment and safety determination under
22 section 4A(d).

23 “(e) PRESERVATION OF CERTAIN STATE LAW.—

24 “(1) IN GENERAL.—Nothing in this Act, sub-
25 ject to subsection (g) of this section, shall—

1 “(A) be construed to preempt or otherwise
2 affect the authority of a State or political sub-
3 division of a State to continue to enforce any
4 action taken before August 1, 2015, under the
5 authority of a State law that prohibits or other-
6 wise restricts manufacturing, processing, dis-
7 tribution in commerce, use, or disposal of a
8 chemical substance; or

9 “(B) be construed to preempt or otherwise
10 affect any action taken pursuant to a State law
11 that was in effect on August 31, 2003.

12 “(2) EFFECT OF SUBSECTION.—This sub-
13 section does not affect, modify, or alter the relation-
14 ship between State and Federal law pursuant to any
15 other Federal law.

16 “(f) STATE WAIVERS.—

17 “(1) DISCRETIONARY EXEMPTIONS.—Upon ap-
18 plication of a State or political subdivision of a
19 State, the Administrator may by rule, exempt from
20 subsection (a), under such conditions as may be pre-
21 scribed in the rule, a statute or administrative action
22 of that State or political subdivision of the State
23 that relates to the effects of, or exposure to, a chem-
24 ical substance under the conditions of use if the Ad-
25 ministrator determines that—

1 “(A) compelling State or local conditions
2 warrant granting the waiver to protect health
3 or the environment;

4 “(B) compliance with the proposed require-
5 ment of the State or political subdivision of the
6 State would not unduly burden interstate com-
7 merce in the manufacture, processing, distribu-
8 tion in commerce, or use of a chemical sub-
9 stance;

10 “(C) compliance with the proposed require-
11 ment of the State or political subdivision of the
12 State would not cause a violation of any appli-
13 cable Federal law, rule, or order; and

14 “(D) based on the judgment of the Admin-
15 istrator, the proposed requirement of the State
16 or political subdivision of the State is consistent
17 with sound objective scientific practices, the
18 weight of the evidence, and the best available
19 science.

20 “(2) REQUIRED EXEMPTIONS.—Upon applica-
21 tion of a State or political subdivision of a State, the
22 Administrator shall exempt from subsection (b) a
23 statute or administrative action of a State or polit-
24 ical subdivision of a State that relates to the effects

1 of exposure to a chemical substance under the condi-
2 tions of use if the Administrator determines that—

3 “(A) compliance with the proposed require-
4 ment of the State will not unduly burden inter-
5 state commerce in the manufacture, processing,
6 distribution in commerce, or use of a chemical
7 substance;

8 “(B) compliance with the proposed require-
9 ment would not cause a violation of any appli-
10 cable Federal law, rule, or order; and

11 “(C) the State or political subdivision of a
12 State has a concern about the chemical sub-
13 stance or use of the chemical substance based
14 in peer-reviewed science.

15 “(3) DETERMINATION OF A STATE WAIVER RE-
16 QUEST.—The duty of the Administrator to grant or
17 deny a waiver application shall be nondelegable and
18 shall be exercised—

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

22 “(B) not later than 90 days after the date
23 on which an application under paragraph (2) is
24 submitted.

1 “(4) FAILURE TO MAKE DETERMINATION.—If
2 the Administrator fails to make a determination
3 under paragraph (3)(B) during the 90-day period
4 beginning on the date on which an application under
5 paragraph (2) is submitted, the State statute or ad-
6 ministrative action that was the subject of the appli-
7 cation shall not be considered to be an existing stat-
8 ute or administrative action for purposes of sub-
9 section (a) by reason of the failure of the Adminis-
10 trator to make a determination.

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

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

19 “(A) considered to be a final agency ac-
20 tion; and

21 “(B) subject to judicial review.

22 “(7) DURATION OF WAIVERS.—

23 “(A) IN GENERAL.—Except as provided in
24 subparagraph (B), a waiver granted under

1 paragraph (2) or approved under paragraph (9)
2 shall remain in effect—

3 “(i) until such time as the safety as-
4 sessment and safety determination is com-
5 pleted; or

6 “(ii) subject to subparagraph (B),
7 until judicial review of the failure of the
8 Administrator to make a determination
9 under paragraph (3) is sought under para-
10 graph (8).

11 “(B) REINSTATEMENT OF WAIVER.—A
12 waiver described in subparagraph (A)(ii) shall
13 again take effect upon the earlier of—

14 “(i) the date of approval by the Ad-
15 ministrator of the waiver application;

16 “(ii) the effective date of a court
17 order directing the Administrator to ap-
18 prove the waiver application; or

19 “(iii) 90 days after the date on which
20 judicial review under paragraph (8) is
21 sought.

22 “(8) JUDICIAL REVIEW OF WAIVERS.—Not later
23 than 60 days after the date on which the Adminis-
24 trator makes a determination on an application of a
25 State or political subdivision of the State under

1 paragraph (1) or (2), or not later than 60 days after
2 the date on which the Administrator fails to make
3 a determination under paragraph (3), 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 “(9) APPROVAL.—

9 “(A) IN GENERAL.—If the Administrator
10 fails to meet the deadline under section 6(a)(4)
11 (including an extension granted under section
12 6(a)(6)), or the deadline established under
13 paragraph (3)(B), the application of a State or
14 political subdivision of a State under paragraph
15 (2) shall be automatically approved.

16 “(B) REQUIREMENTS.—Notwithstanding
17 paragraph (6), approval of a waiver application
18 under subparagraph (A) for failure to meet the
19 deadlines under section 6(a)(4) (including an
20 extension granted under section 6(a)(6)) shall
21 not be considered final agency action or be sub-
22 ject to judicial review or public notice and com-
23 ment.

24 “(10) JUDICIAL REVIEW OF LOW-PRIORITY DE-
25 CISIONS.—

1 “(A) IN GENERAL.—Not later than 60
2 days after the publication of a designation
3 under section 4A(b)(4), any person may com-
4 mence a civil action to challenge the designa-
5 tion.

6 “(B) JURISDICTION.—The United States
7 Court of Appeals for the District of Columbia
8 Circuit shall have exclusive jurisdiction over a
9 civil action filed under this paragraph.

10 “(g) SAVINGS.—

11 “(1) NO PREEMPTION OF COMMON LAW OR
12 STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF
13 OR CRIMINAL CONDUCT.—

14 “(A) IN GENERAL.—Nothing in this Act,
15 nor any amendment made by this Act, nor any
16 safety standard, rule, requirement, standard of
17 performance, safety determination, or scientific
18 assessment implemented pursuant to this Act,
19 shall be construed to preempt, displace, or sup-
20 plant any state or Federal common law rights
21 or any state or Federal statute creating a rem-
22 edy for civil relief, including those for civil dam-
23 age, or a penalty for a criminal conduct.

24 “(B) CLARIFICATION OF NO PREEMP-
25 TION.—Notwithstanding any other provision of

1 this Act, nothing in this Act, nor any amend-
2 ments made by this Act, shall preempt or pre-
3 clude any cause of action for personal injury,
4 wrongful death, property damage, or other in-
5 jury based on negligence, strict liability, prod-
6 ucts liability, failure to warn, or any other legal
7 theory of liability under any State law, mari-
8 time law, or Federal common law or statutory
9 theory.

10 “(2) NO EFFECT ON PRIVATE REMEDIES.—

11 “(A) IN GENERAL.—Nothing in this Act,
12 nor any amendments made by this Act, nor any
13 rules, regulations, requirements, safety assess-
14 ments, safety determinations, scientific assess-
15 ments, or orders issued pursuant to this Act
16 shall be interpreted as, in either the plaintiff’s
17 or defendant’s favor, dispositive in any civil ac-
18 tion.

19 “(B) AUTHORITY OF COURTS.—This Act
20 does not affect the authority of any court to
21 make a determination in an adjudicatory pro-
22 ceeding under applicable State or Federal law
23 with respect to the admission into evidence or
24 any other use of this Act or rules, regulations,
25 requirements, standards of performance, safety

1 assessments, scientific assessments, or orders
2 issued pursuant to this Act.”.

3 **SEC. 18. JUDICIAL REVIEW.**

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

6 (1) in subsection (a)—

7 (A) in paragraph (1)—

8 (i) in subparagraph (A), by striking
9 “section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e),
10 or 8, or under title II or IV” and inserting
11 “section 4(a), 5(d), 6(c), 6(d), 6(g), or 8,
12 or title II or IV”; and

13 (ii) in subparagraph (B), by striking
14 “an order issued under subparagraph (A)
15 or (B) of section 6(b)(1)” and inserting
16 “an order issued under this title”; and

17 (B) in paragraph (2), in the first sentence,
18 by striking “paragraph (1)(A)” and inserting
19 “paragraph (1)”; and

20 (C) by striking paragraph (3); and

21 (2) in subsection (c)(1)(B)—

22 (A) in clause (i)—

23 (i) by striking “section 4(a), 5(b)(4),
24 6(a), or 6(e)” and inserting “section 4(a),
25 5(d), 6(d), or 6(g)”; and

1 (ii) by striking “evidence in the rule-
2 making record (as defined in subsection
3 (a)(3)) taken as a whole;” and inserting
4 “evidence (including any matter) in the
5 rulemaking record, taken as a whole; and”;
6 and

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

10 “(ii) the court may not review the
11 contents and adequacy of any statement of
12 basis and purpose required by section
13 553(c) of title 5, United States Code, to be
14 incorporated in the rule, except as part of
15 the rulemaking record, taken as a whole.”.

16 **SEC. 19. CITIZENS’ PETITIONS.**

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

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

22 (2) in subsection (b)—

23 (A) in paragraph (1), by striking “an
24 order under section 5(e), 6(b)(1)(A), or

1 6(b)(1)(B)” and inserting “an order under sec-
2 tion 4 or 5(d)”;

3 (B) in paragraph (4), by striking subpara-
4 graph (B) and inserting the following:

5 “(B) DE NOVO PROCEEDING.—

6 “(i) IN GENERAL.—In an action
7 under subparagraph (A) to initiate a pro-
8 ceeding to promulgate a rule pursuant to
9 section 4, 5, 6, or 8 or an order issued
10 under section 4 or 5, the petitioner shall be
11 provided an opportunity to have the peti-
12 tion considered by the court in a de novo
13 proceeding.

14 “(ii) DEMONSTRATION.—

15 “(I) IN GENERAL.—The court in
16 a de novo proceeding under this sub-
17 paragraph shall order the Adminis-
18 trator to initiate the action requested
19 by the petitioner if the petitioner dem-
20 onstrates to the satisfaction of the
21 court by a preponderance of the evi-
22 dence that—

23 “(aa) in the case of a peti-
24 tion to initiate a proceeding for
25 the issuance of a rule or order

1 under section 4, the information
2 available to the Administrator is
3 insufficient for the Administrator
4 to perform an action described in
5 section 4, 4A, 5, or 6(d);

6 “(bb) in the case of a peti-
7 tion to issue an order under sec-
8 tion 5(d), there is a reasonable
9 basis to conclude that the chem-
10 ical substance is not likely to
11 meet the safety standard;

12 “(cc) in the case of a peti-
13 tion to initiate a proceeding for
14 the issuance of a rule under sec-
15 tion 6(d), there is a reasonable
16 basis to conclude that the chem-
17 ical substance will not meet the
18 safety standard; or

19 “(dd) in the case of a peti-
20 tion to initiate a proceeding for
21 the issuance of a rule under sec-
22 tion 8, there is a reasonable basis
23 to conclude that the rule is nec-
24 essary to protect health or the
25 environment or ensure that the

1 chemical substance meets the
2 safety standard.

3 “(II) DEFERMENT.—The court
4 in a de novo proceeding under this
5 subparagraph may permit the Admin-
6 istrator to defer initiating the action
7 requested by the petitioner until such
8 time as the court prescribes, if the
9 court finds that—

10 “(aa) the extent of the risk
11 to health or the environment al-
12 leged by the petitioner is less
13 than the extent of risks to health
14 or the environment with respect
15 to which the Administrator is
16 taking action under this Act; and

17 “(bb) there are insufficient
18 resources available to the Admin-
19 istrator to take the action re-
20 quested by the petitioner.”.

21 **SEC. 20. EMPLOYMENT EFFECTS.**

22 Section 24(b)(2)(B)(ii) of the Toxic Substances Con-
23 trol Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by
24 striking “section 6(c)(3),” and inserting “the applicable
25 requirements of this Act;”.

1 **SEC. 21. STUDIES.**

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

4 **SEC. 22. ADMINISTRATION.**

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

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

9 “(b) FEES.—

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

14 “(A) the payment of 1 or more reasonable
15 fees as a condition of submitting a notice or re-
16 questing an exemption under section 5;

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

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

23 “(ii) is required to submit a notice
24 pursuant to section 8(b)(5)(B)(i) changing
25 the status of a chemical substance from in-
26 active to active;

1 “(iii) is required to report information
2 pursuant to the rules promulgated under
3 section 8(a)(4); and

4 “(iv) manufactures or processes a
5 chemical substance subject to a safety as-
6 sessment and safety determination pursu-
7 ant to section 6.

8 “(2) UTILIZATION AND COLLECTION OF
9 FEES.—The Administrator shall—

10 “(A) utilize the fees collected under para-
11 graph (1) only to defray costs associated with
12 the actions of the Administrator—

13 “(i) to collect, process, review, provide
14 access to, and protect from disclosure
15 (where appropriate) information on chem-
16 ical substances under this Act;

17 “(ii) to review notices and make de-
18 terminations for chemical substances under
19 paragraphs (1) and (3) of section 5(d) and
20 impose any necessary restrictions under
21 section 5(d)(4);

22 “(iii) to make prioritization decisions
23 under section 4A;

1 “(iv) to conduct and complete safety
2 assessments and determinations under sec-
3 tion 6; and

4 “(v) to conduct any necessary rule-
5 making pursuant to section 6(d);

6 “(B) insofar as possible, collect the fees
7 described in paragraph (1) in advance of con-
8 ducting any fee-supported activity;

9 “(C) deposit the fees in the Fund estab-
10 lished by paragraph (4)(A); and

11 “(D) not collect excess fees or retain a sig-
12 nificant amount of unused fees.

13 “(3) AMOUNT AND ADJUSTMENT OF FEES; RE-
14 FUNDS.—In setting fees under this section, the Ad-
15 ministrators shall—

16 “(A) take into account the cost to the Ad-
17 ministrators of conducting the activities de-
18 scribed in paragraph (2);

19 “(B) prescribe lower fees for small busi-
20 ness concerns, after consultation with the Ad-
21 ministrators of the Small Business Administra-
22 tion;

23 “(C) set the fees established under para-
24 graph (1) at levels such that the fees will, in
25 aggregate, provide a sustainable source of funds

1 to defray approximately 25 percent of the costs
2 of conducting the activities identified in para-
3 graph (2)(A), not to exceed \$18,000,000, not
4 including fees under subparagraph (E) of this
5 paragraph;

6 “(D) reflect an appropriate balance in the
7 assessment of fees between manufacturers and
8 processors, and allow the payment of fees by
9 consortia of manufacturers or processors;

10 “(E) for substances designated as addi-
11 tional priorities pursuant to section 4A(c), es-
12 tablish the fee at a level sufficient to defray the
13 full costs to the Administrator of conducting
14 the safety assessment and safety determination
15 under section 6, except that for substances sub-
16 ject to section 4A(c)(3), the Administrator shall
17 establish the fee at a level sufficient to defray
18 50 percent of those costs;

19 “(F) prior to the establishment or amend-
20 ment of any fees under paragraph (1), consult
21 and meet with parties potentially subject to the
22 fees or their representatives, subject to the con-
23 dition that no obligation under the Federal Ad-
24 visory Committee Act (5 U.S.C. App.) or sub-
25 chapter III of chapter 5 of title 5, United

1 States Code, is applicable with respect to such
2 meetings;

3 “(G) beginning with the fiscal year that is
4 3 years after the date of enactment of the
5 Frank R. Lautenberg Chemical Safety for the
6 21st Century Act, and every 3 years thereafter,
7 after consultation with parties potentially sub-
8 ject to the fees and their representatives, in-
9 crease or decrease the fees established under
10 paragraph (1) as necessary—

11 “(i) to ensure that funds deposited in
12 the Fund are sufficient to conduct the ac-
13 tivities identified in paragraph (2)(A) and
14 the full costs of safety assessments and
15 safety determinations pursuant to subpara-
16 graph (E); and

17 “(ii) to account for inflation;

18 “(H) adjust fees established under para-
19 graph (1) as necessary to vary on account of
20 differing circumstances, including reduced fees
21 or waivers in appropriate circumstances, to re-
22 duce the burden on manufacturing or proc-
23 essing, remove barriers to innovation, or where
24 the costs to the Administrator of collecting the

1 fees exceed the fee revenue anticipated to be
2 collected; and

3 “(I) if a notice submitted under section 5
4 is refused or subsequently withdrawn, refund
5 the fee or a portion of the fee if no substantial
6 work was performed on the notice.

7 “(4) TSCA IMPLEMENTATION FUND.—

8 “(A) ESTABLISHMENT.—There is estab-
9 lished in the Treasury of the United States a
10 fund, to be known as the ‘TSCA Implementa-
11 tion Fund’ (referred to in this subsection as the
12 ‘Fund’), consisting of—

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

15 “(ii) any interest earned on the in-
16 vestment of amounts in the Fund; and

17 “(iii) any proceeds from the sale or
18 redemption of investments held in the
19 Fund.

20 “(B) CREDITING AND AVAILABILITY OF
21 FEES.—

22 “(i) IN GENERAL.—Fees authorized
23 under this section shall be collected and
24 available for obligation only to the extent
25 and in the amount provided in advance in

1 appropriations Acts, and shall be available
2 without fiscal year limitation.

3 “(ii) REQUIREMENTS.—Fees collected
4 under this section shall not—

5 “(I) be made available or obli-
6 gated for any purpose other than to
7 defray the costs of conducting the ac-
8 tivities identified in paragraph (2)(A);

9 “(II) otherwise be available for
10 any purpose other than implementa-
11 tion of this Act; and

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

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

19 “(i) maintained readily available or on
20 deposit;

21 “(ii) invested in obligations of the
22 United States or guaranteed by the United
23 States; or

24 “(iii) invested in obligations, partici-
25 pations, or other instruments that are law-

1 ful investments for fiduciary, trust, or pub-
2 lic funds.

3 “(D) MINIMUM AMOUNT OF APPROPRIA-
4 TIONS.—Fees may not be assessed for a fiscal
5 year under this section unless the amount of
6 appropriations for salaries, contracts, and ex-
7 penses for the functions (as in existence in fis-
8 cal year 2015) of the Office of Pollution Pre-
9 vention and Toxics of the Environmental Pro-
10 tection Agency for the fiscal year (excluding the
11 amount of any fees appropriated for the fiscal
12 year) are equal to or greater than the amount
13 of appropriations for covered functions for fiscal
14 year 2015 (excluding the amount of any fees
15 appropriated for the fiscal year).

16 “(5) AUDITING.—

17 “(A) FINANCIAL STATEMENTS OF AGEN-
18 CIES.—For the purpose of section 3515(c) of
19 title 31, United States Code, the Fund shall be
20 considered a component of an executive agency.

21 “(B) COMPONENTS.—The annual audit re-
22 quired under sections 3515(b) and 3521 of that
23 title of the financial statements of activities
24 under this subsection shall include an analysis
25 of—

1 “(i) the fees collected under para-
2 graph (1) and disbursed;

3 “(ii) compliance with the deadlines es-
4 tablished in section 6 of this Act;

5 “(iii) the amounts budgeted, appro-
6 priated, collected from fees, and disbursed
7 to meet the requirements of sections 4, 4A,
8 5, 6, 8, and 14, including the allocation of
9 full time equivalent employees to each such
10 section or activity; and

11 “(iv) the reasonableness of the alloca-
12 tion of the overhead associated with the
13 conduct of the activities described in para-
14 graph (2)(A).

15 “(C) INSPECTOR GENERAL.—The Inspec-
16 tor General of the Environmental Protection
17 Agency shall—

18 “(i) conduct the annual audit required
19 under this subsection; and

20 “(ii) report the findings and rec-
21 ommendations of the audit to the Adminis-
22 trator and to the appropriate committees
23 of Congress.

24 “(6) TERMINATION.—The authority provided by
25 this section shall terminate at the conclusion of the

1 fiscal year that is 10 years after the date of enact-
2 ment of the Frank R. Lautenberg Chemical Safety
3 for the 21st Century Act, unless otherwise reauthor-
4 ized or modified by Congress.”;

5 (2) in subsection (e), by striking “Health, Edu-
6 cation, and Welfare” each place it appears and in-
7 serting “Health and Human Services”; and

8 (3) adding at the end the following:

9 “(h) PRIOR ACTIONS.—Nothing in this Act elimi-
10 nates, modifies, or withdraws any rule promulgated, order
11 issued, or exemption established pursuant to this Act be-
12 fore the date of enactment of the Frank R. Lautenberg
13 Chemical Safety for the 21st Century Act.”.

14 **SEC. 23. DEVELOPMENT AND EVALUATION OF TEST METH-**
15 **ODS AND SUSTAINABLE CHEMISTRY.**

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

18 (1) in subsection (a), in the first sentence by
19 striking “Health, Education, and Welfare” and in-
20 serting “Health and Human Services”; and

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

22 “(c) SUSTAINABLE CHEMISTRY PROGRAM.—The
23 President shall establish an interagency Sustainable
24 Chemistry Program to promote and coordinate Federal
25 sustainable chemistry research, development, demonstra-

1 tion, technology transfer, commercialization, education,
2 and training activities.

3 “(d) PROGRAM ACTIVITIES.—The activities of the
4 Program shall be designed to—

5 “(1) provide sustained support for sustainable
6 chemistry research, development, demonstration,
7 technology transfer, commercialization, education,
8 and training through—

9 “(A) coordination of sustainable chemistry
10 research, development, demonstration, and tech-
11 nology transfer conducted at Federal labora-
12 tories and agencies; and

13 “(B) to the extent practicable, encourage-
14 ment of consideration of sustainable chemistry
15 in, as appropriate—

16 “(i) the conduct of Federal and State
17 science and engineering research and de-
18 velopment; and

19 “(ii) the solicitation and evaluation of
20 applicable proposals for science and engi-
21 neering research and development;

22 “(2) examine methods by which the Federal
23 Government can create incentives for consideration
24 and use of sustainable chemistry processes and prod-
25 ucts, including innovative financing mechanisms;

1 “(3) expand the education and training of un-
2 dergraduate and graduate students and professional
3 scientists and engineers, including through partner-
4 ships with industry, in sustainable chemistry science
5 and engineering;

6 “(4) collect and disseminate information on sus-
7 tainable chemistry research, development, and tech-
8 nology transfer including information on—

9 “(A) incentives and impediments to devel-
10 opment, manufacturing, and commercialization;

11 “(B) accomplishments;

12 “(C) best practices; and

13 “(D) costs and benefits;

14 “(5) support (including through technical as-
15 sistance, participation, financial support, or other
16 forms of support) economic, legal, and other appro-
17 priate social science research to identify barriers to
18 commercialization and methods to advance commer-
19 cialization of sustainable chemistry.

20 “(e) INTERAGENCY WORKING GROUP.—

21 “(1) ESTABLISHMENT.—Not later than 180
22 days after the date of enactment of the Frank R.
23 Lautenberg Chemical Safety for the 21st Century
24 Act, the President, in consultation with the Office of
25 Science and Technology Policy, shall establish an

1 Interagency Working Group that shall include rep-
2 resentatives from the National Science Foundation,
3 the National Institute of Standards and Technology,
4 the Department of Energy, the Environmental Pro-
5 tection Agency, the Department of Agriculture, the
6 Department of Defense, the National Institutes of
7 Health, and any other agency that the President
8 may designate to oversee the planning, management,
9 and coordination of the Program.

10 “(2) GOVERNANCE.—The Director of the Na-
11 tional Science Foundation and the Assistant Admin-
12 istrator for Research and Development of the Envi-
13 ronmental Protection Agency, or their designees,
14 shall serve as co-chairs of the Interagency Working
15 Group.

16 “(3) RESPONSIBILITIES.—In overseeing the
17 planning, management, and coordination of the Pro-
18 gram, the Interagency Working Group shall—

19 “(A) establish goals and priorities for the
20 Program, in consultation with the Advisory
21 Council;

22 “(B) provide for interagency coordination,
23 including budget coordination, of activities
24 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 Advi-
4 sory 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
9 (including small- and medium-sized enterprises from
10 across the value chain), academia, State and tribal
11 governments, and nongovernmental organizations
12 and others who are in a position to provide exper-
13 tise.

14 “(f) AGENCY BUDGET REQUESTS.—

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

20 “(A) identifies the activities of the agency
21 or department that contribute directly to the
22 Program; and

23 “(B) states the portion of the agency or
24 department’s request for appropriations that is
25 allocated to those activities.

1 “(2) ANNUAL BUDGET REQUEST TO CON-
2 GRESS.—The President shall include in the annual
3 budget request to Congress a statement of the por-
4 tion of the annual budget request for each agency or
5 department that will be allocated to activities under-
6 taken pursuant to the Program.

7 “(g) REPORT TO CONGRESS.—

8 “(1) IN GENERAL.—Not later than 2 years
9 after the date of enactment of the Frank R. Lauten-
10 berg Chemical Safety for the 21st Century Act, the
11 Interagency Working Group shall submit a report to
12 the Committee on Science, Space, and Technology
13 and Committee on Energy and Commerce of the
14 House of Representatives and the Committee on En-
15 vironment and Public Works and the Committee on
16 Commerce, Science, and Transportation of the Sen-
17 ate that shall 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 this

1 Act, and recommendations for future program
2 activities;

3 “(D) an assessment of the benefits of ex-
4 panding existing, federally-supported regional
5 innovation and manufacturing hubs to include
6 sustainable chemistry and the value of directing
7 the creation of 1 or more dedicated sustainable
8 chemistry centers of excellence or hubs; and

9 “(E) an evaluation of steps taken and fu-
10 ture strategies to avoid duplication of efforts,
11 streamline interagency coordination, facilitate
12 information sharing, and spread best practices
13 between participating agencies in the Program.

14 “(2) SUBMISSION TO GAO.—The Interagency
15 Working Group shall also submit the report de-
16 scribed in paragraph (1) to the Government Ac-
17 countability Office for consideration in future Con-
18 gressional inquiries.”.

19 **SEC. 24. STATE PROGRAMS.**

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

22 (1) in subsection (b)(1)—

23 (A) in subparagraphs (A) through (D), by
24 striking the comma at the end of each subpara-
25 graph and inserting a semicolon; and

1 (B) in subparagraph (E), by striking “,
2 and” and inserting “; and”; and
3 (2) by striking subsections (c) and (d).

4 **SEC. 25. AUTHORIZATION OF APPROPRIATIONS.**

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

7 **SEC. 26. ANNUAL REPORT.**

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

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

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

17 **SEC. 27. EFFECTIVE DATE.**

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

20 (1) by striking “Except as provided in section
21 4(f), this” and inserting the following:

22 “(a) IN GENERAL.—This”; and

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

24 “(b) RETROACTIVE APPLICABILITY.—Nothing in this
25 Act shall be interpreted to apply retroactively to any State,

1 Federal, or maritime legal action commenced prior to the
2 effective date of the Frank R. Lautenberg Chemical Safety
3 for the 21st Century Act.”.