

From: AF&PA Government Affairs [mailto:Government_Affairs@afandpa.org]
Sent: Wednesday, May 25, 2016 4:22 PM
Subject: TSCA Update

DATE: May 25, 2016
TO: Government Affairs Resource Committee
State Affairs Task Force
Chemical & Product Stewardship Subcommittee
Environmental Resource Committee
FROM: AF&PA Government Affairs
Stewart Holm
RE: TSCA Update

As mentioned on the joint GARC / SATF call last Friday, May 20, the final House and Senate compromise language amending the Toxic Substance Control Act (TSCA) was released as H.R. 2576: "The TSCA Modernization Act of 2015". Both chambers have been working through an informal conference process to combine the two pieces of legislation.

A copy of the final compromise legislation and summary are attached.

DISCUSSION:

Timing

With the release of the final compromise language last week, TSCA reform remains on track to pass both the House and Senate before the Memorial Day recess. Yesterday (May 24), the House of Representatives passed the compromise legislation by a vote of 403-12. It now heads to the Senate.

Summary of Final Language

Two summaries are attached. One provided by House Energy and Commerce Committee staff and a simplified version provided by the American Alliance for Innovation (AAI) coalition. AF&PA's primary concerns with TSCA reform were related to federal preemption of state chemical laws and regulations and so a summary of the final language, alongside those specific priorities, is detailed below:

AF&PA Priorities Document (attached): Maintain Strong Preemption Provisions

Specifically, the priorities document outlines four components for maintaining strong preemption:

- Retain high priority "pause" on State actions taken after the federal risk assessment process begins.
- Retain conflict limitation on grandfathered State laws.
- Ensure waiver provisions are consistent with a nationally uniform chemical regulatory system.
- Retain exemption for state actions related to clean air and clean water laws.

Final TSCA Compromise Language Summary (attached)

In general, the final TSCA compromise language on preemption addresses these priorities.

States and local governments may not (1) duplicate federal information development requirements, (2) restrict a chemical that EPA's scientific risk evaluation found does not present an unreasonable risk, or (3) restrict a chemical that EPA has published a risk management regulation for, or required notification for, a significant new use of a chemical or a new chemical. Preemption begins when the administrator defines the scope of a risk evaluation and ends either 30 months after that or when a risk evaluation is completed, whichever is earlier.

This preemption rule does not restrict a states authority to continue enforcing a law enacted prior to the risk evaluation, but rather only prevents a state from enforcing a new restriction established after the EPA risk evaluation process has been started. It is also worth mentioning that federal preemption applies only to the scope of the risk evaluation, allowing states to create and enforce laws that do not fall within the scope of the evaluation.

Exceptions to Preemption

Exceptions to the general preemption rules include (1) state laws carrying out federal laws, (2) states enacting reporting requirements that are not otherwise required under federal law, or (3) laws related to water or air quality, or waste treatment or disposal. Also, state laws restricting chemicals that were enacted prior to April 22, 2016, are not preempted, nor are any actions taken by a state pursuant to a law enacted prior to September 2003. This includes Proposition 65 in California. EPA may also waive preemption if it determines that compelling conditions warrant it, if the state law is scientifically based, and/ or the state law would not unduly burden interstate commerce.

RECOMMENDATIONS:

No recommendations at this time. If you have questions or need additional information, please contact TJ Struhs at tj_struhs@afandpa.org or (202) 463-2433 or Stewart Holm at stewart_holm@afandpa.org or (202) 463-2709

Summary of Compromise TSCA Reform Language
May 23, 2016

Major Provisions of the Compromise

- **TSCA safety standard:** The “unreasonable risk of injury to health or the environment” standard of current TSCA is retained but not defined. This standard is applied in risk evaluations of high priority chemicals.
 - **Conditions of use:** The term “conditions of use” is defined in the bill and incorporated into all references to the “unreasonable risk” standard. As defined, EPA has discretion to determine the conditions of use of priority chemicals that are the subject of risk evaluations.
 - **Potentially exposed or susceptible subpopulations:** Requires EPA to consider these subpopulations in the risk evaluations if EPA identifies them as relevant to the risk evaluation under the conditions of use. If EPA determines there is an unreasonable risk, EPA must take the necessary steps to protect those subgroups in risk management rules.
- **Review of Existing Chemicals:** Requires EPA to screen existing chemicals in commerce to decide whether they warrant additional review and regulation. The review process has several important steps: distinguishing active from inactive chemicals on the TSCA Inventory; prioritizing existing chemicals in commerce for risk evaluations; conducting risk evaluations of identified high priority chemicals; and regulating those chemicals that don’t meet the “unreasonable risk” standard under the conditions of use.
 - **Inventory Reset:** Within 1 year of enactment, companies will be required, by rule, to identify all chemicals they are currently manufacturing or processing through an inventory reset process.
 - **Prioritization for Risk Evaluation:** Within 18 months of enactment, EPA is required to establish by rule a screening process to designate chemicals as high priorities for risk evaluations or as low priorities for which risk evaluations aren’t warranted at the time.
 - The prioritization process must include consideration of hazard and exposure potential of a chemical or category of chemicals, (including consideration of persistence and bioaccumulation), potentially exposed or susceptible subpopulations, storage near significant sources of drinking water, the conditions of use or significant changes in conditions of use, or significant changes in volume of the chemical manufactured or processed.
 - Initial high priorities for risk evaluations must be drawn from the TSCA Work Plan chemicals.
 - Within 180 days after enactment, EPA must ensure risk evaluations are underway on a minimum of 10 chemical substances drawn from the Work Plan. EPA must have 20 risk evaluations underway within 3 and ½ years from enactment and must also designate at least 20 substances as low priorities.
 - **Risk Evaluations:** EPA shall conduct risk evaluations of chemicals identified by the Agency as high priority chemicals.
 - Manufacturers may also request EPA to conduct a risk evaluation on a chemical. Manufacturer-requested risk evaluations cannot exceed 50% of the total number of evaluations EPA has underway. Manufacturers must pay 100%

- of the costs of the risk evaluations (except that Work Plan chemicals requested by manufacturers only require payment of 50% of the costs).
 - EPA must complete risk evaluations no later than 3 years after EPA initiation, with a 1 year extension possible.
 - The risk evaluation does not consider costs or other non-risk factors. Cost-benefit considerations only come into play in a risk management rule, once EPA determines in a risk evaluation that a chemical does not meet the unreasonable risk standard.
- **Regulation:**
 - If EPA determines a chemical presents an unreasonable risk under conditions of use, the Agency shall propose a rule imposing prohibitions and other restrictions on the chemical no later than 1 year after publication of final risk evaluation and publish a final rule no later than 2 years after publication of final risk evaluation, and may extend deadlines for not more than 2 years, (subject to 2 year limit on aggregate extensions, and limitations on deadline extensions for P & B Work Plan chemicals).
 - The rule shall include a statement about the effects of the chemical on health or environment, the benefits of the chemical for various uses and the reasonably ascertainable economic consequences of the proposed and final regulatory action and the considered alternatives.
 - All steps in the regulatory process are subject to full APA notice and comment rulemaking.
- **Expedited Action on PBTs:** Not later than 3 years after enactment the Administrator shall propose rules regarding substances on the 2014 TSCA Work Plan that Administrator has a reasonable basis to conclude are toxic and that are high for P or B and either high or moderate for the other P/B criteria and for which Administrator has not completed problem formulation, initiated a review under section 5, or entered into consent agreement under section 4, prior to enactment, and exposure under conditions of use is likely to general population or to a potentially exposed or susceptible subpopulation identified by Administrator, or to environment on the basis of an exposure and use assessment completed by Administrator. EPA is not required to conduct risk evaluations on these substances. Not later than 18 months after proposing a rule, Administrator shall promulgate a final rule selecting restrictions and reducing exposures to extent practicable.
- **New Chemicals:** EPA shall review PMNs and determine whether the new chemical may present an unreasonable risk – without consideration of cost or non-risk factors – including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA under the conditions of use, and take applicable action. If EPA finds a new chemical is not likely to pose an unreasonable risk, manufacture may commence and EPA is to issue a statement as soon as practicable before the end of the review period.
- **Testing Authority:** The compromise continues EPA’s existing authority to require testing through rulemaking, but also expands EPA’s authority to require testing through orders or consent agreements.
 - Among other things, this new authority could be used to require development of new information needed for EPA’s review of Section 5 PMNs, for EPA’s risk evaluations

or risk management rules under Section 6, as well for prioritizing a chemical (subject to certain limitations).

- EPA must develop a statement of need to use this new order authority.
- The testing provisions also require EPA to use tiered screening and testing processes.
- The testing provisions also require EPA to minimize to the extent practicable the use of vertebrate animals in testing.
- **Confidential business information (CBI):** Requires EPA to review past claims for confidential chemical identity for active chemicals on the TSCA Inventory. All CBI claims must be asserted. Some claims (e.g., sales and marketing data, and confidential chemical identity prior to commercialization) do not need to be substantiated, and the protection from disclosure for those claims does not expire. Specific claims, such as claims to protect chemical identity after commercialization, must be substantiated. Substantiated claims are protected for 10-years, which can be renewed for 10 year periods. Inserts the terms “including formulas (including molecular structures) of a chemical substance or mixture” to modify data which cannot be disclosed in a health and safety study if it would reveal processing or concentration in a mixture. Retains the provision from S.697 that protects confidential information from disclosure when contained in material that is mixed with non-confidential information. Requires EPA to review all new claims for confidential chemical identity and a representative sample of all other claims. Provides authority for EPA to share CBI information with state governments, health and environmental professionals and first responders, under certain conditions.
- **Nomenclature:** Maintains Class 2 nomenclature system. On request by a manufacturer or processor to review information reasonably available to the Administrator that demonstrates that a chemical appears multiple times on the Active List under different CAS numbers, the Administrator may recognize the multiple listings as a single substance.
- **Federal-State authority:**
 - Preempts:
 - State action to conduct chemical testing that duplicates an EPA testing requirement.
 - State action if EPA finds that a chemical substance does not present an unreasonable risk.
 - State requirement to notify of a chemical use if EPA already requires notification under a Significant New Use Rule.
 - Pause (temporary preemption):
 - Bars States from passing any new laws or promulgating any new regulations for high priority chemicals from publication of the scope of the risk evaluation until it is either done or the deadline for completion expires.
 - No preemption “pause” for chemical evaluations requested by manufacturers.
 - Does not preempt:
 - Identical state actions to that taken by EPA. Both EPA and States can enforce their identical regulations, but the combined penalties cannot exceed the federal statutory maximum.

- States can get waivers from EPA from preemption and proceed with state action:
 - If EPA conducts a rulemaking in which the state demonstrates a compelling justification for the waiver.
 - If the state shows that peer-reviewed science establishes a concern about the chemical or its use.
 - If a state takes action (passes a law, proposes agency action, or finalizes an agency action) within 18 months of EPA beginning the prioritization process for the chemical or publishing the scope of the risk evaluation for the chemical.
 - States must apply for a waiver.
- Exempts from preemption:
 - State actions taken prior to April 22, 2016 or under a law in effect on August 31, 2003.
- **Fees:** Authorizes EPA to collect fees to defray the costs of implementing the chemical review program. Caps fees at 25% of EPA's program costs, except that manufacturer-requested reviews are to pay 100% of costs (or 50% of costs in the case of substances already in EPA's Work Plan Chemicals Program).
- **Other Relevant Provisions:**
 - **Reporting and Recordkeeping:** Requires EPA to minimize the impacts of reporting and recordkeeping rules on small manufacturers and processors. EPA must consult with the SBA Administrator not later than 180 days after enactment and not less frequently than once every 10 years thereafter to review and potentially revise the standards for determining whether small businesses shall report differently, e.g., level of detail, etc., subject to notice and comment.
 - **Policies, Procedures and Guidance (PPGs):** EPA must develop any PPGs that Administrator deems necessary to carry out the amendments to TSCA. These shall be reviewed at least once every 5 years.
 - **Scientific Standards:** Requires EPA in carrying out sections 4, 5 and 6, to extent decision is based on science, to use best available science and consider reasonableness, relevance, clarity, completeness, variability, uncertainty, extent of independent verification or peer review, of the information or procedures, methods, etc. Also requires EPA to make decisions under Sections 4, 5 or 6 based on the weight of the scientific evidence.
 - **Availability of Information:** Requires EPA in carrying out sections 4, 5 and 6 to take into consideration information relating to a chemical substance or mixture, including hazard and exposure information under the conditions of use that is reasonably available to the Administrator.
 - **Mercury:** Requires development of a long-term storage facility for elemental mercury, and provides for interim storage by generators; creates an inventory of supply, use, and trade of mercury; and prohibits export of certain mercury compounds.
 - **Cancer Clusters:** Amends the Public Health Service Act by providing direction for the identification, designation, and investigation of potential cancer clusters.

MAY 20, 2016

RULES COMMITTEE PRINT 114-54
TEXT OF HOUSE AMENDMENT TO THE SENATE
AMENDMENT TO H.R. 2576, TSCA MOD-
ERNIZATION ACT OF 2015

**[Showing the text of the Frank R. Lautenberg Chemical
Safety for the 21st Century Act.]**

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Frank R. Lautenberg Chemical Safety for the 21st Cen-
4 tury Act”.

5 (b) TABLE OF CONTENTS.—The table of contents of
6 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—CHEMICAL SAFETY

Sec. 2. Findings, policy, and intent.

Sec. 3. Definitions.

Sec. 4. Testing of chemical substances and mixtures.

Sec. 5. Manufacturing and processing notices.

Sec. 6. Prioritization, risk evaluation, and regulation of chemical substances
and mixtures.

Sec. 7. Imminent hazards.

Sec. 8. Reporting and retention of information.

Sec. 9. Relationship to other Federal laws.

Sec. 10. Exports of elemental mercury.

Sec. 11. Confidential information.

Sec. 12. Penalties.

Sec. 13. State-Federal relationship.

Sec. 14. Judicial review.

Sec. 15. Citizens’ civil actions.

Sec. 16. Studies.

Sec. 17. Administration of the Act.

Sec. 18. State programs.

Sec. 19. Conforming amendments.

Sec. 20. No retroactivity.

Sec. 21. Trevor's Law.

TITLE II—RURAL HEALTHCARE CONNECTIVITY

Sec. 201. Short title.

Sec. 202. Telecommunications services for skilled nursing facilities.

1 **TITLE I—CHEMICAL SAFETY**

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

3 Section 2(c) of the Toxic Substances Control Act (15
4 U.S.C. 2601(c)) is amended by striking “proposes to
5 take” and inserting “proposes as provided”.

6 **SEC. 3. DEFINITIONS.**

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

9 (1) by redesignating paragraphs (4) through
10 (14) as paragraphs (5), (6), (8), (9), (10), (11),
11 (13), (14), (15), (16), and (17), respectively;

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

14 “(4) The term ‘conditions of use’ means the cir-
15 cumstances, as determined by the Administrator, under
16 which a chemical substance is intended, known, or reason-
17 ably foreseen to be manufactured, processed, distributed
18 in commerce, used, or disposed of.”;

19 (3) by inserting after paragraph (6), as so re-
20 designated, the following:

21 “(7) The term ‘guidance’ means any significant writ-
22 ten guidance of general applicability prepared by the Ad-
23 ministrators.”; and

1 (4) by inserting after paragraph (11), as so re-
2 designated, the following:

3 “(12) The term ‘potentially exposed or susceptible
4 subpopulation’ means a group of individuals within the
5 general population identified by the Administrator who,
6 due to either greater susceptibility or greater exposure,
7 may be at greater risk than the general population of ad-
8 verse health effects from exposure to a chemical substance
9 or mixture, such as infants, children, pregnant women,
10 workers, or the elderly.”.

11 **SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIX-**
12 **TURES.**

13 Section 4 of the Toxic Substances Control Act (15
14 U.S.C. 2603) is amended—

15 (1) by striking “standards” each place it ap-
16 pears and inserting “protocols and methodologies”;

17 (2) in subsection (a)—

18 (A) by striking “If the Administrator
19 finds” and inserting “(1) If the Administrator
20 finds”;

21 (B) in paragraph (1), as so designated—

22 (i) by striking “(1)(A)(i)” and insert-
23 ing “(A)(i)(I)”;

24 (ii) by striking “(ii)” each place it ap-
25 pears and inserting “(II)”;

1 (iii) by striking “are insufficient data”
2 and inserting “is insufficient information”
3 each place it appears;

4 (iv) by striking “(iii)” each place it
5 appears and inserting “(III)”;

6 (v) by striking “such data” and in-
7 serting “such information” each place it
8 appears;

9 (vi) by striking “(B)(i)” and inserting
10 “(ii)(I)”;

11 (vii) by striking “(I)” and inserting
12 “(aa)”;

13 (viii) by striking “(II)” and inserting
14 “(bb)”;

15 (ix) by striking “(2)” and inserting
16 “(B)”;

17 (x) in the matter following subpara-
18 graph (B), as so redesignated—

19 (I) by inserting “, or, in the case
20 of a chemical substance or mixture
21 described in subparagraph (A)(i), by
22 rule, order, or consent agreement,”
23 after “rule”;

1 (II) by striking “data” each place
2 it appears and inserting “informa-
3 tion”; and

4 (III) by striking “and which are
5 relevant” and inserting “and which is
6 relevant”; and

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

8 “(2) ADDITIONAL TESTING AUTHORITY.—In
9 addition to the authority provided under paragraph
10 (1), the Administrator may, by rule, order, or con-
11 sent agreement—

12 “(A) require the development of new infor-
13 mation relating to a chemical substance or mix-
14 ture if the Administrator determines that the
15 information is necessary—

16 “(i) to review a notice under section 5
17 or to perform a risk evaluation under sec-
18 tion 6(b);

19 “(ii) to implement a requirement im-
20 posed in a rule, order, or consent agree-
21 ment under subsection (e) or (f) of section
22 5 or in a rule promulgated under section
23 6(a);

24 “(iii) at the request of a Federal im-
25 plementing authority under another Fed-

1 eral law, to meet the regulatory testing
2 needs of that authority with regard to tox-
3 icity and exposure; or

4 “(iv) pursuant to section 12(a)(2);
5 and

6 “(B) require the development of new infor-
7 mation for the purposes of prioritizing a chem-
8 ical substance under section 6(b) only if the Ad-
9 ministrator determines that such information is
10 necessary to establish the priority of the sub-
11 stance, subject to the limitations that—

12 “(i) not later than 90 days after the
13 date of receipt of information regarding a
14 chemical substance complying with a rule,
15 order, or consent agreement under this
16 subparagraph, the Administrator shall des-
17 ignate the chemical substance as a high-
18 priority substance or a low-priority sub-
19 stance; and

20 “(ii) information required by the Ad-
21 ministrator under this subparagraph shall
22 not be required for the purposes of estab-
23 lishing or implementing a minimum infor-
24 mation requirement of broader applica-
25 bility.

1 “(3) STATEMENT OF NEED.—When requiring
2 the development of new information relating to a
3 chemical substance or mixture under paragraph (2),
4 the Administrator shall identify the need for the new
5 information, describe how information reasonably
6 available to the Administrator was used to inform
7 the decision to require new information, explain the
8 basis for any decision that requires the use of
9 vertebrate animals, and, as applicable, explain why
10 issuance of an order is warranted instead of promul-
11 gating a rule or entering into a consent agreement.

12 “(4) TIERED TESTING.—When requiring the
13 development of new information under this sub-
14 section, the Administrator shall employ a tiered
15 screening and testing process, under which the re-
16 sults of screening-level tests or assessments of avail-
17 able information inform the decision as to whether
18 1 or more additional tests are necessary, unless in-
19 formation available to the Administrator justifies
20 more advanced testing of potential health or environ-
21 mental effects or potential exposure without first
22 conducting screening-level testing.”;

23 (3) in subsection (b)—

24 (A) in paragraph (1)—

1 (i) in subparagraph (B), by striking
2 “test data” and inserting “information”;

3 (ii) in subparagraph (C), by striking
4 “data” and inserting “information”; and

5 (iii) in the matter following subpara-
6 graph (C), by striking “data” and insert-
7 ing “information”;

8 (B) in paragraph (2)—

9 (i) in subparagraph (A)—

10 (I) by striking “test data” and
11 inserting “information”;

12 (II) by inserting “Protocols and
13 methodologies for the development of
14 information may also be prescribed
15 for the assessment of exposure or ex-
16 posure potential to humans or the en-
17 vironment.” after the first sentence;
18 and

19 (III) by striking “hierarchical
20 tests” and inserting “tiered testing”;
21 and

22 (ii) in subparagraph (B), by striking
23 “data” and inserting “information”;

24 (C) in paragraph (3)—

1 (i) by striking “data” each place it
2 appears and inserting “information”;

3 (ii) in subparagraph (A), by inserting
4 “or (C), as applicable,” after “subpara-
5 graph (B)”;

6 (iii) by striking “(a)(1)(A)(ii) or
7 (a)(1)(B)(ii)” each place it appears in sub-
8 paragraph (B) and inserting
9 “(a)(1)(A)(i)(II) or (a)(1)(A)(ii)(II)”;

10 (iv) in subparagraph (B), in the mat-
11 ter before clause (i), by striking “sub-
12 section (a)” and inserting “subsection
13 (a)(1)”;

14 (v) by adding at the end the following:
15 “(C) A rule or order under paragraph (1) or (2) of
16 subsection (a) may require the development of information
17 by any person who manufactures or processes, or intends
18 to manufacture or process, a chemical substance or mix-
19 ture subject to the rule or order.”;

20 (D) in paragraph (4)—

21 (i) by striking “of data” each place it
22 appears and inserting “of information”;
23 and

1 (ii) by striking “test data” each place
2 it appears and inserting “information”;
3 and

4 (E) by striking paragraph (5);
5 (4) in subsection (c)—

6 (A) in paragraph (1), by striking “data”
7 and inserting “information”;

8 (B) in paragraph (2), by striking “data”
9 each place it appears and inserting “informa-
10 tion”;

11 (C) in paragraph (3)—

12 (i) by striking “test data” each place
13 it appears and inserting “information”;
14 and

15 (ii) by striking “such data” each place
16 it appears and inserting “such informa-
17 tion”; and

18 (D) in paragraph (4) by striking “test
19 data” each place it appears and inserting “in-
20 formation”;

21 (5) in subsection (d)—

22 (A) by striking “test data” each place it
23 appears and inserting “information”;

24 (B) by striking “such data” each place it
25 appears and inserting “such information”; and

1 (C) by striking “for which data have” and
2 inserting “for which information has”;

3 (6) in subsection (e)—

4 (A) in paragraph (1)—

5 (i) in subparagraph (A)—

6 (I) by striking “promulgation of
7 a rule” and inserting “development of
8 information”; and

9 (II) by striking “data” each place
10 it appears and inserting “informa-
11 tion”; and

12 (ii) in subparagraph (B), by striking
13 “either initiate a rulemaking proceeding
14 under subsection (a) or if such a pro-
15 ceeding is not initiated within such period,
16 publish in the Federal Register the Admin-
17 istrator’s reason for not initiating such a
18 proceeding” and insert “issue an order,
19 enter into a consent agreement, or initiate
20 a rulemaking proceeding under subsection
21 (a), or, if such an order or consent agree-
22 ment is not issued or such a proceeding is
23 not initiated within such period, publish in
24 the Federal Register the Administrator’s
25 reason for not issuing such an order, en-

1 tering into such a consent agreement, or
2 initiating such a proceeding”; and

3 (B) in paragraph (2)(A)—

4 (i) by striking “eight members” and
5 inserting “ten members”; and

6 (ii) by adding at the end the fol-
7 lowing:

8 “(ix) One member appointed by the Chairman
9 of the Consumer Product Safety Commission from
10 Commissioners or employees of the Commission.

11 “(x) One member appointed by the Commis-
12 sioner of Food and Drugs from employees of the
13 Food and Drug Administration.”;

14 (7) in subsection (f)—

15 (A) in paragraph (1), by striking “test
16 data” and inserting “information”; and

17 (B) in the matter following paragraph
18 (2)—

19 (i) by striking “from cancer, gene
20 mutations, or birth defects”;

21 (ii) by striking “data or”;

22 (iii) by striking “appropriate” and in-
23 serting “applicable”; and

24 (iv) by inserting “, made without con-
25 sideration of costs or other nonrisk fac-

1 tors,” after “publish in the Federal Reg-
2 ister a finding”;

3 (8) in subsection (g)—

4 (A) by amending the subsection heading to
5 read as follows:“PETITION FOR PROTOCOLS
6 AND METHODOLOGIES FOR THE DEVELOPMENT
7 OF INFORMATION”;

8 (B) by striking “test data” each place it
9 appears and inserting “information”; and

10 (C) by striking “submit data” and insert-
11 ing “submit information”; and

12 (9) by adding at the end the following:

13 “(h) REDUCTION OF TESTING ON VERTEBRATES.—

14 “(1) IN GENERAL.—The Administrator shall re-
15 duce and replace, to the extent practicable, scientif-
16 ically justified, and consistent with the policies of
17 this title, the use of vertebrate animals in the testing
18 of chemical substances or mixtures under this title
19 by—

20 “(A) prior to making a request or adopting
21 a requirement for testing using vertebrate ani-
22 mals, and in accordance with subsection (a)(3),
23 taking into consideration, as appropriate and to
24 the extent practicable and scientifically justi-

1 fied, reasonably available existing information,
2 including—

3 “(i) toxicity information;

4 “(ii) computational toxicology and
5 bioinformatics; and

6 “(iii) high-throughput screening meth-
7 ods and the prediction models of those
8 methods; and

9 “(B) encouraging and facilitating—

10 “(i) the use of scientifically valid test
11 methods and strategies that reduce or re-
12 place the use of vertebrate animals while
13 providing information of equivalent or bet-
14 ter scientific quality and relevance that will
15 support regulatory decisions under this
16 title;

17 “(ii) the grouping of 2 or more chem-
18 ical substances into scientifically appro-
19 priate categories in cases in which testing
20 of a chemical substance would provide sci-
21 entifically valid and useful information on
22 other chemical substances in the category;
23 and

24 “(iii) the formation of industry con-
25 sortia to jointly conduct testing to avoid

1 unnecessary duplication of tests, provided
2 that such consortia make all information
3 from such testing available to the Adminis-
4 trator.

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

10 “(A) not later than 2 years after the date
11 of enactment of the Frank R. Lautenberg
12 Chemical Safety for the 21st Century Act, de-
13 velop a strategic plan to promote the develop-
14 ment and implementation of alternative test
15 methods and strategies to reduce, refine, or re-
16 place vertebrate animal testing and provide in-
17 formation of equivalent or better scientific qual-
18 ity and relevance for assessing risks of injury to
19 health or the environment of chemical sub-
20 stances or mixtures through, for example—

21 “(i) computational toxicology and
22 bioinformatics;

23 “(ii) high-throughput screening meth-
24 ods;

1 “(iii) testing of categories of chemical
2 substances;

3 “(iv) tiered testing methods;

4 “(v) in vitro studies;

5 “(vi) systems biology;

6 “(vii) new or revised methods identi-
7 fied by validation bodies such as the Inter-
8 agency Coordinating Committee on the
9 Validation of Alternative Methods or the
10 Organization for Economic Co-operation
11 and Development; or

12 “(viii) industry consortia that develop
13 information submitted under this title;

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

18 “(C) include in the strategic plan devel-
19 oped under subparagraph (A) a list, which the
20 Administrator shall update on a regular basis,
21 of particular alternative test methods or strate-
22 gies the Administrator has identified that do
23 not require new vertebrate animal testing and
24 are scientifically reliable, relevant, and capable
25 of providing information of equivalent or better

1 scientific reliability and quality to that which
2 would be obtained from vertebrate animal test-
3 ing;

4 “(D) provide an opportunity for public no-
5 tice and comment on the contents of the plan
6 developed under subparagraph (A), including
7 the criteria for considering scientific reliability
8 and relevance of the test methods and strate-
9 gies that may be identified pursuant to sub-
10 paragraph (C);

11 “(E) beginning on the date that is 5 years
12 after the date of enactment of the Frank R.
13 Lautenberg Chemical Safety for the 21st Cen-
14 tury Act, and every 5 years thereafter, submit
15 to Congress a report that describes the progress
16 made in implementing the plan developed under
17 subparagraph (A) and goals for future alter-
18 native test methods and strategies implementa-
19 tion; and

20 “(F) prioritize and, to the extent con-
21 sistent with available resources and the Admin-
22 istrator’s other responsibilities under this title,
23 carry out performance assessment, validation,
24 and translational studies to accelerate the devel-
25 opment of scientifically valid test methods and

1 strategies that reduce, refine, or replace the use
2 of vertebrate animals, including minimizing du-
3 plication, in any testing under this title.

4 “(3) VOLUNTARY TESTING.—

5 “(A) IN GENERAL.—Any person developing
6 information for submission under this title on a
7 voluntary basis and not pursuant to any request
8 or requirement by the Administrator shall first
9 attempt to develop the information by means of
10 an alternative test method or strategy identified
11 by the Administrator pursuant to paragraph
12 (2)(C), if the Administrator has identified such
13 a test method or strategy for the development
14 of such information, before conducting new
15 vertebrate animal testing.

16 “(B) EFFECT OF PARAGRAPH.—Nothing
17 in this paragraph shall, under any cir-
18 cumstance, limit or restrict the submission of
19 any existing information to the Administrator.

20 “(C) RELATIONSHIP TO OTHER LAW.—A
21 violation of this paragraph shall not be a pro-
22 hibited act under section 15.

23 “(D) REVIEW OF MEANS.—This paragraph
24 authorizes, but does not require, the Adminis-
25 trator to review the means by which a person

1 conducted testing described in subparagraph
2 (A).”.

3 **SEC. 5. MANUFACTURING AND PROCESSING NOTICES.**

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

6 (1) in subsection (a)—

7 (A) in paragraph (1)—

8 (i) by striking “Except as provided
9 in” and inserting “(A) Except as provided
10 in subparagraph (B) of this paragraph
11 and”;

12 (ii) by redesignating subparagraphs
13 (A) and (B) as clauses (i) and (ii), respec-
14 tively;

15 (iii) by striking all that follows “sig-
16 nificant new use” and inserting a period;
17 and

18 (iv) by adding at the end the fol-
19 lowing:

20 “(B) A person may take the actions described
21 in subparagraph (A) if—

22 “(i) such person submits to the Adminis-
23 trator, at least 90 days before such manufac-
24 ture or processing, a notice, in accordance with
25 subsection (d), of such person’s intention to

1 manufacture or process such substance and
2 such person complies with any applicable re-
3 quirement of, or imposed pursuant to, sub-
4 section (b), (e), or (f); and

5 “(ii) the Administrator—

6 “(I) conducts a review of the notice;

7 and

8 “(II) makes a determination under
9 subparagraph (A), (B), (C), or (D) of
10 paragraph (3) and takes the actions re-
11 quired in association with that determina-
12 tion under such subparagraph within the
13 applicable review period.”; and

14 (B) by adding at the end the following new
15 paragraphs:

16 “(3) REVIEW AND DETERMINATION.—Within
17 the applicable review period, subject to section 18,
18 the Administrator shall review such notice and de-
19 termine—

20 “(A) that the relevant chemical substance
21 or significant new use presents or will present
22 an unreasonable risk of injury to health or the
23 environment, without consideration of costs or
24 other nonrisk factors, including an unreason-
25 able risk to a potentially exposed or susceptible

1 subpopulation identified as relevant by the Ad-
2 ministrator under the conditions of use, in
3 which case the Administrator shall take the ac-
4 tions required under subsection (f);

5 “(B) that—

6 “(i) the information available to the
7 Administrator is insufficient to permit a
8 reasoned evaluation of the health and envi-
9 ronmental effects of the relevant chemical
10 substance or significant new use; or

11 “(ii)(I) in the absence of sufficient in-
12 formation to permit the Administrator to
13 make such an evaluation, the manufacture,
14 processing, distribution in commerce, use,
15 or disposal of such substance, or any com-
16 bination of such activities, may present an
17 unreasonable risk of injury to health or the
18 environment, without consideration of costs
19 or other nonrisk factors, including an un-
20 reasonable risk to a potentially exposed or
21 susceptible subpopulation identified as rel-
22 evant by the Administrator; or

23 “(II) such substance is or will be pro-
24 duced in substantial quantities, and such
25 substance either enters or may reasonably

1 be anticipated to enter the environment in
2 substantial quantities or there is or may be
3 significant or substantial human exposure
4 to the substance,

5 in which case the Administrator shall take the
6 actions required under subsection (e);

7 “(C) that the relevant chemical substance
8 or significant new use is likely not to present an
9 unreasonable risk of injury to health or the en-
10 vironment, without consideration of costs or
11 other nonrisk factors, including an unreason-
12 able risk to a potentially exposed or susceptible
13 subpopulation identified as relevant by the Ad-
14 ministrator under the conditions of use, in
15 which case the submitter of the notice may
16 commence manufacture of the chemical sub-
17 stance or manufacture or processing for a sig-
18 nificant new use; or

19 “(D) that the relevant chemical substance
20 is a low-hazard substance, in which case the
21 submitter of the notice may commence manu-
22 facture of the chemical substance or manufac-
23 ture or processing of the chemical substance for
24 a significant new use.

25 “(4) FAILURE TO RENDER DETERMINATION.—

1 “(A) FAILURE TO RENDER DETERMINA-
2 TION.—If the Administrator fails to make a de-
3 termination on a notice under paragraph (3) by
4 the end of the applicable review period and the
5 notice has not been withdrawn by the sub-
6 mitter, the Administrator shall refund to the
7 submitter all applicable fees charged to the sub-
8 mitter for review of the notice pursuant to sec-
9 tion 26(b), and the Administrator shall not be
10 relieved of any requirement to make such deter-
11 mination.

12 “(B) LIMITATIONS.—(i) A refund of appli-
13 cable fees under subparagraph (A) shall not be
14 made if the Administrator certifies that the
15 submitter has not provided information required
16 under subsection (b) or has otherwise unduly
17 delayed the process such that the Administrator
18 is unable to render a determination within the
19 applicable review period.

20 “(ii) A failure of the Administrator to
21 render a decision shall not be deemed to con-
22 stitute a withdrawal of the notice.

23 “(iii) Nothing in this paragraph shall be
24 construed as relieving the Administrator or the

1 submitter of the notice from any requirement of
2 this section.

3 “(5) ARTICLE CONSIDERATION.—The Adminis-
4 trator may require notification under this section for
5 the import or processing of a chemical substance as
6 part of an article or category of articles under para-
7 graph (1)(A)(ii) if the Administrator makes an af-
8 firmative finding in a rule under paragraph (2) that
9 the reasonable potential for exposure to the chemical
10 substance through the article or category of articles
11 subject to the rule justifies notification.”;

12 (2) in subsection (b)—

13 (A) in the subsection heading, by striking
14 “TEST DATA” and inserting “INFORMATION”;

15 (B) in paragraph (1)—

16 (i) in subparagraph (A)—

17 (I) by striking “test data” and
18 inserting “information”; and

19 (II) by striking “such data” and
20 inserting “such information”; and

21 (ii) in subparagraph (B)—

22 (I) by striking “test data” and
23 inserting “information”;

1 (II) by striking “subsection
2 (a)(1)(A)” and inserting “subsection
3 (a)(1)(A)(i)”; and

4 (III) by striking “subsection
5 (a)(1)(B)” and inserting “subsection
6 (a)(1)(A)(ii)”;

7 (C) in paragraph (2)—

8 (i) in subparagraph (A)—

9 (I) by striking “test data” in
10 clause (ii) and inserting “informa-
11 tion”;

12 (II) by striking “shall” and in-
13 serting “may”; and

14 (III) by striking “data pre-
15 scribed” and inserting “information
16 prescribed”; and

17 (ii) in subparagraph (B)—

18 (I) by striking “Data” and in-
19 serting “Information”;

20 (II) by striking “data” both
21 places it appears and inserting “infor-
22 mation”;

23 (III) by striking “show” and in-
24 serting “shows”;

1 (IV) by striking “subsection
2 (a)(1)(A)” in clause (i) and inserting
3 “subsection (a)(1)(A)(i)”; and

4 (V) by striking “subsection
5 (a)(1)(B)” in clause (ii) and inserting
6 “subsection (a)(1)(A)(ii)”;

7 (D) in paragraph (3)—

8 (i) by striking “Data” and inserting
9 “Information”; and

10 (ii) by striking “paragraph (1) or (2)”
11 and inserting “paragraph (1) or (2) of this
12 subsection or under subsection (e)”; and

13 (E) in paragraph (4)—

14 (i) in subparagraph (A)(i), by insert-
15 ing “, without consideration of costs or
16 other nonrisk factors” after “health or the
17 environment”; and

18 (ii) in subparagraph (C), by striking
19 “, except that” and all that follows
20 through “subparagraph (A)”;

21 (3) in subsection (c)—

22 (A) in the subsection heading, by striking
23 “NOTICE” and inserting “REVIEW”; and

24 (B) by striking “before which” and all that
25 follows through “subsection may begin”;

1 (4) in subsection (d)—

2 (A) by striking “test data” in paragraph
3 (1)(B) and inserting “information”;

4 (B) by striking “data” each place it ap-
5 pears in paragraph (1)(C) and paragraph (2)
6 and inserting “information”;

7 (C) in paragraph (2)(B), by striking “uses
8 or intended uses of such substance” and insert-
9 ing “uses of such substance identified in the no-
10 tice”; and

11 (D) in paragraph (3)—

12 (i) by striking “for which the notifica-
13 tion period prescribed by subsection (a),
14 (b), or (c)” and inserting “for which the
15 applicable review period”; and

16 (ii) by striking “such notification pe-
17 riod” and inserting “such period”;

18 (5) in subsection (e)—

19 (A) in paragraph (1)(A)—

20 (i) in clause (i), by striking “; and”
21 and inserting “; or”;

22 (ii) in clause (ii)(I), by inserting
23 “without consideration of costs or other
24 nonrisk factors, including an unreasonable
25 risk to a potentially exposed subpopulation

1 identified as relevant by the Administrator
2 under the conditions of use;” after “health
3 or the environment,”; and

4 (iii) in the matter after clause
5 (ii)(II)—

6 (I) by striking “may issue a pro-
7 posed order” and inserting “shall
8 issue an order”;

9 (II) by striking “notification pe-
10 riod applicable to the manufacturing
11 or processing of such substance under
12 subsection (a), (b), (c)” and inserting
13 “applicable review period”; and

14 (III) by inserting “to the extent
15 necessary to protect against an unrea-
16 sonable risk of injury to health or the
17 environment, without consideration of
18 costs or other nonrisk factors, includ-
19 ing an unreasonable risk to a poten-
20 tially exposed or susceptible sub-
21 population identified as relevant by
22 the Administrator under the condi-
23 tions of use, and the submitter of the
24 notice may commence manufacture of
25 the chemical substance, or manufac-

1 ture or processing of the chemical
2 substance for a significant new use,
3 including while any required informa-
4 tion is being developed, only in com-
5 pliance with the order” before the pe-
6 riod at the end;

7 (B) in paragraph (1)(B)—

8 (i) by striking “A proposed order”
9 and inserting “An order”;

10 (ii) by striking “notification period
11 applicable to the manufacture or proc-
12 essing of such substance under subsection
13 (a), (b), (c)” and inserting “applicable re-
14 view period”; and

15 (iii) by striking “of the proposed
16 order” and inserting “of the order”;

17 (C) by striking paragraph (1)(C); and

18 (D) by striking paragraph (2);

19 (6) in subsection (f)—

20 (A) in paragraph (1)—

21 (i) by striking “finds that there is a
22 reasonable basis to conclude that the man-
23 ufacture, processing, distribution in com-
24 merce, use, or disposal of a chemical sub-
25 stance with” and inserting “determines

1 that a chemical substance or significant
2 new use with”;

3 (ii) by striking “, or that any com-
4 bination of such activities,”;

5 (iii) by striking “before a rule promul-
6 gated under section 6 can protect against
7 such risk,” and inserting “, without con-
8 sideration of costs or other nonrisk factors,
9 including an unreasonable risk to a poten-
10 tially exposed subpopulation identified as
11 relevant by the Administrator under the
12 conditions of use,”; and

13 (iv) by striking “notification period
14 applicable under subsection (a), (b), or (c)
15 to the manufacturing or processing of such
16 substance” and inserting “applicable re-
17 view period”;

18 (B) in paragraph (2), the matter following
19 subparagraph (C), by striking “Section
20 6(d)(2)(B)” and inserting “Section
21 6(d)(3)(B)”;

22 (C) in paragraph (3)—

23 (i) in subparagraph (A)—

24 (I) by striking “Administrator
25 may” and all that follows through

1 “issue a proposed order to prohibit
2 the” and inserting “Administrator
3 may issue an order to prohibit or limit
4 the”; and

5 (II) by striking “under para-
6 graph (1)” and all that follows
7 through “processing of such sub-
8 stance.” and inserting “under para-
9 graph (1). Such order shall take effect
10 on the expiration of the applicable re-
11 view period.”;

12 (ii) by striking subparagraph (B) and
13 redesignating subparagraph (C) as sub-
14 paragraph (B);

15 (iii) in subparagraph (B), as so redes-
16 ignated—

17 (I) by striking “subparagraphs
18 (B) and (C)” and inserting “subpara-
19 graph (B)”;

20 (II) by striking “clause (i) of”;
21 and

22 (III) by striking “; and the provi-
23 sions of subparagraph (C) of sub-
24 section (e)(2) shall apply with respect

1 to an injunction issued under sub-
2 paragraph (B)”; and

3 (iv) by striking subparagraph (D);

4 and

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

6 “(4) TREATMENT OF NONCONFORMING USES.—

7 Not later than 90 days after taking an action under
8 paragraph (2) or (3) or issuing an order under sub-
9 section (e) relating to a chemical substance with re-
10 spect to which the Administrator has made a deter-
11 mination under subsection (a)(3)(A) or (B), the Ad-
12 ministrator shall consider whether to promulgate a
13 rule pursuant to subsection (a)(2) that identifies as
14 a significant new use any manufacturing, processing,
15 use, distribution in commerce, or disposal of the
16 chemical substance that does not conform to the re-
17 strictions imposed by the action or order, and, as ap-
18 plicable, initiate such a rulemaking or publish a
19 statement describing the reasons of the Adminis-
20 trator for not initiating such a rulemaking.

21 “(5) WORKPLACE EXPOSURES.—To the extent
22 practicable, the Administrator shall consult with the
23 Assistant Secretary of Labor for Occupational Safe-
24 ty and Health prior to adopting any prohibition or
25 other restriction relating to a chemical substance

1 with respect to which the Administrator has made a
2 determination under subsection (a)(3)(A) or (B) to
3 address workplace exposures.”;

4 (7) by amending subsection (g) to read as fol-
5 lows:

6 “(g) STATEMENT ON ADMINISTRATOR FINDING.—If
7 the Administrator finds in accordance with subsection
8 (a)(3)(C) that a chemical substance or significant new use
9 is likely not to present an unreasonable risk of injury to
10 health or the environment, or in accordance with sub-
11 section (a)(3)(D) that the chemical substance is a low-haz-
12 ard substance, then notwithstanding any remaining por-
13 tion of the applicable review period, the submitter of the
14 notice may commence manufacture of the chemical sub-
15 stance or manufacture or processing for the significant
16 new use, and the Administrator shall make public a state-
17 ment of the Administrator’s finding. Such a statement
18 shall be submitted for publication in the Federal Register
19 as soon as is practicable before the expiration of such pe-
20 riod. Publication of such statement in accordance with the
21 preceding sentence is not a prerequisite to the manufac-
22 turing or processing of the substance with respect to which
23 the statement is to be published.”;

24 (8) in subsection (h)—

1 (A) in paragraph (1)(A), by inserting “,
2 including an unreasonable risk to a potentially
3 exposed or susceptible subpopulation identified
4 by the Administrator for the specific conditions
5 of use identified in the application” after
6 “health or the environment”;

7 (B) in paragraph (2), by striking “data”
8 each place it appears and inserting “informa-
9 tion”; and

10 (C) in paragraph (4), by striking “. A rule
11 promulgated” and all that follows through “sec-
12 tion 6(c)” and inserting “, including an unrea-
13 sonable risk to a potentially exposed or suscep-
14 tible subpopulation identified by the Adminis-
15 trator under the conditions of use”; and

16 (9) by amending subsection (i) to read as fol-
17 lows:

18 “(i) DEFINITIONS.—(1) For purposes of this section,
19 the terms ‘manufacture’ and ‘process’ mean manufac-
20 turing or processing for commercial purposes.

21 “(2) For purposes of this Act, the term ‘requirement’
22 as used in this section shall not displace any statutory or
23 common law.

24 “(3) For purposes of this section, the term ‘applicable
25 review period’ means the period starting on the date the

1 Administrator receives a notice under subsection (a)(1)
2 and ending 90 days after that date, or on such date as
3 is provided for in subsection (b)(1) or (c).”.

4 **SEC. 6. PRIORITIZATION, RISK EVALUATION, AND REGULA-**
5 **TION OF CHEMICAL SUBSTANCES AND MIX-**
6 **TURES.**

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

9 (1) by striking the section heading and insert-
10 ing “**PRIORITIZATION, RISK EVALUATION, AND**
11 **REGULATION OF CHEMICAL SUBSTANCES AND**
12 **MIXTURES**”;

13 (2) in subsection (a)—

14 (A) by striking “finds that there is a rea-
15 sonable basis to conclude” and inserting “deter-
16 mines in accordance with subsection (b)(4)(A)”;

17 (B) by inserting “and subject to section
18 18, and in accordance with subsection (c)(2),”
19 after “shall by rule”;

20 (C) by striking “to protect adequately
21 against such risk using the least burdensome
22 requirements” and inserting “so that the chem-
23 ical substance or mixture no longer presents
24 such risk”;

1 (D) by inserting “or otherwise restricting”
2 after “prohibiting” in paragraphs (1)(A) and
3 (2)(A);

4 (E) by inserting “minimum” before “warn-
5 ings” both places it appears in paragraph (3);

6 (F) by striking “and monitor or conduct
7 tests” and inserting “or monitor or conduct
8 tests” in paragraph (4); and

9 (G) in paragraph (7)—

10 (i) by striking “such unreasonable
11 risk of injury” and inserting “such deter-
12 mination”; and

13 (ii) by striking “such risk of injury”
14 and inserting “such determination”;

15 (3) by amending subsection (b) to read as fol-
16 lows:

17 “(b) RISK EVALUATIONS.—

18 “(1) PRIORITIZATION FOR RISK EVALUA-
19 TIONS.—

20 “(A) ESTABLISHMENT OF PROCESS.—Not
21 later than 1 year after the date of enactment of
22 the Frank R. Lautenberg Chemical Safety for
23 the 21st Century Act, the Administrator shall
24 establish, by rule, a risk-based screening proc-
25 ess, including criteria for designating chemical

1 substances as high-priority substances for risk
2 evaluations or low-priority substances for which
3 risk evaluations are not warranted at the time.
4 The process to designate the priority of chem-
5 ical substances shall include a consideration of
6 the hazard and exposure potential of a chemical
7 substance or a category of chemical substances
8 (including consideration of persistence and bio-
9 accumulation, potentially exposed or susceptible
10 subpopulations and storage near significant
11 sources of drinking water), the conditions of use
12 or significant changes in the conditions of use
13 of the chemical substance, and the volume or
14 significant changes in the volume of the chem-
15 ical substance manufactured or processed.

16 “(B) IDENTIFICATION OF PRIORITIES FOR
17 RISK EVALUATION.—

18 “(i) HIGH-PRIORITY SUBSTANCES.—

19 The Administrator shall designate as a
20 high-priority substance a chemical sub-
21 stance that the Administrator concludes,
22 without consideration of costs or other
23 nonrisk factors, may present an unreason-
24 able risk of injury to health or the environ-
25 ment because of a potential hazard and a

1 potential route of exposure under the con-
2 ditions of use, including an unreasonable
3 risk to a potentially exposed or susceptible
4 subpopulation identified as relevant by the
5 Administrator.

6 “(ii) LOW-PRIORITY SUBSTANCES.—
7 Except as provided in clause (iii), the Ad-
8 ministrator shall designate a chemical sub-
9 stance as a low-priority substance if the
10 Administrator concludes, based on infor-
11 mation sufficient to establish, without con-
12 sideration of costs or other nonrisk factors,
13 that such substance does not meet the
14 standard identified in clause (i) for desig-
15 nating a chemical substance a high-priority
16 substance.

17 “(iii) LOW-HAZARD SUBSTANCES.—
18 The Administrator may designate a low-
19 priority substance as a low-hazard sub-
20 stance if the Administrator concludes,
21 based on information sufficient to estab-
22 lish, without consideration of costs or other
23 nonrisk factors or exposure, that the chem-
24 ical substance poses no or low hazard to
25 health or the environment, including any

1 hazard to a potentially exposed or suscep-
2 tible subpopulation identified as relevant
3 by the Administrator.

4 “(C) INFORMATION REQUEST AND REVIEW
5 AND PROPOSED AND FINAL PRIORITIZATION
6 DESIGNATION.—The rulemaking required in
7 subparagraph (A) shall ensure that the time re-
8 quired to make a priority designation of a
9 chemical substance be no shorter than nine
10 months and no longer than 1 year, and that the
11 process for such designations includes—

12 “(i) a requirement that the Adminis-
13 trator request interested persons to submit
14 relevant information on a chemical sub-
15 stance that the Administrator has initiated
16 the prioritization process on, before pro-
17 posing a priority designation for the chem-
18 ical substance, and provide 90 days for
19 such information to be provided;

20 “(ii) a requirement that the Adminis-
21 trator publish each proposed designation of
22 a chemical substance as a high- or low-pri-
23 ority substance, along with an identifica-
24 tion of the information, analysis, and basis
25 used to make the proposed designations,

1 and provide 90 days for public comment on
2 each such proposed designation; and

3 “(iii) a process by which the Adminis-
4 trator may extend the deadline in clause
5 (i) for up to three months in order to re-
6 ceive or evaluate information required to
7 be submitted in accordance with section
8 4(a)(2)(B), subject to the limitation that if
9 the information available to the Adminis-
10 trator at the end of such an extension re-
11 mains insufficient to enable the designa-
12 tion of the chemical substance as a low-pri-
13 ority substance, the Administrator shall
14 designate the chemical substance as a
15 high-priority substance.

16 “(2) INITIAL RISK EVALUATIONS AND SUBSE-
17 QUENT DESIGNATIONS OF HIGH- AND LOW-PRIORITY
18 SUBSTANCES.—

19 “(A) INITIAL RISK EVALUATIONS.—Not
20 later than 180 days after the date of enactment
21 of the Frank R. Lautenberg Chemical Safety
22 for the 21st Century Act, the Administrator
23 shall ensure that risk evaluations are being con-
24 ducted on at least 10 chemical substances
25 drawn from the 2014 update of the TSCA

1 Work Plan for Chemical Assessments and shall
2 publish the list of such chemical substances
3 during the 180 day period.

4 “(B) ADDITIONAL RISK EVALUATIONS.—
5 Not later than three and one half years after
6 the date of enactment of the Frank R. Lauten-
7 berg Chemical Safety for the 21st Century Act,
8 the Administrator shall ensure that risk evalua-
9 tions are being conducted on at least 20 high-
10 priority substances and that at least 20 chem-
11 ical substances have been designated as low-pri-
12 ority or low-hazard substances, subject to the
13 limitation that at least 50 percent of all chem-
14 ical substances on which risk evaluations are
15 being conducted by the Administrator are
16 drawn from the 2014 update of the TSCA
17 Work Plan for Chemical Assessments.

18 “(C) CONTINUING DESIGNATIONS AND
19 RISK EVALUATIONS.—The Administrator shall
20 continue to designate priority substances and
21 conduct risk evaluations in accordance with this
22 subsection at a pace consistent with the ability
23 of the Administrator to complete risk evalua-
24 tions in accordance with the deadlines under
25 paragraph (4)(G).

1 “(D) PREFERENCE.—In designating high-
2 priority substances, the Administrator shall give
3 preference to—

4 “(i) chemical substances that are list-
5 ed in the 2014 update of the TSCA Work
6 Plan for Chemical Assessments as having a
7 Persistence and Bioaccumulation Score of
8 3; and

9 “(ii) chemical substances that are list-
10 ed in the 2014 update of the TSCA Work
11 Plan for Chemical Assessments that are
12 known human carcinogens and have high
13 acute and chronic toxicity.

14 “(E) METALS AND METAL COMPOUNDS.—
15 In identifying priorities for risk evaluation and
16 conducting risk evaluations of metals and metal
17 compounds, the Administrator shall use the
18 Framework for Metals Risk Assessment of the
19 Office of the Science Advisor, Risk Assessment
20 Forum, and dated March 2007, or a successor
21 document that addresses metals risk assessment
22 and is peer reviewed by the Science Advisory
23 Board.

24 “(3) INITIATION OF RISK EVALUATIONS; DES-
25 IGNATIONS.—

1 “(A) RISK EVALUATION INITIATION.—
2 Upon designating a chemical substance as a
3 high-priority substance, the Administrator shall
4 initiate a risk evaluation on the substance.

5 “(B) REVISION.—The Administrator may
6 revise the designation of a low-priority sub-
7 stance or a low-hazard substance based on in-
8 formation made available to the Administrator.

9 “(C) ONGOING DESIGNATIONS.—The Ad-
10 ministrator shall designate at least one high-
11 priority substance upon the completion of each
12 risk evaluation (other than risk evaluations for
13 chemical substances designated under para-
14 graph (4)(C)(ii)).

15 “(4) RISK EVALUATION PROCESS AND DEAD-
16 LINES.—

17 “(A) IN GENERAL.—The Administrator
18 shall conduct risk evaluations pursuant to this
19 paragraph to determine whether a chemical
20 substance presents an unreasonable risk of in-
21 jury to health or the environment, without con-
22 sideration of costs or other nonrisk factors, in-
23 cluding an unreasonable risk to a potentially ex-
24 posed or susceptible subpopulation identified as

1 relevant to the risk evaluation by the Adminis-
2 trator, under the conditions of use.

3 “(B) ESTABLISHMENT OF PROCESS.—Not
4 later than 1 year after the date of enactment of
5 the Frank R. Lautenberg Chemical Safety for
6 the 21st Century Act, the Administrator shall
7 establish, by rule, a process to conduct risk
8 evaluations in accordance with subparagraph
9 (A).

10 “(C) REQUIREMENT.—The Administrator
11 shall conduct and publish risk evaluations, in
12 accordance with the rule promulgated under
13 subparagraph (B), for a chemical substance—

14 “(i) that has been identified under
15 paragraph (2)(A) or designated under
16 paragraph (1)(B)(i); and

17 “(ii) subject to subparagraph (E),
18 that a manufacturer of the chemical sub-
19 stance has requested, in a form and man-
20 ner and using the criteria prescribed by
21 the Administrator in the rule promulgated
22 under subparagraph (B), be subjected to a
23 risk evaluation.

24 “(D) SCOPE.—The Administrator shall,
25 not later than 6 months after the initiation of

1 a risk evaluation, publish the scope of the risk
2 evaluation to be conducted, including the haz-
3 ards, exposures, conditions of use, and the po-
4 tentially exposed or susceptible subpopulations
5 the Administrator expects to consider, and, for
6 each designation of a high-priority substance,
7 ensure not less than 12 months between the ini-
8 tiation of the prioritization process for the
9 chemical substance and the publication of the
10 scope of the risk evaluation for the chemical
11 substance, and for risk evaluations conducted
12 on chemical substances that have been identi-
13 fied under paragraph (2)(A) or selected under
14 subparagraph (E)(iv)(II) of this paragraph, en-
15 sure not less than 3 months before the Admin-
16 istrator publishes the scope of the risk evalua-
17 tion.

18 “(E) LIMITATION AND CRITERIA.—

19 “(i) PERCENTAGE REQUIREMENTS.—

20 The Administrator shall ensure that, of the
21 number of chemical substances that under-
22 go a risk evaluation under clause (i) of
23 subparagraph (C), the number of chemical
24 substances undergoing a risk evaluation
25 under clause (ii) of subparagraph (C) is—

1 “(I) not less than 25 percent, if
2 sufficient requests are made under
3 clause (ii) of subparagraph (C); and

4 “(II) not more than 50 percent.

5 “(ii) REQUESTED RISK EVALUA-
6 TIONS.—Requests for risk evaluations
7 under subparagraph (C)(ii) shall be subject
8 to the payment of fees pursuant to section
9 26(b), and the Administrator shall not ex-
10 pedite or otherwise provide special treat-
11 ment to such risk evaluations.

12 “(iii) PREFERENCE.—In deciding
13 whether to grant requests under subpara-
14 graph (C)(ii), the Administrator shall give
15 preference to requests for risk evaluations
16 on chemical substances for which the Ad-
17 ministrator determines that restrictions
18 imposed by 1 or more States have the po-
19 tential to have a significant impact on
20 interstate commerce or health or the envi-
21 ronment.

22 “(iv) EXCEPTIONS.—(I) Chemical
23 substances for which requests have been
24 granted under subparagraph (C)(ii) and
25 that are not drawn from the 2014 update

1 of the TSCA Work Plan for Chemical As-
2 sessments shall not be subject to section
3 18(b).

4 “(II) Requests for risk evaluations on
5 chemical substances which are made under
6 subparagraph (C)(ii) and that are drawn
7 from the 2014 update of the TSCA Work
8 Plan for Chemical Assessments shall be
9 granted at the discretion of the Adminis-
10 trator and not be subject to clause (i)(II).

11 “(F) REQUIREMENTS.—In conducting a
12 risk evaluation under this subsection, the Ad-
13 ministrator shall—

14 “(i) integrate and assess available in-
15 formation on hazards and exposures for
16 the conditions of use of the chemical sub-
17 stance, including information that is rel-
18 evant to specific risks of injury to health or
19 the environment and information on poten-
20 tially exposed or susceptible subpopulations
21 identified as relevant by the Administrator;

22 “(ii) describe whether aggregate or
23 sentinel exposures to a chemical substance
24 under the conditions of use were consid-
25 ered, and the basis for that consideration;

1 “(iii) not consider costs or other
2 nonrisk factors;

3 “(iv) take into account, where rel-
4 evant, the likely duration, intensity, fre-
5 quency, and number of exposures under
6 the conditions of use of the chemical sub-
7 stance; and

8 “(v) describe the weight of the sci-
9 entific evidence for the identified hazard
10 and exposure.

11 “(G) DEADLINES.—The Administrator—

12 “(i) shall complete a risk evaluation
13 for a chemical substance as soon as prac-
14 ticable, but not later than 3 years after the
15 date on which the Administrator initiates
16 the risk evaluation under subparagraph
17 (C); and

18 “(ii) may extend the deadline for a
19 risk evaluation for not more than 6
20 months.

21 “(H) NOTICE AND COMMENT.—The Ad-
22 ministrator shall provide no less than 30 days
23 public notice and an opportunity for comment
24 on a draft risk evaluation prior to publishing a
25 final risk evaluation.”;

1 (4) by amending subsection (c) to read as fol-
2 lows:

3 “(c) PROMULGATION OF SUBSECTION (a) RULES.—

4 “(1) DEADLINES.—If the Administrator deter-
5 mines that a chemical substance presents an unrea-
6 sonable risk of injury to health or the environment
7 in accordance with subsection (b)(4)(A), the Admin-
8 istrator—

9 “(A) shall propose in the Federal Register
10 a rule under subsection (a) for the chemical
11 substance not later than 1 year after the date
12 on which the final risk evaluation regarding the
13 chemical substance is published;

14 “(B) shall publish in the Federal Register
15 a final rule not later than 2 years after the date
16 on which the final risk evaluation regarding the
17 chemical substance is published; and

18 “(C) may extend the deadlines under this
19 paragraph for not more than two years, subject
20 to the condition that the aggregate length of ex-
21 tensions under this subparagraph and sub-
22 section (b)(4)(G)(ii) does not exceed two years,
23 and subject to the limitation that the Adminis-
24 trator may not extend a deadline for the publi-
25 cation of a proposed or final rule regarding a

1 chemical substance drawn from the 2014 up-
2 date of the TSCA Work Plan for Chemical As-
3 sessments or a chemical substance that, with
4 respect to persistence and bioaccumulation,
5 scores high for 1 and either high or moderate
6 for the other, pursuant to the TSCA Work Plan
7 Chemicals Methods Document published by the
8 Administrator in February 2012 (or a successor
9 scoring system), without adequate public jus-
10 tification that demonstrates, following a review
11 of the information reasonably available to the
12 Administrator, that the Administrator cannot
13 complete the proposed or final rule without ad-
14 ditional information regarding the chemical
15 substance.

16 “(2) REQUIREMENTS FOR RULE.—

17 “(A) STATEMENT OF EFFECTS.—In pro-
18 posing and promulgating a rule under sub-
19 section (a) with respect to a chemical substance
20 or mixture, the Administrator shall consider
21 and publish a statement based on reasonably
22 available information with respect to—

23 “(i) the effects of the chemical sub-
24 stance or mixture on health and the mag-

1 nitude of the exposure of human beings to
2 the chemical substance or mixture;

3 “(ii) the effects of the chemical sub-
4 stance or mixture on the environment and
5 the magnitude of the exposure of the envi-
6 ronment to such substance or mixture;

7 “(iii) the benefits of the chemical sub-
8 stance or mixture for various uses; and

9 “(iv) the reasonably ascertainable eco-
10 nomic consequences of the rule, including
11 consideration of—

12 “(I) the likely effect of the rule
13 on the national economy, small busi-
14 ness, technological innovation, the en-
15 vironment, and public health;

16 “(II) the costs and benefits of
17 the proposed and final regulatory ac-
18 tion and of the 1 or more primary al-
19 ternative regulatory actions considered
20 by the Administrator; and

21 “(III) the cost effectiveness of
22 the proposed regulatory action and of
23 the 1 or more primary alternative reg-
24 ulatory actions considered by the Ad-
25 ministrator.

1 “(B) SELECTING REQUIREMENTS.—In se-
2 lecting among prohibitions and other restric-
3 tions, the Administrator shall factor in, to the
4 extent practicable, the considerations under
5 subparagraph (A) in accordance with subsection
6 (a).

7 “(C) CONSIDERATION OF ALTER-
8 NATIVES.—Based on the information published
9 under subparagraph (A), in deciding whether to
10 prohibit or restrict in a manner that substan-
11 tially prevents a specific condition of use of a
12 chemical substance or mixture, and in setting
13 an appropriate transition period for such ac-
14 tion, the Administrator shall consider, to the
15 extent practicable, whether technically and eco-
16 nomically feasible alternatives that benefit
17 health or the environment, compared to the use
18 so proposed to be prohibited or restricted, will
19 be reasonably available as a substitute when the
20 proposed prohibition or other restriction takes
21 effect.

22 “(D) REPLACEMENT PARTS.—

23 “(i) IN GENERAL.—The Administrator
24 shall exempt replacement parts for complex
25 durable goods and complex consumer goods

1 that are designed prior to the date of pub-
2 lication in the Federal Register of the rule
3 under subsection (a), unless the Adminis-
4 trator finds that such replacement parts
5 contribute significantly to the risk, identi-
6 fied in a risk evaluation conducted under
7 subsection (b)(4)(A), to the general popu-
8 lation or to an identified potentially ex-
9 posed or susceptible subpopulation.

10 “(ii) DEFINITIONS.—In this subpara-
11 graph—

12 “(I) the term ‘complex consumer
13 goods’ means electronic or mechanical
14 devices composed of multiple manu-
15 factured components, with an in-
16 tended useful life of 3 or more years,
17 where the product is typically not con-
18 sumed, destroyed, or discarded after a
19 single use, and the components of
20 which would be impracticable to rede-
21 sign or replace; and

22 “(II) the term ‘complex durable
23 goods’ means manufactured goods
24 composed of 100 or more manufac-
25 tured components, with an intended

1 useful life of 5 or more years, where
2 the product is typically not consumed,
3 destroyed, or discarded after a single
4 use.

5 “(E) ARTICLES.—In selecting among pro-
6 hibitions and other restrictions, the Adminis-
7 trator shall apply such prohibitions or other re-
8 strictions to an article or category of articles
9 containing the chemical substance or mixture
10 only to the extent necessary to address the
11 identified risks from exposure to the chemical
12 substance or mixture from the article or cat-
13 egory of articles so that the substance or mix-
14 ture does not present an unreasonable risk of
15 injury to health or the environment identified in
16 the risk evaluation conducted in accordance
17 with subsection (b)(4)(A).

18 “(3) PROCEDURES.—When prescribing a rule
19 under subsection (a) the Administrator shall proceed
20 in accordance with section 553 of title 5, United
21 States Code (without regard to any reference in such
22 section to sections 556 and 557 of such title), and
23 shall also—

1 “(A) publish a notice of proposed rule-
2 making stating with particularity the reason for
3 the proposed rule;

4 “(B) allow interested persons to submit
5 written data, views, and arguments, and make
6 all such submissions publicly available;

7 “(C) promulgate a final rule based on the
8 matter in the rulemaking record; and

9 “(D) make and publish with the rule the
10 determination described in subsection (a).”;

11 (5) in subsection (d)—

12 (A) by redesignating paragraph (2) as
13 paragraph (3);

14 (B) by striking paragraph (1) and insert-
15 ing the following:

16 “(1) IN GENERAL.—In any rule under sub-
17 section (a), the Administrator shall—

18 “(A) specify the date on which it shall take
19 effect, which date shall be as soon as prac-
20 ticable;

21 “(B) except as provided in subparagraphs
22 (C) and (D), specify mandatory compliance
23 dates for all of the requirements under a rule
24 under subsection (a), which shall be as soon as
25 practicable, but not later than 5 years after the

1 date of promulgation of the rule, except in a
2 case of a use exempted under subsection (g);

3 “(C) specify mandatory compliance dates
4 for the start of ban or phase-out requirements
5 under a rule under subsection (a), which shall
6 be as soon as practicable, but not later than 5
7 years after the date of promulgation of the rule,
8 except in the case of a use exempted under sub-
9 section (g);

10 “(D) specify mandatory compliance dates
11 for full implementation of ban or phase-out re-
12 quirements under a rule under subsection (a),
13 which shall be as soon as practicable; and

14 “(E) provide for a reasonable transition
15 period.

16 “(2) VARIABILITY.—As determined by the Ad-
17 ministrator, the compliance dates established under
18 paragraph (1) may vary for different affected per-
19 sons.”; and

20 (C) in paragraph (3), as so redesignated
21 by subparagraph (A) of this paragraph—

22 (i) in subparagraph (A)—

23 (I) by striking “upon its publica-
24 tion” and all that follows through “re-
25 specting such rule if” and inserting “,

1 and compliance with the proposed re-
2 quirements to be mandatory, upon
3 publication in the Federal Register of
4 the proposed rule and until the com-
5 pliance dates applicable to such re-
6 quirements in a final rule promul-
7 gated under section 6(a) or until the
8 Administrator revokes such proposed
9 rule, in accordance with subparagraph
10 (B), if”; and

11 (II) in clause (i)(I), by inserting
12 “without consideration of costs or
13 other non-risk factors” after “effective
14 date”; and

15 (ii) in subparagraph (B), by striking
16 “, provide reasonable opportunity” and all
17 that follows through the period at the end
18 and inserting “in accordance with sub-
19 section (c), and either promulgate such
20 rule (as proposed or with modifications) or
21 revoke it.”;

22 (6) in subsection (e)(4), by striking “para-
23 graphs (2), (3), and (4)” and inserting “paragraph
24 (3)”; and

1 (7) by adding at the end the following new sub-
2 sections:

3 “(g) EXEMPTIONS.—

4 “(1) CRITERIA FOR EXEMPTION.—The Admin-
5 istrator may, as part of a rule promulgated under
6 subsection (a), or in a separate rule, grant an ex-
7 emption from a requirement of a subsection (a) rule
8 for a specific condition of use of a chemical sub-
9 stance or mixture, if the Administrator finds that—

10 “(A) the specific condition of use is a crit-
11 ical or essential use for which no technically
12 and economically feasible safer alternative is
13 available, taking into consideration hazard and
14 exposure;

15 “(B) compliance with the requirement, as
16 applied with respect to the specific condition of
17 use, would significantly disrupt the national
18 economy, national security, or critical infra-
19 structure; or

20 “(C) the specific condition of use of the
21 chemical substance or mixture, as compared to
22 reasonably available alternatives, provides a
23 substantial benefit to health, the environment,
24 or public safety.

1 “(2) EXEMPTION ANALYSIS AND STATEMENT.—

2 In proposing an exemption under this subsection,
3 the Administrator shall analyze the need for the ex-
4 emption, and shall make public the analysis and a
5 statement describing how the analysis was taken
6 into account.

7 “(3) PERIOD OF EXEMPTION.—The Adminis-
8 trator shall establish, as part of a rule under this
9 subsection, a time limit on any exemption for a time
10 to be determined by the Administrator as reasonable
11 on a case-by-case basis, and, by rule, may extend,
12 modify, or eliminate an exemption if the Adminis-
13 trator determines, on the basis of reasonably avail-
14 able information and after adequate public justifica-
15 tion, the exemption warrants extension or modifica-
16 tion or is no longer necessary.

17 “(4) CONDITIONS.—As part of a rule promul-
18 gated under this subsection, the Administrator shall
19 include conditions, including reasonable record-
20 keeping, monitoring, and reporting requirements, to
21 the extent that the Administrator determines the
22 conditions are necessary to protect health and the
23 environment while achieving the purposes of the ex-
24 emption.

1 “(h) CHEMICALS THAT ARE PERSISTENT, BIO-
2 ACCUMULATIVE, AND TOXIC.—

3 “(1) EXPEDITED ACTION.—Not later than 3
4 years after the date of enactment of the Frank R.
5 Lautenberg Chemical Safety for the 21st Century
6 Act, the Administrator shall propose rules under
7 subsection (a) with respect to chemical substances
8 identified in the 2014 update of the TSCA Work
9 Plan for Chemical Assessments—

10 “(A) that the Administrator has a reason-
11 able basis to conclude are toxic and that with
12 respect to persistence and bioaccumulation
13 score high for one and either high or moderate
14 for the other, pursuant to the TSCA Work Plan
15 Chemicals Methods Document published by the
16 Administrator in February 2012 (or a successor
17 scoring system), and are not a metal or a metal
18 compound, and for which the Administrator has
19 not completed a Work Plan Problem Formula-
20 tion, initiated a review under section 5, or en-
21 tered into a consent agreement under section 4,
22 prior to the date of enactment of the Frank R.
23 Lautenberg Chemical Safety for the 21st Cen-
24 tury Act; and

1 “(B) exposure to which under the condi-
2 tions of use is likely to the general population
3 or to a potentially exposed or susceptible sub-
4 population identified by the Administrator, or
5 the environment, on the basis of an exposure
6 and use assessment conducted by the Adminis-
7 trator.

8 “(2) NO RISK EVALUATION REQUIRED.—The
9 Administrator shall not be required to conduct risk
10 evaluations on chemical substances that are subject
11 to paragraph (1).

12 “(3) FINAL RULE.—Not later than 18 months
13 after proposing a rule pursuant to paragraph (1),
14 the Administrator shall promulgate a final rule
15 under subsection (a).

16 “(4) SELECTING RESTRICTIONS.—In selecting
17 among prohibitions and other restrictions promul-
18 gated in a rule under subsection (a) pursuant to
19 paragraph (1), the Administrator shall address the
20 risks of injury to health or the environment that the
21 Administrator determines are presented by the
22 chemical substance and shall reduce exposure to the
23 substance to the extent practicable.

24 “(5) RELATIONSHIP TO SUBSECTION (b).—If,
25 at any time prior to the date that is 90 days after

1 the date of enactment of the Frank R. Lautenberg
2 Chemical Safety for the 21st Century Act, the Ad-
3 ministrator makes a designation under subsection
4 (b)(1)(B)(i), or receives a request under subsection
5 (b)(4)(C)(ii) that meets the criteria prescribed by
6 the Administrator in the rule promulgated under
7 subsection (b)(4)(B), such chemical substance shall
8 not be subject to this subsection, except that in se-
9 lecting among prohibitions and other restrictions
10 promulgated in a rule pursuant to subsection (a),
11 the Administrator shall both ensure that the chem-
12 ical substance meets the rulemaking standard under
13 subsection (a) and reduce exposure to the substance
14 to the extent practicable.

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

17 “(1) a determination by the Administrator
18 under subsection (b)(4)(A) that a chemical sub-
19 stance does not present an unreasonable risk of in-
20 jury to health or the environment shall be issued by
21 order and considered to be a final agency action, ef-
22 fective beginning on the date of issuance of the
23 order; and

24 “(2) a final rule promulgated under subsection
25 (a), including the associated determination by the

1 Administrator under subsection (b)(4)(A) that a
2 chemical substance presents an unreasonable risk of
3 injury to health or the environment, shall be consid-
4 ered to be a final agency action, effective beginning
5 on the date of promulgation of the final rule.

6 “(j) DEFINITION.—For the purposes of this Act, the
7 term ‘requirement’ as used in this section shall not dis-
8 place statutory or common law.”.

9 **SEC. 7. IMMINENT HAZARDS.**

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

12 (1) in subsection (b)(1), by inserting “(as iden-
13 tified by the Administrator without consideration of
14 costs or other nonrisk factors)” after “from the un-
15 reasonable risk”; and

16 (2) in subsection (f), by inserting “, without
17 consideration of costs or other nonrisk factors” after
18 “widespread injury to health or the environment”.

19 **SEC. 8. REPORTING AND RETENTION OF INFORMATION.**

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

22 (1) in subsection (a)—

23 (A) in paragraph (2), by striking the mat-
24 ter that follows subparagraph (G);

1 (B) in paragraph (3), by adding at the end
2 the following:

3 “(C) Not later than 180 days after the date of enact-
4 ment of the Frank R. Lautenberg Chemical Safety for the
5 21st Century Act, and not less frequently than once every
6 10 years thereafter, the Administrator, after consultation
7 with the Administrator of the Small Business Administra-
8 tion, shall—

9 “(i) review the adequacy of the standards pre-
10 scribed under subparagraph (B); and

11 “(ii) after providing public notice and an oppor-
12 tunity for comment, make a determination as to
13 whether revision of the standards is warranted.”;
14 and

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

16 “(4) CONTENTS.—The rules promulgated pur-
17 suant to paragraph (1)—

18 “(A) may impose differing reporting and
19 recordkeeping requirements on manufacturers
20 and processors; and

21 “(B) shall include the level of detail nec-
22 essary to be reported, including the manner by
23 which use and exposure information may be re-
24 ported.

1 “(5) ADMINISTRATION.—In carrying out this
2 section, the Administrator shall, to the extent fea-
3 sible—

4 “(A) not require reporting which is unnec-
5 essary or duplicative;

6 “(B) minimize the cost of compliance with
7 this section and the rules issued thereunder on
8 small manufacturers and processors; and

9 “(C) apply any reporting obligations to
10 those persons likely to have information rel-
11 evant to the effective implementation of this
12 title.

13 “(6) NEGOTIATED RULEMAKING.—(A) The Ad-
14 ministrator shall enter into a negotiated rulemaking
15 pursuant to subchapter III of chapter 5 of title 5,
16 United States Code, to develop and publish, not
17 later than 3 years after the date of enactment of the
18 Frank R. Lautenberg Chemical Safety for the 21st
19 Century Act, a proposed rule providing for limiting
20 the reporting requirements, under this subsection,
21 for manufacturers of any inorganic byproducts,
22 when such byproducts, whether by the byproduct
23 manufacturer or by any other person, are subse-
24 quently recycled, reused, or reprocessed.

1 “(B) Not later than 3 and one-half years after
2 such date of enactment, the Administrator shall pub-
3 lish a final rule resulting from such negotiated rule-
4 making.”; and

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

7 “(3) NOMENCLATURE.—

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

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

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

24 “(iii) treat the individual members of
25 the categories of chemical substances iden-

1 tified by the Administrator as statutory
2 mixtures, as defined in Inventory descrip-
3 tions established by the Administrator, as
4 being included on the list established under
5 paragraph (1).

6 “(B) MULTIPLE NOMENCLATURE LIST-
7 INGS.—If a manufacturer or processor dem-
8 onstrates to the Administrator that a chemical
9 substance appears multiple times on the list
10 published under paragraph (1) under different
11 CAS numbers, the Administrator may recognize
12 the multiple listings as a single chemical sub-
13 stance.

14 “(C) RELATIONSHIP TO SECTION 5.—
15 Nothing in subparagraph (B), nor any action of
16 the Administrator pursuant to subparagraph
17 (B), shall be construed as a basis to conclude
18 that any chemical substance is not a new chem-
19 ical substance.

20 “(4) CHEMICAL SUBSTANCES IN COMMERCE.—

21 “(A) RULES.—

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

1 by rule, shall require manufacturers, and
2 may require processors, subject to the limi-
3 tations under subsection (a)(5)(A), to no-
4 tify the Administrator, by not later than
5 180 days after the date on which the final
6 rule is published in the Federal Register,
7 of each chemical substance on the list pub-
8 lished under paragraph (1) that the manu-
9 facturer or processor, as applicable, has
10 manufactured or processed for a non-
11 exempt commercial purpose during the 10-
12 year period ending on the day before the
13 date of enactment of the Frank R. Lauten-
14 berg Chemical Safety for the 21st Century
15 Act.

16 “(ii) ACTIVE SUBSTANCES.—The Ad-
17 ministrator shall designate chemical sub-
18 stances for which notices are received
19 under clause (i) to be active substances on
20 the list published under paragraph (1).

21 “(iii) INACTIVE SUBSTANCES.—The
22 Administrator shall designate chemical
23 substances for which no notices are re-
24 ceived under clause (i) to be inactive sub-

1 stances on the list published under para-
2 graph (1).

3 “(iv) LIMITATION.—No chemical sub-
4 stance on the list published under para-
5 graph (1) shall be removed from such list
6 by reason of the implementation of this
7 subparagraph, or be subject to section
8 5(a)(1)(A)(i) by reason of a change to ac-
9 tive status under paragraph (5)(B).

10 “(B) CONFIDENTIAL CHEMICAL SUB-
11 STANCES.—In promulgating a rule under sub-
12 paragraph (A), the Administrator shall—

13 “(i) maintain the list under paragraph
14 (1), which shall include a confidential por-
15 tion and a nonconfidential portion con-
16 sistent with this section and section 14;

17 “(ii) require any manufacturer or
18 processor of a chemical substance on the
19 confidential portion of the list published
20 under paragraph (1) that seeks to main-
21 tain an existing claim for protection
22 against disclosure of the specific chemical
23 identity of the chemical substance as con-
24 fidential pursuant to section 14 to submit

1 a notice under subparagraph (A) that in-
2 cludes such request;

3 “(iii) require the substantiation of
4 those claims pursuant to section 14 and in
5 accordance with the review plan described
6 in subparagraph (C); and

7 “(iv) move any active chemical sub-
8 stance for which no request was received to
9 maintain an existing claim for protection
10 against disclosure of the specific chemical
11 identity of the chemical substance as con-
12 fidential from the confidential portion of
13 the list published under paragraph (1) to
14 the nonconfidential portion of that list.

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

1 “(D) REQUIREMENTS OF REVIEW PLAN.—

2 In establishing the review plan under subpara-
3 graph (C), the Administrator shall—

4 “(i) require, at a time specified by the
5 Administrator, all manufacturers or proc-
6 essors asserting claims under subpara-
7 graph (B) to substantiate the claim, in ac-
8 cordance with section 14, unless the manu-
9 facturer or processor has substantiated the
10 claim in a submission made to the Admin-
11 istrator during the 5-year period ending on
12 the last day of the of the time period speci-
13 fied by the Administrator; and

14 “(ii) in accordance with section 14—

15 “(I) review each substantiation—

16 “(aa) submitted pursuant to
17 clause (i) to determine if the
18 claim qualifies for protection
19 from disclosure; and

20 “(bb) submitted previously
21 by a manufacturer or processor
22 and relied on in lieu of the sub-
23 stantiation required pursuant to
24 clause (i), if the substantiation
25 has not been previously reviewed

1 by the Administrator, to deter-
2 mine if the claim warrants pro-
3 tection from disclosure;

4 “(II) approve, approve in part
5 and deny in part, or deny each claim;
6 and

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

13 “(aa) the person notifies the
14 Administrator that the person is
15 withdrawing the claim, in which
16 case the Administrator shall not
17 protect the information from dis-
18 closure; or

19 “(bb) the Administrator oth-
20 erwise becomes aware that the
21 information does not qualify for
22 protection from disclosure, in
23 which case the Administrator
24 shall take the actions described
25 in section 14(g)(2).

1 “(E) TIMELINE FOR COMPLETION OF RE-
2 VIEWS.—

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

10 “(ii) CONSIDERATIONS.—

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

20 “(II) ANNUAL REVIEW GOAL AND
21 RESULTS.—At the beginning of each
22 year, the Administrator shall publish
23 an annual goal for reviews and the
24 number of reviews completed in the
25 prior year.

1 “(5) ACTIVE AND INACTIVE SUBSTANCES.—

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

6 “(B) CHANGE TO ACTIVE STATUS.—

7 “(i) IN GENERAL.—Any person that
8 intends to manufacture or process for a
9 nonexempt commercial purpose a chemical
10 substance that is designated as an inactive
11 substance shall notify the Administrator
12 before the date on which the inactive sub-
13 stance is manufactured or processed.

14 “(ii) CONFIDENTIAL CHEMICAL IDEN-
15 TITY.—If a person submitting a notice
16 under clause (i) for an inactive substance
17 on the confidential portion of the list pub-
18 lished under paragraph (1) seeks to main-
19 tain an existing claim for protection
20 against disclosure of the specific chemical
21 identity of the inactive substance as con-
22 fidential, the person shall, consistent with
23 the requirements of section 14—

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

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

4 “(iii) ACTIVE STATUS.—On receiving
5 a notification under clause (i), the Admin-
6 istrator shall—

7 “(I) designate the applicable
8 chemical substance as an active sub-
9 stance;

10 “(II) pursuant to section 14,
11 promptly review any claim and associ-
12 ated substantiation submitted pursu-
13 ant to clause (ii) for protection
14 against disclosure of the specific
15 chemical identity of the chemical sub-
16 stance and approve, approve in part
17 and deny in part, or deny the claim;

18 “(III) except as provided in this
19 section and section 14, protect from
20 disclosure the specific chemical iden-
21 tity of the chemical substance for
22 which the Administrator approves a
23 claim under subclause (II) for a pe-
24 riod of 10 years, unless, prior to the
25 expiration of the period—

1 “(aa) the person notifies the
2 Administrator that the person is
3 withdrawing the claim, in which
4 case the Administrator shall not
5 protect the information from dis-
6 closure; or

7 “(bb) the Administrator oth-
8 erwise becomes aware that the
9 information does not qualify for
10 protection from disclosure, in
11 which case the Administrator
12 shall take the actions described
13 in section 14(g)(2); and

14 “(IV) pursuant to section 6(b),
15 review the priority of the chemical
16 substance as the Administrator deter-
17 mines to be necessary.

18 “(C) CATEGORY STATUS.—The list of inac-
19 tive substances shall not be considered to be a
20 category for purposes of section 26(c).

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

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

8 “(7) PUBLIC INFORMATION.—Subject to this
9 subsection and section 14, the Administrator shall
10 make available to the public—

11 “(A) each specific chemical identity on the
12 nonconfidential portion of the list published
13 under paragraph (1) along with the Administra-
14 tor’s designation of the chemical substance as
15 an active or inactive substance;

16 “(B) the unique identifier assigned under
17 section 14, accession number, generic name,
18 and, if applicable, premanufacture notice case
19 number for each chemical substance on the con-
20 fidential portion of the list published under
21 paragraph (1) for which a claim of confiden-
22 tiality was received; and

23 “(C) the specific chemical identity of any
24 active substance for which—

1 “(i) a claim for protection against dis-
2 closure of the specific chemical identity of
3 the active substance was not asserted, as
4 required under this subsection or section
5 14;

6 “(ii) all claims for protection against
7 disclosure of the specific chemical identity
8 of the active substance have been denied
9 by the Administrator; or

10 “(iii) the time period for protection
11 against disclosure of the specific chemical
12 identity of the active substance has ex-
13 pired.

14 “(8) LIMITATION.—No person may assert a
15 new claim under this subsection or section 14 for
16 protection from disclosure of a specific chemical
17 identity of any active or inactive substance for which
18 a notice is received under paragraph (4)(A)(i) or
19 (5)(B)(i) that is not on the confidential portion of
20 the list published under paragraph (1).

21 “(9) CERTIFICATION.—Under the rules promul-
22 gated under this subsection, manufacturers and
23 processors, as applicable, shall be required—

24 “(A) to certify that each notice or substan-
25 tiation the manufacturer or processor submits

1 complies with the requirements of the rule, and
2 that any confidentiality claims are true and cor-
3 rect; and

4 “(B) to retain a record documenting com-
5 pliance with the rule and supporting confiden-
6 tiality claims for a period of 5 years beginning
7 on the last day of the submission period.”.

8 (b) MERCURY INVENTORY.—Section 8(b) of the
9 Toxic Substances Control Act (15 U.S.C. 2607(b)) (as
10 amended by subsection (a)) is further amended by adding
11 at the end the following:

12 “(10) MERCURY.—

13 “(A) DEFINITION OF MERCURY.—In this
14 paragraph, notwithstanding section 3(2)(B), the
15 term ‘mercury’ means—

16 “(i) elemental mercury; and

17 “(ii) a mercury compound.

18 “(B) PUBLICATION.—Not later than April
19 1, 2017, and every 3 years thereafter, the Ad-
20 ministrator shall carry out and publish in the
21 Federal Register an inventory of mercury sup-
22 ply, use, and trade in the United States.

23 “(C) PROCESS.—In carrying out the inven-
24 tory under subparagraph (B), the Adminis-
25 trator shall—

1 “(i) identify any manufacturing proc-
2 esses or products that intentionally add
3 mercury; and

4 “(ii) recommend actions, including
5 proposed revisions of Federal law or regu-
6 lations, to achieve further reductions in
7 mercury use.

8 “(D) REPORTING.—

9 “(i) IN GENERAL.—To assist in the
10 preparation of the inventory under sub-
11 paragraph (B), any person who manufac-
12 tures mercury or mercury-added products
13 or otherwise intentionally uses mercury in
14 a manufacturing process shall make peri-
15 odic reports to the Administrator, at such
16 time and including such information as the
17 Administrator shall determine by rule pro-
18 mulgated not later than 2 years after the
19 date of enactment of this paragraph.

20 “(ii) COORDINATION.—To avoid dupli-
21 cation, the Administrator shall coordinate
22 the reporting under this subparagraph
23 with the Interstate Mercury Education and
24 Reduction Clearinghouse.

1 “(iii) EXEMPTION.—Clause (i) shall
2 not apply to a person engaged in the gen-
3 eration, handling, or management of mer-
4 cury-containing waste, unless that person
5 manufactures or recovers mercury in the
6 management of that waste.”.

7 **SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.**

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

10 (1) in subsection (a)—

11 (A) in paragraph (1)—

12 (i) by striking “has reasonable basis
13 to conclude” and inserting “determines”;
14 and

15 (ii) by inserting “, without consider-
16 ation of costs or other nonrisk factors, in-
17 cluding an unreasonable risk to a poten-
18 tially exposed or susceptible subpopulation
19 identified as relevant by the Administrator,
20 under the conditions of use,” after “or the
21 environment”;

22 (B) in paragraph (2)—

23 (i) in subparagraph (A), by inserting
24 “, within the time period specified by the

1 Administrator in the report,” after “issues
2 an order”; and

3 (ii) in subparagraph (B), by inserting
4 “responds within the time period specified
5 by the Administrator in the report and”
6 before “initiates, within 90”;

7 (C) by redesignating paragraph (3) as
8 paragraph (6); and

9 (D) by inserting after paragraph (2) the
10 following:

11 “(3) The Administrator shall take the actions de-
12 scribed in paragraph (4) if the Administrator makes a re-
13 port under paragraph (1) with respect to a chemical sub-
14 stance or mixture and the agency to which the report was
15 made does not—

16 “(A) issue the order described in paragraph
17 (2)(A) within the time period specified by the Ad-
18 ministrator in the report; or

19 “(B)(i) respond under paragraph (1) within the
20 timeframe specified by the Administrator in the re-
21 port; and

22 “(ii) initiate action within 90 days of publica-
23 tion in the Federal Register of the response de-
24 scribed in clause (i).

1 “(4) If an agency to which a report is submitted
2 under paragraph (1) does not take the actions described
3 in subparagraph (A) or (B) of paragraph (3), the Admin-
4 istrator shall—

5 “(A) initiate or complete appropriate action
6 under section 6; or

7 “(B) take any action authorized or required
8 under section 7, as applicable.

9 “(5) This subsection shall not relieve the Adminis-
10 trator of any obligation to take any appropriate action
11 under section 6(a) or 7 to address risks from the manufac-
12 ture, processing, distribution in commerce, use, or disposal
13 of a chemical substance or mixture, or any combination
14 of those activities, that are not identified in a report issued
15 by the Administrator under paragraph (1).”;

16 (2) in subsection (b)—

17 (A) by striking “The Administrator shall
18 coordinate” and inserting “(1) The Adminis-
19 trator shall coordinate”; and

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

21 “(2) In making a determination under paragraph (1)
22 that it is in the public interest for the Administrator to
23 take an action under this title with respect to a chemical
24 substance or mixture rather than under another law ad-
25 ministered in whole or in part by the Administrator, the

1 Administrator shall consider, based on information rea-
2 sonably available to the Administrator, all relevant aspects
3 of the risk described in paragraph (1) and a comparison
4 of the estimated costs and efficiencies of the action to be
5 taken under this title and an action to be taken under
6 such other law to protect against such risk.”; and

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

8 “(e) EXPOSURE INFORMATION.—In addition to the
9 requirements of subsection (a), if the Administrator ob-
10 tains information related to exposures or releases of a
11 chemical substance or mixture that may be prevented or
12 reduced under another Federal law, including a law not
13 administered by the Administrator, the Administrator
14 shall make such information available to the relevant Fed-
15 eral agency or office of the Environmental Protection
16 Agency.”.

17 **SEC. 10. EXPORTS OF ELEMENTAL MERCURY.**

18 (a) PROHIBITION ON EXPORT OF CERTAIN MERCURY
19 COMPOUNDS.—Section 12(c) of the Toxic Substances
20 Control Act (15 U.S.C. 2611(c)) is amended—

21 (1) in the subsection heading, by inserting
22 “AND MERCURY COMPOUNDS” after “MERCURY”;
23 and

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

1 “(7) PROHIBITION ON EXPORT OF CERTAIN
2 MERCURY COMPOUNDS.—

3 “(A) IN GENERAL.—Effective January 1,
4 2020, the export of the following mercury com-
5 pounds is prohibited:

6 “(i) Mercury (I) chloride or calomel.

7 “(ii) Mercury (II) oxide.

8 “(iii) Mercury (II) sulfate.

9 “(iv) Mercury (II) nitrate.

10 “(v) Cinnabar or mercury sulphide.

11 “(vi) Any mercury compound that the
12 Administrator adds to the list published
13 under subparagraph (B) by rule, on deter-
14 mining that exporting that mercury com-
15 pound for the purpose of regenerating ele-
16 mental mercury is technically feasible.

17 “(B) PUBLICATION.—Not later than 90
18 days after the date of enactment of the Frank
19 R. Lautenberg Chemical Safety for the 21st
20 Century Act, and as appropriate thereafter, the
21 Administrator shall publish in the Federal Reg-
22 ister a list of the mercury compounds that are
23 prohibited from export under this paragraph.

1 “(C) PETITION.—Any person may petition
2 the Administrator to add a mercury compound
3 to the list published under subparagraph (B).

4 “(D) ENVIRONMENTALLY SOUND DIS-
5 POSAL.—This paragraph does not prohibit the
6 export of mercury compounds on the list pub-
7 lished under subparagraph (B) to member
8 countries of the Organization for Economic Co-
9 operation and Development for environmentally
10 sound disposal, on the condition that no mer-
11 cury or mercury compounds so exported are to
12 be recovered, recycled, or reclaimed for use, or
13 directly reused, after such export.

14 “(E) REPORT.—Not later than 5 years
15 after the date of enactment of the Frank R.
16 Lautenberg Chemical Safety for the 21st Cen-
17 tury Act, the Administrator shall evaluate any
18 exports of mercury compounds on the list pub-
19 lished under subparagraph (B) for disposal that
20 occurred after such date of enactment and shall
21 submit to Congress a report that—

22 “(i) describes volumes and sources of
23 mercury compounds on the list published
24 under subparagraph (B) exported for dis-
25 posal;

1 “(ii) identifies receiving countries of
2 such exports;

3 “(iii) describes methods of disposal
4 used after such export;

5 “(iv) identifies issues, if any, pre-
6 sented by the export of mercury com-
7 pounds on the list published under sub-
8 paragraph (B);

9 “(v) includes an evaluation of man-
10 agement options in the United States for
11 mercury compounds on the list published
12 under subparagraph (B), if any, that are
13 commercially available and comparable in
14 cost and efficacy to methods being utilized
15 in such receiving countries; and

16 “(vi) makes a recommendation re-
17 garding whether Congress should further
18 limit or prohibit the export of mercury
19 compounds on the list published under
20 subparagraph (B) for disposal.

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

1 (b) TEMPORARY GENERATOR ACCUMULATION.—Sec-
2 tion 5 of the Mercury Export Ban Act of 2008 (42 U.S.C.
3 6939f) is amended—

4 (1) in subsection (a)(2), by striking “2013” and
5 inserting “2019”;

6 (2) in subsection (b)—

7 (A) in paragraph (1)—

8 (i) by redesignating subparagraphs
9 (A), (B), and (C), as clauses (i), (ii), and
10 (iii), respectively and indenting appro-
11 priately;

12 (ii) in the first sentence, by striking
13 “After consultation” and inserting the fol-
14 lowing:

15 “(A) ASSESSMENT AND COLLECTION.—
16 After consultation”;

17 (iii) in the second sentence, by strik-
18 ing “The amount of such fees” and insert-
19 ing the following:

20 “(B) AMOUNT.—The amount of the fees
21 described in subparagraph (A)”;

22 (iv) in subparagraph (B) (as so des-
23 ignated)—

24 (I) in clause (i) (as so redesign-
25 ated), by striking “publically avail-

1 able not later than October 1, 2012”
2 and inserting “publicly available not
3 later than October 1, 2018”;

4 (II) in clause (ii) (as so redesign-
5 nated), by striking “and”;

6 (III) in clause (iii) (as so redesign-
7 nated), by striking the period at the
8 end and inserting “, subject to clause
9 (iv); and”; and

10 (IV) by adding at the end the fol-
11 lowing:

12 “(iv) for generators temporarily accu-
13 mulating elemental mercury in a facility
14 subject to subparagraphs (B) and (D)(iv)
15 of subsection (g)(2) if the facility des-
16 ignated in subsection (a) is not operational
17 by January 1, 2019, shall be adjusted to
18 subtract the cost of the temporary accumu-
19 lation during the period in which the facil-
20 ity designated under subsection (a) is not
21 operational.”; and

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

23 “(C) CONVEYANCE OF TITLE AND PERMIT-
24 TING.—If the facility designated in subsection

1 (a) is not operational by January 1, 2020, the
2 Secretary—

3 “(i) shall immediately accept the con-
4 veyance of title to all elemental mercury
5 that has accumulated in facilities in ac-
6 cordance with subsection (g)(2)(D), before
7 January 1, 2020, and deliver the accumu-
8 lated mercury to the facility designated
9 under subsection (a) on the date on which
10 the facility becomes operational;

11 “(ii) shall pay any applicable Federal
12 permitting costs, including the costs for
13 permits issued under section 3005(c) of
14 the Solid Waste Disposal Act (42 U.S.C.
15 6925(c)); and

16 “(iii) shall store, or pay the cost of
17 storage of, until the time at which a facil-
18 ity designated in subsection (a) is oper-
19 ational, accumulated mercury to which the
20 Secretary has title under this subpara-
21 graph in a facility that has been issued a
22 permit under section 3005(c) of the Solid
23 Waste Disposal Act (42 U.S.C. 6925(c)).”;
24 and

1 (B) in paragraph (2), in the first sentence,
2 by striking “paragraph (1)(C)” and inserting
3 “paragraph (1)(B)(iii)”; and
4 (3) in subsection (g)(2)—

5 (A) in the undesignated material at the
6 end, by striking “This subparagraph” and in-
7 serting the following:

8 “(C) Subparagraph (B)”;

9 (B) in subparagraph (C) (as designated by
10 subparagraph (A)), by inserting “of that sub-
11 paragraph” before the period at the end; and

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

13 “(D) A generator producing elemental
14 mercury incidentally from the beneficiation or
15 processing of ore or related pollution control ac-
16 tivities may accumulate the mercury produced
17 onsite that is destined for a facility designated
18 by the Secretary under subsection (a) for more
19 than 90 days without a permit issued under
20 section 3005(e) of the Solid Waste Disposal Act
21 (42 U.S.C. 6925(e)), and shall not be subject to
22 the storage prohibition of section 3004(j) of
23 that Act (42 U.S.C. 6924(j)), if—

24 “(i) the Secretary is unable to accept
25 the mercury at a facility designated by the

1 Secretary under subsection (a) for reasons
2 beyond the control of the generator;

3 “(ii) the generator certifies in writing
4 to the Secretary that the generator will
5 ship the mercury to a designated facility
6 when the Secretary is able to accept the
7 mercury;

8 “(iii) the generator certifies in writing
9 to the Secretary that the generator is stor-
10 ing only mercury the generator has pro-
11 duced or recovered onsite and will not sell,
12 or otherwise place into commerce, the mer-
13 cury; and

14 “(iv) the generator has obtained an
15 identification number under section 262.12
16 of title 40, Code of Federal Regulations,
17 and complies with the requirements de-
18 scribed in paragraphs (1) through (4) of
19 section 262.34(a) of title 40, Code of Fed-
20 eral Regulations (as in effect on the date
21 of enactment of this subparagraph).

22 “(E) MANAGEMENT STANDARDS FOR TEM-
23 PORARY STORAGE.—Not later than January 1,
24 2017, the Secretary, after consultation with the
25 Administrator of the Environmental Protection

1 Agency and State agencies in affected States,
2 shall develop and make available guidance that
3 establishes procedures and standards for the
4 management and short-term storage of ele-
5 mental mercury at a generator covered under
6 subparagraph (D), including requirements to
7 ensure appropriate use of flasks or other suit-
8 able containers. Such procedures and standards
9 shall be protective of health and the environ-
10 ment and shall ensure that the elemental mer-
11 cury is stored in a safe, secure, and effective
12 manner. A generator may accumulate mercury
13 in accordance with subparagraph (D) imme-
14 diately upon enactment of this subparagraph,
15 and notwithstanding that guidance called for by
16 this paragraph has not been developed or made
17 available.”.

18 (c) INTERIM STATUS.—Section 5(d)(1) of the Mer-
19 cury Export Ban Act of 2008 (42 U.S.C. 6939f(d)(1)) is
20 amended—

21 (1) in the fourth sentence, by striking “in exist-
22 ence on or before January 1, 2013,”; and

23 (2) in the last sentence, by striking “January
24 1, 2015” and inserting “January 1, 2020”.

1 **SEC. 11. 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 provided in this sec-
6 tion, the Administrator shall not disclose information that
7 is exempt from disclosure pursuant to subsection (a) of
8 section 552 of title 5, United States Code, by reason of
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 (c) are met.

14 In any proceeding under section 552(a) of title 5, United
15 States Code, to obtain information the disclosure of which
16 has been denied because of the provisions of this sub-
17 section, the Administrator may not rely on section
18 552(b)(3) of such title to sustain the Administrator’s ac-
19 tion.

20 “(b) INFORMATION NOT PROTECTED FROM DISCLO-
21 SURE.—

22 “(1) MIXED CONFIDENTIAL AND NONCON-
23 FIDENTIAL INFORMATION.—Information that is pro-
24 tected from disclosure under this section, and which
25 is mixed with information that is not protected from
26 disclosure under this section, does not lose its pro-

1 tection from disclosure notwithstanding that it is
2 mixed with information that is not protected from
3 disclosure.

4 “(2) INFORMATION FROM HEALTH AND SAFETY
5 STUDIES.—Subsection (a) does not prohibit the dis-
6 closure of—

7 “(A) any health and safety study which is
8 submitted under this Act with respect to—

9 “(i) any chemical substance or mix-
10 ture which, on the date on which such
11 study is to be disclosed has been offered
12 for commercial distribution; or

13 “(ii) any chemical substance or mix-
14 ture for which testing is required under
15 section 4 or for which notification is re-
16 quired under section 5; and

17 “(B) any information reported to, or other-
18 wise obtained by, the Administrator from a
19 health and safety study which relates to a
20 chemical substance or mixture described in
21 clause (i) or (ii) of subparagraph (A).

22 This paragraph does not authorize the disclosure of
23 any information, including formulas (including mo-
24 lecular structures) of a chemical substance or mix-
25 ture, that discloses processes used in the manufac-

1 turing or processing of a chemical substance or mix-
2 ture or, in the case of a mixture, the portion of the
3 mixture comprised by any of the chemical substances
4 in the mixture.

5 “(3) OTHER INFORMATION NOT PROTECTED
6 FROM DISCLOSURE.—Subsection (a) does not pro-
7 hibit the disclosure of—

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

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

23 “(4) BANS AND PHASE-OUTS.—

24 “(A) IN GENERAL.—If the Administrator
25 promulgates a rule pursuant to section 6(a)

1 that establishes a ban or phase-out of a chem-
2 ical substance or mixture, the protection from
3 disclosure of any information under this section
4 with respect to the chemical substance or mix-
5 ture shall be presumed to no longer apply, sub-
6 ject to subsection (g)(1)(E) and subparagraphs
7 (B) and (C) of this paragraph.

8 “(B) LIMITATIONS.—

9 “(i) CRITICAL USE.—In the case of a
10 chemical substance or mixture for which a
11 specific condition of use is subject to an
12 exemption pursuant to section 6(g), if the
13 Administrator establishes a ban or phase-
14 out described in subparagraph (A) with re-
15 spect to the chemical substance or mixture,
16 the presumption against protection under
17 such subparagraph shall only apply to in-
18 formation that relates solely to any condi-
19 tions of use of the chemical substance or
20 mixture to which the exemption does not
21 apply.

22 “(ii) EXPORT.—In the case of a chem-
23 ical substance or mixture for which there is
24 manufacture, processing, or distribution in
25 commerce that meets the conditions of sec-

1 tion 12(a)(1), if the Administrator estab-
2 lishes a ban or phase-out described in sub-
3 paragraph (A) with respect to the chemical
4 substance or mixture, the presumption
5 against protection under such subpara-
6 graph shall only apply to information that
7 relates solely to any other manufacture,
8 processing, or distribution in commerce of
9 the chemical substance or mixture for the
10 conditions of use subject to the ban or
11 phase-out, unless the Administrator makes
12 the determination in section 12(a)(2).

13 “(iii) SPECIFIC CONDITIONS OF
14 USE.—In the case of a chemical substance
15 or mixture for which the Administrator es-
16 tablishes a ban or phase-out described in
17 subparagraph (A) with respect to a specific
18 condition of use of the chemical substance
19 or mixture, the presumption against pro-
20 tection under such subparagraph shall only
21 apply to information that relates solely to
22 the condition of use of the chemical sub-
23 stance or mixture for which the ban or
24 phase-out is established.

25 “(C) REQUEST FOR NONDISCLOSURE.—

1 “(i) IN GENERAL.—A manufacturer
2 or processor of a chemical substance or
3 mixture subject to a ban or phase-out de-
4 scribed in this paragraph may submit to
5 the Administrator, within 30 days of re-
6 ceiving a notification under subsection
7 (g)(2)(A), a request, including documenta-
8 tion supporting such request, that some or
9 all of the information to which the notice
10 applies should not be disclosed or that its
11 disclosure should be delayed, and the Ad-
12 ministrator shall review the request under
13 subsection (g)(1)(E).

14 “(ii) EFFECT OF NO REQUEST OR DE-
15 NIAL.—If no request for nondisclosure or
16 delay is submitted to the Administrator
17 under this subparagraph, or the Adminis-
18 trator denies such a request under sub-
19 section (g)(1)(A), the information shall not
20 be protected from disclosure under this
21 section.

22 “(5) CERTAIN REQUESTS.—If a request is made
23 to the Administrator under section 552(a) of title 5,
24 United States Code, for information reported to or
25 otherwise obtained by the Administrator under this

1 Act that is not protected from disclosure under this
2 subsection, the Administrator may not deny the re-
3 quest on the basis of section 552(b)(4) of title 5,
4 United States Code.

5 “(c) REQUIREMENTS FOR CONFIDENTIALITY
6 CLAIMS.—

7 “(1) ASSERTION OF CLAIMS.—

8 “(A) IN GENERAL.—A person seeking to
9 protect from disclosure any information that
10 person submits under this Act (including infor-
11 mation described in paragraph (2)) shall assert
12 to the Administrator a claim for protection
13 from disclosure concurrent with submission of
14 the information, in accordance with such rules
15 regarding a claim for protection from disclosure
16 as the Administrator has promulgated or may
17 promulgate pursuant to this title.

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

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

23 “(ii) determined that the information
24 is not required to be disclosed or otherwise

1 made available to the public under any
2 other Federal law;

3 “(iii) a reasonable basis to conclude
4 that disclosure of the information is likely
5 to cause substantial harm to the competi-
6 tive position of the person; and

7 “(iv) a reasonable basis to believe that
8 the information is not readily discoverable
9 through reverse engineering.

10 “(C) ADDITIONAL REQUIREMENTS FOR
11 CLAIMS REGARDING CHEMICAL IDENTITY IN-
12 FORMATION.—In the case of a claim under sub-
13 paragraph (A) for protection from disclosure of
14 a specific chemical identity, the claim shall in-
15 clude a structurally descriptive generic name for
16 the chemical substance that the Administrator
17 may disclose to the public, subject to the condi-
18 tion that such generic name shall—

19 “(i) be consistent with guidance devel-
20 oped by the Administrator under para-
21 graph (4)(A); and

22 “(ii) describe the chemical structure
23 of the chemical substance as specifically as
24 practicable while protecting those features
25 of the chemical structure—

1 “(I) that are claimed as confiden-
2 tial; and

3 “(II) the disclosure of which
4 would be likely to cause substantial
5 harm to the competitive position of
6 the person.

7 “(2) INFORMATION GENERALLY NOT SUBJECT
8 TO SUBSTANTIATION REQUIREMENTS.—Subject to
9 subsection (f), the following information shall not be
10 subject to substantiation requirements under para-
11 graph (3):

12 “(A) Specific information describing the
13 processes used in manufacture or processing of
14 a chemical substance, mixture, or article.

15 “(B) Marketing and sales information.

16 “(C) Information identifying a supplier or
17 customer.

18 “(D) In the case of a mixture, details of
19 the full composition of the mixture and the re-
20 spective percentages of constituents.

21 “(E) Specific information regarding the
22 use, function, or application of a chemical sub-
23 stance or mixture in a process, mixture, or arti-
24 cle.

1 “(F) Specific production or import volumes
2 of the manufacturer or processor.

3 “(G) Prior to the date on which a chemical
4 substance is first offered for commercial dis-
5 tribution, the specific chemical identity of the
6 chemical substance, including the chemical
7 name, molecular formula, Chemical Abstracts
8 Service number, and other information that
9 would identify the specific chemical substance,
10 if the specific chemical identity was claimed as
11 confidential at the time it was submitted in a
12 notice under section 5.

13 “(3) SUBSTANTIATION REQUIREMENTS.—Ex-
14 cept as provided in paragraph (2), a person assert-
15 ing a claim to protect information from disclosure
16 under this section shall substantiate the claim, in ac-
17 cordance with such rules as the Administrator has
18 promulgated or may promulgate pursuant to this
19 section.

20 “(4) GUIDANCE.—The Administrator shall de-
21 velop guidance regarding—

22 “(A) the determination of structurally de-
23 scriptive generic names, in the case of claims
24 for the protection from disclosure of specific
25 chemical identity; and

1 “(B) the content and form of the state-
2 ments of need and agreements required under
3 paragraphs (4), (5), and (6) of subsection (d).

4 “(5) CERTIFICATION.—An authorized official of
5 a person described in paragraph (1)(A) shall certify
6 that the statement required to assert a claim sub-
7 mitted pursuant to paragraph (1)(B), and any infor-
8 mation required to substantiate a claim submitted
9 pursuant to paragraph (3), are true and correct.

10 “(d) EXCEPTIONS TO PROTECTION FROM DISCLO-
11 SURE.—Information described in subsection (a)—

12 “(1) shall be disclosed to an officer or employee
13 of the United States—

14 “(A) in connection with the official duties
15 of that person under any Federal law for the
16 protection of health or the environment; or

17 “(B) for a specific Federal law enforce-
18 ment purpose;

19 “(2) shall be disclosed to a contractor of the
20 United States and employees of that contractor—

21 “(A) if, in the opinion of the Adminis-
22 trator, the disclosure is necessary for the satis-
23 factory performance by the contractor of a con-
24 tract with the United States for the perform-
25 ance of work in connection with this Act; and

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

3 “(3) shall be disclosed if the Administrator de-
4 termines that disclosure is necessary to protect
5 health or the environment against an unreasonable
6 risk of injury to health or the environment, without
7 consideration of costs or other nonrisk factors, in-
8 cluding an unreasonable risk to a potentially exposed
9 or susceptible subpopulation identified as relevant by
10 the Administrator under the conditions of use;

11 “(4) shall be disclosed to a State, political sub-
12 division of a State, or tribal government, on written
13 request, for the purpose of administration or en-
14 forcement of a law, if such entity has 1 or more ap-
15 plicable agreements with the Administrator that are
16 consistent with the guidance developed under sub-
17 section (c)(4)(B) and ensure that the entity will take
18 appropriate measures, and has adequate authority,
19 to maintain the confidentiality of the information in
20 accordance with procedures comparable to the proce-
21 dures used by the Administrator to safeguard the in-
22 formation;

23 “(5) shall be disclosed to a health or environ-
24 mental professional employed by a Federal or State
25 agency or tribal government or a treating physician

1 or nurse in a nonemergency situation if such person
2 provides a written statement of need and agrees to
3 sign a written confidentiality agreement with the Ad-
4 ministrators, subject to the conditions that—

5 “(A) the statement of need and confiden-
6 tiality agreement are consistent with the guid-
7 ance developed under subsection (c)(4)(B);

8 “(B) the statement of need shall be a
9 statement that the person has a reasonable
10 basis to suspect that—

11 “(i) the information is necessary for,
12 or will assist in—

13 “(I) the diagnosis or treatment of
14 1 or more individuals; or

15 “(II) responding to an environ-
16 mental release or exposure; and

17 “(ii) 1 or more individuals being diag-
18 nosed or treated have been exposed to the
19 chemical substance or mixture concerned,
20 or an environmental release of or exposure
21 to the chemical substance or mixture con-
22 cerned has occurred; and

23 “(C) the person will not use the informa-
24 tion for any purpose other than the health or
25 environmental needs asserted in the statement

1 of need, except as otherwise may be authorized
2 by the terms of the agreement or by the person
3 who has a claim under this section with respect
4 to the information, except that nothing in this
5 title prohibits the disclosure of any such infor-
6 mation through discovery, subpoena, other
7 court order, or any other judicial process other-
8 wise allowed under applicable Federal or State
9 law;

10 “(6) shall be disclosed in the event of an emer-
11 gency to a treating or responding physician, nurse,
12 agent of a poison control center, public health or en-
13 vironmental official of a State, political subdivision
14 of a State, or tribal government, or first responder
15 (including any individual duly authorized by a Fed-
16 eral agency, State, political subdivision of a State, or
17 tribal government who is trained in urgent medical
18 care or other emergency procedures, including a po-
19 lice officer, firefighter, or emergency medical techni-
20 cian) if such person requests the information, sub-
21 ject to the conditions that such person shall—

22 “(A) have a reasonable basis to suspect
23 that—

24 “(i) a medical, public health, or envi-
25 ronmental emergency exists;

1 “(ii) the information is necessary for,
2 or will assist in, emergency or first-aid di-
3 agnosis or treatment; or

4 “(iii) 1 or more individuals being di-
5 agnosed or treated have likely been ex-
6 posed to the chemical substance or mixture
7 concerned, or a serious environmental re-
8 lease of or exposure to the chemical sub-
9 stance or mixture concerned has occurred;
10 and

11 “(B) if requested by a person who has a
12 claim with respect to the information under this
13 section—

14 “(i) provide a written statement of
15 need and agree to sign a confidentiality
16 agreement, as described in paragraph (5);
17 and

18 “(ii) submit to the Administrator such
19 statement of need and confidentiality
20 agreement as soon as practicable, but not
21 necessarily before the information is dis-
22 closed;

23 “(7) may be disclosed if the Administrator de-
24 termines that disclosure is relevant in a proceeding
25 under this Act, subject to the condition that the dis-

1 closure is made in such a manner as to preserve con-
2 fidentiality to the extent practicable without impair-
3 ing the proceeding; and

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

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

9 “(1) IN GENERAL.—Subject to paragraph (2),
10 subsection (f)(3), and section 8(b), the Adminis-
11 trator shall protect from disclosure information de-
12 scribed in subsection (a)—

13 “(A) in the case of information described
14 in subsection (c)(2), until such time as—

15 “(i) the person that asserted the claim
16 notifies the Administrator that the person
17 is withdrawing the claim, in which case the
18 information shall not be protected from
19 disclosure under this section; or

20 “(ii) the Administrator becomes aware
21 that the information does not qualify for
22 protection from disclosure under this sec-
23 tion, in which case the Administrator shall
24 take any actions required under sub-
25 sections (f) and (g); and

1 “(B) in the case of information other than
2 information described in subsection (c)(2)—

3 “(i) for a period of 10 years from the
4 date on which the person asserts the claim
5 with respect to the information submitted
6 to the Administrator; or

7 “(ii) if applicable before the expiration
8 of such 10-year period, until such time
9 as—

10 “(I) the person that asserted the
11 claim notifies the Administrator that
12 the person is withdrawing the claim,
13 in which case the information shall
14 not be protected from disclosure
15 under this section; or

16 “(II) the Administrator becomes
17 aware that the information does not
18 qualify for protection from disclosure
19 under this section, in which case the
20 Administrator shall take any actions
21 required under subsections (f) and
22 (g).

23 “(2) EXTENSIONS.—

24 “(A) IN GENERAL.—In the case of infor-
25 mation other than information described in sub-

1 section (c)(2), not later than the date that is 60
2 days before the expiration of the period de-
3 scribed in paragraph (1)(B)(i), the Adminis-
4 trator shall provide to the person that asserted
5 the claim a notice of the impending expiration
6 of the period.

7 “(B) REQUEST.—

8 “(i) IN GENERAL.—Not later than the
9 date that is 30 days before the expiration
10 of the period described in paragraph
11 (1)(B)(i), a person reasserting the relevant
12 claim shall submit to the Administrator a
13 request for extension substantiating, in ac-
14 cordance with subsection (c)(3), the need
15 to extend the period.

16 “(ii) ACTION BY ADMINISTRATOR.—
17 Not later than the date of expiration of the
18 period described in paragraph (1)(B)(i),
19 the Administrator shall, in accordance with
20 subsection (g)(1)—

21 “(I) review the request submitted
22 under clause (i);

23 “(II) make a determination re-
24 garding whether the claim for which
25 the request was submitted continues

1 to meet the relevant requirements of
2 this section; and

3 “(III)(aa) grant an extension of
4 10 years; or

5 “(bb) deny the request.

6 “(C) NO LIMIT ON NUMBER OF EXTEN-
7 SIONS.—There shall be no limit on the number
8 of extensions granted under this paragraph, if
9 the Administrator determines that the relevant
10 request under subparagraph (B)(i)—

11 “(i) establishes the need to extend the
12 period; and

13 “(ii) meets the requirements estab-
14 lished by the Administrator.

15 “(f) REVIEW AND RESUBSTANTIATION.—

16 “(1) DISCRETION OF ADMINISTRATOR.—The
17 Administrator may require any person that has
18 claimed protection for information from disclosure
19 under this section, whether before, on, or after the
20 date of enactment of the Frank R. Lautenberg
21 Chemical Safety for the 21st Century Act, to re-
22 assert and substantiate or resubstantiate the claim
23 in accordance with this section—

1 “(A) after the chemical substance is des-
2 ignated as a high-priority substance under sec-
3 tion 6(b);

4 “(B) for any chemical substance des-
5 ignated as an active substance under section
6 8(b)(5)(B)(iii); or

7 “(C) if the Administrator determines that
8 disclosure of certain information currently pro-
9 tected from disclosure would be important to
10 assist the Administrator in conducting risk
11 evaluations or promulgating rules under section
12 6.

13 “(2) REVIEW REQUIRED.—The Administrator
14 shall review a claim for protection of information
15 from disclosure under this section and require any
16 person that has claimed protection for that informa-
17 tion, whether before, on, or after the date of enact-
18 ment of the Frank R. Lautenberg Chemical Safety
19 for the 21st Century Act, to reassert and substan-
20 tiate or resubstantiate the claim in accordance with
21 this section—

22 “(A) as necessary to determine whether
23 the information qualifies for an exemption from
24 disclosure in connection with a request for in-

1 formation received by the Administrator under
2 section 552 of title 5, United States Code;

3 “(B) if the Administrator has a reasonable
4 basis to believe that the information does not
5 qualify for protection from disclosure under this
6 section; or

7 “(C) for any chemical substance the Ad-
8 ministrator determines under section 6(b)(4)(A)
9 presents an unreasonable risk of injury to
10 health or the environment.

11 “(3) PERIOD OF PROTECTION.—If the Adminis-
12 trator requires a person to reassert and substantiate
13 or resubstantiate a claim under this subsection, and
14 determines that the claim continues to meet the rel-
15 evant requirements of this section, the Administrator
16 shall protect the information subject to the claim
17 from disclosure for a period of 10 years from the
18 date of such determination, subject to any subse-
19 quent requirement by the Administrator under this
20 subsection.

21 “(g) DUTIES OF ADMINISTRATOR.—

22 “(1) DETERMINATION.—

23 “(A) IN GENERAL.—Except for claims re-
24 garding information described in subsection
25 (c)(2), the Administrator shall, subject to sub-

1 paragraph (C), not later than 90 days after the
2 receipt of a claim under subsection (c), and not
3 later than 30 days after the receipt of a request
4 for extension of a claim under subsection (e) or
5 a request under subsection (b)(4)(C), review
6 and approve, approve in part and deny in part,
7 or deny the claim or request.

8 “(B) REASONS FOR DENIAL.—If the Ad-
9 ministrator denies or denies in part a claim or
10 request under subparagraph (A) the Adminis-
11 trator shall provide to the person that asserted
12 the claim or submitted the request a written
13 statement of the reasons for the denial or de-
14 nial in part of the claim or request.

15 “(C) SUBSETS.—The Administrator
16 shall—

17 “(i) except with respect to information
18 described in subsection (c)(2)(G), review
19 all claims or requests under this section for
20 the protection from disclosure of the spe-
21 cific chemical identity of a chemical sub-
22 stance; and

23 “(ii) review a representative subset,
24 comprising at least 25 percent, of all other

1 claims or requests for protection from dis-
2 closure under this section.

3 “(D) EFFECT OF FAILURE TO ACT.—The
4 failure of the Administrator to make a decision
5 regarding a claim or request for protection from
6 disclosure or extension under this section shall
7 not have the effect of denying or eliminating a
8 claim or request for protection from disclosure.

9 “(E) DETERMINATION OF REQUESTS
10 UNDER SUBSECTION (b)(4)(C).—With respect to
11 a request submitted under subsection (b)(4)(C),
12 the Administrator shall, with the objective of
13 ensuring that information relevant to the pro-
14 tection of health and the environment is dis-
15 closed to the extent practicable, determine
16 whether the documentation provided by the per-
17 son rebuts what shall be the presumption of the
18 Administrator that the public interest in the
19 disclosure of the information outweighs the
20 public or proprietary interest in maintaining the
21 protection for all or a portion of the informa-
22 tion that the person has requested not be dis-
23 closed or for which disclosure be delayed.

24 “(2) NOTIFICATION.—

1 “(A) IN GENERAL.—Except as provided in
2 subparagraph (B) and subsections (b), (d), and
3 (e), if the Administrator denies or denies in
4 part a claim or request under paragraph (1),
5 concludes, in accordance with this section, that
6 the information does not qualify for protection
7 from disclosure, intends to disclose information
8 pursuant to subsection (d), or promulgates a
9 rule under section 6(a) establishing a ban or
10 phase-out with respect to a chemical substance
11 or mixture, the Administrator shall notify, in
12 writing, the person that asserted the claim or
13 submitted the request of the intent of the Ad-
14 ministrator to disclose the information or not
15 protect the information from disclosure under
16 this section. The notice shall be furnished by
17 certified mail (return receipt requested), by per-
18 sonal delivery, or by other means that allows
19 verification of the fact and date of receipt.

20 “(B) DISCLOSURE OF INFORMATION.—Ex-
21 cept as provided in subparagraph (C), the Ad-
22 ministrator shall not disclose information under
23 this subsection until the date that is 30 days
24 after the date on which the person that asserted

1 the claim or submitted the request receives noti-
2 fication under subparagraph (A).

3 “(C) EXCEPTIONS.—

4 “(i) FIFTEEN DAY NOTIFICATION.—

5 For information the Administrator intends
6 to disclose under subsections (d)(3), (d)(4),
7 (d)(5), and (j), the Administrator shall not
8 disclose the information until the date that
9 is 15 days after the date on which the per-
10 son that asserted the claim or submitted
11 the request receives notification under sub-
12 paragraph (A), except that, with respect to
13 information to be disclosed under sub-
14 section (d)(3), if the Administrator deter-
15 mines that disclosure of the information is
16 necessary to protect against an imminent
17 and substantial harm to health or the envi-
18 ronment, no prior notification shall be nec-
19 essary.

20 “(ii) NOTIFICATION AS SOON AS PRAC-
21 TICABLE.—For information the Adminis-
22 trator intends to disclose under paragraph
23 (6) of subsection (d), the Administrator
24 shall notify the person that submitted the
25 information that the information has been

1 disclosed as soon as practicable after dis-
2 closure of the information.

3 “(iii) NO NOTIFICATION REQUIRED.—
4 Notification shall not be required—

5 “(I) for the disclosure of infor-
6 mation under paragraphs (1), (2), (7),
7 or (8) of subsection (d); or

8 “(II) for the disclosure of infor-
9 mation for which—

10 “(aa) the Administrator has
11 provided to the person that as-
12 serted the claim a notice under
13 subsection (e)(2)(A); and

14 “(bb) such person does not
15 submit to the Administrator a re-
16 quest under subsection (e)(2)(B)
17 on or before the deadline estab-
18 lished in subsection (e)(2)(B)(i).

19 “(D) APPEALS.—

20 “(i) ACTION TO RESTRAIN DISCLO-
21 SURE.—If a person receives a notification
22 under this paragraph and believes the in-
23 formation is protected from disclosure
24 under this section, before the date on
25 which the information is to be disclosed

1 pursuant to subparagraph (B) or (C) the
2 person may bring an action to restrain dis-
3 closure of the information in—

4 “(I) the United States district
5 court of the district in which the com-
6 plainant resides or has the principal
7 place of business; or

8 “(II) the United States District
9 Court for the District of Columbia.

10 “(ii) NO DISCLOSURE.—

11 “(I) IN GENERAL.—Subject to
12 subsection (d), the Administrator shall
13 not disclose information that is the
14 subject of an appeal under this para-
15 graph before the date on which the
16 applicable court rules on an action
17 under clause (i).

18 “(II) EXCEPTION.—Subclause (I)
19 shall not apply to disclosure of infor-
20 mation described under subsections
21 (d)(4) and (j).

22 “(3) REQUEST AND NOTIFICATION SYSTEM.—
23 The Administrator, in consultation with the Director
24 of the Centers for Disease Control and Prevention,
25 shall develop a request and notification system that,

1 in a format and language that is readily accessible
2 and understandable, allows for expedient and swift
3 access to information disclosed pursuant to para-
4 graphs (5) and (6) of subsection (d).

5 “(4) UNIQUE IDENTIFIER.—The Administrator
6 shall—

7 “(A)(i) develop a system to assign a
8 unique identifier to each specific chemical iden-
9 tity for which the Administrator approves a re-
10 quest for protection from disclosure, which shall
11 not be either the specific chemical identity or a
12 structurally descriptive generic term; and

13 “(ii) apply that identifier consistently to all
14 information relevant to the applicable chemical
15 substance;

16 “(B) annually publish and update a list of
17 chemical substances, referred to by their unique
18 identifiers, for which claims to protect the spe-
19 cific chemical identity from disclosure have been
20 approved, including the expiration date for each
21 such claim;

22 “(C) ensure that any nonconfidential infor-
23 mation received by the Administrator with re-
24 spect to a chemical substance included on the
25 list published under subparagraph (B) while the

1 specific chemical identity of the chemical sub-
2 stance is protected from disclosure under this
3 section identifies the chemical substance using
4 the unique identifier; and

5 “(D) for each claim for protection of a spe-
6 cific chemical identity that has been denied by
7 the Administrator or expired, or that has been
8 withdrawn by the person who asserted the
9 claim, and for which the Administrator has
10 used a unique identifier assigned under this
11 paragraph to protect the specific chemical iden-
12 tity in information that the Administrator has
13 made public, clearly link the specific chemical
14 identity to the unique identifier in such infor-
15 mation to the extent practicable.

16 “(h) CRIMINAL PENALTY FOR WRONGFUL DISCLO-
17 SURE.—

18 “(1) INDIVIDUALS SUBJECT TO PENALTY.—

19 “(A) IN GENERAL.—Subject to subpara-
20 graph (C) and paragraph (2), an individual de-
21 scribed in subparagraph (B) shall be fined
22 under title 18, United States Code, or impris-
23 oned for not more than 1 year, or both.

1 “(B) DESCRIPTION.—An individual re-
2 ferred to in subparagraph (A) is an individual
3 who—

4 “(i) pursuant to this section, obtained
5 possession of, or has access to, information
6 protected from disclosure under this sec-
7 tion; and

8 “(ii) knowing that the information is
9 protected from disclosure under this sec-
10 tion, willfully discloses the information in
11 any manner to any person not entitled to
12 receive that information.

13 “(C) EXCEPTION.—This paragraph shall
14 not apply to any medical professional (including
15 an emergency medical technician or other first
16 responder) who discloses any information ob-
17 tained under paragraph (5) or (6) of subsection
18 (d) to a patient treated by the medical profes-
19 sional, or to a person authorized to make med-
20 ical or health care decisions on behalf of such
21 a patient, as needed for the diagnosis or treat-
22 ment of the patient.

23 “(2) OTHER LAWS.—Section 1905 of title 18,
24 United States Code, shall not apply with respect to
25 the publishing, divulging, disclosure, or making

1 known of, or making available, information reported
2 to or otherwise obtained by the Administrator under
3 this Act.

4 “(i) APPLICABILITY.—

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

9 “(A) to require the substantiation or re-
10 substantiation of a claim for the protection
11 from disclosure of information reported to or
12 otherwise obtained by the Administrator under
13 this Act prior to the date of enactment of the
14 Frank R. Lautenberg Chemical Safety for the
15 21st Century Act; or

16 “(B) to impose substantiation or re-
17 substantiation requirements, with respect to the
18 protection of information described in sub-
19 section (a), under this Act that are more exten-
20 sive than those required under this section.

21 “(2) ACTIONS PRIOR TO PROMULGATION OF
22 RULES.—Nothing in this Act prevents the Adminis-
23 trator from reviewing, requiring substantiation or re-
24 substantiation of, or approving, approving in part, or
25 denying any claim for the protection from disclosure

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

6 “(j) ACCESS BY CONGRESS.—Notwithstanding any
7 limitation contained in this section or any other provision
8 of law, all information reported to or otherwise obtained
9 by the Administrator (or any representative of the Admin-
10 istrator) under this Act shall be made available, upon writ-
11 ten request of any duly authorized committee of the Con-
12 gress, to such committee.”.

13 **SEC. 12. PENALTIES.**

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

16 (1) in subsection (a)(1), by striking “\$25,000”
17 and inserting “\$37,500”; and

18 (2) in subsection (b)—

19 (A) by striking “Any person” and inserting
20 the following:

21 “(1) IN GENERAL.—Any person”;

22 (B) by striking “\$25,000” and inserting
23 “\$50,000”; and

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

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

3 “(A) IN GENERAL.—Any person who
4 knowingly and willfully violates any provision of
5 section 15 or 409, and who knows at the time
6 of the violation that the violation places an indi-
7 vidual in imminent danger of death or serious
8 bodily injury, shall be subject on conviction to
9 a fine of not more than \$250,000, or imprison-
10 ment for not more than 15 years, or both.

11 “(B) ORGANIZATIONS.—Notwithstanding
12 the penalties described in subparagraph (A), an
13 organization that commits a knowing violation
14 described in subparagraph (A) shall be subject
15 on conviction to a fine of not more than
16 \$1,000,000 for each violation.

17 “(C) INCORPORATION OF CORRESPONDING
18 PROVISIONS.—Subparagraphs (B) through (F)
19 of section 113(c)(5) of the Clean Air Act (42
20 U.S.C. 7413(c)(5)(B)–(F)) shall apply to the
21 prosecution of a violation under this para-
22 graph.”.

23 **SEC. 13. STATE-FEDERAL RELATIONSHIP.**

24 Section 18 of the Toxic Substances Control Act (15
25 U.S.C. 2617) is amended—

1 (1) by amending subsection (a) to read as fol-
2 lows:

3 “(a) IN GENERAL.—

4 “(1) ESTABLISHMENT OR ENFORCEMENT.—Ex-
5 cept as otherwise provided in subsections (c), (d),
6 (e), (f), and (g), and subject to paragraph (2), no
7 State or political subdivision of a State may estab-
8 lish or continue to enforce any of the following:

9 “(A) DEVELOPMENT OF INFORMATION.—A
10 statute or administrative action to require the
11 development of information about a chemical
12 substance or category of chemical substances
13 that is reasonably likely to produce the same in-
14 formation required under section 4, 5, or 6 in—

15 “(i) a rule promulgated by the Admin-
16 istrator;

17 “(ii) a consent agreement entered into
18 by the Administrator; or

19 “(iii) an order issued by the Adminis-
20 trator.

21 “(B) CHEMICAL SUBSTANCES FOUND NOT
22 TO PRESENT AN UNREASONABLE RISK OR RE-
23 STRICTED.—A statute, criminal penalty, or ad-
24 ministrative action to prohibit or otherwise re-
25 strict the manufacture, processing, or distribu-

1 tion in commerce or use of a chemical sub-
2 stance—

3 “(i) for which the determination de-
4 scribed in section 6(i)(1) is made, con-
5 sistent with the scope of the risk evalua-
6 tion under section (6)(b)(4)(D); or

7 “(ii) for which a final rule is promul-
8 gated under section 6(a), after the effective
9 date of the rule issued under section 6(a)
10 for the chemical substance, consistent with
11 the scope of the risk evaluation under sec-
12 tion (6)(b)(4)(D).

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

20 “(2) EFFECTIVE DATE OF PREEMPTION.—
21 Under this subsection, Federal preemption of stat-
22 utes and administrative actions applicable to specific
23 chemical substances shall not occur until the effec-
24 tive date of the applicable action described in para-
25 graph (1) taken by the Administrator.”;

1 (2) by amending subsection (b) to read as fol-
2 lows:

3 “(b) NEW STATUTES, CRIMINAL PENALTIES, OR AD-
4 MINISTRATIVE ACTIONS CREATING PROHIBITIONS OR
5 OTHER RESTRICTIONS.—

6 “(1) IN GENERAL.—Except as provided in sub-
7 sections (c), (d), (e), (f), and (g), beginning on the
8 date on which the Administrator defines the scope of
9 a risk evaluation for a chemical substance under sec-
10 tion 6(b)(4)(D) and ending on the date on which the
11 deadline established pursuant to section 6(b)(4)(G)
12 for completion of the risk evaluation expires, or on
13 the date on which the Administrator publishes the
14 risk evaluation under section 6(b)(4)(C), whichever
15 is earlier, no State or political subdivision of a State
16 may establish a statute, criminal penalty, or admin-
17 istrative action prohibiting or otherwise restricting
18 the manufacture, processing, distribution in com-
19 merce, or use of such chemical substance that is a
20 high-priority substance designated under
21 6(b)(1)(B)(i), such chemical substance that has been
22 identified under section 6(b)(2)(A) (except for the
23 first 10 chemical substances so identified), or such
24 chemical substance that has been selected for risk
25 evaluation under section 6(b)(4)(E)(iv)(II).

1 “(2) EFFECT OF SUBSECTION.—This sub-
2 section does not restrict the authority of a State or
3 political subdivision of a State to continue to enforce
4 any statute enacted, or administrative action taken,
5 prior to the date on which the Administrator defines
6 and publishes the scope of a risk evaluation under
7 section 6(b)(4)(D).”; and

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

9 “(c) SCOPE OF PREEMPTION.—Federal preemption
10 under subsections (a) and (b) of statutes, criminal pen-
11 alties, and administrative actions applicable to specific
12 chemical substances shall apply only to—

13 “(1) with respect to subsection (a)(1)(A), the
14 chemical substances or category of chemical sub-
15 stances subject to a rule, order, or consent agree-
16 ment under section 4;

17 “(2) with respect to subsections (a)(1)(B) and
18 (b), the hazards, exposures, risks, and uses or condi-
19 tions of use of such chemical substances consistent
20 with the scope of the risk evaluation under
21 6(b)(4)(D); or

22 “(3) with respect to subsection (a)(1)(C), the
23 uses of such chemical substances that the Adminis-
24 trator has specified as significant new uses and for

1 which the Administrator has required notification
2 pursuant to a rule promulgated under section 5.

3 “(d) EXCEPTIONS.—

4 “(1) NO PREEMPTION OF STATUTES AND AD-
5 MINISTRATIVE ACTIONS.—

6 “(A) IN GENERAL.—Nothing in this Act,
7 nor any amendment made by the Frank R.
8 Lautenberg Chemical Safety for the 21st Cen-
9 tury Act, nor any rule, standard of perform-
10 ance, risk evaluation, or scientific assessment
11 implemented pursuant to this Act, shall affect
12 the right of a State or a political subdivision of
13 a State to adopt or enforce any rule, standard
14 of performance, risk evaluation, scientific as-
15 sessment, or any other protection for public
16 health or the environment that—

17 “(i) is adopted or authorized under
18 the authority of any other Federal law or
19 adopted to satisfy or obtain authorization
20 or approval under any other Federal law;

21 “(ii) implements a reporting, moni-
22 toring, or other information obligation for
23 the chemical substance not otherwise re-
24 quired by the Administrator under this Act
25 or required under any other Federal 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 risk evalua-
15 tion published pursuant to section
16 6(b)(4)(D), but is inconsistent with
17 the action of the 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 “(i) IN GENERAL.—The penalties and
2 other sanctions applicable under a law of a
3 State or political subdivision of a State in
4 the event of noncompliance with the iden-
5 tical requirement shall be no more strin-
6 gent than the penalties and other sanctions
7 available to the Administrator under sec-
8 tion 16 of this Act.

9 “(ii) PENALTIES.—In the case of an
10 identical requirement—

11 “(I) a State or political subdivi-
12 sion of a State may not assess a pen-
13 alty for a specific violation for which
14 the Administrator has assessed an
15 adequate penalty under section 16;
16 and

17 “(II) if a State or political sub-
18 division of a State has assessed a pen-
19 alty for a specific violation, the Ad-
20 ministrator may not assess a penalty
21 for that violation in an amount that
22 would cause the total of the penalties
23 assessed for the violation by the State
24 or political subdivision of a State and
25 the Administrator combined to exceed

1 the maximum amount that may be as-
2 sessed for that violation by the Ad-
3 ministrator under section 16.

4 “(2) APPLICABILITY TO CERTAIN RULES OR OR-
5 DERS.—

6 “(A) PRIOR RULES AND ORDERS.—Noth-
7 ing in this section shall be construed as modi-
8 fying the preemptive effect under this section,
9 as in effect on the day before the effective date
10 of the Frank R. Lautenberg Chemical Safety
11 for the 21st Century Act, of any rule or order
12 promulgated or issued under this Act prior to
13 that effective date.

14 “(B) CERTAIN CHEMICAL SUBSTANCES
15 AND MIXTURES.—With respect to a chemical
16 substance or mixture for which any rule or
17 order was promulgated or issued under section
18 6 prior to the effective date of the Frank R.
19 Lautenberg Chemical Safety for the 21st Cen-
20 tury Act with respect to manufacturing, proc-
21 essing, distribution in commerce, use, or dis-
22 posal of the chemical substance or mixture,
23 nothing in this section shall be construed as
24 modifying the preemptive effect of this section
25 as in effect prior to the enactment of the Frank

1 R. Lautenberg Chemical Safety for the 21st
2 Century Act of any rule or order that is pro-
3 mulgated or issued with respect to such chem-
4 ical substance or mixture under section 6 after
5 that effective date, unless the latter rule or
6 order is with respect to a chemical substance or
7 mixture containing a chemical substance and
8 follows a designation of that chemical substance
9 as a high-priority substance under section
10 6(b)(1)(B)(i), the identification of that chemical
11 substance under section 6(b)(2)(A), or the se-
12 lection of that chemical substance for risk eval-
13 uation under section 6(b)(4)(E)(iv)(II).

14 “(e) PRESERVATION OF CERTAIN LAWS.—

15 “(1) IN GENERAL.—Nothing in this Act, sub-
16 ject to subsection (g) of this section, shall—

17 “(A) be construed to preempt or otherwise
18 affect the authority of a State or political sub-
19 division of a State to continue to enforce any
20 action taken or requirement imposed or require-
21 ment enacted relating to a specific chemical
22 substance before April 22, 2016, under the au-
23 thority of a law of the State or political subdivi-
24 sion of the State that prohibits or otherwise re-
25 stricts manufacturing, processing, distribution

1 in commerce, use, or disposal of a chemical sub-
2 stance; or

3 “(B) be construed to preempt or otherwise
4 affect any action taken pursuant to a State law
5 that was in effect on August 31, 2003.

6 “(2) EFFECT OF SUBSECTION.—This sub-
7 section does not affect, modify, or alter the relation-
8 ship between Federal law and laws of a State or po-
9 litical subdivision of a State pursuant to any other
10 Federal law.

11 “(f) WAIVERS.—

12 “(1) DISCRETIONARY EXEMPTIONS.—Upon ap-
13 plication of a State or political subdivision of a
14 State, the Administrator may, by rule, exempt from
15 subsection (a), under such conditions as may be pre-
16 scribed in the rule, a statute, criminal penalty, or
17 administrative action of that State or political sub-
18 division of the State that relates to the effects of ex-
19 posure to a chemical substance under the conditions
20 of use if the Administrator determines that—

21 “(A) compelling conditions warrant grant-
22 ing the waiver to protect health or the environ-
23 ment;

24 “(B) compliance with the proposed require-
25 ment of the State or political subdivision of the

1 State would not unduly burden interstate com-
2 merce in the manufacture, processing, distribu-
3 tion in commerce, or use of a chemical sub-
4 stance;

5 “(C) compliance with the proposed require-
6 ment of the State or political subdivision of the
7 State would not cause a violation of any appli-
8 cable Federal law, rule, or order; and

9 “(D) in the judgment of the Adminis-
10 trator, the proposed requirement of the State or
11 political subdivision of the State is designed to
12 address a risk of a chemical substance, under
13 the conditions of use, that was identified—

14 “(i) consistent with the best available
15 science;

16 “(ii) using supporting studies con-
17 ducted in accordance with sound and ob-
18 jective scientific practices; and

19 “(iii) based on the weight of the sci-
20 entific evidence.

21 “(2) REQUIRED EXEMPTIONS.—Upon applica-
22 tion of a State or political subdivision of a State, the
23 Administrator shall exempt from subsection (b) a
24 statute or administrative action of a State or polit-
25 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)(i) compliance with the proposed re-
4 quirement of the State or political subdivision
5 of the State would not unduly burden interstate
6 commerce in the manufacture, processing, dis-
7 tribution in commerce, or use of a chemical
8 substance;

9 “(ii) compliance with the proposed require-
10 ment of the State or political subdivision of the
11 State would not cause a violation of any appli-
12 cable Federal law, rule, or order; and

13 “(iii) the State or political subdivision of
14 the State has a concern about the chemical sub-
15 stance or use of the chemical substance based
16 in peer-reviewed science; or

17 “(B) no later than the date that is 18
18 months after the date on which the Adminis-
19 trator has initiated the prioritization process for
20 a chemical substance under the rule promul-
21 gated pursuant to section 6(b)(1)(A), or the
22 date on which the Administrator publishes the
23 scope of the risk evaluation for a chemical sub-
24 stance under section 6(b)(4)(D), whichever is
25 sooner, the State or political subdivision of the

1 State has enacted a statute or proposed or fi-
2 nalized an administrative action intended to
3 prohibit or otherwise restrict the manufacture,
4 processing, distribution in commerce, or use of
5 the chemical substance.

6 “(3) DETERMINATION OF A WAIVER RE-
7 QUEST.—The duty of the Administrator to grant or
8 deny a waiver application shall be nondelegable and
9 shall be exercised—

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

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

16 “(4) FAILURE TO MAKE A DETERMINATION.—
17 If the Administrator fails to make a determination
18 under paragraph (3)(B) during the 110-day period
19 beginning on the date on which an application under
20 paragraph (2) is submitted, the statute or adminis-
21 trative action of the State or political subdivision of
22 the State that was the subject of the application
23 shall not be considered to be an existing statute or
24 administrative action for purposes of subsection (b)

1 by reason of the failure of the Administrator to
2 make a determination.

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

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

11 “(A) considered to be a final agency ac-
12 tion; and

13 “(B) subject to judicial review.

14 “(7) DURATION OF WAIVERS.—A waiver grant-
15 ed under paragraph (2) or approved under para-
16 graph (9) shall remain in effect until such time as
17 the Administrator publishes the risk evaluation
18 under section 6(b).

19 “(8) JUDICIAL REVIEW OF WAIVERS.—Not later
20 than 60 days after the date on which the Adminis-
21 trator makes a determination on an application of a
22 State or political subdivision of a State under para-
23 graph (1) or (2), any person may file a petition for
24 judicial review in the United States Court of Appeals

1 for the District of Columbia Circuit, which shall
2 have exclusive jurisdiction over the determination.

3 “(9) APPROVAL.—

4 “(A) AUTOMATIC APPROVAL.—If the Ad-
5 ministrator fails to meet the deadline estab-
6 lished under paragraph (3)(B), the application
7 of a State or political subdivision of a State
8 under paragraph (2) shall be automatically ap-
9 proved, effective on the date that is 10 days
10 after the deadline.

11 “(B) REQUIREMENTS.—Notwithstanding
12 paragraph (6), approval of a waiver application
13 under subparagraph (A) for failure to meet the
14 deadline under paragraph (3)(B) shall not be
15 considered final agency action or be subject to
16 judicial review or public notice and comment.

17 “(g) SAVINGS.—

18 “(1) NO PREEMPTION OF COMMON LAW OR
19 STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF
20 OR CRIMINAL CONDUCT.—

21 “(A) IN GENERAL.—Nothing in this Act,
22 nor any amendment made by the Frank R.
23 Lautenberg Chemical Safety for the 21st Cen-
24 tury Act, nor any standard, rule, requirement,
25 standard of performance, risk evaluation, or sci-

1 entific assessment implemented pursuant to this
2 Act, shall be construed to preempt, displace, or
3 supplant any State or Federal common law
4 rights or any State or Federal statute creating
5 a remedy for civil relief, including those for civil
6 damage, or a penalty for a criminal conduct.

7 “(B) CLARIFICATION OF NO PREEMP-
8 TION.—Notwithstanding any other provision of
9 this Act, nothing in this Act, nor any amend-
10 ments made by the Frank R. Lautenberg
11 Chemical Safety for the 21st Century Act, shall
12 preempt or preclude any cause of action for
13 personal injury, wrongful death, property dam-
14 age, or other injury based on negligence, strict
15 liability, products liability, failure to warn, or
16 any other legal theory of liability under any
17 State law, maritime law, or Federal common
18 law or statutory theory.

19 “(2) NO EFFECT ON PRIVATE REMEDIES.—

20 “(A) IN GENERAL.—Nothing in this Act,
21 nor any amendments made by the Frank R.
22 Lautenberg Chemical Safety for the 21st Cen-
23 tury Act, nor any rules, regulations, require-
24 ments, risk evaluations, scientific assessments,
25 or orders issued pursuant to this Act shall be

1 interpreted as, in either the plaintiff's or de-
2 fendant's favor, dispositive in any civil action.

3 “(B) AUTHORITY OF COURTS.—This Act
4 does not affect the authority of any court to
5 make a determination in an adjudicatory pro-
6 ceeding under applicable State or Federal law
7 with respect to the admission into evidence or
8 any other use of this Act or rules, regulations,
9 requirements, standards of performance, risk
10 evaluations, scientific assessments, or orders
11 issued pursuant to this Act.”.

12 **SEC. 14. JUDICIAL REVIEW.**

13 Section 19(a) of the Toxic Substances Control Act
14 (15 U.S.C. 2618(a)) is amended—

15 (1) in paragraph (1), by adding at the end the
16 following:

17 “(C)(i) Not later than 60 days after the publi-
18 cation of a designation under section 6(b)(1)(B)(ii)
19 or (iii), any person may commence a civil action to
20 challenge the designation.

21 “(ii) The United States Court of Appeals for
22 the District of Columbia Circuit shall have exclusive
23 jurisdiction over a civil action filed under this sub-
24 paragraph.”; and

25 (2) by striking paragraph (3).

1 **SEC. 15. CITIZENS' CIVIL ACTIONS.**

2 Section 20(b) of the Toxic Substances Control Act
3 (15 U.S.C. 2619(b)) is amended—

4 (1) in paragraph (1)(B), by striking “or” at the
5 end; and

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

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

15 **SEC. 16. STUDIES.**

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

18 **SEC. 17. ADMINISTRATION OF THE ACT.**

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

21 (1) in subsection (b)(1)—

22 (A) by striking “of a reasonable fee”;

23 (B) by striking “data under section 4 or 5
24 to defray the cost of administering this Act”
25 and inserting “information under section 4 or a
26 notice or other information to be reviewed by

1 the Administrator under section 5, or who man-
2 ufactures or processes a chemical substance
3 that is the subject of a risk evaluation under
4 section 6(b), of a fee that is sufficient and not
5 more than reasonably necessary to defray the
6 cost related to such chemical substance of ad-
7 ministering sections 4, 5, and 6, and collecting,
8 processing, reviewing, and providing access to
9 and protecting from disclosure as appropriate
10 under section 14 information on chemical sub-
11 stances under this title, including contractor
12 costs incurred by the Administrator”;

13 (C) by striking “Such rules shall not pro-
14 vide for any fee in excess of \$2,500 or, in the
15 case of a small business concern, any fee in ex-
16 cess of \$100.”; and

17 (D) by striking “submit the data and the
18 cost to the Administrator of reviewing such
19 data” and inserting “pay such fee and the cost
20 to the Administrator of carrying out the activi-
21 ties described in this paragraph”;

22 (2) in subsection (b)—

23 (A) in paragraph (2), by striking “para-
24 graph (1)” and inserting “paragraph (4)”;

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

1 “(3) FUND.—

2 “(A) ESTABLISHMENT.—There is established in
3 the Treasury of the United States a fund, to be
4 known as the TSCA Service Fee Fund (in this para-
5 graph referred to as the ‘Fund’), consisting of such
6 amounts as are deposited in the Fund under this
7 paragraph.

8 “(B) COLLECTION AND DEPOSIT OF FEES.—
9 Subject to the conditions of subparagraph (C), the
10 Administrator shall collect the fees described in this
11 subsection and deposit those fees in the Fund.

12 “(C) USE OF FUNDS BY ADMINISTRATOR.—
13 Fees authorized under this section shall be collected
14 and available for obligation only to the extent and in
15 the amount provided in advance in appropriations
16 Acts, and shall be available without fiscal year limi-
17 tation for use in defraying the costs of the activities
18 described in paragraph (1).

19 “(D) ACCOUNTING AND AUDITING.—

20 “(i) ACCOUNTING.—The Administrator
21 shall biennially prepare and submit to the Com-
22 mittee on Environment and Public Works of the
23 Senate and the Committee on Energy and Com-
24 merce of the House of Representatives a report
25 that includes an accounting of the fees paid to

1 the Administrator under this paragraph and
2 amounts disbursed from the Fund for the pe-
3 riod covered by the report, as reflected by fi-
4 nancial statements provided in accordance with
5 sections 3515 and 3521 of title 31, United
6 States Code.

7 “(ii) AUDITING.—

8 “(I) IN GENERAL.—For the purpose
9 of section 3515(c) of title 31, United
10 States Code, the Fund shall be considered
11 a component of a covered executive agency.

12 “(II) COMPONENTS OF AUDIT.—The
13 annual audit required in accordance with
14 sections 3515 and 3521 of title 31, United
15 States Code, of the financial statements of
16 activities carried out using amounts from
17 the Fund shall include an analysis of—

18 “(aa) the fees collected and
19 amounts disbursed under this sub-
20 section;

21 “(bb) the reasonableness of the
22 fees in place as of the date of the
23 audit to meet current and projected
24 costs of administering the provisions

1 of this title for which the fees may be
2 used; and

3 “(cc) the number of requests for
4 a risk evaluation made by manufac-
5 turers under section 6(b)(4)(C)(ii).

6 “(III) FEDERAL RESPONSIBILITY.—
7 The Inspector General of the Environ-
8 mental Protection Agency shall conduct
9 the annual audit described in subclause
10 (II) and submit to the Administrator a re-
11 port that describes the findings and any
12 recommendations of the Inspector General
13 resulting from the audit.

14 “(4) AMOUNT AND ADJUSTMENT OF FEES; RE-
15 FUNDS.—In setting fees under this section, the Adminis-
16 trator shall—

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

20 “(B) set the fees established under paragraph
21 (1) at levels such that the fees will, in aggregate,
22 provide a sustainable source of funds to annually de-
23 fray—

24 “(i) the lower of—

1 “(I) 25 percent of the costs to the Ad-
2 ministrator of carrying out sections 4, 5,
3 and 6, and of collecting, processing, re-
4 viewing, and providing access to and pro-
5 tecting from disclosure as appropriate
6 under section 14 information on chemical
7 substances under this title, other than the
8 costs to conduct and complete risk evalua-
9 tions under section 6(b); or

10 “(II) \$25,000,000 (subject to adjust-
11 ment pursuant to subparagraph (F)); and

12 “(ii) the costs of risk evaluations specified
13 in subparagraph (D);

14 “(C) reflect an appropriate balance in the as-
15 sessment of fees between manufacturers and proc-
16 essors, and allow the payment of fees by consortia
17 of manufacturers or processors;

18 “(D) notwithstanding subparagraph (B)—

19 “(i) except as provided in clause (ii), for
20 chemical substances for which the Adminis-
21 trator has granted a request from a manufac-
22 turer pursuant to section 6(b)(4)(C)(ii), estab-
23 lish the fee at a level sufficient to defray the
24 full costs to the Administrator of conducting
25 the risk evaluation under section 6(b);

1 “(ii) for chemical substances for which the
2 Administrator has granted a request from a
3 manufacturer pursuant to section
4 6(b)(4)(C)(ii), and which are included in the
5 2014 update of the TSCA Work Plan for
6 Chemical Assessments, establish the fee at a
7 level sufficient to defray 50 percent of the costs
8 to the Administrator of conducting the risk
9 evaluation under section 6(b); and

10 “(iii) apply fees collected pursuant to
11 clauses (i) and (ii) only to defray the costs de-
12 scribed in those clauses;

13 “(E) prior to the establishment or amendment
14 of any fees under paragraph (1), consult and meet
15 with parties potentially subject to the fees or their
16 representatives, subject to the condition that no obli-
17 gation under the Federal Advisory Committee Act (5
18 U.S.C. App.) or subchapter II of chapter 5 of title
19 5, United States Code, is applicable with respect to
20 such meetings;

21 “(F) beginning with the fiscal year that is 3
22 years after the date of enactment of the Frank R.
23 Lautenberg Chemical Safety for the 21st Century
24 Act, and every 3 years thereafter, after consultation
25 with parties potentially subject to the fees and their

1 representatives pursuant to subparagraph (E), in-
2 crease or decrease the fees established under para-
3 graph (1) as necessary to adjust for inflation and to
4 ensure that funds deposited in the Fund are suffi-
5 cient to defray—

6 “(i) approximately but not more than 25
7 percent of the costs to the Administrator of car-
8 rying out sections 4, 5, and 6, and of collecting,
9 processing, reviewing, and providing access to
10 and protecting from disclosure as appropriate
11 under section 14 information on chemical sub-
12 stances under this title, other than the costs to
13 conduct and complete risk evaluations requested
14 under section 6(b)(4)(C)(ii); and

15 “(ii) the costs of risk evaluations specified
16 in subparagraph (D); and

17 “(G) if a notice submitted under section 5 is
18 not reviewed or such a notice is withdrawn, refund
19 the fee or a portion of the fee if no substantial work
20 was performed on the notice.

21 “(5) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees
22 may not be assessed for a fiscal year under this section
23 unless the amount of appropriations for the Chemical Risk
24 Review and Reduction program project of the Environ-
25 mental Protection Agency for the fiscal year (excluding

1 the amount of any fees appropriated for the fiscal year)
2 are equal to or greater than the amount of appropriations
3 for that program project for fiscal year 2014.

4 “(6) TERMINATION.—The authority provided by this
5 subsection shall terminate at the conclusion of the fiscal
6 year that is 10 years after the date of enactment of the
7 Frank R. Lautenberg Chemical Safety for the 21st Cen-
8 tury Act unless otherwise reauthorized or modified by
9 Congress.”; and

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

11 “(h) SCIENTIFIC STANDARDS.—In carrying out sec-
12 tions 4, 5, and 6, to the extent that the Administrator
13 makes a decision based on science, the Administrator shall
14 use scientific information, technical procedures, measures,
15 methods, protocols, methodologies, or models, employed in
16 a manner consistent with the best available science, and
17 shall consider as applicable—

18 “(1) the extent to which the scientific informa-
19 tion, technical procedures, measures, methods, proto-
20 cols, methodologies, or models employed to generate
21 the information are reasonable for and consistent
22 with the intended use of the information;

23 “(2) the extent to which the information is rel-
24 evant for the Administrator’s use in making a deci-
25 sion about a chemical substance or mixture;

1 “(3) the degree of clarity and completeness with
2 which the data, assumptions, methods, quality assur-
3 ance, and analyses employed to generate the infor-
4 mation are documented;

5 “(4) the extent to which the variability and un-
6 certainty in the information, or in the procedures,
7 measures, methods, protocols, methodologies, or
8 models, are evaluated and characterized; and

9 “(5) the extent of independent verification or
10 peer review of the information or of the procedures,
11 measures, methods, protocols, methodologies, or
12 models.

13 “(i) WEIGHT OF SCIENTIFIC EVIDENCE.—The Ad-
14 ministrators shall make decisions under sections 4, 5, and
15 6 based on the weight of the scientific evidence.

16 “(j) AVAILABILITY OF INFORMATION.—Subject to
17 section 14, the Administrator shall make available to the
18 public—

19 “(1) all notices, determinations, findings, rules,
20 consent agreements, and orders of the Administrator
21 under this title;

22 “(2) any information required to be provided to
23 the Administrator under section 4;

24 “(3) a nontechnical summary of each risk eval-
25 uation conducted under section 6(b);

1 “(4) a list of the studies considered by the Ad-
2 ministrator in carrying out each such risk evalua-
3 tion, along with the results of those studies; and

4 “(5) each designation of a chemical substance
5 under section 6(b), along with an identification of
6 the information, analysis, and basis used to make
7 the designations.

8 “(k) REASONABLY AVAILABLE INFORMATION.—In
9 carrying out sections 4, 5, and 6, the Administrator shall
10 take into consideration information relating to a chemical
11 substance or mixture, including hazard and exposure in-
12 formation, under the conditions of use, that is reasonably
13 available to the Administrator.

14 “(l) POLICIES, PROCEDURES, AND GUIDANCE.—

15 “(1) DEVELOPMENT.—Not later than 2 years
16 after the date of enactment of the Frank R. Lauten-
17 berg Chemical Safety for the 21st Century Act, the
18 Administrator shall develop any policies, procedures,
19 and guidance the Administrator determines are nec-
20 essary to carry out the amendments to this Act
21 made by the Frank R. Lautenberg Chemical Safety
22 for the 21st Century Act.

23 “(2) REVIEW.—Not later than 5 years after the
24 date of enactment of the Frank R. Lautenberg
25 Chemical Safety for the 21st Century Act, and not

1 less frequently than once every 5 years thereafter,
2 the Administrator shall—

3 “(A) review the adequacy of the policies,
4 procedures, and guidance developed under para-
5 graph (1), including with respect to animal,
6 nonanimal, and epidemiological test methods
7 and procedures for assessing and determining
8 risk under this title; and

9 “(B) revise such policies, procedures, and
10 guidance as the Administrator determines nec-
11 essary to reflect new scientific developments or
12 understandings.

13 “(3) TESTING OF CHEMICAL SUBSTANCES AND
14 MIXTURES.—The policies, procedures, and guidance
15 developed under paragraph (1) applicable to testing
16 chemical substances and mixtures shall—

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

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

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

4 “(4) CHEMICAL SUBSTANCES WITH COMPLETED
5 RISK ASSESSMENTS.—With respect to a chemical
6 substance listed in the 2014 update to the TSCA
7 Work Plan for Chemical Assessments for which the
8 Administrator has published a completed risk assess-
9 ment prior to the date of enactment of the Frank
10 R. Lautenberg Chemical Safety for the 21st Century
11 Act, the Administrator may publish proposed and
12 final rules under section 6(a) that are consistent
13 with the scope of the completed risk assessment for
14 the chemical substance and consistent with other ap-
15 plicable requirements of section 6.

16 “(5) GUIDANCE.—Not later than 1 year after
17 the date of enactment of the Frank R. Lautenberg
18 Chemical Safety for the 21st Century Act, the Ad-
19 ministrator shall develop guidance to assist inter-
20 ested persons in developing and submitting draft
21 risk evaluations which shall be considered by the Ad-
22 ministrator. The guidance shall, at a minimum, ad-
23 dress the quality of the information submitted and
24 the process to be followed in developing draft risk
25 evaluations for consideration by the Administrator.

1 “(m) REPORT TO CONGRESS.—

2 “(1) INITIAL REPORT.—Not later than 6
3 months after the date of enactment of the Frank R.
4 Lautenberg Chemical Safety for the 21st Century
5 Act, the Administrator shall submit to the Commit-
6 tees on Energy and Commerce and Appropriations
7 of the House of Representatives and the Committees
8 on Environment and Public Works and Appropria-
9 tions of the Senate a report containing an estimation
10 of—

11 “(A) the capacity of the Environmental
12 Protection Agency to conduct and publish risk
13 evaluations under section 6(b)(4)(C)(i) and(ii),
14 and the resources necessary to conduct the min-
15 imum number of risk evaluations required
16 under section 6(b)(2);

17 “(B) the capacity of the Environmental
18 Protection Agency to conduct and publish risk
19 evaluations under section 6(b)(4)(A)(ii), the
20 likely demand for such risk evaluations, and the
21 anticipated schedule for accommodating that
22 demand;

23 “(C) the capacity of the Environmental
24 Protection Agency to promulgate rules under
25 section 6(a) as required based on risk evalua-

1 tions conducted and published under section
2 6(b); and

3 “(D) the actual and anticipated efforts of
4 the Environmental Protection Agency to in-
5 crease the Agency’s capacity to conduct and
6 publish risk evaluations under section 6(b).

7 “(2) SUBSEQUENT REPORTS.—The Adminis-
8 trator shall update and resubmit the report de-
9 scribed in paragraph (1) not less frequently than
10 once every 5 years.

11 “(n) ANNUAL PLAN.—

12 “(1) IN GENERAL.—The Administrator shall in-
13 form the public regarding the schedule and the re-
14 sources necessary for the completion of each risk
15 evaluation as soon as practicable after initiating the
16 risk evaluation.

17 “(2) PUBLICATION OF PLAN.—At the beginning
18 of each calendar year, the Administrator shall pub-
19 lish an annual plan that—

20 “(A) identifies the chemical substances for
21 which risk evaluations are expected to be initi-
22 ated or completed that year and the resources
23 necessary for their completion;

1 “(B) describes the status of each risk eval-
2 uation that has been initiated but not yet com-
3 pleted; and

4 “(C) if the schedule for completion of a
5 risk evaluation has changed, includes an up-
6 dated schedule for that risk evaluation.

7 “(o) CONSULTATION WITH SCIENCE ADVISORY COM-
8 MITTEE ON CHEMICALS.—

9 “(1) ESTABLISHMENT.—Not later than 1 year
10 after the date of enactment of the Frank R. Lauten-
11 berg Chemical Safety for the 21st Century Act, the
12 Administrator shall establish an advisory committee,
13 to be known as the Science Advisory Committee on
14 Chemicals (referred to in this subsection as the
15 ‘Committee’).

16 “(2) PURPOSE.—The purpose of the Committee
17 shall be to provide independent advice and expert
18 consultation, at the request of the Administrator,
19 with respect to the scientific and technical aspects of
20 issues relating to the implementation of this title.

21 “(3) COMPOSITION.—The Committee shall be
22 composed of representatives of such science, govern-
23 ment, labor, public health, public interest, animal
24 protection, industry, and other groups as the Admin-
25 istrator determines to be advisable, including rep-

1 representatives that have specific scientific expertise in
2 the relationship of chemical exposures to women,
3 children, and other potentially exposed or susceptible
4 subpopulations.

5 “(4) SCHEDULE.—The Administrator shall con-
6 vene the Committee in accordance with such sched-
7 ule as the Administrator determines to be appro-
8 priate, but not less frequently than once every 2
9 years.

10 “(p) PRIOR ACTIONS.—

11 “(1) RULES, ORDERS, AND EXEMPTIONS.—
12 Nothing in the Frank R. Lautenberg Chemical Safe-
13 ty for the 21st Century Act eliminates, modifies, or
14 withdraws any rule promulgated, order issued, or ex-
15 emption established pursuant to this Act before the
16 date of enactment of the Frank R. Lautenberg
17 Chemical Safety for the 21st Century Act.

18 “(2) PRIOR-INITIATED EVALUATIONS.—Nothing
19 in this Act prevents the Administrator from initi-
20 ating a risk evaluation regarding a chemical sub-
21 stance, or from continuing or completing such risk
22 evaluation, prior to the effective date of the policies,
23 procedures, and guidance required to be developed
24 by the Administrator pursuant to the amendments

1 made by the Frank R. Lautenberg Chemical Safety
2 for the 21st Century Act.

3 “(3) ACTIONS COMPLETED PRIOR TO COMPLE-
4 TION OF POLICIES, PROCEDURES, AND GUIDANCE.—
5 Nothing in this Act requires the Administrator to re-
6 vise or withdraw a completed risk evaluation, deter-
7 mination, or rule under this Act solely because the
8 action was completed prior to the development of a
9 policy, procedure, or guidance pursuant to the
10 amendments made by the Frank R. Lautenberg
11 Chemical Safety for the 21st Century Act.”.

12 **SEC. 18. STATE PROGRAMS.**

13 Section 28 of the Toxic Substances Control Act (15
14 U.S.C. 2627) is amended by striking subsections (c) and
15 (d).

16 **SEC. 19. CONFORMING AMENDMENTS.**

17 (a) TABLE OF CONTENTS.—The table of contents in
18 section 1 of the Toxic Substances Control Act is amend-
19 ed—

20 (1) by striking the item relating to section 6
21 and inserting the following:

“Sec. 6. Prioritization, risk evaluation, and regulation of chemical substances
and mixtures.”;

22 (2) by striking the item relating to section 10
23 and inserting the following:

“Sec. 10. Research, development, collection, dissemination, and utilization of in-
formation.”;

1 (3) by striking the item relating to section 14
2 and inserting the following:

“Sec. 14. Confidential information.”; and

3 (4) by striking the item relating to section 25.

4 (b) SECTION 2.—Section 2(b)(1) of the Toxic Sub-
5 stances Control Act (15 U.S.C. 2601(b)(1)) is amended
6 by striking “data” both places it appears and inserting
7 “information”.

8 (c) SECTION 3.—Section 3 of the Toxic Substances
9 Control Act (15 U.S.C. 2602) is amended—

10 (1) in paragraph (8) (as redesignated by section
11 3 of this Act), by striking “data” and inserting “in-
12 formation”; and

13 (2) in paragraph (15) (as redesignated by sec-
14 tion 3 of this Act)—

15 (A) by striking “standards” and inserting
16 “protocols and methodologies”;

17 (B) by striking “test data” both places it
18 appears and inserting “information”; and

19 (C) by striking “data” each place it ap-
20 pears and inserting “information”.

21 (d) SECTION 4.—Section 4 of the Toxic Substances
22 Control Act (15 U.S.C. 2603) is amended—

23 (1) in subsection (b)—

24 (A) in paragraph (1)—

1 (i) in the paragraph heading, by add-
2 ing “, ORDER, OR CONSENT AGREEMENT”
3 at the end; and

4 (ii) by striking “rule” each place it
5 appears and inserting “rule, order, or con-
6 sent agreement”;

7 (B) in paragraph (2)(B), by striking
8 “rules” and inserting “rules, orders, and con-
9 sent agreements”;

10 (C) in paragraph (3)(A), by striking “rule”
11 and inserting “rule or order”; and

12 (D) in paragraph (4)—

13 (i) by striking “rule under subsection
14 (a)” each place it appears and inserting
15 “rule, order, or consent agreement under
16 subsection (a)”;

17 (ii) by striking “repeals the rule” each
18 place it appears and inserting “repeals the
19 rule or order or modifies the consent
20 agreement to terminate the requirement”;
21 and

22 (iii) by striking “repeals the applica-
23 tion of the rule” and inserting “repeals or
24 modifies the application of the rule, order,
25 or consent agreement”;

1 (2) in subsection (c)—

2 (A) in paragraph (1), by striking “rule”
3 and inserting “rule or order”;

4 (B) in paragraph (2)—

5 (i) in subparagraph (A), by striking
6 “a rule under subsection (a) or for which
7 data is being developed pursuant to such a
8 rule” and inserting “a rule, order, or con-
9 sent agreement under subsection (a) or for
10 which information is being developed pur-
11 suant to such a rule, order, or consent
12 agreement”;

13 (ii) in subparagraph (B), by striking
14 “such rule or which is being developed pur-
15 suant to such rule” and inserting “such
16 rule, order, or consent agreement or which
17 is being developed pursuant to such rule,
18 order, or consent agreement”; and

19 (iii) in the matter following subpara-
20 graph (B), by striking “the rule” and in-
21 serting “the rule or order”;

22 (C) in paragraph (3)(B)(i), by striking
23 “rule promulgated” and inserting “rule, order,
24 or consent agreement”; and

25 (D) in paragraph (4)—

1 (i) by striking “rule promulgated”
2 each place it appears and inserting “rule,
3 order, or consent agreement”;

4 (ii) by striking “such rule” each place
5 it appears and inserting “such rule, order,
6 or consent agreement”; and

7 (iii) in subparagraph (B), by striking
8 “the rule” and inserting “the rule or
9 order”;

10 (3) in subsection (d), by striking “rule” and in-
11 serting “rule, order, or consent agreement”; and

12 (4) in subsection (g), by striking “rule” and in-
13 serting “rule, order, or consent agreement”.

14 (e) SECTION 5.—Section 5 of the Toxic Substances
15 Control Act (15 U.S.C. 2604) is amended—

16 (1) in subsection (b)—

17 (A) in paragraph (1)(A)—

18 (i) by striking “rule promulgated”
19 and inserting “rule, order, or consent
20 agreement”; and

21 (ii) by striking “such rule” and insert-
22 ing “such rule, order, or consent agree-
23 ment”;

1 (B) in paragraph (1)(B), by striking “rule
2 promulgated” and inserting “rule or order”;
3 and

4 (C) in paragraph (2)(A)(ii), by striking
5 “rule promulgated” and inserting “rule, order,
6 or consent agreement”; and

7 (2) in subsection (d)(2)(C), by striking “rule”
8 and inserting “rule, order, or consent agreement”.

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

11 (1) in paragraph (1), in the matter following
12 subparagraph (C), by striking “a rule under section
13 4, 5, 6, or title IV or an order under section 5 or
14 title IV” and inserting “a determination under sec-
15 tion 5 or 6, a rule under section 4, 5, or 6 or title
16 IV, an order under section 4, 5, or 6 or title IV, or
17 a consent agreement under section 4”; and

18 (2) in paragraph (2), by striking “subsection
19 6(d)(2)(A)(i)” and inserting “section 6(d)(3)(A)(i)”.

20 (g) SECTION 8.—Section 8(a) of the Toxic Sub-
21 stances Control Act (15 U.S.C. 2607(a)) is amended—

22 (1) in paragraph (2)(E), by striking “data” and
23 inserting “information”; and

24 (2) in paragraph (3)(A)(ii)(I), by striking “or
25 an order in effect under section 5(e)” and inserting

1 “, an order in effect under section 4 or 5(e), or a
2 consent agreement under section 4”.

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

5 (1) in subsection (a), by striking “section 6”
6 each place it appears and inserting “section 6(a)”;
7 and

8 (2) in subsection (d), by striking “Health, Edu-
9 cation, and Welfare” and inserting “Health and
10 Human Services”.

11 (i) SECTION 10.—Section 10 of the Toxic Substances
12 Control Act (15 U.S.C. 2609) is amended—

13 (1) in the section heading, by striking “**DATA**”
14 and inserting “**INFORMATION**”;

15 (2) by striking “Health, Education, and Wel-
16 fare” each place it appears and inserting “Health
17 and Human Services”;

18 (3) in subsection (b)—

19 (A) in the subsection heading, by striking
20 “DATA” and inserting “INFORMATION”;

21 (B) by striking “data” and inserting “in-
22 formation” in paragraph (1);

23 (C) by striking “data” and inserting “in-
24 formation” in paragraph (2)(A); and

1 (D) by striking “a data” and inserting “an
2 information” in paragraph (2)(B); and
3 (4) in subsection (g), by striking “data” and in-
4 serting “information”.

5 (j) SECTION 11.—Section 11(b)(2) of the Toxic Sub-
6 stances Control Act (15 U.S.C. 2610(b)(2)) is amended—

7 (1) by striking “data” each place it appears
8 and inserting “information”; and

9 (2) in subparagraph (E), by striking “rule pro-
10 mulgated” and inserting “rule promulgated, order
11 issued, or consent agreement entered into”.

12 (k) SECTION 12.—Section 12(b)(1) of the Toxic Sub-
13 stances Control Act (15 U.S.C. 2611(b)(1)) is amended
14 by striking “data” both places it appears and inserting
15 “information”.

16 (l) SECTION 15.—Section 15(1) of the Toxic Sub-
17 stances Control Act (15 U.S.C. 2614(1)) is amended by
18 striking “(A) any rule” and all that follows through “or
19 (D)” and inserting “any requirement of this title or any
20 rule promulgated, order issued, or consent agreement en-
21 tered into under this title, or”.

22 (m) SECTION 19.—Section 19 of the Toxic Sub-
23 stances Control Act (15 U.S.C. 2618) is amended—

24 (1) in subsection (a)—

25 (A) in paragraph (1)(A)—

1 (i) by striking “Not later than 60
2 days after the date of the promulgation of
3 a rule under section 4(a), 5(a)(2), 5(b)(4),
4 6(a), 6(e), or 8, or under title II or IV”
5 and inserting “Except as otherwise pro-
6 vided in this title, not later than 60 days
7 after the date on which a rule is promul-
8 gated under this title, title II, or title IV,
9 or the date on which an order is issued
10 under section 4, 5(e), 5(f), or 6(i)(1),”;

11 (ii) by striking “such rule” and insert-
12 ing “such rule or order”; and

13 (iii) by striking “such a rule” and in-
14 serting “such a rule or order”;

15 (B) in paragraph (1)(B)—

16 (i) by striking “Courts” and inserting
17 “Except as otherwise provided in this title,
18 courts”; and

19 (ii) by striking “subparagraph (A) or
20 (B) of section 6(b)(1)” and inserting “this
21 title, other than an order under section 4,
22 5(e), 5(f), or 6(i)(1),”;

23 (C) in paragraph (2)—

24 (i) by striking “rulemaking record”
25 and inserting “record”; and

1 (ii) by striking “based the rule” and
2 inserting “based the rule or order”;

3 (2) in subsection (b)—

4 (A) by striking “review a rule” and insert-
5 ing “review a rule, or an order under section 4,
6 5(e), 5(f), or 6(i)(1),”;

7 (B) by striking “such rule” and inserting
8 “such rule or order”;

9 (C) by striking “the rule” and inserting
10 “the rule or order”;

11 (D) by striking “new rule” each place it
12 appears and inserting “new rule or order”; and

13 (E) by striking “modified rule” and insert-
14 ing “modified rule or order”; and

15 (3) in subsection (c)—

16 (A) in paragraph (1)—

17 (i) in subparagraph (A)—

18 (I) by striking “a rule” and in-
19 serting “a rule or order”; and

20 (II) by striking “such rule” and
21 inserting “such rule or order”;

22 (ii) in subparagraph (B)—

23 (I) in the matter preceding clause

24 (i), by striking “a rule” and inserting
25 “a rule or order”;

1 (II) by amending clause (i) to
2 read as follows:

3 “(i) in the case of review of—

4 “(I) a rule under section 4(a), 5(b)(4),
5 6(a) (including review of the associated deter-
6 mination under section 6(b)(4)(A)), or 6(e), the
7 standard for review prescribed by paragraph
8 (2)(E) of such section 706 shall not apply and
9 the court shall hold unlawful and set aside such
10 rule if the court finds that the rule is not sup-
11 ported by substantial evidence in the rule-
12 making record taken as a whole; and

13 “(II) an order under section 4, 5(e), 5(f),
14 or 6(i)(1), the standard for review prescribed by
15 paragraph (2)(E) of such section 706 shall not
16 apply and the court shall hold unlawful and set
17 aside such order if the court finds that the
18 order is not supported by substantial evidence
19 in the record taken as a whole; and”;

20 (III) by striking clauses (ii) and
21 (iii) and the matter after clause (iii)
22 and inserting the following:

23 “(ii) the court may not review the contents and
24 adequacy of any statement of basis and purpose re-
25 quired by section 553(c) of title 5, United States

1 Code, to be incorporated in the rule or order, except
2 as part of the record, taken as a whole.”; and

3 (iii) by striking subparagraph (C);

4 and

5 (B) in paragraph (2), by striking “any
6 rule” and inserting “any rule or order”.

7 (n) SECTION 20.—Section 20(a)(1) of the Toxic Sub-
8 stances Control Act (15 U.S.C. 2619(a)(1)) is amended
9 by striking “order issued under section 5” and inserting
10 “order issued under section 4 or 5”.

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

13 (1) in subsection (a), by striking “order under
14 section 5(e) or (6)(b)(2)” and inserting “order
15 under section 4 or 5(e) or (f)”;

16 (2) in subsection (b)—

17 (A) in paragraph (1), by striking “order
18 under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)”
19 and inserting “order under section 4 or 5(e) or
20 (f)”;

21 (B) in paragraph (4)(B)—

22 (i) in the matter preceding clause (i),
23 by striking “order under section 5(e) or
24 6(b)(2)” and inserting “order under sec-
25 tion 4 or 5(e) or (f)”;

1 (ii) in clause (i), by striking “order
2 under section 5(e)” and inserting “order
3 under section 4 or 5(e) or (f)”;

4 (iii) in clause (ii), by striking “section
5 6 or 8 or an order under section 6(b)(2)”
6 and inserting “section 6(a) or 8 or an
7 order under section 5(f)”.

8 (p) SECTION 24.—Section 24(b)(2)(B) of the Toxic
9 Substances Control Act (15 U.S.C. 2623(b)(2)(B)) is
10 amended—

11 (1) by inserting “and” at the end of clause (i);

12 (2) by striking clause (ii); and

13 (3) by redesignating clause (iii) as clause (ii).

14 (q) SECTION 26.—Section 26 of the Toxic Substances
15 Control Act (15 U.S.C. 2625) is amended—

16 (1) in subsection (e), by striking “Health, Edu-
17 cation, and Welfare” each place it appears and in-
18 serting “Health and Human Services”; and

19 (2) in subsection (g)(1), by striking “data” and
20 inserting “information”.

21 (r) SECTION 27.—Section 27(a) of the Toxic Sub-
22 stances Control Act (15 U.S.C. 2626(a)) is amended—

23 (1) by striking “Health, Education, and Wel-
24 fare” and inserting “Health and Human Services”;

1 (2) by striking “test data” both places it ap-
2 pears and inserting “information”;

3 (3) by striking “rules promulgated” and insert-
4 ing “rules, orders, or consent agreements”; and

5 (4) by striking “standards” and inserting “pro-
6 tocols and methodologies”.

7 (s) SECTION 30.—Section 30(2) of the Toxic Sub-
8 stances Control Act (15 U.S.C. 2629(2)) is amended by
9 striking “rule” and inserting “rule, order, or consent
10 agreement”.

11 **SEC. 20. NO RETROACTIVITY.**

12 Nothing in sections 1 through 19, or the amendments
13 made by sections 1 through 19, shall be interpreted to
14 apply retroactively to any State, Federal, or maritime legal
15 action filed before the date of enactment of this Act.

16 **SEC. 21. TREVOR’S LAW.**

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

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

21 (2) to ensure that Federal agencies have the
22 authority to undertake actions to help address can-
23 cer clusters and factors that may contribute to the
24 creation of potential cancer clusters; and

1 (3) to enable Federal agencies to coordinate
2 with other Federal, State, and local agencies, insti-
3 tutes of higher education, and the public in inves-
4 tigating and addressing cancer clusters.

5 (b) DESIGNATION AND INVESTIGATION OF POTEN-
6 TIAL CANCER CLUSTERS.—Part P of title III of the Pub-
7 lic Health Service Act (42 U.S.C. 280g et seq.) is amended
8 by adding at the end the following:

9 **“SEC. 399V-6. DESIGNATION AND INVESTIGATION OF PO-**
10 **TENTIAL CANCER CLUSTERS.**

11 “(a) DEFINITIONS.—In this section:

12 “(1) CANCER CLUSTER.—The term ‘cancer
13 cluster’ means the incidence of a particular cancer
14 within a population group, a geographical area, and
15 a period of time that is greater than expected for
16 such group, area, and period.

17 “(2) PARTICULAR CANCER.—The term ‘par-
18 ticular cancer’ means one specific type of cancer or
19 a type of cancers scientifically proven to have the
20 same cause.

21 “(3) POPULATION GROUP.—The term ‘popu-
22 lation group’ means a group, for purposes of calcu-
23 lating cancer rates, defined by factors such as race,
24 ethnicity, age, or gender.

1 “(b) CRITERIA FOR DESIGNATION OF POTENTIAL
2 CANCER CLUSTERS.—

3 “(1) DEVELOPMENT OF CRITERIA.—The Sec-
4 retary shall develop criteria for the designation of
5 potential cancer clusters.

6 “(2) REQUIREMENTS.—The criteria developed
7 under paragraph (1) shall consider, as appropriate—

8 “(A) a standard for cancer cluster identi-
9 fication and reporting protocols used to deter-
10 mine when cancer incidence is greater than
11 would be typically observed;

12 “(B) scientific screening standards that
13 ensure that a cluster of a particular cancer in-
14 volves the same type of cancer, or types of can-
15 cers;

16 “(C) the population in which the cluster of
17 a particular cancer occurs by factors such as
18 race, ethnicity, age, and gender, for purposes of
19 calculating cancer rates;

20 “(D) the boundaries of a geographic area
21 in which a cluster of a particular cancer occurs
22 so as not to create or obscure a potential clus-
23 ter by selection of a specific area; and

1 “(E) the time period over which the num-
2 ber of cases of a particular cancer, or the cal-
3 culation of an expected number of cases, occurs.

4 “(c) GUIDELINES FOR INVESTIGATION OF POTEN-
5 TIAL CANCER CLUSTERS.—The Secretary, in consultation
6 with the Council of State and Territorial Epidemiologists
7 and representatives of State and local health departments,
8 shall develop, publish, and periodically update guidelines
9 for investigating potential cancer clusters. The guidelines
10 shall—

11 “(1) recommend that investigations of cancer
12 clusters—

13 “(A) use the criteria developed under sub-
14 section (b);

15 “(B) use the best available science; and

16 “(C) rely on a weight of the scientific evi-
17 dence;

18 “(2) provide standardized methods of reviewing
19 and categorizing data, including from health surveil-
20 lance systems and reports of potential cancer clus-
21 ters; and

22 “(3) provide guidance for using appropriate epi-
23 demiological and other approaches for investigations.

24 “(d) INVESTIGATION OF CANCER CLUSTERS.—

1 “(1) SECRETARY DISCRETION.—The Sec-
2 retary—

3 “(A) in consultation with representatives of
4 the relevant State and local health departments,
5 shall consider whether it is appropriate to con-
6 duct an investigation of a potential cancer clus-
7 ter; and

8 “(B) in conducting investigations shall
9 have the discretion to prioritize certain poten-
10 tial cancer clusters, based on the availability of
11 resources.

12 “(2) COORDINATION.—In investigating poten-
13 tial cancer clusters, the Secretary shall coordinate
14 with agencies within the Department of Health and
15 Human Services and other Federal agencies, such as
16 the Environmental Protection Agency.

17 “(3) BIOMONITORING.—In investigating poten-
18 tial cancer clusters, the Secretary shall rely on all
19 appropriate biomonitoring information collected
20 under other Federal programs, such as the National
21 Health and Nutrition Examination Survey. The Sec-
22 retary may provide technical assistance for relevant
23 biomonitoring studies of other Federal agencies.

24 “(e) DUTIES.—The Secretary shall—

1 “(1) ensure that appropriate staff of agencies
2 within the Department of Health and Human Serv-
3 ices are prepared to provide timely assistance, to the
4 extent practicable, upon receiving a request to inves-
5 tigate a potential cancer cluster from a State or
6 local health authority;

7 “(2) maintain staff expertise in epidemiology,
8 toxicology, data analysis, environmental health and
9 cancer surveillance, exposure assessment, pediatric
10 health, pollution control, community outreach, health
11 education, laboratory sampling and analysis, spatial
12 mapping, and informatics;

13 “(3) consult with community members as inves-
14 tigations into potential cancer clusters are con-
15 ducted, as the Secretary determines appropriate;

16 “(4) collect, store, and disseminate reports on
17 investigations of potential cancer clusters, the pos-
18 sible causes of such clusters, and the actions taken
19 to address such clusters; and

20 “(5) provide technical assistance for inves-
21 tigating cancer clusters to State and local health de-
22 partments through existing programs, such as the
23 Epi-Aids program of the Centers for Disease Control
24 and Prevention and the Assessments of Chemical

1 Exposures Program of the Agency for Toxic Sub-
2 stances and Disease Registry.”.

3 **TITLE II—RURAL HEALTHCARE**
4 **CONNECTIVITY**

5 **SEC. 201. SHORT TITLE.**

6 This title may be cited as the “Rural Healthcare
7 Connectivity Act of 2016”.

8 **SEC. 202. TELECOMMUNICATIONS SERVICES FOR SKILLED**
9 **NURSING FACILITIES.**

10 (a) IN GENERAL.—Section 254(h)(7)(B) of the Com-
11 munications Act of 1934 (47 U.S.C. 254(h)(7)(B)) is
12 amended—

13 (1) in clause (vi), by striking “and” at the end;

14 (2) by redesignating clause (vii) as clause (viii);

15 (3) by inserting after clause (vi) the following:

16 “(vii) skilled nursing facilities (as de-

17 fined in section 1819(a) of the Social Secu-

18 rity Act (42 U.S.C. 1395i–3(a))); and”;

19 and

20 (4) in clause (viii), as redesignated, by striking

21 “clauses (i) through (vi)” and inserting “clauses (i)

22 through (vii)”.

23 (b) SAVINGS CLAUSE.—Nothing in subsection (a)

24 shall be construed to affect the aggregate annual cap on

25 Federal universal service support for health care providers

1 under section 54.675 of title 47, Code of Federal Regula-
2 tions, or any successor regulation.

3 (c) EFFECTIVE DATE.—The amendments made by
4 subsection (a) shall apply beginning on the date that is
5 180 days after the date of the enactment of this Act.



CONFIDENTIAL NOT FOR DISTRIBUTION**PRIORITIES TO ADDRESS IN HOUSE-SENATE CONFERENCE DISCUSSIONS
ON TSCA REFORM**

We support the AAI Priorities document and have additional areas that need clarification. The House of Representatives and the Senate are expected to reconcile their versions of legislation to modernize the Toxic Substances Control Act (TSCA) upon passage of the Senate bill. As the conference process unfolds, the following technical objectives and outcomes should be priorities for consideration.

Objective	Preferred Outcome(s)
Maintain strong preemption provisions	<ul style="list-style-type: none"> • Retain high priority “pause” on State actions taken after the federal risk assessment process begins. • Retain conflict limitation on grandfathered State laws. • Ensure waiver provisions are consistent with a nationally uniform chemical regulatory system. <ul style="list-style-type: none"> ○ Delete the required exemption under Sec. 18(f)(2) and retain the discretionary exemption under Sec. 18(f)(1). ○ Delete the automatic waiver provisions for States, as outlined in the Senate bill, if EPA fails to respond to a State waiver request. ○ Decisions on waiver need to be made on a risk based system. • Retain exemption for state actions related to clean air and clean water laws.
Ensure that confidentiality provisions protect proprietary information	<ul style="list-style-type: none"> • Retain approach that distinguishes information that must be asserted and that which must be substantiated in order to obtain CBI protection. • Retain provision prohibiting the disclosure of chemical ID, including molecular structure and formula information in the context of health and safety studies. • When CBI is shared with specified personnel for emergency purposes or with States, that CBI submitter is notified. Maintain provisions requiring confidentiality agreements with receivers. • CBI submitters should be notified by the Administrator that their CBI claim is set expire. <ul style="list-style-type: none"> ○ Include CBI expiration notification provision in the Senate bill, and increase notification from 60 days to 90 days prior to the time a CBI claim will expire.
Ensure a risk based prioritization system	<ul style="list-style-type: none"> • Preserve requirement that EPA designate low priority substances. • Ensure a focus on chemicals that are actually in commerce (including chemicals on the EPA Work Plan Chemicals list).
Adopt a risk-based approach to assessment of all high-priority substances, including PBTs	<ul style="list-style-type: none"> • Ensure that PBT characteristics are simply one criterion in the prioritization process, and that full risk assessment processes apply to such substances. • Eliminate a list-based approach to PBTs that requires risk management actions on all listed substances regardless of risk. • Maintain the requirement that risk management actions for PBTs reduce exposures “to the extent practicable” by deleting the word “maximum.”

	<ul style="list-style-type: none"> Recognize that PBT criteria should not be applied to metals and metal compounds. <ul style="list-style-type: none"> Metals and metal compounds should not be identified as persistent, bioaccumulative, and toxic substances, as specified in EPA's 2007 Framework for Metals Risk Assessment.
Industry-initiated Assessments	<ul style="list-style-type: none"> Allow processors and manufacturers to voluntarily submit safety assessments without arbitrary caps and include provisions that allow EPA to manage the process if resources become constrained. Retain provisions that require EPA to develop guidance for voluntary assessment submissions.
Adopt workable amendments and clarifications to TSCA reporting and recordkeeping provisions	<ul style="list-style-type: none"> If an inventory reset is required, reporting provisions should reduce reporting burdens on manufacturers and processors, including small businesses. <ul style="list-style-type: none"> Clarify ability to seek inventory corrections. Corrections should not be subject to penalties. Retain provisions that require EPA to develop guidance for nomenclature equivalents. Limit reporting to identifying chemicals, manufactured or processed, that are not already reported under CDR/IUR <ul style="list-style-type: none"> The lookback period for reporting should be something more reasonable and open to notice and comment Chemical Manufacturers and Processors need more than 6 months to report chemicals manufactured or processed in the last ten years during the inventory reset Retain provisions that allow EPA to develop different Sec. 8 record keeping/reporting requirements for manufacturers and processors. Rules issued under Section 8(A) should target entities most likely to have relevant information. Require EPA to accept existing Class 2 nomenclature practices for UVCBs.
Provide authority to ensure efficient and effective consideration and implementation of risk management measures	<ul style="list-style-type: none"> Maintain requirement that risk management measures apply to articles only to the extent necessary to protect against an identified risk. Retain EPA authority to adopt critical use and other appropriate exemptions from risk management measures.
Sustainable Chemistry	<ul style="list-style-type: none"> TSCA reform should not contain sustainable chemistry provisions. <ul style="list-style-type: none"> If Section 24, in the Senate bill is included in TSCA reform, this section should clarify that it will not conflict with a safety determination. Clarify what is meant by a national strategy on sustainable chemistry.

	<ul style="list-style-type: none"> ○ Limit Section 24 to the coordination and promotion of sustainable chemistry research conducted at Federal and national laboratories and Federal agencies and at public institutions of higher education.
Ensure Congressional direction to manage EPA imposition and collection of fees	<ul style="list-style-type: none"> ● Provide EPA sufficient direction and authority to assess fees in appropriate circumstances. <ul style="list-style-type: none"> ○ Restrain EPA authority to impose fees arbitrarily on any TSCA-related activity. ○ Delete language related to fees for exemptions and reporting (CDR, Inventory Reset, etc.) and make sure fees are related to reviews and other types of services. ○ Ensure that fees for manufacturer-led risk assessments are used only for that purpose. ○ Support a cap on fees as outlined in the Senate bill.
Retain appropriate definitions in a revised TSCA	<ul style="list-style-type: none"> ● Preserve a definition of “susceptible subpopulation” that EPA has a mandate to identify specific subpopulations that are affected/to be addressed in a given risk assessment. ● Delete the inclusion of workers in vulnerable populations
New Chemicals	<ul style="list-style-type: none"> ● Maintain Section 5 of current TSCA <ul style="list-style-type: none"> ○ Concerns over positive affirmation, which could lead to an implicit minimum data set because EPA is reticent to call something “safe” based on a screening-level assessment. ○ Concern over changing the standard to “intended conditions of use” could result in a de facto SNUR on everything that isn’t covered under the initial PMN, similar to a registration process.
Testing	<ul style="list-style-type: none"> ● Retain current provisions that EPA make a finding of exposure when issuing test rules, consent agreements and orders. ● Delete 5-year deadline for the reimbursement period.
Sound Science	<ul style="list-style-type: none"> ● Retain the sound science provisions explicitly outlined in Sec. 3A of S.697. ● Incorporate explicit authorization for EPA to use sentinel exposure assessment approach rather than aggregate. ● Delete aggregate and replace with sentinel.



COMMITTEE ON ENERGY AND COMMERCE

Chairman Fred Upton
114th Congress

TSCA REFORM – COMPROMISE TEXT

Existing Chemicals

Concern with Current Law. In the 40 years since TSCA was enacted there have been few EPA actions to regulate existing chemicals. Many blame the current law, including the requirement that EPA manage existing chemicals using the “least burdensome” regulatory option, as the reason for the lack of chemical regulation. Absent EPA action under TSCA, some states, litigants, and even consumer product retailers have been increasingly taking steps to restrict certain chemicals, not always relying on objective scientific analysis to make these decisions. Within the last year, both the House and Senate have passed bills to address the legal impediments to managing chemical risks under TSCA.

Compromise Approach. The House and Senate bills and the compromise text approach this problem similarly: by bifurcating the chemical regulation process into two steps (risk evaluation of a chemical and risk management of chemicals found to be problematic).

Risk Evaluation. The first step to deciding whether regulation of a chemical is warranted is a scientific evaluation of the risk posed by a chemical, looking at its hazards and exposures without considering cost or other non-risk factors. If that analysis indicates that a chemical’s use presents an unreasonable risk, including to a vulnerable or susceptible population, then EPA will turn to the second step, a rulemaking to manage the risk.

Risk Management. Once EPA decides a chemical poses an unreasonable risk, the agency is required to issue a risk management rule, ranging from minimum labeling or notice requirements to an outright ban. In choosing regulatory options EPA must consider the effects of a chemical on health and the environment, the chemical’s benefits, and economic consequences of the regulation including effects on the national economy, small business, and technology innovation. The considerations and the cost and benefits of the rule and cost effectiveness of the regulation must, to the extent practicable, also be factored in.

When deciding whether to ban or restrict a chemical, EPA must consider the availability of feasible alternatives. Unless they contribute significantly to the risk, replacement parts for certain complex durable and electronic goods that are designed prior to the risk management rule are exempt from a ban or restrictions. Articles may be restricted only to the extent necessary to address risk from exposure to that article. Critical uses of a chemical may be exempt from restriction if there is no safer alternative, the restriction would disrupt the economy, national security or critical infrastructure, or the chemical provides a substantial benefit to health, safety, or the environment.

New Chemicals

Concern with Current Law. Under TSCA section 5, 90 days before a new chemical goes on the market (or a significant new use is commercially introduced for an existing chemical) the manufacturer or processor must send EPA a notice and supporting information alerting EPA of its

intent to manufacture or process the chemical. If EPA takes no explicit action within those 90 days, commercial manufacturing may begin. The House-passed bill made no changes to TSCA section 5. The Senate-passed bill provides that EPA must review new chemicals and new uses, without regard to cost or other nonrisk factors, and affirmatively make an educated decision on the potential risk of the chemical – including regulation, before manufacturing begins.

Compromise Approach. The compromise text contains the key elements of the Senate-passed bill. EPA is required to review and make an affirmative finding about the level of risk posed by the new chemical without regard to cost. The chemical may not be commercially produced until EPA rules on it, and the chemical cannot be produced without being in compliance with EPA restrictions on the chemical that are without regard to cost. The compromise text attempts to tighten the timeline for EPA to take action requiring EPA to make a determination about, and choose a necessary regulatory option for, a chemical within 90 days, but no later than 180 days if more time is needed.

The compromise text gives EPA four determinations from which to choose regarding whether the new chemical or new use: (1) *presents* an unreasonable risk (in which case EPA must immediately take regulatory action under current law subsection (f)); (2) *may present* an unreasonable risk, is made in large quantities, or there isn't enough information to make a determination (which would trigger order requirements under subsection (e)); (3) is *likely not to present a risk* under the conditions of use (in which case manufacture may begin); or (4) is a subset of option #3, a *low hazard*, and manufacture may begin.

Chemical Testing

Concern with Current Law. TSCA Section 4 provides EPA sweeping authority to require testing of new and existing chemicals under a wide variety of circumstances so long as EPA has a reasonable basis for concern about the chemical. In order to require testing, EPA must also lack information that only new testing can address, the new testing must be mandated by rulemaking, and be subject to notice and comment. In the last 40 years, EPA has issued approximately 400 test rules due to the burden of issuing rules. The House-passed bill changed the testing section by giving EPA more deference with respect to the agency's authority for new testing. The Senate-passed bill replaced existing law by adding specific points in the chemical evaluation and regulatory process where EPA may require testing. The Senate bill also allows EPA to use order authority instead of being required to issue a rule. The Senate-passed version also contains language aimed at reducing animal testing.

Compromise Approach. The compromise text maintains existing law, but also specifies key points in the evaluation and regulatory process where EPA may order testing (e.g. prioritization for risk evaluation and the risk evaluation itself). In addition, the compromise text reduces animal testing required under TSCA.

Chemical Reporting

Concern with Current Law. TSCA Section 8 requires EPA to maintain an inventory of all chemicals that have ever been on the U.S. market. The House-passed bill did not amend this part of TSCA. The Senate-passed bill contained many details requiring EPA to update the inventory and it also required the use of certain chemical naming or nomenclature conventions.

Compromise Approach. The compromise text updates EPA's inventory and codifies industry nomenclature conventions.

Protection of trade secrets

Concern with Current Law. Existing TSCA Section 14 has stringent provisions for protection of confidential business information (CBI) that must be shared with EPA during the regulatory process. Once claimed, CBI remains protected until EPA finds it does not meet legal requirements for

protection. Some groups claim that these stringent protections allow industry to hide information about chemicals from the public. While the House-passed bill maintained the essence of existing law and clarified that trade secrets were protectable within health and safety studies, it also limited duration of protection to 10 years and allowed more categories of people to obtain trade secret information to protect health or the environment. The Senate-passed bill created a system to claim, substantiate and re-substantiate, review, adjudicate claims, and mandatorily disclose trade secrets.

Compromise Approach. The compromise text specifies that EPA must continue protecting trade secrets submitted to it for 10 years, including when disclosure of proprietary chemical formulas would reveal secrets about the chemical manufacturing process. The compromise text adopts the Senate's system to claim, substantiate and re-substantiate, review, and adjudicate claims for protection of trade secrets.

State-Federal Relationship

Concern with Current Law. There is little concern with existing law because EPA has regulated so little. The concern would be that if EPA became more active, federal preemption would nullify existing state and local laws – including judicial rulings – and give preemption to certain new chemicals uses. The House bill generally maintains the preemption provisions of existing TSCA, but inserted language that: prevents state and local laws from conflicting with federal requirements; saves certain types of state laws from preemption – including California's Proposition 65 and Green Chemistry laws; and protects state tort and contract laws. The Senate bill instituted a preemption "pause" (a time period during which states are not allowed to enact or enforce certain statutes and regulations); permitted several exemptions to preemption; ensured state court decision for criminal, tort, and contract cases were not preempted; and maintained California labeling and chemical control laws.

Compromise Approach. Preemption under the compromise text begins with a general rule (subject to later provisions saving certain state laws) that states and local governments may not (1) duplicate federal information developments requirements, (2) restrict a chemical that EPA's scientific risk evaluation found does not present an unreasonable risk, EPA has published risk management regulation; or required notification for a significant new use or a new chemical. Preemption begins when the administrator defines the scope of a risk evaluation and ends either 30 months after that or when a risk evaluation is completed, whichever is earlier. This provision does not restrict state authority to continue enforcing a law enacted prior to the risk evaluation scoping, but this does not allow a state to enforce a new restriction established after the risk evaluation scoping. Federal preemption applies only to the scope of the risk evaluation or to the significant new uses under section 5.

There are exceptions to the general preemption rule. These include state laws carrying out federal laws, reporting requirements that are not otherwise required under federal law, or related to water or air quality, or waste treatment or disposal. Also state laws restricting chemicals that were enacted prior to April 22, 2016, are not preempted, nor are any actions taken by a state pursuant to a law enacted prior to September 2003.

EPA may waive preemption if EPA determines that compelling conditions warrant it, the state law is scientifically based, and the state law would not unduly burden interstate commerce. EPA may also waive the preemption pause if, no later than 18 months after EPA has initiated the prioritization process for a chemical substance or 6 months after scoping the risk evaluation, whichever is sooner, a state has acted to restrict the chemical. Common law rights of action, and laws for civil relief, including those for civil damage or penalties for criminal conduct are saved from preemption.

Finally, the preemptive effect under TSCA prior to enactment of this bill will govern actions taken by EPA prior to enactment of the new bill as well as on chemicals subject to EPA section 6 action.

Science

Concern with Current Law. Concerns have been raised by the National Academy of Sciences about how EPA has been doing risk assessments on chemicals. Since regulation is predicated purely on a review of risks, the concern is that EPA not make determinations that are inconsistent with the best available, objective, and high quality scientific practices.

Compromise Approach. The compromise text (like both the House and Senate-passed bills) requires that science-based decisions be made based upon the weight of the scientific evidence. The compromise text (like the Senate-passed bill) requires that EPA use scientific information, technical procedures, measures, methods, and protocols predicated on the high quality science elements of the House-passed bill.

Fees

Concern with Current Law. TSCA section 26 provides that EPA can only collect fees for information collected pursuant to testing rules in section 4 and new chemicals and new uses in section 5. The fees, based on 1976 costs, are capped at \$2,500 and small businesses were required to pay no more than \$100. In light of the major new requirements imposed by the underlying text, increased fees are necessary to offset the resultant costs. The House-passed bill maintained existing user fees with two exceptions: the House bill lifted the caps based on 1976 costs and added user fees in cases when a manufacturer initiates a risk evaluation on an existing chemical. The Senate-passed bill also removed the statutory caps on fees and included fees for other steps in the regulatory process, including submitting reporting data. The Senate version would allow fees collected under one provision to be used to fund activities in other provisions, but capped most total fee collection at 25% of EPA's TSCA chemical regulation budget or \$25 million, whichever is lower.

Compromise Approach. The compromise text allows fees collected under one provision to be used to work on the same chemical under testing, evaluation and regulation, and information protection provisions. The bill caps overall fee collection (with some exceptions) to 25% of EPA's cost for regulating new and existing chemicals and test orders or \$25 million, whichever is lower, and requires manufacturers who request risk evaluations of their chemicals to pay the full cost of the evaluation and regulation.

Other Provisions

Amendments to the Mercury Export Ban Act of 2008 clarifying waste management obligations of the U.S. government and of elemental mercury producers.

"Trevor's Law" to designate and investigate cancer clusters.

S. 1916 (H.R. 4111), the Rural Health Care Connectivity Act of 2016, authored by Senator John Thune (R-SD). This section adds "skilled nursing facilities" to the definition of a Health Provider in Section 254 of the Communications Act related to Universal Service. The section defines skilled nursing facility by cross-reference to the definition used in the Social Security Act. The section requires the changes identified in the bill be made six months after the legislation is enacted.

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