

113TH CONGRESS
1ST SESSION

S. 1009

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

IN THE SENATE OF THE UNITED STATES

MAY 22, 2013

Mr. LAUTENBERG (for himself, Mr. VITTER, Mrs. GILLIBRAND, Mr. CRAPO, Mr. DURBIN, Mr. ALEXANDER, Mr. SCHUMER, Mr. INHOFE, Mr. UDALL of New Mexico, Ms. COLLINS, Ms. LANDRIEU, Mr. RUBIO, Mr. MANCHIN, Mr. BOOZMAN, Mr. MENENDEZ, Mr. HOEVEN, and Mr. BEGICH) introduced the following bill; which was read twice and referred to the Committee on Environment and Public Works

A BILL

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

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

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS; REF-**
4 **ERENCES.**

5 (a) SHORT TITLE.—This Act may be cited as the
6 “Chemical Safety Improvement Act”.

7 (b) TABLE OF CONTENTS.—The table of contents for
8 this Act is as follows:

- Sec. 1. Short title; table of contents; references.
- Sec. 2. Findings, policy, and intent.
- Sec. 3. Definitions.
- Sec. 4. Chemical assessment framework; prioritization screening; testing.
- Sec. 5. New chemicals and significant new uses.
- Sec. 6. Safety assessments and determinations.
- Sec. 7. Imminent hazards.
- Sec. 8. Information collection and reporting.
- Sec. 9. Relationship to other Federal laws.
- Sec. 10. Research, development, collection, dissemination, and utilization of data.
- Sec. 11. Exports.
- Sec. 12. Imports.
- Sec. 13. Confidential information.
- Sec. 14. Prohibited acts.
- Sec. 15. Preemption.
- Sec. 16. Judicial review.
- Sec. 17. Citizens' petitions.
- Sec. 18. Studies.
- Sec. 19. Administration.
- Sec. 20. Development and evaluation of test methods.
- Sec. 21. State programs.
- Sec. 22. Authorization of appropriations.
- Sec. 23. Annual report.

1 (c) REFERENCES.—Except as otherwise expressly
 2 provided, wherever in this Act an amendment or repeal
 3 is expressed in terms of an amendment to, or repeal of,
 4 a section or other provision, the reference shall be consid-
 5 ered to be made to a section or other provision of the Toxic
 6 Substances Control Act (15 U.S.C. 2601 et seq.).

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

8 (a) PURPOSES.—The purposes of this Act are—

9 (1) to improve the safety of consumers in the
 10 United States; and

11 (2) to ensure that risks from chemical sub-
 12 stances are adequately understood and managed by
 13 modernizing title I of the Toxic Substances Control
 14 Act (15 U.S.C. 2601 et seq.).

1 (b) FINDINGS, POLICY, AND INTENT.—Section 2 (15
2 U.S.C. 2601) is amended by striking subsections (a)
3 through (c) and inserting the following:

4 “(a) FINDINGS.—Congress finds that—

5 “(1) chemicals should be safe for the intended
6 use of the chemicals;

7 “(2) the unmanaged risks of chemical sub-
8 stances may pose a danger to human health and the
9 environment;

10 “(3) public confidence in the Federal chemical
11 regulatory program has diminished over time;

12 “(4) scientific understanding of chemicals and
13 the possible risks of the chemicals has evolved great-
14 ly since 1976, requiring that Congress update the
15 law to ensure that chemical regulation in the United
16 States reflects modern science, technology and
17 knowledge;

18 “(5) this Act should be modernized to create a
19 robust Federal system for assessing and managing
20 chemical risks;

21 “(6) chemicals are used in diverse manufac-
22 turing industries and other valuable commercial, in-
23 stitutional, and consumer applications that have ben-
24 efitting society;

1 “(7) for the purposes of promoting uniform
2 protections through regulation of chemical sub-
3 stances in commerce, to minimize undue burdens on
4 commerce, and to minimize burdens on States, speci-
5 fied actions by the Administrator should preempt re-
6 quirements by States and political subdivisions of
7 States that relate to the effects of or exposure to a
8 chemical substance under the intended conditions of
9 use; and

10 “(8) innovation in the development of new
11 chemical substances, especially safer chemical sub-
12 stances, should be encouraged to reduce risk, provide
13 improved products, stimulate the economy, create
14 jobs, and protect interstate commerce.

15 “(b) POLICY.—It is the policy of the United States
16 that—

17 “(1) this Act—

18 “(A) should protect the health of people
19 and the environment from the unmanaged risks
20 of chemical substances; and

21 “(B) should be modernized to build public
22 confidence in the ability of the Federal regu-
23 latory system to protect health and the environ-
24 ment, promote innovation, and sustain a glob-

1 ally competitive chemical industry in the United
2 States;

3 “(2) the Administrator—

4 “(A) should have the appropriate hazard,
5 use, and exposure information necessary to
6 make safety determinations;

7 “(B) should minimize the use of animal
8 testing through the use of scientifically reliable
9 and relevant test methods, where appropriate;

10 “(C) should encourage the use of best lab-
11 oratory practices to ensure high quality, rel-
12 evant, and reliable results from test methods
13 and studies;

14 “(D) should have the authority to share
15 confidential business information with States
16 and political subdivisions of the States, subject
17 to appropriate safeguards against inappropriate
18 disclosure;

19 “(E) should have the resources and tools
20 necessary to implement this Act; and

21 “(F) should implement this Act in a man-
22 ner that promotes transparency of information
23 and decisionmaking, protects substantiated con-
24 fidential business information, and promotes in-
25 novation, including innovation in chemical sub-

1 stances that have reduced hazard, exposure,
2 and risk patterns;

3 “(3) adequate data and information should be
4 available with respect to the effect of and exposure
5 to chemical substances and mixtures on health and
6 the environment, to the extent necessary for safety
7 assessments and determinations, and that, where
8 necessary, the development of such test data and in-
9 formation should be the primary responsibility of
10 those who manufacture or process such chemical
11 substances and mixtures; and

12 “(4) States have an important role in pro-
13 tecting health and the environment from the
14 unmanaged risks of chemical substances in com-
15 merce, particularly in recommending priorities for
16 Federal assessment and regulation, providing safety
17 assessment information, and fostering programs to
18 protect consumers.

19 “(c) INTENT OF CONGRESS.—It is the intent of Con-
20 gress that the Administrator shall—

21 “(1) rely on robust scientific evidence to imple-
22 ment this Act in a way that balances the mutual
23 goals of promoting the safety of American con-
24 sumers and preventing harm to American innova-
25 tion, manufacturing, and the economy; and

1 “(2) implement this Act to protect the health of
2 the people of the United States and the environment
3 in such a manner as not to unduly impede commerce
4 or create unnecessary economic barriers to techno-
5 logical innovation, including safer chemistry.”.

6 **SEC. 3. DEFINITIONS.**

7 Section 3 (15 U.S.C. 2602) is amended—

8 (1) by redesignating paragraphs (2) through
9 (6), (7) through (11), and (12) through (14) as
10 paragraphs (3) through (7), (9) through (13), and
11 (17) through (19), respectively;

12 (2) by inserting after paragraph (1) the fol-
13 lowing:

14 “(2) **BEST AVAILABLE SCIENCE.**—The term
15 ‘best available science’ means science that—

16 “(A) maximizes the quality, objectivity,
17 and integrity of information, including statis-
18 tical information;

19 “(B) uses peer-reviewed and publically
20 available data; and

21 “(C) clearly documents and communicates
22 risks and uncertainties in the scientific basis for
23 decisions.”;

24 (3) by inserting after paragraph (7) (as so re-
25 designated) the following:

1 “(8) INTENDED CONDITIONS OF USE.—The
2 term ‘intended conditions of use’ means the cir-
3 cumstances under which a chemical substance is in-
4 tended or reasonably anticipated to be manufac-
5 tured, processed, distributed in commerce, used, and
6 disposed of.”; and

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

9 “(14) SAFETY ASSESSMENT.—The term ‘safety
10 assessment’ means a risk-based assessment of the
11 safety of a chemical substance that—

12 “(A) integrates hazard; use; and exposure
13 information about a chemical substance; and

14 “(B) includes—

15 “(i) an assessment of exposure under
16 the intended conditions of use; and

17 “(ii) reference parameters that may
18 be appropriate with regard to a specific
19 chemical substance (such as a margin of
20 exposure).

21 “(15) SAFETY DETERMINATION.—The term
22 ‘safety determination’ means a determination by the
23 Administrator as to whether a chemical substance
24 meets the safety standard under the intended condi-
25 tions of use.

1 “(16) SAFETY STANDARD.—The term ‘safety
2 standard’ means a standard that ensures that no
3 unreasonable risk of harm to human health or the
4 environment will result from exposure to a chemical
5 substance.”.

6 **SEC. 4. CHEMICAL ASSESSMENT FRAMEWORK;**
7 **PRIORITIZATION SCREENING; TESTING.**

8 (a) IN GENERAL.—Section 4 (15 U.S.C. 2603) is
9 amended—

10 (1) in the heading, by striking “**TESTING OF**
11 **CHEMICAL SUBSTANCES AND MIXTURES**” and
12 inserting “**CHEMICAL ASSESSMENT FRAME-**
13 **WORK; PRIORITIZATION SCREENING; TEST-**
14 **ING**”.

15 (2) by redesignating subsection (e) as sub-
16 section (l);

17 (3) in subsection (l) (as so redesignated)—

18 (A) by striking “rule” each place it ap-
19 pears and inserting “rule, testing consent
20 agreement, or order”;

21 (B) by striking “under subsection (a)”
22 each place it appears and inserting “under this
23 subsection”; and

24 (C) in paragraph (1)(B), by striking “rule-
25 making”; and

1 (4) by striking subsections (a) through (d), (f),
2 and (g) and inserting the following:

3 “(a) CHEMICAL ASSESSMENT FRAMEWORK.—

4 “(1) IN GENERAL.—The Administrator shall
5 develop a framework in accordance with subsection
6 (e) and sections 5 and 6 for evaluating the safety of
7 chemical substances in commerce that shall employ
8 the best available science and risk assessment prin-
9 ciples in existence at the time the Administrator is
10 developing the framework.

11 “(2) POLICIES AND PROCEDURES.—

12 “(A) IN GENERAL.—After the date of en-
13 actment of the Chemical Safety Improvement
14 Act, the Administrator shall promptly develop
15 appropriate policies and procedures for imple-
16 menting the framework, including procedures
17 on the collection, evaluation, and development
18 of data and information.

19 “(B) CONTENTS.—The policies and proce-
20 dures shall require—

21 “(i) the collection of existing data and
22 information from manufacturers and proc-
23 essors of chemical substances and other
24 sources, including the use of voluntary

1 agreements to provide the data and infor-
2 mation;

3 “(ii) an evaluation of the quality of
4 existing data and information;

5 “(iii) an analysis of data and informa-
6 tion;

7 “(iv) a determination of the need for
8 additional data and information, including
9 information related to the exposures of dif-
10 ferent subpopulations; and

11 “(v) subject to section 14, trans-
12 parency of data and information consid-
13 ered by the Administrator, including both
14 positive and negative findings.

15 “(3) TRANSPARENCY AND VALIDITY.—The Ad-
16 ministrator shall ensure that the evaluation frame-
17 work described in subsection (a)(1)—

18 “(A) is transparent;

19 “(B) assures that data and information
20 are valid;

21 “(C) addresses the strengths and limita-
22 tions of—

23 “(i) the design of the framework,

24 “(ii) the reliability of the test meth-
25 ods; and

1 “(iii) the quality of the data and in-
2 formation; and

3 “(D) pursues the goal of maximizing the
4 quality, objectivity, utility, and integrity of the
5 data and information.

6 “(b) DATA AND INFORMATION QUALITY.—

7 “(1) IN GENERAL.—The Administrator shall es-
8 tablish and publish scientifically sound criteria for
9 evaluating all of the data and information, including
10 the results of animal and nonanimal testing, regard-
11 less of affiliation or funding source, on which the
12 Administrator relies in making a decision under this
13 Act.

14 “(2) DISCLOSURE OF SOURCES OF FUNDING.—
15 The Administrator shall require that the submitter
16 of any health and safety study disclose to the Ad-
17 ministrator and to the public the sources of any
18 funding used for the study or publication of the
19 study received by the researcher who conducted the
20 study, to the extent reasonably ascertainable.

21 “(3) TEST DATA.—For test data developed
22 under this Act, the Administrator shall encourage
23 the use of good laboratory practices, peer review, sci-
24 entifically reliable and relevant test methods, stand-
25 ardized protocols, and other methods to ensure sci-

1 entific quality for all data and information sub-
2 mitted under this Act.

3 “(4) DATA AND INFORMATION THAT DO NOT
4 MEET CRITERIA.—

5 “(A) IN GENERAL.—Nothing in this sub-
6 section shall preclude the Administrator from
7 considering data and information which do not
8 meet the quality criteria established under
9 paragraph (1).

10 “(B) IDENTIFICATION.—The Adminis-
11 trator shall—

12 “(i) identify any data and information
13 described in subparagraph (A) on which
14 the Administrator relies;

15 “(ii) describe the quality of the data
16 and information described in subparagraph
17 (A) and the extent to which the data and
18 information depart from those criteria;

19 “(iii) indicate any limitations on the
20 usefulness of the data and information de-
21 scribed in subparagraph (A); and

22 “(iv) explain how the data and infor-
23 mation described in subparagraph (A) was
24 used and the basis for reliance on the data
25 and information.

1 “(5) EVALUATIVE FRAMEWORK FOR DECISION-
2 MAKING.—

3 “(A) IN GENERAL.—The Administrator
4 shall develop and use a structured evaluative
5 framework consisting of science-based criteria,
6 consistent with the protection of human health
7 and the environment, for making any decision
8 under this Act, and for determining the rel-
9 evance, quality, and reliability of data and in-
10 formation.

11 “(B) CONTENTS.—The framework de-
12 scribed in subparagraph (A) shall, at a min-
13 imum—

14 “(i) use sound and objective scientific
15 practices in assessing risks;

16 “(ii) consider the current best avail-
17 able science (including peer-reviewed stud-
18 ies);

19 “(iii) when consistent with the under-
20 lying data, consider, for both cancer and
21 noncancer endpoints, whether available
22 data support or do not support the identi-
23 fication of threshold doses of a chemical
24 substance below which no adverse effects
25 can be expected to occur; and

1 “(iv) include a description of the
2 weight of the scientific evidence concerning
3 risks, including mechanistic information
4 (such as appropriate modes of action).

5 “(c) DATA AND INFORMATION SOURCES.—In making
6 any decision with respect to a chemical substance under
7 subsection (e) and sections 5 and 6, the Administrator
8 shall consider data and information relevant to the sub-
9 stance that are reasonably available to the Administrator
10 at that time, including data and information that are—

11 “(1) submitted to the Administrator by—

12 “(A) manufacturers and processors of the
13 substance;

14 “(B) the public; or

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

18 “(2) submitted to a governmental body in an-
19 other jurisdiction under a governmental requirement
20 relating to the protection of human health and the
21 environment, if the information is accessible to the
22 Administrator;

23 “(3) derived through the application of scientif-
24 ically reliable and relevant structure-activity rela-
25 tionship, or other methods or models to estimate the

1 environmental and human health effects, environ-
2 mental and biological fate and behavior, and expo-
3 sure potential for the substance;

4 “(4) inferred based on the degree of structural
5 similarity or properties of the substance, or cat-
6 egories of substances, to those of 1 or more other
7 chemical substances for which reliable information
8 exists that is relevant to predicting the potential en-
9 vironmental or human health effects, environmental
10 or biological fate and behavior, or exposure potential
11 for the chemical substance; and

12 “(5) identified through an active search by the
13 Administrator of information sources that are pub-
14 licly available or otherwise accessible to the Adminis-
15 trator.

16 “(d) TRANSPARENCY.—

17 “(1) IN GENERAL.—Subject to section 14, the
18 data and information considered by the Adminis-
19 trator in taking action under this Act shall be avail-
20 able to the public.

21 “(2) TYPES OF INFORMATION AVAILABLE TO
22 THE PUBLIC.—The Administrator shall make avail-
23 able to the public the guidance, procedures, and
24 tools used in evaluating data and information under

1 this section, including models, studies, and, as ap-
2 propriate, the data underlying any study.

3 “(3) GUIDANCE.—Any written guidance of gen-
4 eral applicability prepared by the Administrator
5 under this Act shall be subject to public notice and
6 an opportunity for comment.

7 “(e) PRIORITIZATION SCREENING PROCESS.—

8 “(1) IN GENERAL.—

9 “(A) PROCESS.—Not later than 1 year
10 after the date of enactment of the Chemical
11 Safety Improvement Act, the Administrator
12 shall establish a risk-based screening process
13 for identifying existing chemical substances that
14 are—

15 “(i) a high priority for a safety as-
16 sessment and determination under section
17 6, to be known as ‘high-priority sub-
18 stances’; and

19 “(ii) a low priority for a safety assess-
20 ment and determination, to be known as
21 ‘low-priority substances’.

22 “(B) CONSIDERATION OF ACTIVE AND IN-
23 ACTIVE SUBSTANCES.—

24 “(i) CONSIDERATION OF ACTIVE SUB-
25 STANCES.—In implementing the process

1 described in subparagraph (A), the Admin-
2 istrator shall only consider active sub-
3 stances, as determined under section
4 8(b)(6), as either high-priority substances
5 or low-priority substances.

6 “(ii) CONSIDERATION OF INACTIVE
7 SUBSTANCES.—In implementing the proc-
8 ess described in subparagraph (A), the Ad-
9 ministrator shall only consider inactive
10 substances, as determined under section
11 8(b)(7), that the Administrator deter-
12 mines, on the basis of credible scientific
13 evidence that—

14 “(I) have not been subject to a
15 regulatory or other enforceable action
16 by the Administrator to ban or phase
17 out the substances; and

18 “(II) demonstrate high hazard
19 and high exposure.

20 “(C) TIMELY COMPLETION OF
21 PRIORITIZATION PROCESS.—

22 “(i) IN GENERAL.—The Administrator
23 shall make every effort to complete the
24 prioritization of all active substances in a
25 timely manner.

1 “(ii) CONSIDERATION.—The Adminis-
2 trator shall prioritize substances taking
3 into consideration the ability of the Admin-
4 istrator to schedule and complete safety as-
5 sessments and determinations under sec-
6 tion 6 in a timely manner.

7 “(D) USE OF DATA.—In making a decision
8 under the prioritization screening process, the
9 Administrator shall use reasonably available
10 data and information concerning the hazard,
11 exposure, and use characteristics of chemical
12 substances on the list developed by the Admin-
13 istrator under section 8(b)(1) at the time the
14 decision is made.

15 “(E) SCREENING OF CATEGORIES OR
16 CLASSES OF SUBSTANCES.—The Administrator
17 may screen categories or classes of chemical
18 substances to ensure an efficient prioritization
19 screening process to allow for timely and ade-
20 quate safety assessments and determinations.

21 “(F) PUBLICATION OF LIST OF CHEMICAL
22 SUBSTANCES.—From time to time the Adminis-
23 trator shall—

1 “(i) publish a list of chemical sub-
2 stances being considered in the
3 prioritization screening process; and

4 “(ii) request the submission of data
5 and information on the chemical sub-
6 stances.

7 “(2) PROPOSED PROCESS.—

8 “(A) IN GENERAL.—The Administrator
9 shall—

10 “(i) publish for public comment a pro-
11 posed prioritization screening process; and

12 “(ii) establish criteria for determining
13 whether a substance is a high or low pri-
14 ority for a safety assessment and deter-
15 mination.

16 “(B) INITIAL LIST.—

17 “(i) IN GENERAL.—The proposal shall
18 include an initial list of chemical sub-
19 stances that includes, at a minimum, those
20 substances prioritized by the Administrator
21 before the date of enactment of the Chem-
22 ical Safety Improvement Act and for which
23 assessments or safety determinations have
24 not been completed, and proposed

1 prioritization outcomes based on the pro-
2 posed criteria.

3 “(ii) CONTENTS.—The initial list shall
4 contain as many chemical substances as
5 the Administrator determines appropriate.

6 “(iii) MODIFICATION.—The Adminis-
7 trator may modify the initial list on the
8 basis of comments received on the pro-
9 posed process and criteria.

10 “(C) CRITERIA.—The criteria described in
11 subparagraph (A) shall consider—

12 “(i) the recommendation of a Gov-
13 ernor of a State or a State agency with re-
14 sponsibility for protecting health or the en-
15 vironment from chemical substances appro-
16 priate for prioritization screening;

17 “(ii) the hazard and exposure poten-
18 tial of the chemical substance (or category
19 or class of substances), including specific
20 scientific classifications and designations
21 by authoritative governmental entities;

22 “(iii) the intended conditions of use or
23 significant changes in the conditions of use
24 of the chemical substance;

1 “(iv) evidence and indicators of expo-
2 sure potential to humans or the environ-
3 ment from the chemical substance;

4 “(v) the volume of a chemical sub-
5 stance manufactured or processed;

6 “(vi) whether the volume of a chem-
7 ical substance as reported under a regula-
8 tion issued under section 8(a) (as in effect
9 on the date on which the criteria are pro-
10 posed) has significantly increased or de-
11 creased since a previous report or since the
12 date on which a notice has been submitted
13 under section 5(a);

14 “(vii) the availability of information
15 about potential hazards and exposures
16 needed for conducting a safety assessment
17 or determination, with limited availability
18 of relevant data and information to be a
19 factor in designating a substance as a high
20 priority; and

21 “(viii) the extent of Federal or State
22 regulation of the chemical substance or the
23 extent of the impact of State regulation of
24 the chemical substance on the United
25 States, with existing Federal or State reg-

1 ulation of any uses evaluated in the
2 prioritization screening process as a factor
3 in designating a chemical substance to be
4 a low priority.

5 “(3) PRIORITIZATION SCREENING DECISIONS.—

6 “(A) IN GENERAL.—For the chemical sub-
7 stances considered for prioritization screening,
8 the Administrator shall apply the criteria iden-
9 tified in paragraph (2), using the information
10 identified in subsection (c), to identify a chem-
11 ical substance as a high-priority substance or a
12 low-priority substance.

13 “(B) ADDITIONAL TEST DATA.—If the Ad-
14 ministrator determines that additional test data
15 and information are needed to establish the pri-
16 ority of a chemical substance, the Administrator
17 shall provide an opportunity for interested per-
18 sons to submit data and information to the ex-
19 tent that it is reasonably ascertainable.

20 “(C) DEFERRING A DECISION.—If the Ad-
21 ministrator determines that it is appropriate,
22 the Administrator may defer a prioritization
23 screening decision for a chemical substance
24 under subparagraph (A) for a reasonable period

1 to allow for the submission and evaluation of
2 additional data and information.

3 “(D) INTEGRATION OF DATA AND INFOR-
4 MATION.—During the prioritization screening of
5 a chemical substance, the Administrator shall
6 integrate any hazard and exposure data and in-
7 formation related to a chemical substance avail-
8 able to the Administrator.

9 “(E) IDENTIFICATION OF HIGH-PRIORITY
10 SUBSTANCES.—The Administrator—

11 “(i) shall identify as a high-priority
12 substance a chemical substance that, rel-
13 ative to other substances, has the potential
14 for high hazard and high exposure;

15 “(ii) may identify as a high-priority
16 substance a chemical substance that, rel-
17 ative to other substances, has the potential
18 for high hazard or high exposure; and

19 “(iii) may identify as a high-priority
20 substance an inactive substance, as deter-
21 mined under section 8(b)(7), that the Ad-
22 ministrator determines, on the basis of
23 credible scientific evidence that—

24 “(I) has not been subject to a
25 regulatory action by the Adminis-

1 trator to ban or phase out the sub-
2 stance; and

3 “(II) demonstrates high hazard
4 and high exposure.

5 “(F) IDENTIFICATION OF LOW-PRIORITY
6 SUBSTANCES.—The Administrator shall identify
7 as a low-priority substance a chemical sub-
8 stance that the Administrator on the basis of
9 the available information determines is likely to
10 meet the safety standard under the intended
11 conditions of use.

12 “(G) NOTICE AND COMMENT.—The identi-
13 fications made under subparagraphs (E) and
14 (F) shall be subject to notice and an oppor-
15 tunity for comment.

16 “(H) ORDER OF SAFETY ASSESSMENTS.—

17 “(i) HIGH-PRIORITY SUBSTANCES.—
18 The Administrator—

19 “(I) shall determine the order for
20 performing safety assessments on
21 high-priority substances under section
22 6; and

23 “(II) may revise the order as the
24 Administrator determines appropriate.

1 “(ii) LOW-PRIORITY SUBSTANCE.—

2 The Administrator shall not perform safety
3 assessments on low-priority substances, un-
4 less a low-priority substance is redesign-
5 ated under subparagraph (I).

6 “(I) REVISION BASED ON NEW DATA.—

7 “(i) IN GENERAL.—Subject to sub-
8 paragraph (D), at any time the Adminis-
9 trator may revise the identification of a
10 chemical substance as a high-priority sub-
11 stance or a low-priority substance based on
12 consideration of data or information made
13 available to the Administrator after the
14 date on which the Administrator makes the
15 identification under subparagraphs (E)
16 and (F).

17 “(ii) REEVALUATION.—

18 “(I) IN GENERAL.—The Admin-
19 istrator shall evaluate the data or in-
20 formation described in clause (i) on a
21 high-priority substance or a low-pri-
22 ority substance for possible reevalua-
23 tion of the priority of the substance.

24 “(II) LIMITED AVAILABILITY.—If
25 limited availability of relevant data

1 and information was a factor in the
2 original identification of a chemical
3 substance as a high-priority sub-
4 stance, the Administrator shall re-
5 evaluate the prioritization screening of
6 the substance on receiving the rel-
7 evant data and information.

8 “(J) PUBLICATION OF A LIST OF HIGH-
9 PRIORITY AND LOW-PRIORITY SUBSTANCES.—

10 “(i) IN GENERAL.—The Administrator
11 shall publish and keep current a list of
12 high-priority substances and a list of low-
13 priority substances.

14 “(ii) JUSTIFICATION.—Whenever the
15 Administrator places a chemical substance
16 on one of the lists described in clause (i)
17 or changes the priority of the chemical
18 substance, the Administrator shall include
19 a justification for the decision in accord-
20 ance with paragraph (2)(C).

21 “(K) REMOVAL.—The Administrator shall
22 remove a chemical substance from the list of
23 high-priority substances on the date on which a
24 safety determination for the chemical substance
25 is published.

1 “(L) EFFECT.—Subject to section 18, a
2 decision by the Administrator under this para-
3 graph with respect to a chemical substance
4 shall not affect the manufacture, processing,
5 distribution, use, or disposal of the chemical
6 substance, or regulation of those activities.

7 “(4) EXPEDITED PRIORITIZATION SCREEN-
8 ING.—

9 “(A) IN GENERAL.—Not later than 180
10 days after the date on which the Administrator
11 receives a recommendation and relevant data
12 and information from a Governor of a State or
13 a State agency with responsibility for protecting
14 health and the environment that an active
15 chemical substance be identified as a high-pri-
16 ority or low-priority substance, the Adminis-
17 trator shall make a prioritization screening de-
18 cision for the substance.

19 “(B) NOTICE AND COMMENT.—The public
20 shall be provided notice and an opportunity to
21 comment on the recommendation described in
22 subparagraph (A).

23 “(C) EXPLANATION OF REASONS.—The
24 Administrator shall—

1 “(i) make available to the Governor or
2 the appropriate State agency, as applica-
3 ble, and to the public a brief explanation of
4 reasons for identifying a chemical sub-
5 stance recommended by the Governor or
6 the agency for prioritization screening as
7 either a high-priority substance or a low-
8 priority substance; and

9 “(ii) identify the information relied
10 upon in making that identification.

11 “(5) FINAL AGENCY ACTION.—Any action by
12 the Administrator under this subsection shall not
13 be—

14 “(A) considered to be a final agency ac-
15 tion; or

16 “(B) subject to judicial review.

17 “(f) DEVELOPMENT OF NEW TEST DATA AND IN-
18 FORMATION.—

19 “(1) IN GENERAL.—The Administrator may re-
20 quire the development of new test data and informa-
21 tion related to a chemical substance or mixture in
22 accordance with this section if the Administration
23 determines that the data and information are need-
24 ed—

25 “(A) to perform a safety assessment;

1 “(B) to make a safety determination; or

2 “(C) to meet the testing needs of the im-
3 plementing authority under another Federal
4 statute.

5 “(2) FORM.—The Administrator may require
6 the development of test data and information de-
7 scribed in paragraph (1) by—

8 “(A) promulgating a rule;

9 “(B) entering into a testing consent agree-
10 ment; or

11 “(C) issuing an order.

12 “(3) REQUIREMENTS.—

13 “(A) IN GENERAL.—In promulgating a
14 rule, adopting a testing consent agreement, or
15 issuing an order described in paragraph (2), the
16 Administrator shall require the use of—

17 “(i) an evaluation framework that,
18 prior to requiring additional testing of
19 vertebrate animals, integrates relevant in-
20 formation from multiple sources, including,
21 to the extent reliable—

22 “(I) toxicity information;

23 “(II) computational toxicology;

24 “(III) bioinformatics;

1 “(IV) high-throughput screening
2 methods; and

3 “(V) scientifically reliable and
4 relevant alternatives to vertebrate ani-
5 mal tests; and

6 “(ii) tiered testing in accordance with
7 subsection (h), wherein the results of a
8 screening level tier of tests relating to a
9 toxicity pathway or target organ or target
10 system inform the decision of the Adminis-
11 trator as to whether tests from a higher
12 tier related to that pathway or organ or
13 system are necessary.

14 “(B) STATEMENT TO THE PUBLIC.—The
15 Administrator shall explain the basis for a deci-
16 sion made in subparagraph (A)(ii) in a state-
17 ment made available to the public.

18 “(4) CONTENTS.—

19 “(A) IN GENERAL.—A rule, testing con-
20 sent agreement, or order issued under para-
21 graph (2) shall include—

22 “(i) identification of the chemical sub-
23 stance or mixture for which testing is re-
24 quired;

1 “(ii) identification of the persons re-
2 quired to conduct the testing;

3 “(iii) procedures for the development
4 of test data and information for the chem-
5 ical substance or mixture, including spe-
6 cific reference to reliable nonanimal test
7 procedures; and

8 “(iv) specification of the period within
9 which persons required to conduct the test-
10 ing shall submit to the Administrator test
11 data and information developed in accord-
12 ance with the procedures described in
13 clause (iii).

14 “(B) DURATION.—The period described in
15 subparagraph (A)(iv) shall not be of an unrea-
16 sonable duration.

17 “(C) CONSIDERATIONS.—In determining
18 the procedures and period to be required under
19 subparagraph (A), the Administrator shall con-
20 sider—

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

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

4 “(g) STATEMENT OF NEED.—

5 “(1) IN GENERAL.—In promulgating a rule, en-
6 tering into a testing consent agreement, or issuing
7 an order for development of additional data and in-
8 formation (including information on exposure or ex-
9 posure potential) under subsection (f)(2), the Ad-
10 ministrators shall issue a statement—

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

13 “(B) explaining why existing data and in-
14 formation reasonably available to the Adminis-
15 trator at that time are inadequate to meet that
16 need; and

17 “(C) encouraging, to the extent possible,
18 the use of nonanimal test methods to develop
19 additional data and information.

20 “(2) CONTENTS OF STATEMENT IN CASE OF
21 ORDER.—

22 “(A) IN GENERAL.—If the Administrator
23 issues an order, the statement described in
24 paragraph (1) shall explain why good cause ex-
25 ists for issuance of an order instead of promul-

1 gating a rule or entering into a testing consent
2 agreement.

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

6 “(i) data and information that are
7 readily accessible to the Administrator, in-
8 cluding data and information submitted
9 under any other provision of law;

10 “(ii) the extent to which the Adminis-
11 trator has obtained or attempted to obtain
12 the data and information through vol-
13 untary submissions;

14 “(iii) the extent to which the Adminis-
15 trator may use available data and informa-
16 tion for structurally related substances
17 (grouping or read-across), or use valid
18 structure-activity relationship models or
19 nonanimal test alternatives; and

20 “(iv) safety assessments, and the data
21 and information relied on in the assess-
22 ments, on other chemical substances to the
23 extent relevant to the chemical substances
24 that would be the subject of the rule or
25 order.

1 “(h) TIERED TOXICITY TESTING AND EVALUA-
2 TION.—

3 “(1) IN GENERAL.—The Administrator shall
4 develop an evidence-based review system for con-
5 ducting consistent evaluations of the relevance and
6 reliability of studies of chemical substances and their
7 exposure (including exposure pathways), and a
8 structured evaluative framework to provide a sys-
9 tematic and transparent approach for assessing the
10 overall weight of the evidence for observed biological
11 or other effects, mechanistic information, and expo-
12 sure.

13 “(2) TIERS.—Subject to subsections (b) and
14 (c), the framework shall have 2 tiers.

15 “(A) TIER 1.—

16 “(i) IN GENERAL.—Tier 1 shall in-
17 clude both a screening level exposure as-
18 sessment, including modeling if appro-
19 priate, and screening tests for hazard.

20 “(ii) USES OF SCREENING TESTS AND
21 MODELING.—Screening tests for hazard
22 (which may include, as appropriate, sci-
23 entifically reliable and relevant in silico, in
24 vitro, and focused in vivo tests) and expo-

1 sure information and modeling shall be
2 used—

3 “(I) to screen chemical sub-
4 stances or mixtures for major toxic ef-
5 fects (including acute toxicity, sub-
6 chronic toxicity, chronic toxicity, car-
7 cinogenicity, genotoxicity, develop-
8 mental toxicity, and neurotoxicity);
9 and

10 “(II) to direct planning for more
11 complex and targeted testing in tier 2,
12 if necessary.

13 “(B) TIER 2.—If the Administrator deter-
14 mines that additional testing is necessary,
15 based on the results of tier 1 testing and mod-
16 eling and any other available relevant informa-
17 tion, tier 2 shall include—

18 “(i) an exposure assessment and tests
19 for specific endpoints triggered on the
20 basis of biologically based decisions; and

21 “(ii) an assessment of potential expo-
22 sure using scientifically valid approaches.

23 “(3) GUIDANCE.—The Administrator shall pre-
24 pare guidance for implementing this subsection and

1 review that guidance not less than once every 5
2 years thereafter.

3 “(i) REDUCTION OF ANIMAL-BASED TESTING.—

4 “(1) IN GENERAL.—The Administrator shall
5 minimize the use of animals in testing of chemical
6 substances or mixtures, including by—

7 “(A) encouraging and facilitating, to the
8 maximum extent practicable—

9 “(i) the use of integrated and tiered
10 testing and assessment strategies;

11 “(ii) the use of data and information
12 of sufficient scientific quality in existence
13 on the date on which the test is conducted;

14 “(iii) the use of test methods that
15 eliminate or reduce the use of animals
16 while providing test data and information
17 of high scientific quality;

18 “(iv) the grouping of 2 or more chem-
19 ical substances into scientifically appro-
20 priate categories in cases in which testing
21 of a chemical substance would provide reli-
22 able and useful test data and information
23 on others in the category;

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

4 “(vi) the submission of test data and
5 information from animal-based studies and
6 from emerging methods and models; and

7 “(vii) the use of exposure potential as
8 a factor in decisions to require new testing;
9 and

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

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

18 “(A) after providing an opportunity for
19 public comment, develop a strategic plan to pro-
20 mote the development and implementation of al-
21 ternative test methods and testing strategies to
22 generate information used for any safety-stand-
23 ard determination made that reduce, refine, or
24 replace the use of laboratory animals, including
25 toxicity pathway-based risk assessment, in vitro

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

4 “(B) beginning on the date that is 5 years
5 after the date of enactment of the Chemical
6 Safety Improvement Act and every 5 years
7 thereafter, submit to Congress a report that de-
8 scribes the progress made in implementing this
9 section; and

10 “(C) fund and carry out research, develop-
11 ment, performance assessment, and translation-
12 al studies to accelerate the development of test
13 methods and testing strategies that reduce, re-
14 fine, or replace the use of laboratory animals in
15 any safety-standard determination made under
16 this section.

17 “(3) CRITERIA FOR ADAPTING OR WAIVING ANI-
18 MAL TESTING REQUIREMENTS.—On request from a
19 manufacturer or processor that is required to con-
20 duct animal-based testing of a chemical substance or
21 mixture under this title, the Administrator may
22 adapt or waive the animal-testing requirement if the
23 Administrator determines that—

24 “(A) there is sufficient evidence from sev-
25 eral independent sources of information to sup-

1 port a conclusion that a chemical substance or
2 mixture has, or does not have, a particular
3 property if the information from each individual
4 source alone is insufficient to support the con-
5 elusion;

6 “(B) because of one or more physical or
7 chemical properties of the chemical substance
8 or mixture or other toxicokinetic consider-
9 ations—

10 “(i) the material cannot be absorbed;

11 or

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

14 “(C) a chemical substance or mixture can-
15 not be tested in animals at concentrations that
16 do not result in significant pain or distress, be-
17 cause of physical or chemical properties of the
18 chemical substance or mixture, such as a poten-
19 tial to cause severe corrosion or severe irritation
20 to the tissues of the animal.

21 “(j) TESTING REQUIREMENTS.—

22 “(1) PERSONS REQUIRED TO DEVELOP TEST
23 DATA AND INFORMATION.—

1 “(A) IN GENERAL.—The Administrator
2 may require the following persons to develop
3 test data and information:

4 “(i) Manufacturers and processors of
5 the chemical substance or mixture identi-
6 fied in subsection (f)(4)(A)(i).

7 “(ii) Persons who begin to manufac-
8 ture or process such chemical substance or
9 mixture—

10 “(I) after the effective date of
11 the rule, testing consent agreement,
12 or order; but

13 “(II) subject to subparagraph
14 (C), before the period ending 180
15 days after the end of the period iden-
16 tified in subsection (f)(4)(A)(iv).

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

21 “(i) to develop the data and informa-
22 tion; and

23 “(ii) to submit the data and informa-
24 tion on behalf of the persons making the
25 designation.

1 “(C) EXEMPTIONS.—

2 “(i) IN GENERAL.—A person other-
3 wise subject to a rule, testing consent
4 agreement, or order under subsection (f)
5 may submit to the Administrator an appli-
6 cation for an exemption on the basis that
7 the data and information are being devel-
8 oped by a person designated under sub-
9 paragraph (B).

10 “(ii) FAIR AND EQUITABLE REIM-
11 BURSEMENT TO DESIGNEE.—

12 “(I) IN GENERAL.—If the Ad-
13 ministrator accepts an application
14 submitted under clause (i), the Ad-
15 ministrator shall direct the applicant
16 to provide to the person designated
17 under subparagraph (B) fair and eq-
18 uitable reimbursement, as agreed to
19 between the applicant and the person
20 designated.

21 “(II) ARBITRATION.—If the ap-
22 plicant and a person designated under
23 subparagraph (B) cannot reach agree-
24 ment on the amount of fair and equi-

1 table reimbursement, the amount shall
2 be determined by arbitration.

3 “(iii) TERMINATION.—If, after grant-
4 ing an exemption under this subparagraph,
5 the Administrator determines that no per-
6 son has complied with the rule, testing
7 consent agreement, or order, the Adminis-
8 trator shall—

9 “(I) by order terminate the ex-
10 emption; and

11 “(II) notify in writing each per-
12 son who received an exemption of the
13 requirements with respect to which
14 the exemption was granted.

15 “(2) TYPES OF HEALTH AND ENVIRONMENTAL
16 DATA AND INFORMATION.—

17 “(A) IN GENERAL.—The Administrator
18 may prescribe guidelines for the development of
19 test data and information under subsection (f)
20 for health and environmental information, in-
21 cluding—

22 “(i) test data pertaining to acute tox-
23 icity, subchronic toxicity, chronic toxicity,
24 carcinogenicity, genotoxicity, developmental

1 toxicity, and neurotoxicity that may be in-
2 dicative of an adverse effect;

3 “(ii) test data and information per-
4 taining to exposure to the chemical sub-
5 stance or mixture, including information
6 regarding bioaccumulation, persistence,
7 and the presence of the chemical substance
8 or mixture in human blood, fluids, or tis-
9 sue; and

10 “(iii) information pertaining to aggre-
11 gate exposure, or other effects that may be
12 considered in a safety assessment.

13 “(B) METHODOLOGIES.—

14 “(i) IN GENERAL.—The Adminis-
15 trator—

16 “(I) may prescribe methodologies
17 in guidelines for the development of
18 data and information; and

19 “(II) shall encourage the use of
20 nonanimal methodologies.

21 “(ii) DEVELOPMENT OF GUIDE-
22 LINES.—The Administrator may develop
23 guidelines for evaluating data from bio-
24 monitoring studies.

1 “(iii) REQUIREMENT.—Prior to pre-
2 scribing epidemiologic studies of employ-
3 ees, the Administrator shall coordinate
4 with the Director of the National Institute
5 for Occupational Safety and Health.

6 “(C) REVIEW.—Periodically, but not less
7 frequently than once every 5 years, the Admin-
8 istrator shall—

9 “(i) review the adequacy of the guide-
10 lines for development of data and informa-
11 tion prescribed under subparagraph (B);

12 “(ii) if necessary, institute pro-
13 ceedings to make appropriate revisions of
14 the guidelines; and

15 “(iii) revise the guidelines as appro-
16 priate, particularly to—

17 “(I) reflect the availability of sci-
18 entifically reliable and relevant non-
19 animal test methods; and

20 “(II) eliminate obsolete meth-
21 odologies that do not produce reliable
22 and relevant results.

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

1 consent agreements and orders and all data and informa-
2 tion submitted under this section.”.

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

8 **SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.**

9 Section 5 (15 U.S.C. 2604) is amended—

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

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

13 (2) in subsection (a)(1), in the matter following
14 subparagraph (B)—

15 (A) by striking “subsection (d)” and in-
16 serting “subsection (b)”; and

17 (B) by striking “and such person complies
18 with any applicable requirement of subsection
19 (b)”;

20 (3) by striking subsection (b);

21 (4) by redesignating subsection (d) as sub-
22 section (b) and moving the subsection so as to ap-
23 pear after subsection (a);

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

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

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

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

9 “(B) information regarding intended condi-
10 tions of use and reasonably anticipated expo-
11 sure.”;

12 (B) in paragraph (2)—

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

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

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

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

21 (C) in paragraph (3), by striking “, (b),”;

22 (6) by striking subsection (c) and inserting the
23 following:

24 “(c) REVIEW OF NOTICE.—

25 “(1) INITIAL REVIEW.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graph (B), not later than 90 days after the date
3 of receipt of a notice submitted under sub-
4 section (a), the Administrator shall—

5 “(i) conduct an initial review of the
6 notice;

7 “(ii) as needed, develop a profile of
8 the relevant chemical substance and the
9 potential for exposure to humans and the
10 environment; and

11 “(iii) make any necessary determina-
12 tion under paragraph (4).

13 “(B) EXTENSION.—Except as provided in
14 paragraph (6), the Administrator may extend
15 the period described in subparagraph (A) for
16 good cause for one or more periods, the total of
17 which shall be not more than 90 days.

18 “(2) NOTICE OF COMMENCEMENT.—Unless the
19 Administrator determines under paragraph (4)(A)
20 that a chemical substance is not likely to meet the
21 safety standard, at the end of the applicable period
22 for review under paragraph (1), a chemical sub-
23 stance may be the subject of a notice of commence-
24 ment under subsection (d).

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

4 “(A) the information identified in section
5 4(e); and

6 “(B) any additional information provided
7 by the submitter.

8 “(4) DETERMINATIONS.—Before the end of the
9 applicable period for review under paragraph (1),
10 based on the information described in paragraph (3),
11 the Administrator shall determine that—

12 “(A) the relevant chemical substance is not
13 likely to meet the safety standard under the in-
14 tended conditions of use, in which case the Ad-
15 ministrator shall take appropriate action under
16 paragraph (5);

17 “(B) the relevant chemical substance is
18 likely to meet the safety standard under the in-
19 tended conditions of use, in which case the Ad-
20 ministrator shall allow the review period to ex-
21 pire without additional restrictions; or

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

1 trator shall take appropriate action under para-
2 graph (6).

3 “(5) PROHIBITIONS AND LIMITATIONS.—

4 “(A) IN GENERAL.—If the Administrator
5 makes a determination under paragraph (4)(A)
6 with respect to a notice, before the end of the
7 applicable period for review under paragraph
8 (1), the Administrator shall, by consent agree-
9 ment or order, as appropriate—

10 “(i) prohibit manufacture of the
11 chemical substance, or prohibit such manu-
12 facture without compliance with restric-
13 tions specified in a relevant consent agree-
14 ment or order; or

15 “(ii) prohibit manufacture or proc-
16 essing of the chemical substance for a sig-
17 nificant new use, or prohibit such manu-
18 facture or processing without compliance
19 with restrictions specified in a relevant
20 consent agreement or order.

21 “(B) INCLUSIONS.—A prohibition or limi-
22 tation under subparagraph (A) may include, as
23 appropriate—

24 “(i) a requirement that a chemical
25 substance be marked with, or accompanied

1 by, clear and adequate warnings and in-
2 structions with respect to use, distribution
3 in commerce, or disposal, or any combina-
4 tion of those activities, with the form and
5 content of the warnings and instructions to
6 be prescribed by the Administrator;

7 “(ii) a requirement that manufactur-
8 ers or processors, as applicable, of the
9 chemical substance make and retain
10 records of the processes used to manufac-
11 ture or process the chemical substance;

12 “(iii) a requirement that manufactur-
13 ers or processors, as applicable, monitor or
14 conduct such additional tests as are rea-
15 sonably necessary to ensure compliance
16 with this Act, subject to section 4(g);

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

21 “(v) a limitation on the quantity of
22 the chemical substance that may be manu-
23 factured, processed, or distributed in com-
24 merce for a particular use;

1 “(vi) a prohibition or other regulation
2 of the manufacture, processing, or dis-
3 tribution in commerce of the chemical sub-
4 stance for a significant new use;

5 “(vii) a prohibition or other regulation
6 of any method of commercial use of the
7 chemical substance;

8 “(viii) a prohibition or other regula-
9 tion of any method of disposal of the
10 chemical substance;

11 “(ix) a prohibition on the manufac-
12 ture, processing, or distribution in com-
13 merce of the chemical substance;

14 “(x) a prohibition on the manufac-
15 ture, processing, or distribution in com-
16 merce of the chemical substance for a par-
17 ticular use; or

18 “(xi) such other requirements as the
19 Administrator determines to be necessary.

20 “(6) ADDITIONAL DATA AND INFORMATION.—If
21 the Administrator determines under paragraph
22 (4)(C) that additional data and information (includ-
23 ing, for example, information on exposure or expo-
24 sure potential) are needed in order to conduct a re-
25 view under this subsection, the Administrator—

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

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

8 “(C) on receipt of the information, shall
9 promptly make a determination under para-
10 graph (4); and

11 “(D) may take action under paragraph (5)
12 pending receipt of the additional data and in-
13 formation, which may, as appropriate, permit
14 the submitter of the notice to file a notice of
15 commencement under subsection (d).”;

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

18 “(d) NOTICE OF COMMENCEMENT.—

19 “(1) IN GENERAL.—Not later than 30 days
20 after the date on which a manufacturer or processor
21 that has submitted a notice under subsection (a)
22 commences nonexempt commercial manufacture of a
23 chemical substance or nonexempt commercial manu-
24 facture or processing of a chemical substance for a
25 significant new use, as applicable, the manufacturer

1 or processor shall submit to the Administrator a no-
2 tice of commencement that identifies—

3 “(A) the name of the manufacturer or
4 processor; and

5 “(B) the initial date of nonexempt com-
6 mercial manufacture or nonexempt commercial
7 manufacture or processing for a significant new
8 use.

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

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

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

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

21 “(f) TRANSPARENCY.—Subject to section 14, the Ad-
22 ministrator shall make available to the public all notices,
23 rules and orders of the Administrator, and all data and
24 information submitted or issued under this section.”;

1 (8) by redesignating subsections (h) and (i) as
2 subsections (g) and (h), respectively; and

3 (9) in subsection (g) (as so redesignated)—

4 (A) in paragraph (1), in the matter pre-
5 ceeding subparagraph (A), by striking “or (b)”;

6 (B) by striking paragraph (2);

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

10 (D) in paragraph (2) (as so redesignated),
11 by striking “subsections (a) and (b)” and in-
12 serting “subsection (a)”;

13 (E) in paragraph (3) (as so redesignated),
14 in the first sentence, by striking “will not
15 present an unreasonable risk of injury to health
16 or the environment” and inserting “is expected
17 to meet the safety standard under the intended
18 conditions of use”;

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

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

1 **SEC. 6. SAFETY ASSESSMENTS AND DETERMINATIONS.**

2 Section 6 (15 U.S.C. 2605) is amended—

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

5 **“SEC. 6. SAFETY ASSESSMENTS AND DETERMINATIONS.”;**

6 (2) by striking subsections (a) through (d) and
7 inserting the following:

8 “(a) IN GENERAL.—The Administrator shall—

9 “(1) conduct a safety assessment of each high-
10 priority substance in accordance with subsection (b);

11 “(2) make a safety determination for each high-
12 priority substance; and

13 “(3) as appropriate based on the results of a
14 safety determination, establish requirements for risk
15 management of a high-priority substance.

16 “(b) SAFETY ASSESSMENTS.—

17 “(1) IN GENERAL.—The Administrator shall
18 conduct a risk-based safety assessment of each high-
19 priority substance, in accordance with such schedule
20 as the Administrator establishes, to be based solely
21 on considerations of risk to human health and the
22 environment.

23 “(2) PROCEDURAL RULES.—

24 “(A) IN GENERAL.—The Administrator
25 shall establish procedural rules for safety as-
26 sessments and determinations under this sub-

1 section, including schedules for the submission
2 of relevant data and information and the initi-
3 ation and completion of safety assessments and
4 safety determinations.

5 “(B) REQUIREMENTS.—

6 “(i) IN GENERAL.—The rules under
7 subparagraph (A) shall—

8 “(I) identify the basis on which
9 the Administrator shall decide which
10 high-priority substances take prece-
11 dence in the safety assessment and
12 determination process;

13 “(II) require the Administrator
14 to inform the public regarding—

15 “(aa) the approximate order
16 in which safety assessments and
17 determinations will be performed;

18 “(bb) the informational
19 needs of the Administrator relat-
20 ing to the safety assessment and
21 determination process;

22 “(cc) the importance of ex-
23 peditiously completing safety as-
24 sements and determinations

1 and the need for rigorous evalua-
2 tion of the data and information;
3 “(dd) the schedule by which
4 each assessment and determina-
5 tion will be conducted; and
6 “(ee) subject to clause (ii),
7 the deadline for the completion of
8 each assessment and determina-
9 tion;
10 “(III) allow interested persons,
11 including States, to submit informa-
12 tion, including safety assessments, re-
13 garding high-priority substances that
14 may facilitate the safety assessment
15 and determination process; and
16 “(IV) subject to section 14, re-
17 quire the Administrator—
18 “(aa) to make available to
19 the public the information taken
20 into consideration in preparing
21 each safety assessment and de-
22 termination;
23 “(bb) to publish and provide
24 an opportunity for comment on

1 proposed safety assessments and
2 determinations; and

3 “(cc) to publish final safety
4 assessments and determinations.

5 “(ii) DEADLINES.—

6 “(I) IN GENERAL.—The rules de-
7 scribed in subparagraph (A) shall also
8 include—

9 “(aa) a schedule by which
10 each safety assessment and de-
11 termination is expected to be con-
12 ducted; and

13 “(bb) a deadline for the
14 completion of each assessment
15 and determination.

16 “(II) FLEXIBILITY AND REASON-
17 ABLE EXTENSIONS.—The deadlines
18 described in subclause (I)(bb)—

19 “(aa) may vary among
20 chemical substances to grant the
21 Administrator flexibility; and

22 “(bb) shall allow for reason-
23 able extensions after an adequate
24 public justification.

1 “(C) INCLUSIONS IN FINAL ASSESS-
2 MENTS.—Each safety assessment under this
3 subsection shall include—

4 “(i) a weight-of-the evidence sum-
5 mary; and

6 “(ii) a nontechnical summary explain-
7 ing what the relevant information dem-
8 onstrates in the context of the intended
9 conditions of use and exposure patterns of
10 the chemical substance.

11 “(3) DATA AND INFORMATION SOURCES.—In
12 conducting a safety assessment under this sub-
13 section, the Administrator shall, at a minimum, take
14 into consideration—

15 “(A) the information described in section
16 4(e); and

17 “(B) any additional information submitted
18 under paragraph (5).

19 “(4) METHODOLOGY.—

20 “(A) IN GENERAL.—The Administrator
21 shall—

22 “(i) develop an appropriate science-
23 based methodology for conducting safety
24 assessments under this subsection, which
25 shall include consideration of the weight of

1 the evidence for observed effects, mecha-
2 nistic information, and exposure evalua-
3 tions; and

4 “(ii) make the proposed methodology
5 available for public comment and scientific
6 peer review.

7 “(B) REVIEW AND REVISIONS.—Not later
8 than 5 years after the date of enactment of the
9 Chemical Safety Improvement Act, and not less
10 frequently than once every 5 years thereafter,
11 the Administrator—

12 “(i) shall review the methodology de-
13 veloped under subparagraph (A); and

14 “(ii) may revise the methodology to
15 reflect new scientific developments or un-
16 derstandings, in accordance with subpara-
17 graph (A).

18 “(C) REQUIREMENTS.—The methodology
19 shall apply scientifically recognized factors to
20 address the following topics:

21 “(i) Strengths and limitations of
22 study design.

23 “(ii) Reliability and relevance of test
24 methods to human health and the environ-
25 ment.

1 “(iii) Quality of data.

2 “(iv) Use of good laboratory practices.

3 “(v) Peer review and peer review proc-
4 esses.

5 “(vi) Use of standardized protocols.

6 “(vii) Structured evaluative frame-
7 works to determine the overall weight of
8 the evidence, based on a review of positive
9 and negative findings.

10 “(D) HAZARD, USE, AND EXPOSURE IN-
11 FORMATION.—

12 “(i) IN GENERAL.—A safety assess-
13 ment under this subsection shall evaluate
14 existing hazard, use, and exposure infor-
15 mation for the chemical substance under
16 the intended conditions of use of the chem-
17 ical substance, including information sub-
18 mitted by interested persons.

19 “(ii) EXPOSURE.—For purposes of
20 evaluating exposure under clause (i), a
21 safety assessment shall take into consider-
22 ation—

23 “(I) exposures or significant sub-
24 sets of exposures;

1 “(II) exposure duration, inten-
2 sity, frequency, and number; and

3 “(III) the vulnerability of ex-
4 posed subpopulations.

5 “(E) BEST AVAILABLE SCIENCE.—The Ad-
6 ministrators shall use the best available science
7 in conducting a safety assessment under this
8 subsection.

9 “(5) ADDITIONAL TEST INFORMATION.—If the
10 Administrator determines that additional test infor-
11 mation is needed in order to make a safety assess-
12 ment for a high-priority substance, the Adminis-
13 trator—

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

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

21 “(C) may defer, for a reasonable period, a
22 safety assessment until after receipt of the in-
23 formation.

24 “(6) TREATMENT.—A safety assessment under
25 this subsection—

1 “(A) shall not be considered to be a final
2 agency action; and

3 “(B) shall not be subject to judicial review.

4 “(c) SAFETY DETERMINATION.—

5 “(1) IN GENERAL.—As soon as possible after
6 the date on which the safety assessment is com-
7 pleted for a high-priority substance under subsection
8 (b), the Administrator shall determine whether the
9 chemical substance meets the safety standard under
10 the intended conditions of use of the chemical sub-
11 stance.

12 “(2) DETERMINATIONS.—Based on a review of
13 the information described in paragraph (3), the Ad-
14 ministrator shall determine, based solely on consid-
15 erations of risk to human health and the environ-
16 ment, that—

17 “(A) the relevant chemical substance meets
18 the safety standard under intended conditions
19 of use;

20 “(B) the relevant chemical substance does
21 not meet the safety standard under intended
22 conditions of use, in which case the Adminis-
23 trator shall impose additional restrictions, as
24 appropriate, under paragraph (9); or

1 “(C) additional information is necessary in
2 order to make a determination under subpara-
3 graph (A) or (B), in which case the Adminis-
4 trator shall take appropriate action under para-
5 graph (8).

6 “(3) CONSIDERATIONS.—In making a safety de-
7 termination under this subsection, the Administrator
8 shall take into consideration and publish a statement
9 that includes, at a minimum—

10 “(A) the safety assessment for the chem-
11 ical substance, including the uses considered in
12 the assessment and any uses that are consid-
13 ered critical or essential;

14 “(B) the range of exposure to the chemical
15 substance under the intended conditions of use
16 of the chemical substance and appropriate ref-
17 erence parameters;

18 “(C) the weight of the evidence of risk
19 posed by the chemical substance under the in-
20 tended conditions of use of the chemical sub-
21 stance; and

22 “(D) the magnitude of the risk posed by
23 the chemical substance under the intended con-
24 ditions of use of the chemical substance.

1 “(4) INFORMATION SOURCES.—In making a
2 safety determination under this subsection, the Ad-
3 ministrator shall take into consideration, at a min-
4 imum—

5 “(A) the information described in section
6 4(c); and

7 “(B) the safety assessment conducted with
8 respect to the chemical substance under sub-
9 section (b).

10 “(5) BEST AVAILABLE SCIENCE.—The Adminis-
11 trator shall use the best available science in making
12 a safety determination under this subsection.

13 “(6) NOTICE AND COMMENT.—Subject to sec-
14 tion 14, the Administrator shall provide notice and
15 an opportunity for public comment on each proposed
16 safety determination under this subsection.

17 “(7) TRANSPARENCY.—Subject to section 14,
18 the Administrator shall publish—

19 “(A) each safety determination under this
20 subsection, together with a summary of the in-
21 formation considered in the determination;

22 “(B) a summary of the evaluation by the
23 Administrator of the information; and

24 “(C) an explanation of the reasons for the
25 determination.

1 “(8) ADDITIONAL TEST DATA AND INFORMA-
2 TION.—If the Administrator determines that addi-
3 tional test data and information is needed in order
4 to make a safety determination for a high-priority
5 substance, the Administrator—

6 “(A) shall provide an opportunity for inter-
7 ested persons to submit the additional data and
8 information;

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

13 “(C) may defer, for a reasonable period, a
14 safety determination until after receipt of the
15 data and information; and

16 “(D) on receipt of the data and informa-
17 tion, shall make a determination under para-
18 graph (2).

19 “(9) ADDITIONAL RESTRICTIONS.—

20 “(A) IN GENERAL.—

21 “(i) DETERMINATION.—If the Admin-
22 istrator makes a determination under
23 paragraph (2)(B) with respect to a chem-
24 ical substance, the Administrator shall pro-
25 mulgate a rule establishing necessary re-

1 restrictions (based on the weight of the evi-
2 dence of risk and the magnitude of risk),
3 including if appropriate, a ban or phase
4 out of the manufacture, processing, or use
5 of the chemical substance in accordance
6 with subparagraph (C).

7 “(ii) RULES.—Rules promulgated
8 under this section may apply to mixtures
9 containing the chemical substance, as ap-
10 appropriate.

11 “(B) INCLUSIONS.—A restriction under
12 subparagraph (A) may include, as appro-
13 priate—

14 “(i) a requirement that a chemical
15 substance be marked with, or accompanied
16 by, clear and adequate warnings and in-
17 structions with respect to use, distribution
18 in commerce, or disposal, or any combina-
19 tion of those activities, with the form and
20 content of the warnings and instructions to
21 be prescribed by the Administrator;

22 “(ii) a requirement that manufactur-
23 ers and processors of the chemical sub-
24 stance—

1 “(I) make and retain records of
2 the processes used to manufacture or
3 process the chemical substance; and

4 “(II) subject to section 4(f), de-
5 velop test information that is reason-
6 ably necessary to ensure compliance
7 with this Act;

8 “(iii) a limitation on the quantity of
9 the chemical substance that may be manu-
10 factured, processed, or distributed in com-
11 merce;

12 “(iv) a requirement to ban or phase
13 out or other regulation on the manufac-
14 ture, processing, or distribution in com-
15 merce of the chemical substance—

16 “(I) for a particular use; or

17 “(II) for a particular use at a
18 concentration in excess of a level spec-
19 ified by the Administrator;

20 “(v) a limitation on the quantity of
21 the chemical substance that may be manu-
22 factured, processed, or distributed in com-
23 merce—

24 “(I) for a particular use; or

1 “(II) for a particular use at a
2 concentration in excess of a level spec-
3 ified by the Administrator;

4 “(vi) a requirement to ban or phase
5 out or other regulation of any method of
6 commercial use of the chemical substance;

7 “(vii) a requirement to ban or phase
8 out or other regulation of any method of
9 disposal of the chemical substance or any
10 article containing the chemical substance;

11 “(viii) a requirement directing manu-
12 facturers or processors of the chemical
13 substance to give notice of unreasonable
14 risks of harm to distributors in commerce
15 of the chemical substance and, to the ex-
16 tent reasonably ascertainable, to other per-
17 sons in the chain of commerce in posses-
18 sion of the chemical substance; and

19 “(ix) such other requirements as the
20 Administrator determines to be necessary.

21 “(C) BANS AND PHASE OUTS.—The Ad-
22 ministrator shall base a determination under
23 subparagraph (A) that a ban or phase out of
24 the manufacture, processing, or use of a chem-

1 ical substance is necessary on the consider-
2 ations described in subparagraph (D).

3 “(D) DETERMINATION THAT CHEMICAL
4 SUBSTANCE DOES NOT MEET SAFETY STAND-
5 ARD.—If the Administrator determines that the
6 chemical substance does not meet the safety
7 standard under the intended conditions of use,
8 the Administrator shall consider and publish a
9 statement on—

10 “(i) the availability of technically and
11 economically feasible alternatives for the
12 chemical substance under the intended
13 conditions of use;

14 “(ii) the risks posed by those alter-
15 natives as compared to those of the chem-
16 ical substance;

17 “(iii) the economic and social costs
18 and benefits of the proposed regulatory ac-
19 tion and options considered, and of poten-
20 tial alternatives; and

21 “(iv) the economic and social benefits
22 and costs of—

23 “(I) the chemical substance;

24 “(II) alternatives to the chemical
25 substance; and

1 “(III) any necessary restrictions
2 on the chemical substance or alter-
3 natives.

4 “(10) EXEMPTIONS.—The Administrator may
5 exempt the use of a chemical substance from any ad-
6 ditional restriction established under paragraph (9)
7 if the Administrator determines that—

8 “(A) the exemption is in the interest of na-
9 tional security;

10 “(B) the lack of availability of the chemical
11 substance would cause significant disruption in
12 the national economy;

13 “(C) the use for which the exemption is
14 sought is a critical or essential use for which—

15 “(i) no feasible alternative for the use
16 would materially reduce risk to health or
17 the environment; or

18 “(ii) no feasible alternative for the use
19 is economically, technically, or efficiently
20 available; or

21 “(D) the use, as compared to reasonably
22 available alternatives, provides a net benefit to
23 human health, the environment, or public safe-
24 ty.

1 “(11) FINAL AGENCY ACTION.—A safety deter-
2 mination under this subsection shall be—

3 “(A) considered to be a final agency ac-
4 tion; and

5 “(B) subject to judicial review, including
6 review of the associated safety assessment
7 under this subsection.”;

8 (3) by redesignating subsections (e) and (f) as
9 subsections (d) and (e), respectively; and

10 (4) in subsection (d) (as so redesignated)—

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

12 (B) by redesignating paragraph (5) as
13 paragraph (4).

14 **SEC. 7. IMMINENT HAZARDS.**

15 Section 7 (15 U.S.C. 2606) is amended—

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

18 “(a) CIVIL ACTIONS.—

19 “(1) IN GENERAL.—The Administrator may
20 commence a civil action in an appropriate district
21 court of the United States for—

22 “(A) seizure of an imminently hazardous
23 chemical substance or mixture or any article
24 containing the substance or mixture;

1 “(B) relief (as authorized by subsection
2 (b)) against any person who manufactures,
3 processes, distributes in commerce, uses, or dis-
4 poses of, an imminently hazardous chemical
5 substance or mixture or any article containing
6 the substance or mixture; or

7 “(C) both seizure described in subpara-
8 graph (A) and relief described in subparagraph
9 (B).

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

13 “(A) the existence of—

14 “(i) a decision by the Administrator
15 under section 4(c)(3), 5(c)(4), or 6(c)(2);
16 or

17 “(ii) a rule, testing consent agree-
18 ment, or order under section 4(f), 5(g),
19 6(b)(5), 6(c)(8), 6(c)(9), or 6(d); or

20 “(B) the pendency of any administrative or
21 judicial proceeding under any provision of this
22 Act.”;

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

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

3 **SEC. 8. INFORMATION COLLECTION AND REPORTING.**

4 Section 8 (15 U.S.C. 2607) is amended—

5 (1) in subsection (a), by adding at the end the
6 following:

7 “(4) REGULATIONS.—

8 “(A) IN GENERAL.—The Administrator
9 shall promulgate rules requiring the reporting
10 of information known by, or reasonably ascer-
11 tainable by, the person making the report, in-
12 cluding rules requiring processors to report in-
13 formation, so that the Administrator has the in-
14 formation necessary to carry out sections 4 and
15 6.

16 “(B) CONTENTS.—The rules promulgated
17 under subparagraph (A)—

18 “(i) may impose different reporting
19 requirements on manufacturers and proc-
20 essors;

21 “(ii) shall be limited to active sub-
22 stances or mixtures containing active sub-
23 stances as designated under subsection (b);
24 and

1 “(iii) shall apply only to the extent the
2 Administrator determines the submission
3 of reports is necessary for the effective en-
4 forcement of this Act.

5 “(5) GUIDANCE.—The Administrator shall de-
6 velop guidance relating to the information required
7 to be reported under the rules promulgated under
8 this subsection that—

9 “(A) include the level of detail necessary to
10 be reported; and

11 “(B) describes the manner by which manu-
12 facturers and processors may report use and ex-
13 posure information on a voluntary basis.”;

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

16 “(3) NOMENCLATURE.—

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

19 “(i) maintain the use of Class 2 no-
20 menclature in use on date of enactment of
21 the Chemical Safety Improvement Act;

22 “(ii) maintain the use of the Soap and
23 Detergent Association Nomenclature Sys-
24 tem, published in March 1978 by the Ad-
25 ministrator in section 1 of addendum III

1 of the document entitled ‘Candidate List of
2 Chemical Substances’, and further de-
3 scribed in the appendix A of volume I of
4 the 1985 edition of the Toxic Substances
5 Control Act Substances Inventory (EPA
6 Document No. EPA-560/7-85-002a); and

7 “(iii) treat all components of cat-
8 egories that are considered to be statutory
9 mixtures under this Act as being included
10 on the list published under paragraph (1)
11 under the Chemical Abstracts Service
12 numbers for the respective categories, in-
13 cluding, without limitation—

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

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

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

20 “(IV) frits, chemicals, CAS No.
21 65997-18-4;

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

1 “(VI) ceramic materials and
2 wares, chemicals, CAS No. 66402–
3 68–4.

4 “(B) MULTIPLE NOMENCLATURE CONVEN-
5 TIONS.—

6 “(i) IN GENERAL.—In the event that
7 existing guidance allows for multiple no-
8 menclature conventions, the Administrator
9 shall—

10 “(I) maintain the nomenclature
11 conventions for substances; and

12 “(II) develop new guidance
13 that—

14 “(aa) establishes equivalency
15 between the nomenclature con-
16 ventions for chemical substances
17 on the list published under para-
18 graph (1); and

19 “(bb) permits persons to
20 rely on that new guidance for
21 purposes of determining whether
22 a chemical substance is on the
23 list published under paragraph
24 (1).

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

8 “(4) CANDIDATE LIST OF ACTIVE SUBSTANCES
9 IN COMMERCE.—

10 “(A) IN GENERAL.—Subject to section 14,
11 the Administrator shall make publicly available
12 a candidate list of active chemical substances,
13 which shall include—

14 “(i) any chemical substance reported
15 under part 711 of title 40, Code of Federal
16 Regulations, as in effect on the date of en-
17 actment of the Chemical Safety Improve-
18 ment Act, during the period beginning on
19 the date that is 10 years before the date
20 of enactment of the Chemical Safety Im-
21 provement Act and ending on the date of
22 enactment of the Chemical Safety Improve-
23 ment Act;

1 “(ii) any chemical substance for which
2 a notice of commencement of manufacture
3 has been submitted;

4 “(iii) any chemical substance for
5 which a significant new use notice has
6 been submitted;

7 “(iv) any chemical substance for
8 which an export notification has been sub-
9 mitted during the period beginning on the
10 date that is 10 years before the date of en-
11 actment of the Chemical Safety Improve-
12 ment Act and ending on the date of enact-
13 ment of the Chemical Safety Improvement
14 Act; and

15 “(v) any other chemical substance
16 identified by the Administrator as likely to
17 qualify as active.

18 “(B) RULE.—The Administrator shall, by
19 rule, require manufacturers and processors to
20 notify the Administrator that the manufacturer
21 or processor, as applicable, has manufactured
22 or processed a chemical substance on the list
23 described in subparagraph (A), or the list pub-
24 lished under paragraph (1) for a nonexempt
25 commercial purpose during the 5-year period

1 prior to the date of enactment of the Chemical
2 Safety Improvement Act.

3 “(C) GUIDANCE.—Before issuing a final
4 rule under subparagraph (A), the Administrator
5 shall make publicly available guidance relating
6 to the rule for chemical substances on the con-
7 fidential portion of the candidate list of active
8 substances and of the list published under para-
9 graph (1), including —

10 “(i) accession numbers;

11 “(ii) premanufacture notice case num-
12 bers, if applicable; and

13 “(iii) generic names.

14 “(D) CONFIDENTIAL CHEMICAL SUB-
15 STANCES.—The rule under subparagraph (B)
16 shall require a manufacturer or processor that
17 is reporting information relating to a chemical
18 substance on the confidential portion of the list
19 published under paragraph (1) to indicate
20 whether the manufacturer or processor claims
21 the specific identity of the substance as con-
22 fidential pursuant to section 14.

23 “(E) CERTIFICATION.—The rule under
24 subparagraph (B) shall require a manufacturer
25 or processor—

1 “(i) to certify the accuracy of each re-
2 port of the manufacturer or processor car-
3 ried out under the rule; and

4 “(ii) to retain a record supporting
5 that certification for a period of 5 years
6 beginning on the last day of the submis-
7 sion period.

8 “(F) APPLICABILITY.—Nothing in this
9 paragraph requires the resubstantiation of a
10 claim for protection against disclosure for infor-
11 mation submitted to the Administrator prior to
12 the date of enactment of the Chemical Safety
13 Improvement Act.

14 “(5) LIST.—

15 “(A) IN GENERAL.—Based on the notifica-
16 tions received in response to the rule under
17 paragraph (4), the Administrator shall des-
18 ignate each chemical substance that is on the
19 list published under paragraph (1) on the date
20 of enactment of the Chemical Safety Improve-
21 ment Act as active or inactive.

22 “(B) UPDATE.—The Administrator shall
23 update the list of chemicals designated as active
24 or inactive as soon as practicable following the
25 publication of the most recent data reported

1 under part 711 of title 40, Code of Federal
2 Regulations.

3 “(6) ACTIVE SUBSTANCES.—The Administrator
4 shall designate as an active substance—

5 “(A) a chemical substance that has been
6 manufactured or processed for a nonexempt
7 commercial purposes at any point during the 5-
8 year period prior to the date of enactment of
9 the Chemical Safety Improvement Act;

10 “(B) a chemical substance that is added to
11 the list published under paragraph (1) after the
12 date of enactment of the Chemical Safety Im-
13 provement Act;

14 “(C) a chemical substance for which a no-
15 tice is received under paragraph (7)(C); and

16 “(D) a chemical substance reported under
17 part 711 of title 40, Code of Federal Regula-
18 tions, after the date of enactment of the Chem-
19 ical Safety Improvement Act.

20 “(7) INACTIVE SUBSTANCES.—

21 “(A) IN GENERAL.—The Administrator
22 shall designate as an inactive substance each
23 chemical substance on the list published under
24 paragraph (1) that has not been manufactured
25 or processed for a nonexempt commercial pur-

1 pose in the 5-year period ending on the date of
2 enactment of the Chemical Safety Improvement
3 Act.

4 “(B) TREATMENT.—Each inactive sub-
5 stance shall remain on the list published under
6 paragraph (1).

7 “(C) CHANGE TO ACTIVE STATUS.—

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

15 “(ii) ACTIVE STATUS.—On receiving
16 notification under clause (i), the Adminis-
17 trator—

18 “(I) shall designate the chemical
19 substance as an active substance; and

20 “(II) shall, pursuant to section
21 4(e), review the priority of the chem-
22 ical substance as the Administrator
23 determines necessary.

1 “(D) CATEGORY STATUS.—The list of in-
2 active chemical substances shall not be consid-
3 ered a category for purposes of section 26(c).

4 “(8) PUBLIC PARTICIPATION.—

5 “(A) IN GENERAL.—Subject to subpara-
6 graph (B), the Administrator shall make avail-
7 able to the public—

8 “(i) the specific identity of each chem-
9 ical substance on the nonconfidential por-
10 tion of the list published under paragraph
11 (5) that the Administrator has designated
12 as an active substance;

13 “(ii) the specific identity of each
14 chemical substance on the nonconfidential
15 portion of the list published under para-
16 graph (1) that the Administrator has des-
17 ignated as an inactive substance;

18 “(iii) the accession number, generic
19 name, and, if applicable, premanufacture
20 notice case number for each chemical sub-
21 stance on the confidential portion of the
22 list published under paragraph (1) for
23 which a claim of confidentiality was re-
24 ceived; and

1 “(iv) the specific identity of any active
2 or inactive substance on the confidential
3 portion of the list published under para-
4 graph (1) for which no claim of confiden-
5 tiality was received, subject to the condi-
6 tion that, before revealing the specific iden-
7 tity of the substance, the Administrator
8 shall—

9 “(I) publish a notice in the Fed-
10 eral Register identifying the accession
11 number, generic name, and, if applica-
12 ble, premanufacture notice case num-
13 ber for that substance; and

14 “(II) provide an opportunity for
15 any person—

16 “(aa) to certify to the Ad-
17 ministrator that the person in-
18 tends to manufacture or process
19 the substance at any point in the
20 subsequent 4-year period; and

21 “(bb) to claim confiden-
22 tiality for the specific identity of
23 the substance.

24 “(B) CONFIDENTIALITY.—Subject section
25 14, the Administrator shall not make available

1 to the public the specific chemical identity of
2 any substance for which the Administrator re-
3 ceives a notice under subparagraph (A)(iv).”;
4 and

5 (3) in subsection (e)—

6 (A) by striking “Any person” and inserting
7 the following:

8 “(1) IN GENERAL.—Any person”; and

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

10 “(2) APPLICABILITY.—Any person may submit
11 to the Administrator data and information reason-
12 ably supporting the conclusion that a chemical sub-
13 stance or mixture does not present a substantial risk
14 of injury to health and the environment.”.

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

16 Section 9 (15 U.S.C. 2608) is amended—

17 (1) in subsection (a)—

18 (A) in the first sentence of paragraph

19 (1)—

20 (i) by striking “presents or will
21 present an unreasonable risk to health or
22 the environment” and inserting “does not
23 meet the safety standard under the in-
24 tended conditions of use”; and

1 (ii) by striking “such risk” the first
2 place it appears and inserting “the risk
3 posed by the substance or mixture”;

4 (B) in paragraph (2), in the matter fol-
5 lowing subparagraph (B), by striking “section 6
6 or 7” and inserting “paragraph (8) or (9) of
7 subsection (c) of section 6 or section 7”; and

8 (C) in paragraph (3), by striking “section
9 6 or 7” and inserting “paragraph (8) or (9) of
10 subsection (c) of section 6 or section 7”; and

11 (2) in subsection (d), in the first sentence, by
12 striking “Health, Education, and Welfare” and in-
13 serting “Health and Human Services”.

14 **SEC. 10. RESEARCH, DEVELOPMENT, COLLECTION, DIS-**
15 **SEMINATION, AND UTILIZATION OF DATA.**

16 Section 10 (15 U.S.C. 2609) is amended by striking
17 “Health, Education, and Welfare” each place it appears
18 and inserting “Health and Human Services”.

19 **SEC. 11. EXPORTS.**

20 Section 12 (15 U.S.C. 2611) is amended—

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

23 “(2) EXCEPTION.—Paragraph (1) shall not
24 apply to any chemical substance that the Adminis-
25 trator determines—

1 “(A) under section 5 is not likely to meet
2 the safety standard under the intended condi-
3 tions of use of the chemical substance; or

4 “(B) under section 6 does not meet the
5 safety standard under the intended conditions
6 of use of the chemical substance.

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

10 “(A) determine that paragraph (1) shall
11 not apply to that mixture or article; and

12 “(B) establish a threshold concentration in
13 a mixture or article at which paragraph (1)
14 shall not apply.”;

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

17 “(b) NOTICE.—

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

21 “(A) a chemical substance or a mixture
22 containing a chemical substance that the Ad-
23 ministrator has determined under section 5 is
24 not likely to meet the safety standard under the

1 intended conditions of use of the chemical sub-
2 stance;

3 “(B) a chemical substance or a mixture
4 containing a chemical substance that the Ad-
5 ministrator has determined under section 6
6 does not meet the safety standard under the in-
7 tended conditions of use of the chemical sub-
8 stance; or

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

12 “(2) REGULATIONS.—

13 “(A) IN GENERAL.—The Administrator
14 shall promulgate regulations to carry out para-
15 graph (1).

16 “(B) CONTENTS.—The regulations pro-
17 mulgated under subparagraph (A) shall—

18 “(i) include any exemptions the Ad-
19 ministrator determines to be appropriate,
20 which may include exemptions identified
21 under section 5(g); and

22 “(ii) indicate whether or to what ex-
23 tent the regulations apply to articles con-
24 taining a chemical substance or mixture
25 described in paragraph (1).

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

4 “(A) for a chemical substance or mixture
5 described in subparagraph (A) or (B) of para-
6 graph (1), a notice that information on the
7 chemical substance or mixture can be obtained
8 from the Administrator, unless the Adminis-
9 trator determines that good cause exists not to
10 provide the notice; and

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

15 (3) in subsection (c)—

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

17 (B) by redesignating paragraphs (4)
18 through (6) as paragraphs (3) through (5), re-
19 spectively.

20 **SEC. 12. IMPORTS.**

21 Section 13 (15 U.S.C. 2612) is amended to read as
22 follows:

1 **“SEC. 13. IMPORTS.**

2 “(a) DEFINITION OF CHEMICAL SUBSTANCE OR MIX-
3 TURE.—In this section, the term ‘chemical substance or
4 mixture’ includes—

5 “(1) a mixture containing a chemical substance
6 or mixture; and

7 “(2) an article containing a chemical substance
8 or mixture.

9 “(b) REFUSAL OF ENTRY.—

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

16 “(A) the Administrator has determined
17 under section 6(c) that the chemical substance
18 or mixture does not meet the safety standard
19 under the intended conditions of use of the
20 chemical substance; or

21 “(B) the chemical substance or mixture is
22 offered for entry in violation of a rule or order
23 in effect under this Act.

24 “(2) PROCEDURE.—

25 “(A) IN GENERAL.—Subject to subpara-
26 graph (B), if a chemical substance or mixture

1 is refused entry under paragraph (1), the Sec-
2 retary of Homeland Security—

3 “(i) shall notify the consignee of the
4 entry of the refusal;

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

7 “(iii) shall cause the disposal or stor-
8 age of the chemical substance or mixture
9 under such rules as the Secretary may pre-
10 scribe, if the chemical substance or mix-
11 ture has not been exported by the con-
12 signee in the 90-day period beginning on
13 the date of receipt of the notice of the re-
14 fused entry.

15 “(B) EXCEPTION.—

16 “(i) IN GENERAL.—The Secretary of
17 Homeland Security may, pending a review
18 by the Administrator, release to the con-
19 signee the chemical substance or mixture if
20 the consignee—

21 “(I) executes a bond for the
22 amount of the full invoice of the
23 chemical substance or mixture (as set
24 forth in the customs entry); and

1 “(II) pays a duty on the chemical
2 substance or mixture.

3 “(ii) ADMINISTRATION.—If a con-
4 signee fails to return a chemical substance
5 or mixture released to that consignee
6 under clause (i) for any cause to the cus-
7 tody of the Secretary of Homeland Secu-
8 rity when demanded, the consignee shall be
9 liable to the United States for liquidated
10 damages equal to the full amount of the
11 bond.

12 “(C) STORAGE.—All charges for storage,
13 cartage, and labor on and for the disposal of a
14 chemical substance or mixture that is refused
15 entry or released under this subsection shall be
16 paid by the owner or consignee, and a default
17 on that payment shall constitute a lien against
18 any future entry made by the owner or con-
19 signee.

20 “(c) NOTICE.—

21 “(1) IN GENERAL.—A person offering a chem-
22 ical substance or mixture subject to this Act for
23 entry into the customs territory of the United States
24 shall—

1 “(A) certify to the Secretary of Homeland
2 Security that, after reasonable inquiry and to
3 the best knowledge and belief of the person, the
4 chemical substance or mixture is—

5 “(i) in compliance with any applicable
6 rule, consent agreement, or order under
7 section 5 or 6; and

8 “(ii)(I) included on the list under sec-
9 tion 8(b); or

10 “(II) exempt from any requirement to
11 be included on that list; and

12 “(B) provide to the Secretary of Homeland
13 Security any notice required under paragraph
14 (2).

15 “(2) NOTICE.—A person offering a chemical
16 substance or mixture for entry into the customs ter-
17 ritory of the United States shall notify the Secretary
18 of Homeland Security if—

19 “(A) the chemical substance is a high-pri-
20 ority substance;

21 “(B) the chemical substance is a chemical
22 for which the United States is obligated to pro-
23 vide export notification by treaty; or

1 “(C) the chemical substance or mixture or
2 any article containing the substance or mix-
3 ture—

4 “(i) is the subject of a safety assess-
5 ment and safety determination conducted
6 pursuant to section 6 and has been found
7 not to meet the safety standard; and

8 “(ii) is identified in a rule promul-
9 gated by the Secretary of Homeland Secu-
10 rity pursuant to subsection (c) as meriting
11 notification due to the potential impact of
12 the chemical substance or mixture or any
13 article containing the substance or mixture
14 on human health or the environment.

15 “(d) RULES.—The Secretary of Homeland Security,
16 after consultation with the Administrator, shall issue rules
17 for the administration of subsection (c), including wheth-
18 er, or to what extent, the provisions of subsections (b) and
19 (c) apply.”.

20 **SEC. 13. CONFIDENTIAL INFORMATION.**

21 Section 14 (15 U.S.C. 2613) is amended to read as
22 follows:

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

2 “(a) IN GENERAL.—Except as provided in sub-
3 sections (c) and (e), the Administrator shall not disclose
4 information described in subsection (b)—

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

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

9 “(b) INFORMATION GENERALLY PROTECTED FROM
10 DISCLOSURE.—

11 “(1) IN GENERAL.—Information referred to in
12 subsection (a) includes confidential information that
13 is exempt from disclosure pursuant to subsection (a)
14 of section 552 of title 5, United States Code, under
15 subsection (b)(4) of that section.

16 “(2) PRESUMPTION OF PROTECTION.—The fol-
17 lowing information submitted by a manufacturer,
18 processor, or distributor is presumed to be protected
19 from disclosure:

20 “(A) Specific information describing the
21 manufacture, processing, or distribution in com-
22 merce of a chemical substance, mixture, or arti-
23 cle.

24 “(B) Marketing and sales information.

25 “(C) Information identifying suppliers or
26 customers.

1 “(D) The identity of constituents in a mix-
2 ture and the respective percentages of those
3 constituents.

4 “(E) Specific information about the use,
5 function, or application of a chemical substance
6 or mixture in a process, mixture, or product.

7 “(F) Specific production or import volumes
8 of a manufacturer and specific volumes aggre-
9 gated across manufacturers if the Adminis-
10 trator determines that disclosure of the aggre-
11 gated data could reveal confidential informa-
12 tion.

13 “(G) The specific identity of a chemical
14 substance, including the chemical name, molec-
15 ular formula, Chemical Abstracts Service num-
16 ber, and other information that would identify
17 a specific chemical substance, if—

18 “(i) the specific identity was claimed
19 as confidential information at the time it
20 was submitted; and

21 “(ii) the claim has not subsequently
22 been withdrawn or found by the Adminis-
23 trator not to warrant protection as con-
24 fidential information under subsection (g).

1 “(c) INFORMATION NOT PROTECTED FROM DISCLO-
2 SURE.—

3 “(1) IN GENERAL.—Notwithstanding sub-
4 sections (a) and (b), and except as provided in para-
5 graph (2), the following information shall not be
6 protected from disclosure:

7 “(A) For information submitted after the
8 date of enactment of the Chemical Safety Im-
9 provement Act, the identity of a chemical sub-
10 stance if the person submitting the information
11 does not meet the requirements of subsection
12 (d).

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

15 “(C) Health and safety data that are sub-
16 mitted under this Act with respect to a chem-
17 ical substance or mixture that has been offered
18 for commercial distribution as of the date on
19 which the study is to be disclosed or for which
20 testing is required under section 4.

21 “(D) Health and safety data in notices of
22 substantial risk submitted under section 8(e)
23 and in the underlying studies.

1 “(E) General information describing the
2 manufacturing volumes, expressed in ranges
3 would not reveal confidential information.

4 “(F) General descriptions of industrial,
5 commercial, or consumer functions and uses of
6 a chemical substance or mixture.

7 “(2) EXCEPTION.—Information elements con-
8 tained in submissions described in paragraph (1)
9 that are otherwise eligible for protection under this
10 section shall be protected from disclosure if the sub-
11 mitter complies with subsection (d).

12 “(d) REQUIREMENTS FOR CONFIDENTIALITY
13 CLAIMS.—

14 “(1) CLAIMS.—

15 “(A) IN GENERAL.—For information to be
16 protected from disclosure under this section, a
17 person who submits information to the Admin-
18 istrator under this Act shall—

19 “(i) indicate the information that the
20 person believes is entitled to protection
21 from disclosure under this section in a sub-
22 mission to the Administrator in such man-
23 ner and at such time as the Administrator
24 shall prescribe; and

1 “(ii) except in the case of information
2 described in subparagraphs (A) through
3 (F) of subsection (b)(2), submit written
4 documentation justifying why the informa-
5 tion qualifies for protection from disclo-
6 sure.

7 “(B) CERTIFICATION.—An authorized offi-
8 cial of the person described in subparagraph
9 (A) shall certify that the information that has
10 been submitted is true and correct.

11 “(2) ADDITIONAL REQUIREMENTS FOR CON-
12 FIDENTIALITY CLAIMS FOR CHEMICAL IDENTI-
13 TIES.—A person submitting information under this
14 Act related to a chemical identity and who claims
15 protection from disclosure for that identity shall pro-
16 vide the Administrator with—

17 “(A) information establishing that—

18 “(i) the person takes reasonable meas-
19 ures to protect the confidentiality of the
20 chemical identity;

21 “(ii) the chemical identity is not re-
22 quired to be disclosed, or otherwise made
23 available, to the public under any other
24 Federal law in connection with one or more
25 uses subject to this Act;

1 “(iii) disclosure of the chemical iden-
2 tity is likely to cause substantial harm to
3 the competitive position of the person; and

4 “(iv) the chemical identity is not rea-
5 sonably believed to be readily discoverable
6 through reverse engineering;

7 “(B) the time period for which protection
8 of the chemical identity from disclosure is nec-
9 essary;

10 “(C) a generic name for the chemical sub-
11 stance that the Administrator may disclose to
12 the public, subject to the condition that the ge-
13 neric name discloses a maximum amount of in-
14 formation on the chemical structure of the sub-
15 stance while protecting those features of the
16 chemical structure that are considered confiden-
17 tial and the disclosure of which would poten-
18 tially harm the competitive position of the per-
19 son; and

20 “(D) in the event the Administrator makes
21 a request under subsection (f)—

22 “(i) redocumentation and recertifi-
23 cation of the information submitted under
24 subsection (a); or

1 “(ii) withdrawal of the claim for pro-
2 tection of the chemical identity from disclo-
3 sure.

4 “(3) GUIDANCE.—The Administrator shall de-
5 velop guidance, after notice and opportunity to com-
6 ment, on the determination of generic names for
7 confidential chemical identities.

8 “(e) EXCEPTIONS TO PROTECTION FROM DISCLO-
9 SURE.—Subsection (a) shall not apply if—

10 “(1) the information is to be disclosed to an of-
11 ficer or employee of the United States in connection
12 with the official duties of that person under any law
13 for the protection of human health or the environ-
14 ment or for specific law enforcement purposes;

15 “(2) the information is to be disclosed to a con-
16 tractor with the United States and employees of that
17 contractor if, in the opinion of the Administrator,
18 the disclosure is necessary for the satisfactory per-
19 formance by the contractor of a contract with the
20 United States for the performance of work in con-
21 nection with this Act and under such conditions as
22 the Administrator shall specify;

23 “(3) the Administrator determines that disclo-
24 sure is necessary to protect human health or the en-
25 vironment;

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

5 “(A) one or more applicable agreements
6 with the Administrator ensure that the recipient
7 government will take appropriate steps, and has
8 adequate authority, to maintain the confiden-
9 tiality of the information in accordance with
10 procedures as stringent as those which the Ad-
11 ministrator uses to safeguard the information;
12 and

13 “(B) the Administrator notifies the person
14 who submitted the information that the infor-
15 mation has been disclosed to a State or political
16 subdivision of a State;

17 “(5) a health professional employed by a Fed-
18 eral or State agency or a treating physician or nurse
19 in a nonemergency situation provides a written
20 statement of need and a written confidentiality
21 agreement, subject to the conditions that—

22 “(A) the written statement of need is a
23 statement that the person has a reasonable
24 basis to suspect that—

1 “(i) the information is needed for pur-
2 poses of diagnosis or treatment of one or
3 more individuals;

4 “(ii) one or more individuals being di-
5 agnosed or treated have been exposed to
6 the chemical substance concerned; and

7 “(iii) knowledge of the specific chem-
8 ical identity of the chemical substance will
9 assist in diagnosis or treatment; and

10 “(B) the confidentiality agreement pro-
11 vides that the person will not use the specific
12 chemical identity for any purpose other than
13 the health needs asserted in the statement of
14 need, except as may otherwise be authorized by
15 the terms of the agreement or by the person
16 submitting the specific chemical identity to the
17 Administrator;

18 “(6) a treating physician or nurse requests the
19 information, subject to the conditions that—

20 “(A) the treating physician or nurse deter-
21 mines that—

22 “(i) a medical emergency exists;

23 “(ii) the specific chemical identity of
24 the chemical substance concerned is nec-

1 essary for or will assist in emergency or
2 first-aid diagnosis or treatment; and

3 “(iii) the one or more individuals
4 being diagnosed or treated have likely been
5 exposed to the chemical substance con-
6 cerned;

7 “(B) if requested by the person submitting
8 the specific chemical identity to the Adminis-
9 trator, the treating physician or nurse provides
10 a written statement of need and a confiden-
11 tiality agreement as described in paragraph (5);
12 and

13 “(C) the written confidentiality agreement
14 or statement of need is submitted as soon as
15 practicable, but not necessarily before the infor-
16 mation is disclosed;

17 “(7) the Administrator determines that disclo-
18 sure is necessary in a proceeding under this Act,
19 subject to the condition that the disclosure is made
20 in such a manner as to preserve confidentiality to
21 the maximum extent practicable without impairing
22 the proceeding; or

23 “(8) the information is to be disclosed, on writ-
24 ten request of any duly authorized committee of the
25 Congress, to that committee.

1 “(f) DURATION OF PROTECTION FROM DISCLO-
2 SURE.—

3 “(1) IN GENERAL.—The Administrator shall
4 protect from disclosure information described in sub-
5 section (b) that meets the requirements of sub-
6 section (d)(2) for the period of time requested by the
7 person submitting the claim or for such period of
8 time as the Administrator, after reviewing the re-
9 quest for confidential treatment and the documenta-
10 tion, otherwise determines to be reasonable, unless—

11 “(A) prior to the expiration of the period,
12 the person notifies the Administrator that the
13 person is withdrawing the confidentiality claim,
14 in which case, the Administrator shall promptly
15 make the information available to the public; or

16 “(B) prior to the expiration of the period,
17 the Administrator otherwise becomes aware
18 that the need for protection from disclosure can
19 no longer be substantiated, in which case the
20 Administrator shall take the actions described
21 in subsection (g)(2).

22 “(2) REDOCUMENTATION.—The Administrator
23 may request—

24 “(A) at any time, a person who has re-
25 quested protection from disclosure for the iden-

1 tity of a substance under subsection (d) to re-
2 document the confidentiality claim of the per-
3 son; and

4 “(B) any person who has requested that
5 confidential information be protected from dis-
6 closure under section 8(b) to reassert the con-
7 fidentiality claim of the person after the chem-
8 ical substance is identified as a high-priority
9 substance under section 4(e).

10 “(g) DUTIES OF THE ADMINISTRATOR.—

11 “(1) DETERMINATION.—

12 “(A) IN GENERAL.—Except as provided in
13 subsection (b)(2), the Administrator shall—

14 “(i) review a request received under
15 this section to maintain the confidentiality
16 of information submitted under this Act;
17 and

18 “(ii) determine whether to approve,
19 modify, or deny that request.

20 “(B) DENIAL OR MODIFICATION.—

21 “(i) IN GENERAL.—The Administrator
22 shall deny a claim to protect a chemical
23 identity from disclosure only if the person
24 who has submitted the request fails to
25 meet the requirements of subsection (d).

1 “(ii) REASONS FOR DENIAL OR MODI-
2 FICATION.—The Administrator shall pro-
3 vide to the person who has submitted the
4 request a written statement of the reasons
5 for the denial or modification of the claim.

6 “(C) SUBSETS.—If it is not feasible for the
7 Administrator to review each request under this
8 section, the Administrator shall review a rep-
9 resentative subset.

10 “(2) NOTIFICATION.—

11 “(A) IN GENERAL.—Except as provided in
12 subsections (c) and (e), if the Administrator de-
13 nies a request under paragraph (1), the Admin-
14 istrator shall notify, in writing and by certified
15 mail, the person who submitted the request of
16 the intent of the Administrator to release the
17 information.

18 “(B) RELEASE OF INFORMATION.—

19 “(i) IN GENERAL.—Except as pro-
20 vided in clause (ii), the Administrator may
21 not release information under this sub-
22 section until the date that is 30 days after
23 the date on which the person who sub-
24 mitted the request receives notification
25 under subparagraph (A).

1 “(ii) EXCEPTIONS.—

2 “(I) IN GENERAL.—For informa-
3 tion under paragraph (3) or (8) of
4 subsection (e), the Administrator may
5 not release that information until the
6 date that is 15 days after the date on
7 which the person who submitted the
8 request receives a notification, unless
9 the Administrator determines that re-
10 lease of the information is necessary
11 to protect against an imminent and
12 substantial harm to human health or
13 the environment, in which case, no
14 prior notification is necessary.

15 “(II) NO NOTIFICATION.—For
16 information under paragraph (6) or
17 (7) of subsection (e), no prior notifica-
18 tion is necessary.

19 “(3) APPEALS.—

20 “(A) IN GENERAL.—A person who receives
21 notification under this subsection may, if the
22 person believes disclosure of the information is
23 prohibited under subsection (a), before the date
24 on which the information is to be released,

1 bring an action to restrain disclosure of the in-
2 formation in—

3 “(i) the district court of the United
4 States in the district in which—

5 “(I) the complainant resides or
6 has the principal place of business; or

7 “(II) the information is located;
8 or

9 “(ii) the United States District Court
10 for the District of Columbia.

11 “(B) NO DISCLOSURE.—The Adminis-
12 trator shall not disclose any information under
13 this section prior to the date on which the ap-
14 plicable court rules on an action under subpara-
15 graph (A).

16 “(4) ADMINISTRATION.—In carrying out this
17 subsection, the Administrator shall employ the pro-
18 cedures in part 2 of title 40, Code of Federal Regu-
19 lations (or successor regulations).

20 “(h) CRIMINAL PENALTY FOR WRONGFUL DISCLO-
21 SURE.—

22 “(1) IN GENERAL.—Subject to paragraph (2),
23 any officer or employee of the United States or
24 former officer or employee of the United States,
25 who—

1 “(A) by virtue of that employment or offi-
2 cial position has obtained possession of, or has
3 access to, material the disclosure of which is
4 prohibited by subsection (a); and

5 “(B) knowing that disclosure of that mate-
6 rial is prohibited by subsection (a), willfully dis-
7 closes the material in any manner to any person
8 not entitled to receive that material, shall be—

9 “(i) guilty of a misdemeanor and
10 fined under title 18, United States Code,
11 imprisoned for not more than 1 year, or
12 both; and

13 “(ii) removed from office or employ-
14 ment.

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

20 “(3) CONTRACTORS.—For the purposes of this
21 subsection, any contractor of the United States who
22 is furnished information in accordance with sub-
23 section (e)(2), including any employee of that con-
24 tractor, shall be considered to be an employee of the
25 United States.

1 “(i) APPLICABILITY.—Except as otherwise provided
2 in this section, the Administrator shall have no author-
3 ity—

4 “(1) to require the documentation or redocu-
5 mentation of a claim for the protection from disclo-
6 sure of information submitted to the Administrator
7 under this Act prior to the date of enactment of the
8 Chemical Safety Improvement Act; or

9 “(2) to impose redocumentation requirements
10 under this Act that are more extensive than those
11 required under this section.”.

12 **SEC. 14. PROHIBITED ACTS.**

13 Section 15 (15 U.S.C. 2614) is amended by striking
14 paragraph (1) and inserting the following:

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

16 “(A) any rule promulgated, consent agree-
17 ment entered into, or order issued under section
18 4;

19 “(B) any requirement prescribed by section
20 5 or 6;

21 “(C) any rule promulgated, consent agree-
22 ment entered into, or order issued under section
23 5 or 6;

1 “(D) any requirement of title II or any
2 rule promulgated or order issued under title II;
3 or

4 “(E) any requirement of title VII or any
5 rule promulgated or order issued under title
6 VII;”.

7 **SEC. 15. PREEMPTION.**

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

10 “(a) IN GENERAL.—~~E~~xcept as provided in sub-
11 sections (c) and (d), no State or political subdivision of
12 a State may establish or continue to enforce—

13 “(1) a requirement for the development of test
14 data or information on a chemical substance or cat-
15 egory of substances that is reasonably likely to
16 produce the same data and information required
17 under section 4, 5, or 6 by—

18 “(A) a rule promulgated by the Adminis-
19 trator;

20 “(B) a consent agreement entered into by
21 the Administrator; or

22 “(C) an order issued by the Administrator;

23 “(2) a prohibition or restriction on the manu-
24 facture, processing, or distribution in commerce or
25 use of a chemical substance after issuance of a com-

1 pleted safety determination for a chemical substance
2 under section 6, consistent with the scope of the re-
3 view and decisions addressed by the Administrator;
4 or

5 “(3) a requirement for the notification of a use
6 of a chemical substance that the Administrator has
7 specified as a significant new use and for which the
8 Administrator has required notification pursuant to
9 a rule promulgated under section 5.

10 “(b) NEW PROHIBITIONS OR RESTRICTIONS.—Ex-
11 cept as provided in subsections (c) and (d), no State or
12 political subdivision of a State may establish (after the
13 date of enactment of the Chemical Safety Improvement
14 Act)—

15 “(1) a prohibition or restriction on the manu-
16 facture, processing, distribution in commerce or use
17 of a chemical substance that is a high-priority sub-
18 stance identified under section 4(e)(3) (as of the
19 date on which the Administrator publishes a sched-
20 ule under section 6(b)); or

21 “(2) a prohibition or restriction on the manu-
22 facture, processing, distribution in commerce or use
23 of a chemical substance that is a low-priority sub-
24 stance identified under section 4(e)(3).

1 “(c) EXCEPTIONS.—Subsections (a) and (b) shall not
2 apply to a requirement, prohibition, or restriction of a
3 State or a political subdivision of a State that—

4 “(1) is adopted under the authority of any
5 other Federal law;

6 “(2) implements a reporting or information col-
7 lection requirement not otherwise required by the
8 Administrator under this Act or required under any
9 other Federal law; or

10 “(3) is adopted pursuant to authority under a
11 law of the State or political subdivision of the State
12 related to water quality, air quality, or waste treat-
13 ment or disposal that—

14 “(A) does not impose a restriction on the
15 manufacture, processing, distribution in com-
16 merce, or use of a chemical substance; and

17 “(B) is not otherwise required by or incon-
18 sistent with an action by the Administrator
19 under section 5 or 6.

20 “(d) STATE WAIVERS.—Upon application of a State
21 or political subdivision of a State, the Administrator may
22 provide a waiver from subsection (a) and subsection
23 (b)(1), regarding a requirement of that State or political
24 subdivision of the State that relates to the effects or expo-

1 sure to any chemical substance under the intended condi-
2 tions of use if—

3 “(1)(A) the State or political subdivision of the
4 State determines it cannot wait until the end of the
5 period specified in the established schedule and
6 deadline for the completion of a full safety assess-
7 ment and determination established under section
8 6(b)(2)(B)(ii); and

9 “(B) the Administrator determines that—

10 “(i) compelling State or local conditions
11 warrant granting the waiver to protect human
12 health or the environment;

13 “(ii) compliance with the proposed require-
14 ment of the State or political subdivision of the
15 State does not unduly burden interstate and
16 foreign commerce in the manufacture, proc-
17 essing, distribution in commerce, or use of a
18 chemical substance;

19 “(iii) compliance with the proposed re-
20 quirement of the State or political subdivision
21 of the State would not cause a violation of any
22 applicable Federal law, rule, or order; and

23 “(iv) the proposed requirement of the
24 State or political subdivision of the State is

1 based on the best available science and is sup-
2 ported by the weight of the evidence; or

3 “(2)(A) the Administrator finds a safety assess-
4 ment or determination has been unreasonably de-
5 layed; and

6 “(B) the State certifies that—

7 “(i) the State has a compelling local inter-
8 est to protect human health or the environment;

9 “(ii) compliance with the proposed require-
10 ment of the State does not unduly burden inter-
11 state and foreign commerce in the manufacture,
12 processing, distribution in commerce, or use of
13 a chemical substance;

14 “(iii) compliance with the proposed re-
15 quirement would not cause a violation of any
16 applicable Federal law, rule, or order; and

17 “(iv) the proposed requirement is grounded
18 in reasonable scientific concern.

19 “(3) APPROVAL OF A STATE WAIVER RE-
20 QUEST.—The Administrator shall grant or deny a
21 waiver application—

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

1 “(B) not later than 90 days after the date
2 on which an application under paragraph (2) is
3 submitted.

4 “(4) NOTICE AND COMMENT.—The application
5 of a State or political subdivision of the State shall
6 be subject to public notice and comment.

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

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

12 “(B) subject to judicial review.

13 “(6) DURATION OF STATE WAIVERS.—A State
14 waiver—

15 “(A) granted under paragraph (1) shall re-
16 main in effect unless the waiver is found to be
17 in conflict with a completed safety assessment
18 and determination; and

19 “(B) granted under paragraph (2) shall re-
20 main in effect until such time as the safety as-
21 sessment and determination is completed.

22 “(7) JUDICIAL REVIEW.—Not later than 60
23 days after the date on which the Administrator
24 makes a determination on an application of a State
25 or political subdivision of the State under paragraph

1 (1), any person may file a petition for judicial review
 2 in the United States Court of Appeals for the Dis-
 3 trict of Columbia Circuit, which shall have exclusive
 4 jurisdiction over the determination.

5 “(e) EFFECT ON PRIVATE REMEDIES.—

6 “(1) IN GENERAL.—If the Administrator com-
 7 pletes a safety determination for a high-priority sub-
 8 stance under section 6, the determination shall be
 9 admissible as evidence in any public or private ac-
 10 tion in any court of the United States or State court
 11 for recovery of damages or for equitable relief relat-
 12 ing to injury to human health or the environment
 13 from exposure to a chemical substance.

14 “(2) SAFETY STANDARD.—The safety deter-
 15 mination shall be determinative of whether the sub-
 16 stance meets the safety standard under the condi-
 17 tions of use addressed in the safety determination.”.

18 **SEC. 16. JUDICIAL REVIEW.**

19 Section 19 (15 U.S.C. 2618) is amended—

20 (1) in subsection (a)—

21 (A) by striking paragraph (1) and insert-
 22 ing the following:

23 “(1) FILING OF PETITION.—

24 “(A) IN GENERAL.—Not later than 60
 25 days after the date of the promulgation of a

1 rule under section 4(f), 6(c), 6(e), or 8, any
2 person may file a petition for judicial review of
3 the rule in—

4 “(i) the United States Court of Ap-
5 peals for the District of Columbia Circuit;

6 “(ii) the circuit in which the person
7 resides; or

8 “(iii) the circuit in which the principal
9 place of business of the person is located.

10 “(B) EXCLUSIVE JURISDICTION OF
11 COURTS OF APPEALS.—The courts of appeals of
12 the United States shall have exclusive jurisdic-
13 tion of any action to obtain judicial review
14 (other than in an enforcement proceeding)
15 under subparagraph (A) if any district court of
16 the United States would have had jurisdiction
17 of the action but for this paragraph.”;

18 (B) in paragraph (2), by striking “para-
19 graph (1)(A)” and inserting “paragraph (1)”;
20 and

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

22 (2) in subsection (c)(1), by striking subpara-
23 graph (B) and inserting the following:

24 “(B) APPLICABILITY OF SECTION 706 OF
25 TITLE 5, UNITED STATES CODE.—

1 “(i) DEFINITION OF EVIDENCE.—In
2 this subparagraph, the term ‘evidence’
3 means any matter in the rulemaking
4 record.

5 “(ii) APPLICABILITY.—Section 706 of
6 title 5, United States Code, shall apply to
7 review of a rule under this section, except
8 that—

9 “(I) in the case of a rule under
10 section 4(f), 6(c), or 6(e)—

11 “(aa) the standard of review
12 prescribed in section 706(2)(E)
13 of title 5, United States Code,
14 shall not apply; and

15 “(bb) the court shall hold as
16 unlawful and set aside the rule if
17 the court finds that the rule is
18 not supported by substantial evi-
19 dence in the rulemaking record;
20 and

21 “(II) the court shall not review
22 the contents and adequacy of the
23 statement of basis and purpose re-
24 quired by section 553(e) of title 5,
25 United States Code, to be incor-

1 porated in the rule except as part of
2 a review of the rulemaking record
3 taken as a whole.”.

4 **SEC. 17. CITIZENS’ PETITIONS.**

5 Section 21 (15 U.S.C. 2620) is amended—

6 (1) in subsection (a), by striking “an order
7 under section 5(e) or 6(b)(2)” and inserting “an
8 order under section 4(f) or 5(e)”; and

9 (2) in subsection (b)—

10 (A) in paragraph (1), by striking “an
11 order under section 5(e), 6(b)(1)(A), or
12 6(b)(1)(B)” and inserting “an order under sec-
13 tion 4(f) or 5(c)”; and

14 (B) by striking subparagraph (B) of para-
15 graph (4) and inserting the following:

16 “(B) DE NOVO PROCEEDING.—

17 “(i) IN GENERAL.—In an action
18 under subparagraph (A) to initiate a pro-
19 ceeding to issue a rule under section 4(f),
20 6(b), 6(c), 6(d), or 8 or an order issued
21 under section 4(f) or 5(c), the petitioner
22 shall be provided an opportunity to have
23 the petition considered by the court in a de
24 novo proceeding.

25 “(ii) DEMONSTRATION.—

1 “(I) IN GENERAL.—The court
2 shall order the Administrator to ini-
3 tiate the action requested by the peti-
4 tioner if the petitioner demonstrates
5 to the satisfaction of the court by a
6 preponderance of the evidence that—

7 “(aa) in the case of a peti-
8 tion to initiate a proceeding for
9 the issuance of a rule or order
10 under section 4(f), the informa-
11 tion available to the Adminis-
12 trator is insufficient for the Ad-
13 ministrator to perform an action
14 described in section 4(f), 6(b)(5),
15 or 6(c)(8);

16 “(bb) in the case of a peti-
17 tion to issue an order under sec-
18 tion 5(c), there is a reasonable
19 basis to conclude that the sub-
20 stance is not likely to meet the
21 safety standard under the in-
22 tended conditions of use;

23 “(cc) in the case of a peti-
24 tion to initiate a proceeding for
25 the issuance of a rule under sec-

1 tion 6(c)(9), there is a reasonable
2 basis to conclude that the sub-
3 stance will not meet the safety
4 standard under the intended con-
5 ditions of use; or

6 “(dd) in the case of a peti-
7 tion to initiate a proceeding for
8 the issuance of a rule under sec-
9 tion 6(b)(2), 6(d) or 8, there is a
10 reasonable basis to conclude that
11 the rule is necessary to protect
12 human health or the environment
13 from an unreasonable risk of
14 harm to human health or the en-
15 vironment.

16 “(II) DEFERMENT.—The court
17 may permit the Administrator to defer
18 initiating the action requested by the
19 petitioner until such time as the court
20 prescribes if the court finds that—

21 “(aa) the extent of the risk
22 to human health or the environ-
23 ment alleged by the petitioner is
24 less than the extent of risks to
25 human health or the environment

1 with respect to which the Admin-
2 istrator is taking action under
3 this Act; and

4 “(bb) there are insufficient
5 resources available to the Admin-
6 istrator to take the action re-
7 quested by the petitioner.”.

8 **SEC. 18. STUDIES.**

9 Section 25 (15 U.S.C. 2624) is repealed.

10 **SEC. 19. ADMINISTRATION.**

11 Section 26(e) (15 U.S.C. 2625(e)) is amended by
12 striking “Health, Education, and Welfare” each place it
13 appears and inserting “Health and Human Services”.

14 **SEC. 20. DEVELOPMENT AND EVALUATION OF TEST METH-**
15 **ODS.**

16 Section 27(a) (15 U.S.C. 2626(a)) is amended by
17 striking “Health, Education, and Welfare” and inserting
18 “Health and Human Services”.

19 **SEC. 21. STATE PROGRAMS.**

20 Section 28 (15 U.S.C. 2627) is amended by striking
21 subsections (c) and (d).

22 **SEC. 22. AUTHORIZATION OF APPROPRIATIONS.**

23 Section 29 (15 U.S.C. 2628) is repealed.

1 **SEC. 23. ANNUAL REPORT.**

2 Section 30 (15 U.S.C. 2629) is amended by striking
3 paragraph (2) and inserting the following:

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

6 “(B) the number of the notices described in
7 subparagraph (A) for chemical substances subject to
8 a rule, testing consent agreement, or order under
9 section 4(f);”.

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