

113TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

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

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Chemical Safety Im-
5 provement Act”.

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

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

9 (1) in paragraph (2)—

1 (A) by striking “injury” and inserting
2 “harm”; and

3 (B) by striking “and” at the end;

4 (2) by redesignating paragraph (3) as para-
5 graph (4); and

6 (3) by inserting after paragraph (2) the fol-
7 lowing:

8 “(3) reform of this Act in accordance with the
9 amendments made by the Chemical Safety Improve-
10 ment Act—

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

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

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

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

4 **SEC. 3. DEFINITIONS.**

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

7 (1) by redesignating paragraphs (7), (8), (9),
8 (10) , (11), (12), (13), and (14) as paragraphs (9),
9 (10), (11), (13), (14), (19), (20), and (21), respec-
10 tively;

11 (2) by inserting after paragraph (6) the fol-
12 lowing:

13 “(7) INFORMATION.—The term ‘information’
14 means any qualitative, quantitative, or descriptive
15 facts, data, analysis, or assessment related to chem-
16 ical hazards, use, or exposure (including the nature
17 and extent of exposure to a chemical substance), in-
18 cluding from health and safety studies.

19 “(8) INTENDED OR REASONABLY ANTICIPATED
20 CONDITIONS OF USE.—The term ‘intended or rea-
21 sonably anticipated conditions of use’ means the cir-
22 cumstances the Administrator determines are those
23 under which a chemical substance is intended, rea-
24 sonably known, or reasonably anticipated to be man-

1 ufactured, processed, distributed in commerce, used,
2 and disposed of.”;

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

5 “(12) POTENTIALLY EXPOSED OR SUSCEPTIBLE
6 POPULATION.—The term ‘potentially exposed or sus-
7 ceptible population’ means 1 or more groups—

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

10 “(i) differentially exposed to chemical
11 substances under the intended or reason-
12 ably anticipated conditions of use; or

13 “(ii) susceptible to greater adverse
14 health consequences from chemical expo-
15 sures than the general population; and

16 “(B) that when identified by the Adminis-
17 trator may include such groups as infants, chil-
18 dren, pregnant women, workers, and the elder-
19 ly.”; and

20 (4) by inserting after paragraph (14) (as so re-
21 designated) the following:

22 “(15) PUBLICLY AVAILABLE.—

23 “(A) IN GENERAL.—The term ‘publicly
24 available’, with respect to information, means
25 information that is—

1 “(i) generally accessible and available
2 to the general public; or

3 “(ii) in the public domain.

4 “(B) INCLUSIONS.—The term ‘publicly
5 available’, with respect to information, includes
6 information that has been published in periodi-
7 cals, books, print, an electronic format, or other
8 media available for general distribution to any
9 member of the public.

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

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

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

1 to a chemical substance under the intended or rea-
2 sonably anticipated conditions of use, including no
3 unreasonable risk of harm to—

4 “(A) the general population; or

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

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

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

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

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

16 “(b) DEADLINE.—Not later than 2 years after the
17 date of enactment of the Chemical Safety Improvement
18 Act, the Administrator shall develop, after providing pub-
19 lic notice and an opportunity for comment, any policies,
20 procedures, and guidance the Administrator determines to
21 be necessary to carry out sections 4, 4A, 5, and 6, includ-
22 ing the policies, procedures, and guidance required by this
23 section.

24 “(c) USE OF SCIENCE.—

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

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

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

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

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

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

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

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

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

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

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

1 of a chemical substance under the intended or reasonably
2 anticipated conditions of use that is reasonably available
3 to the Administrator, including information that is—

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

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

11 “(B) the public;

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

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

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

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

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

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

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

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

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

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

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

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

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

8 “(i) toxicity information;

9 “(ii) computational toxicology and
10 bioinformatics;

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

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

17 “(4) TIERED TESTING.—

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

25 “(B) SCREENING-LEVEL TESTS.—

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

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

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

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

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

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

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

10 “(1) SCHEDULE.—

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

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

23 “(2) POLICIES AND PROCEDURES FOR SAFETY
24 ASSESSMENTS AND SAFETY DETERMINATIONS.—

1 “(A) IN GENERAL.—The Administrator
2 shall establish, by regulation, policies and pro-
3 cedures regarding the manner in which the Ad-
4 ministrator shall carry out section 6.

5 “(B) GOAL.—A goal of the policies and
6 procedures under this paragraph shall be to
7 make the basis of decisions of the Adminis-
8 trator clear to the public.

9 “(C) MINIMUM REQUIREMENTS.—At a
10 minimum, the policies and procedures under
11 this paragraph shall—

12 “(i) describe—

13 “(I) the manner in which the Ad-
14 ministrator will identify informational
15 needs and seek that information from
16 the public;

17 “(II) the information (including
18 draft safety assessments) that may be
19 submitted by interested individuals or
20 entities, including States; and

21 “(III) the criteria by which that
22 information will be evaluated;

23 “(ii) require the Administrator—

24 “(I)(aa) to identify the hazards,
25 exposures, intended or reasonably an-

1 anticipated conditions of use, and poten-
2 tially exposed and susceptible popu-
3 lations that the Administrator expects
4 to consider in a safety assessment;

5 “(bb) to explain the basis for
6 those identifications; and

7 “(cc) to accept comments regard-
8 ing the identifications; and

9 “(II)(aa) to identify the items de-
10 scribed in subclause (I) that the Ad-
11 ministrator has considered in the final
12 safety assessment; and

13 “(bb) to explain the basis for the
14 consideration of those items;

15 “(iii) describe the manner in which
16 aggregate exposures, or significant subsets
17 of exposures, to a chemical substance
18 under the intended or reasonably antici-
19 pated conditions of use will be considered,
20 and explain the basis for that consideration
21 in the final safety assessment;

22 “(iv) require that each safety assess-
23 ment and safety determination shall in-
24 clude—

1 “(I) a description of the weight
2 of the scientific evidence of risk; and

3 “(II) a summary of the informa-
4 tion regarding the impact on human
5 health and the environment of the
6 chemical substance that was used to
7 make the assessment or determina-
8 tion, including, as available, mecha-
9 nistic, animal toxicity, and epidemi-
10 ology studies; and

11 “(v) establish a timely and trans-
12 parent process for evaluating whether new
13 information submitted or obtained after
14 the date of a final safety assessment or
15 safety determination warrants reconsider-
16 ation of the safety assessment or safety de-
17 termination.

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

20 “(1) make publicly available a nontechnical
21 summary, and the final version, of each safety as-
22 sessment and safety determination;

23 “(2) provide public notice and an opportunity
24 for comment on each proposed safety assessment
25 and safety determination; and

1 “(3) make public in a final safety assessment
2 and safety determination—

3 “(A) the list of studies considered by the
4 Administrator in carrying out the safety assess-
5 ment or safety determination; and

6 “(B) the list of policies, procedures, and
7 guidance that were followed in carrying out the
8 safety assessment or safety determination.

9 “(j) CONSULTATION WITH SCIENCE ADVISORY COM-
10 MITTEE ON CHEMICALS.—

11 “(1) ESTABLISHMENT.—Not later than 1 year
12 after the date of enactment of this section, the Ad-
13 ministrator shall establish an advisory committee, to
14 be known as the ‘Science Advisory Committee on
15 Chemicals’ (referred to in this subsection as the
16 ‘Committee’).

17 “(2) PURPOSE.—The purpose of the Committee
18 shall be to provide independent advice and expert
19 consultation, on the request of the Administrator,
20 with respect to the scientific and technical aspects of
21 issues relating to the implementation of this title.

22 “(3) COMPOSITION.—The Committee shall be
23 composed of representatives of such science, govern-
24 ment, labor, public health, public interest, industry,
25 and other groups as the Administrator determines to

1 be advisable, including, at a minimum, representa-
2 tives that have specific scientific expertise in the re-
3 lationship of chemical exposures to women, children,
4 and other potentially exposed or susceptible popu-
5 lations.

6 “(4) SCHEDULE.—The Administrator shall con-
7 vene the Committee in accordance with such sched-
8 ule as the Administrator determines to be appro-
9 priate, but not less frequently than once every 2
10 years.

11 “(5) RELATIONSHIP TO OTHER LAW.—All pro-
12 ceedings and meetings of the Committee shall be
13 subject to the Federal Advisory Committee Act (5
14 U.S.C. App.).”.

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

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

18 (1) by striking subsections (a), (b), (c), (d), and
19 (g);

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

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

23 (A) by striking “rule” each place it ap-
24 pears and inserting “regulation, testing consent
25 agreement, or order”;

1 (B) by striking “under subsection (a)”
2 each place it appears and inserting “under this
3 subsection”; and

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

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

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

9 (B) by striking the last sentence; and

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

12 “(a) DEVELOPMENT OF NEW INFORMATION ON
13 CHEMICAL SUBSTANCES AND MIXTURES.—

14 “(1) IN GENERAL.—The Administrator may re-
15 quire the development of new information relating to
16 a chemical substance or mixture in accordance with
17 this section if the Administrator determines that the
18 information is necessary—

19 “(A) to perform a safety assessment or
20 safety determination under section 6;

21 “(B) to implement a requirement imposed
22 in a consent agreement or order issued under
23 section 5(d)(4);

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

1 “(D) at the request of the implementing
2 authority under another Federal law, to meet
3 the regulatory testing needs of that authority.

4 “(2) LIMITED TESTING FOR PRIORITIZATION
5 PURPOSES.—

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

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

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

20 “(3) FORM.—Subject to section 3A(f), the Ad-
21 ministrator may require the development of test data
22 and information described in paragraph (1) or (2)
23 by—

24 “(A) promulgating a regulation;

1 “(B) entering into a testing consent agree-
2 ment; or

3 “(C) issuing an order.

4 “(4) CONTENTS.—

5 “(A) IN GENERAL.—A regulation, testing
6 consent agreement, or order issued under this
7 subsection shall include—

8 “(i) identification of the chemical sub-
9 stance or mixture for which testing is re-
10 quired;

11 “(ii) identification of the persons re-
12 quired to conduct the testing;

13 “(iii) test protocols and methodologies
14 for the development of test data and infor-
15 mation for the chemical substance or mix-
16 ture, including specific reference to reliable
17 nonanimal test procedures; and

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

24 “(B) CONSIDERATIONS.—In determining
25 the procedures and period to be required under

1 subparagraph (A), the Administrator shall take
2 into consideration—

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

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

9 “(b) STATEMENT OF NEED.—

10 “(1) IN GENERAL.—In promulgating a regula-
11 tion, entering into a testing consent agreement, or
12 issuing an order for the development of additional
13 information (including information on exposure or
14 exposure potential) pursuant to this section, the Ad-
15 ministrators shall—

16 “(A) identify the need intended to be met
17 by the regulation, agreement, or order;

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

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

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

1 “(A) IN GENERAL.—If the Administrator
2 issues an order under this section, the Adminis-
3 trator shall issue a statement providing a jus-
4 tification for why issuance of an order is war-
5 ranted instead of promulgating a regulation or
6 entering into a testing consent agreement.

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

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

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

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

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

23 “(1) IN GENERAL.—The Administrator shall
24 minimize, to the extent practicable, the use of

1 vertebrate animals in testing of chemical substances
2 or mixtures, by—

3 “(A) encouraging and facilitating—

4 “(i) the use of integrated and tiered
5 testing and assessment strategies;

6 “(ii) the use of best available science
7 in existence on the date on which the test
8 is conducted;

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

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

19 “(v) the formation of industry con-
20 sortia to jointly conduct testing to avoid
21 unnecessary duplication of tests; and

22 “(vi) the submission of information
23 from—

24 “(I) animal-based studies; and

1 “(II) emerging methods and
2 models; and

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

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

11 “(A) after providing an opportunity for
12 public comment, develop a strategic plan to pro-
13 mote the development and implementation of al-
14 ternative test methods and testing strategies to
15 generate information used in safety assessments
16 and safety determinations under section 6 that
17 can reduce, refine, or replace the use of
18 vertebrate animals, including toxicity pathway-
19 based risk assessment, in vitro studies, systems
20 biology, computational toxicology,
21 bioinformatics, and high-throughput screening;

22 “(B) beginning on the date that is 5 years
23 after the date of enactment of the Chemical
24 Safety Improvement Act and every 5 years
25 thereafter, submit to Congress a report that de-

1 scribes the progress made in implementing this
2 subsection and goals for future alternative test
3 methods implementation; and

4 “(C) fund and carry out research, develop-
5 ment, performance assessment, and
6 translational studies to accelerate the develop-
7 ment of test methods and testing strategies that
8 reduce, refine, or replace the use of vertebrate
9 animals in any safety assessment or safety de-
10 termination under section 6.

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

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

1 “(B) as a result of 1 or more physical or
2 chemical properties of the chemical substance
3 or mixture or other toxicokinetic consider-
4 ations—

5 “(i) the substance cannot be absorbed;
6 or

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

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

16 “(d) TESTING REQUIREMENTS.—

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

19 “(A) manufacturers and processors of the
20 chemical substance or mixture; and

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

23 “(i) after the effective date of the reg-
24 ulation, testing consent agreement, or
25 order; but

1 “(ii) subject to paragraph (3), before
2 the period ending on the date that is 180
3 days after the end of the period described
4 in this section.

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

9 “(A) to develop the information; and

10 “(B) to submit the information on behalf
11 of the persons making the designation.

12 “(3) EXEMPTIONS.—

13 “(A) IN GENERAL.—A person otherwise
14 subject to a regulation, testing consent agree-
15 ment, or order under this section may submit to
16 the Administrator an application for an exemp-
17 tion on the basis that the information is being
18 developed by a person designated under para-
19 graph (2).

20 “(B) FAIR AND EQUITABLE REIMBURSE-
21 MENT TO DESIGNEE.—

22 “(i) IN GENERAL.—If the Adminis-
23 trator accepts an application submitted
24 under subparagraph (A), the Adminis-
25 trator shall direct the applicant to provide

1 to the person designated under paragraph
2 (2) fair and equitable reimbursement, as
3 agreed to between the applicant and the
4 designee.

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

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

16 “(i) by order, terminate the exemp-
17 tion; and

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

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

1 (b) CONFORMING AMENDMENT.—Section
2 104(i)(5)(A) of the Comprehensive Environmental Re-
3 sponse, Compensation, and Liability Act of 1980 (42
4 U.S.C. 9604(i)(5)(A)) is amended in the third sentence
5 by striking “section 4(e)” and inserting “section 4(f)”.

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

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

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

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

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

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

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

23 “(2) INITIAL LIST OF HIGH-PRIORITY SUB-
24 STANCES.—

1 “(A) IN GENERAL.—Before the date of
2 promulgation of the regulation under paragraph
3 (1) and not later than 180 days after the date
4 of enactment of this section, the Adminis-
5 trator—

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

9 “(ii) pursuant to section 6(b)(2), may
10 initiate or continue safety assessments and
11 safety determinations for those chemical
12 substances.

13 “(B) REQUIREMENTS.—The initial list of
14 high-priority substances shall contain at least
15 10 chemical substances.

16 “(3) IMPLEMENTATION.—

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

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

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

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

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

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

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

21 “(iii) REPOPULATION.—

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

1 “(ii) DECISIONS ON SUBSTANCES SUB-
2 JECT TO TESTING FOR PRIORITIZATION
3 PURPOSES.—Not later than 90 days after
4 the date of receipt of information regard-
5 ing a chemical substance complying with a
6 regulation, testing consent agreement, or
7 order issued under section 4(a)(2), the Ad-
8 ministrator shall designate the chemical
9 substance as a high-priority substance or
10 low-priority substance.

11 “(iii) CONSIDERATION.—

12 “(I) IN GENERAL.—The Admin-
13 istrator shall screen substances taking
14 into consideration the ability of the
15 Administrator to schedule and com-
16 plete safety assessments and safety
17 determinations under section 6 in a
18 timely manner.

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

24 “(C) SCREENING OF CATEGORIES OF SUB-
25 STANCES.—The Administrator may screen cat-

1 egories of chemical substances to ensure an effi-
2 cient prioritization screening process to allow
3 for timely and adequate safety assessments and
4 safety determinations.

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

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

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

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

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

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

6 “(C) the intended or reasonably antici-
7 pated conditions of use or significant changes in
8 the conditions of use of the chemical substance;

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

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

15 “(F) whether the volume of a chemical
16 substance as reported under a regulation pro-
17 mulgated pursuant to section 8(a) has signifi-
18 cantly increased or decreased during the period
19 beginning on the date of a previous report or
20 the date on which a notice has been submitted
21 under section 5(b) for that chemical substance;

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

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

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

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

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

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

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

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

25

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 “(8) REVISION BASED ON NEW INFORMA-
12 TION.—

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

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

1 chemical substance on receiving the relevant in-
2 formation.

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

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

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

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

17 “(A) the manufacture, processing, distribu-
18 tion, use, or disposal of the chemical substance;
19 or

20 “(B) the regulation of those activities.

21 “(c) EXPEDITED PRIORITIZATION SCREENING.—

22 “(1) IN GENERAL.—Not later than 180 days
23 after the date on which the Administrator receives
24 from the Governor of a State or a State agency with
25 responsibility for protecting health and the environ-

1 ment a recommendation and relevant information
2 justifying that an active substance be identified as a
3 high-priority substance or a low-priority substance,
4 the Administrator shall make a prioritization screen-
5 ing decision for the active substance.

6 “(2) **LIMITATION.**—The Governor of a State or
7 a State agency with responsibility for protecting
8 health and the environment may annually rec-
9 ommend not more than 2 chemical substances for
10 prioritization screening under paragraph (1).

11 “(3) **RECOMMENDATION.**—Notwithstanding
12 subsection (b)(8), a recommendation by the Gov-
13 ernor of a State or a State agency with responsi-
14 bility for protecting health and the environment with
15 respect to a chemical substance that has been pre-
16 viously prioritized shall not be required to be based
17 on new information.

18 “(4) **NOTICE AND COMMENT.**—The public shall
19 be provided notice and an opportunity to comment
20 regarding the recommendations submitted under this
21 subsection.

22 “(5) **EXPLANATION OF REASONS.**—The Admin-
23 istrator shall—

1 “(A) make available to the Governor or
2 State agency, as applicable, and to the public a
3 brief explanation of the reasons for—

4 “(i) identifying a chemical substance
5 recommended by the Governor or State
6 agency for prioritization screening as a
7 high-priority substance or a low-priority
8 substance; or

9 “(ii) deferring a prioritization screen-
10 ing decision; and

11 “(B) identify the information relied on in
12 making that identification.

13 “(d) TREATMENT.—Except as provided in section
14 18(e)(6)(B), an action by the Administrator under this
15 section shall not be—

16 “(1) considered to be a final agency action; or

17 “(2) subject to judicial review.”.

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

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

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

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

24 (2) by striking subsection (b);

1 (3) by redesignating subsection (a) as sub-
2 section (b);

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

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

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

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

11 (i) by striking “subsection (d)” and
12 inserting “subsection (b)”; and

13 (ii) by striking “and such person com-
14 plies with any applicable requirement of
15 subsection (b)”;

16 (6) by redesignating subsections (c) and (d) as
17 subsection (d) and (c), respectively, and moving sub-
18 section (c) (as so redesigned) so as appear after sub-
19 section (b) (as redesignated by paragraph (3));

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

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

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

1 “(A) the information required by sections
2 720.45 and 720.50 of title 40, Code of Federal
3 Regulations (or successor regulations); and

4 “(B) information regarding intended or
5 reasonably anticipated conditions of use and
6 reasonably anticipated exposures.”;

7 (B) in paragraph (2)—

8 (i) in the matter preceding subpara-
9 graph (A), by striking “or of data under
10 subsection (b)”;

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

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

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

16 (C) in paragraph (3), by striking “sub-
17 section (a) and for which the notification period
18 prescribed by subsection (a), (b), or (c)” and
19 inserting “subsection (b) and for which the no-
20 tification period prescribed by subsection (b) or
21 (d)”;

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

24 “(d) 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 (b), 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 (3).

13 “(B) EXTENSION.—Except as provided in
14 paragraph (5), the Administrator may extend
15 the period described in subparagraph (A) for
16 good cause for 1 or more periods, the total of
17 which shall be not more than 90 days.

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

21 “(A) any relevant information identified in
22 subsection (c)(1); and

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

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

5 “(A) the relevant chemical substance or
6 significant new use is not likely to meet the
7 safety standard, in which case the Adminis-
8 trator shall take appropriate action under para-
9 graph (5);

10 “(B) the relevant chemical substance or
11 significant new use is likely to meet the safety
12 standard, in which case the Administrator shall
13 allow the review period to expire without addi-
14 tional restrictions; or

15 “(C) additional information is necessary in
16 order to make a determination under subpara-
17 graph (A) or (B), in which case the Adminis-
18 trator shall take appropriate action under para-
19 graph (5).

20 “(4) RESTRICTIONS.—

21 “(A) IN GENERAL.—If the Administrator
22 makes a determination under subparagraph (A)
23 or (C) of paragraph (3) with respect to a notice
24 submitted under subsection (b), the Adminis-
25 trator, before the end of the applicable period

1 for review under paragraph (1) and by consent
2 agreement or order, as appropriate, shall pro-
3 hibit or restrict the manufacture, processing,
4 use, distribution in commerce, or disposal (as
5 applicable) of the chemical substance, or of the
6 chemical substance for a significant new use,
7 without compliance with the restrictions speci-
8 fied in the consent agreement or order that the
9 Administrator determines are sufficient to en-
10 sure that the chemical substance or significant
11 new use is likely to meet the safety standard.

12 “(B) REQUIREMENTS.—Not later than 90
13 days after issuing a consent agreement or order
14 under subparagraph (A), the Administrator
15 shall—

16 “(i) take into consideration whether to
17 promulgate a regulation pursuant to sub-
18 section (b)(2) that identifies as a signifi-
19 cant new use any manufacturing, proc-
20 essing, use, distribution in commerce, or
21 disposal of the chemical substance, or of
22 the chemical substance for a new use, that
23 is not in compliance with the restrictions
24 imposed by the consent agreement or
25 order; and

1 “(ii)(I) initiate a rulemaking described
2 in clause (i); or

3 “(II) publish a statement describing
4 the reasons of the Administrator for not
5 initiating a rulemaking.

6 “(C) INCLUSIONS.—A prohibition or re-
7 striction under subparagraph (A) may include,
8 as appropriate—

9 “(i) a requirement that a chemical
10 substance shall be marked with, or accom-
11 panied by, clear and adequate minimum
12 warnings and instructions with respect to
13 use, distribution in commerce, or disposal,
14 or any combination of those activities, with
15 the form and content of the warnings and
16 instructions to be prescribed by the Admin-
17 istrator;

18 “(ii) a requirement that manufactur-
19 ers and processors of the chemical sub-
20 stance shall—

21 “(I) make and retain records of
22 the processes used to manufacture or
23 process, as applicable, the chemical
24 substance; or

1 “(II) monitor or conduct such
2 additional tests as are reasonably nec-
3 essary to address potential risks from
4 the manufacture, processing, distribu-
5 tion in commerce, use, or disposal, as
6 applicable, of the chemical substance,
7 subject to section 4;

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

12 “(I) in general; or

13 “(II) for a particular use;

14 “(iv) a prohibition or other regulation
15 of—

16 “(I) the manufacture, processing,
17 or distribution in commerce of the
18 chemical substance for a significant
19 new use;

20 “(II) any method of commercial
21 use of the chemical substance; or

22 “(III) any method of disposal of
23 the chemical substance; or

24 “(v) a prohibition or other appropriate
25 restriction on the manufacture, processing,

1 or distribution in commerce of the chem-
2 ical substance—

3 “(I) in general; or

4 “(II) for a particular use.

5 “(D) WORKPLACE EXPOSURES.—The Ad-
6 ministrator shall consult with the Assistant Sec-
7 retary of Labor for Occupational Safety and
8 Health prior to adopting any prohibition or re-
9 striction under this subsection to address work-
10 place exposures.

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

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

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

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

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

5 “(6) REGULATION PENDING DEVELOPMENT OF
6 INFORMATION.—Subject to paragraph (4)(B), the
7 Administrator may permit manufacture for commer-
8 cial purposes of a chemical substance to commence
9 pending receipt of the additional information, sub-
10 ject to compliance with any restrictions under para-
11 graph (4) determined by the Administrator to be
12 sufficient to ensure that the chemical substance is
13 likely to meet the safety standard.

14 “(7) COMMENCEMENT OF MANUFACTURE.—
15 Subject to paragraphs (4), (5), and (6), at the end
16 of the applicable period for review under paragraph
17 (1), the submitter of a notice under subsection (a)
18 may commence manufacture for commercial pur-
19 poses of a chemical substance or a chemical sub-
20 stance for a significant new use.”;

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

23 “(e) NOTICE OF COMMENCEMENT.—

24 “(1) IN GENERAL.—Not later than 30 days
25 after the date on which a manufacturer or processor

1 that has submitted a notice under subsection (b)
2 commences nonexempt commercial manufacture of a
3 chemical substance, the manufacturer or processor
4 shall submit to the Administrator a notice of com-
5 mencement that identifies—

6 “(A) the name of the manufacturer or
7 processor; and

8 “(B) the initial date of nonexempt com-
9 mercial manufacture.

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

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

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

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

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

1 “(1) all notices, determinations, consent agree-
2 ments, regulations, and orders of the Administrator;
3 and

4 “(2) all information submitted or issued under
5 this section.”;

6 (10) in subsection (h)—

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

9 (B) by striking paragraph (2);

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

13 (D) in paragraph (2) (as so redesignated),
14 in the matter preceding subparagraph (A), by
15 striking “subsections (a) and (b)” and inserting
16 “subsection (b)”;

17 (E) in paragraph (3) (as so redesi-
18 gnated)—

19 (i) in the first sentence, by striking
20 “will not present an unreasonable risk of
21 injury to health or the environment” and
22 inserting “will meet the safety standard”;
23 and

24 (ii) by striking the second sentence;

1 (F) in paragraph (4) (as so redesignated),
2 by striking “subsections (a) and (b)” and in-
3 serting “subsection (b)”; and

4 (G) in paragraph (5) (as so redesignated),
5 in the first sentence, by striking “paragraph (1)
6 or (5)” and inserting “paragraph (1) or (4),”;
7 and

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

9 “(i) PRIOR ACTIONS.—Nothing in this section re-
10 quires the Administrator to modify or withdraw any regu-
11 lation or order promulgated pursuant to this section before
12 the date of enactment of the Chemical Safety Improve-
13 ment Act.”.

14 **SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINA-**
15 **TIONS.**

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

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

20 **“SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINA-**
21 **TIONS.”;**

22 (2) by redesignating subsections (e) and (f) as
23 subsections (h) and (i), respectively;

24 (3) by striking subsections (a) through (d) and
25 inserting the following:

1 “(a) IN GENERAL.—The Administrator—

2 “(1) shall conduct a safety assessment and
3 make a safety determination of each high-priority
4 substance in accordance with subsections (b) and
5 (c);

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

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

13 “(4) shall promulgate a final regulation pursu-
14 ant to subsection (d) by not later than 2 years after
15 the date on which the safety determination is com-
16 pleted; and

17 “(5) may extend any deadline under this sub-
18 section for a reasonable period of time after an ade-
19 quate public justification, subject to the condition
20 that the aggregate length of all extensions of dead-
21 lines under paragraphs (3) and (4) and any deferral
22 under subsection (c)(2) does not exceed 2 years.

23 “(b) PRIOR ACTIONS.—

24 “(1) PRIOR-INITIATED ASSESSMENTS.—

1 “(A) IN GENERAL.—Nothing in this Act
2 prevents the Administrator from initiating a
3 safety assessment or safety determination re-
4 garding a chemical substance, or from con-
5 tinuing or completing such a safety assessment
6 or safety determination that was initiated be-
7 fore the date of enactment of the Chemical
8 Safety Improvement Act, prior to the effective
9 date of the policies and procedures required to
10 be established by the Administrator under sec-
11 tion 3A or 4A.

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

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

1 validity of a completed assessment, determination, or
2 regulation shall not be determined based on the con-
3 tent of such a policy or procedure.

4 “(c) SAFETY DETERMINATIONS.—

5 “(1) IN GENERAL.—Based on a review of the
6 information available to the Administrator, including
7 draft safety assessments submitted by interested
8 persons, the Administrator shall determine that—

9 “(A) the relevant chemical substance meets
10 the safety standard;

11 “(B) the relevant chemical substance does
12 not meet the safety standard, in which case the
13 Administrator shall, by regulation under sub-
14 section (d)—

15 “(i) impose restrictions necessary to
16 ensure that the chemical substance meets
17 the safety standard under the intended or
18 reasonably anticipated conditions of use; or

19 “(ii) if the safety standard cannot be
20 met with the application of restrictions,
21 ban or phase out the chemical substance,
22 as appropriate; or

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

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

3 “(2) ADDITIONAL INFORMATION.—If the Ad-
4 ministrator determines that additional information is
5 necessary to make a safety assessment or safety de-
6 termination for a high-priority substance, the Ad-
7 ministrator—

8 “(A) shall provide an opportunity for inter-
9 ested persons to submit the additional informa-
10 tion;

11 “(B) may promulgate a regulation, enter
12 into a testing consent agreement, or issue an
13 order under section 4 to require the develop-
14 ment of the information;

15 “(C) may defer, for a reasonable period
16 consistent with the deadlines described in sub-
17 section (a), a safety assessment and safety de-
18 termination until after receipt of the informa-
19 tion; and

20 “(D) consistent with the deadlines de-
21 scribed in subsection (a), on receipt of informa-
22 tion the Administrator finds supports the safety
23 assessment and safety determination, shall
24 make a determination under paragraph (1).

1 “(3) ESTABLISHMENT OF DEADLINE.—In re-
2 questing the development or submission of informa-
3 tion under this section, the Administrator shall es-
4 tablish a deadline for the submission of the informa-
5 tion.

6 “(d) REGULATION.—

7 “(1) IMPLEMENTATION.—If the Administrator
8 makes a determination under subsection (c)(1)(B)
9 with respect to a chemical substance, the Adminis-
10 trator shall promulgate a regulation establishing re-
11 strictions necessary to ensure that the chemical sub-
12 stance meets the safety standard.

13 “(2) SCOPE.—The regulation promulgated pur-
14 suant to this subsection—

15 “(A) may—

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

18 “(ii) exempt replacement parts for ar-
19 ticles manufactured prior to the applicable
20 compliance deadline; and

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

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

24 and

1 “(ii) as determined by the Adminis-
2 trator, may vary for different affected per-
3 sons.

4 “(C) WORKPLACE EXPOSURES.—The Ad-
5 ministrators shall consult with the Assistant Sec-
6 retary of Labor for Occupational Safety and
7 Health before adopting any prohibition or re-
8 striction under this subsection to address work-
9 place exposures.

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

12 “(A) a requirement that a chemical sub-
13 stance shall be marked with, or accompanied
14 by, clear and adequate warnings and instruc-
15 tions with respect to use, distribution in com-
16 merce, or disposal, or any combination of those
17 activities, with the form and content of the
18 warnings and instructions to be prescribed by
19 the Administrator;

20 “(B) a requirement that manufacturers
21 and processors of the chemical substance
22 shall—

23 “(i) make and retain records of the
24 processes used to manufacture or process
25 the chemical substance;

1 “(ii) describe and apply the relevant
2 quality control procedures followed in the
3 manufacturing or processing of the sub-
4 stance; or

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

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

12 “(D) a requirement to ban or phase out, or
13 any other regulation regarding, the manufac-
14 ture, processing, or distribution in commerce of
15 the chemical substance for—

16 “(i) a particular use;

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

20 “(iii) all uses;

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

24 “(i) a particular use; or

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

4 “(F) a requirement to restrict, ban, or
5 phase out, or any other regulation of, any meth-
6 od of commercial use of the chemical substance;

7 “(G) a requirement to restrict, ban, or
8 phase out, or any other regulation of, any meth-
9 od of disposal of the chemical substance or any
10 article containing the chemical substance; and

11 “(H) a requirement directing manufactur-
12 ers or processors of the chemical substance to
13 give notice of unreasonable risks of harm to dis-
14 tributors in commerce of the chemical substance
15 and, to the extent reasonably ascertainable, to
16 other persons in the chain of commerce in pos-
17 session of the chemical substance.

18 “(4) ANALYSIS FOR RULEMAKING.—

19 “(A) CONSIDERATIONS.—In deciding
20 which restrictions to impose under paragraph
21 (3) as part of developing a regulation under
22 paragraph (1), the Administrator shall take
23 into consideration, to the extent practicable
24 based on reasonably available information, the
25 quantifiable and nonquantifiable costs and ben-

1 efits of the proposed regulatory action and of
2 the 1 or more primary alternative regulatory
3 actions considered by the Administrator.

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

10 “(C) PUBLIC AVAILABILITY.—In proposing
11 a regulation under paragraph (1), the Adminis-
12 trator shall make publicly available any analysis
13 conducted under this paragraph.

14 “(D) STATEMENT REQUIRED.—In making
15 final a regulation under paragraph (1), the Ad-
16 ministrator shall include a statement describing
17 how the analysis considered under subpara-
18 graph (A) was taken into account.

19 “(5) EXEMPTIONS.—

20 “(A) IN GENERAL.—The Administrator
21 may exempt 1 or more uses of a chemical sub-
22 stance from any restriction in a regulation pro-
23 mulgated under paragraph (1) if the Adminis-
24 trator determines that—

1 “(i) the regulation cannot be complied
2 with, without—

3 “(I) harming national security;

4 “(II) causing significant disruption
5 tion in the national economy due to
6 the lack of availability of a chemical
7 substance; or

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

13 “(ii) the use of the chemical sub-
14 stance, as compared to reasonably available
15 alternatives, provides a substantial benefit
16 to human health, the environment, or pub-
17 lic safety.

18 “(B) EXEMPTION ANALYSIS.—In pro-
19 posing a regulation under paragraph (1) that
20 includes an exemption under this paragraph,
21 the Administrator shall make publicly available
22 any analysis conducted under this paragraph to
23 assess the need for the exemption.

24 “(C) STATEMENT REQUIRED.—In making
25 final a regulation under paragraph (1) that in-

1 includes an exemption under this paragraph, the
2 Administrator shall include a statement describ-
3 ing how the analysis considered under subpara-
4 graph (B) was taken into account.

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

19 “(E) CONDITIONS.—As part of a regula-
20 tion promulgated under paragraph (1), the Ad-
21 ministrator shall include conditions in any ex-
22 emption established under this paragraph, in-
23 cluding reasonable recordkeeping, monitoring,
24 and reporting requirements, to the extent that
25 the Administrator determines the conditions are

1 necessary to protect human health and the envi-
2 ronment while achieving the purposes of the ex-
3 emption.

4 “(F) DURATION.—

5 “(i) IN GENERAL.—The Administrator
6 shall establish, as part of a regulation
7 under paragraph (1) that contains an ex-
8 emption under this paragraph, a time limit
9 on any exemption for a time to be deter-
10 mined by the Administrator as reasonable
11 on a case-by-case basis.

12 “(ii) AUTHORITY OF ADMINIS-
13 TRATOR.—The Administrator, by regula-
14 tion, may extend, modify, or eliminate the
15 exemption if the Administrator determines,
16 on the basis of reasonably available infor-
17 mation and after adequate public justifica-
18 tion, the exemption warrants extension or
19 is no longer necessary.

20 “(iii) CONSIDERATIONS.—

21 “(I) IN GENERAL.—Subject to
22 subclause (II), the Administrator shall
23 issue exemptions and establish time
24 periods by considering factors deter-
25 mined by the Administrator to be rel-

1 evant to the goals of fostering innova-
2 tion and the development of alter-
3 natives that meet the safety standard.

4 “(II) LIMITATION.—Any renewal
5 of an exemption in the case of a regu-
6 lation requiring the ban or phase-out
7 of a chemical substance shall not ex-
8 ceed 5 years.

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

14 “(1) the Administrator determines that—

15 “(A) the manufacture, processing, distribu-
16 tion in commerce, use, or disposal of the chem-
17 ical substance or mixture subject to the pro-
18 posed regulation or any combination of those
19 activities is likely to result in an unreasonable
20 risk of serious or widespread injury to health or
21 the environment before the effective date; and

22 “(B) making the proposed regulation so ef-
23 fective is necessary to protect the public inter-
24 est; and

1 “(2) in the case of a proposed regulation to
2 prohibit the manufacture, processing, or distribution
3 of a chemical substance or mixture because of the
4 risk determined under paragraph (1)(A), a court has
5 granted relief in an action under section 7 with re-
6 spect to that risk associated with the chemical sub-
7 stance or mixture.

8 “(f) FINAL AGENCY ACTION.—Under this section—

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

15 “(2) a final regulation promulgated under sub-
16 section (d), and the associated safety assessment
17 and safety determination that a chemical substance
18 does not meet the safety standard, shall be consid-
19 ered to be a final agency action, effective beginning
20 on the date of promulgation of the final regulation.”;

21 (4) in subsection (h) (as redesignated by para-
22 graph (2))—

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

24 (B) by redesignating paragraph (5) as
25 paragraph (4); and

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

2 “(j) PRIOR ACTIONS.—Nothing in this section re-
3 quires the Administrator to modify or withdraw any regu-
4 lation or order promulgated pursuant to this section, as
5 in effect on the day before the date of enactment of the
6 Chemical Safety Improvement Act.”.

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

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

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

12 “(a) CIVIL ACTIONS.—

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

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

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

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

4 “(2) REGULATION, ORDER, OR OTHER PRO-
5 CEEDING.—A civil action may be commenced under
6 this paragraph, notwithstanding—

7 “(A) the existence of—

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

10 “(ii) a regulation, testing consent
11 agreement, or order under section 4,
12 5(d)(4), 6(d), or 6(h); or

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

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

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

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

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

23 (1) in subsection (a)—

24 (A) in paragraph (3)(A)(ii)(I)—

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

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

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

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

8 “(4) REGULATIONS.—

9 “(A) DEADLINE.—

10 “(i) IN GENERAL.—Not later than 2
11 years after the date of enactment of the
12 Chemical Safety Improvement Act, the Ad-
13 ministrator shall promulgate regulations
14 requiring the maintenance of records and
15 the reporting of information known or rea-
16 sonably ascertainable by the person mak-
17 ing the report, including regulations re-
18 quiring processors to report information,
19 so that the Administrator has the informa-
20 tion necessary to carry out sections 4 and
21 6.

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

1 fore the date of enactment of the Chemical
2 Safety Improvement Act.

3 “(B) CONTENTS.—The regulations pro-
4 mulgated pursuant to subparagraph (A)—

5 “(i) may impose different reporting
6 requirements on manufacturers and proc-
7 essors;

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

12 “(iii) shall apply only in cases in
13 which the Administrator determines that
14 the submission of reports would assist in
15 the effective implementation of this Act.

16 “(C) ADMINISTRATION.—In implementing
17 this paragraph, the Administrator shall take
18 measures—

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

21 “(ii) to minimize the impact of the
22 regulations on small manufacturers and
23 processors; and

24 “(iii) to apply any reporting obliga-
25 tions to those persons likely to have infor-

1 mation relevant to the effective implemen-
2 tation of this title.

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

7 (2) in subsection (b), by adding at the end the
8 following:

9 “(3) NOMENCLATURE.—

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

12 “(i) maintain the use of Class 2 no-
13 menclature in use on the date of enact-
14 ment of the Chemical Safety Improvement
15 Act;

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

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

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

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

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

14 “(IV) frits, chemicals, CAS No.
15 65997-18-4;

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

18 “(VI) ceramic materials and
19 wares, chemicals, CAS No. 66402-
20 68-4.

21 “(B) MULTIPLE NOMENCLATURE CONVEN-
22 TIONS.—

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

1 “(I) maintain the nomenclature
2 conventions for substances; and

3 “(II) develop new guidance
4 that—

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

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

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

22 “(4) CHEMICAL SUBSTANCES IN COMMERCE.—

23 “(A) REGULATIONS.—

24 “(i) IN GENERAL.—Not later than 1
25 year after the date of enactment of the

1 Chemical Safety Improvement Act, the Ad-
2 ministrator, by regulation, shall require
3 manufacturers and processors to notify the
4 Administrator, by not later than 180 days
5 after the date of promulgation of the regu-
6 lation, of each chemical substance on the
7 list published under paragraph (1) that the
8 manufacturer or processor, as applicable,
9 has manufactured or processed for a non-
10 exempt commercial purpose during the 10-
11 year period ending on the day before the
12 date of enactment of the Chemical Safety
13 Improvement Act.

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

20 “(B) CONFIDENTIAL CHEMICAL SUB-
21 STANCES.—The regulation promulgated by the
22 Administrator pursuant to subparagraph (A)
23 shall require—

24 “(i) the Administrator to maintain the
25 list under paragraph (1), which shall in-

1 clude a confidential portion and a noncon-
2 fidential portion consistent with this sec-
3 tion and section 14;

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

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

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

1 paragraph (1) that are notified pursuant to
2 subparagraph (A) or identified as active sub-
3 stances under subsection (f)(1).

4 “(D) REQUIREMENTS OF REVIEW PLAN.—
5 The review plan under subparagraph (C)
6 shall—

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

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

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

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

24 “(bb) submitted previously
25 by a manufacturer or processor

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

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

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

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

23 “(bb) the Administrator oth-
24 erwise becomes aware that the
25 need for protection from dislo-

1 sure can no longer be substan-
2 tiated, in which case the Admin-
3 istrator shall take the actions de-
4 scribed in section 14(g)(2); and

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

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

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

20 “(ii) CONSIDERATIONS.—

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

1 administrator determines that the exten-
2 sion is necessary based on the number
3 of applicable claims needing review
4 and the available resources.

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

10 “(F) LIMITATION.—The specific identity of
11 any chemical substance that is not on the con-
12 fidential portion of the list published under
13 paragraph (1) or subsequently added to the
14 confidential portion of the list pursuant to sec-
15 tion 14 shall not be eligible for protection from
16 disclosure.

17 “(G) CERTIFICATION.—The regulation
18 under this subsection shall require a manufac-
19 turer or processor—

20 “(i) to certify the accuracy of each re-
21 port of the manufacturer or processor car-
22 ried out under the regulation; and

23 “(ii) to retain a record supporting
24 that certification for a period of 5 years

1 beginning on the last day of the submis-
2 sion period.

3 “(5) ACTIVE AND INACTIVE SUBSTANCES.—

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

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

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

16 “(ii) the regulations promulgated pur-
17 suant to subsection (a)(4).

18 “(C) CHANGE TO ACTIVE STATUS.—

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

1 “(ii) CONFIDENTIAL CHEMICAL IDEN-
2 TITY CLAIMS.—

3 “(I) IN GENERAL.—If a person
4 submitting a notice under clause (i)
5 for an inactive substance on the con-
6 fidential portion of the list published
7 under paragraph (1) seeks to main-
8 tain an existing claim for protection
9 against disclosure of the specific iden-
10 tity of the inactive substance as con-
11 fidential, the person shall—

12 “(aa) in the notice sub-
13 mitted under clause (i), assert
14 the claim; and

15 “(bb) by not later than 30
16 days after providing the notice
17 under clause (i), substantiate the
18 claim.

19 “(II) LIMITATION.—The specific
20 identity of any inactive substance that
21 is not on the confidential portion of
22 the list published under paragraph (1)
23 or subsequently added to the confiden-
24 tial portion of the list pursuant to sec-

1 tion 14 shall not be eligible for protec-
2 tion from disclosure.

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

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

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

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

24 “(aa) the person notifies the
25 Administrator that the person is

1 withdrawing the confidentiality
2 claim, in which case the Adminis-
3 trator shall promptly make the
4 information available to the pub-
5 lic; or

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

13 “(IV) pursuant to section 4A, re-
14 view the priority of the chemical sub-
15 stance as the Administrator deter-
16 mines to be necessary.

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

20 “(6) INTERIM LIST OF ACTIVE SUBSTANCES.—
21 Prior to the promulgation of the regulation required
22 under this subsection, the Administrator shall des-
23 ignate the chemical substances reported under part
24 711 of title 40, Code of Federal Regulations (or suc-
25 cessor regulations), during the reporting period that

1 most closely preceded the date of enactment of the
2 Chemical Safety Improvement Act, as the initial list
3 of active substances for the purposes of section 4A.

4 “(7) PUBLIC PARTICIPATION.—Subject to this
5 subsection, the Administrator shall make available to
6 the public—

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

11 “(i) an active substance; or

12 “(ii) an inactive substance;

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

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

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

1 “(ii) a claim for protection against
2 disclosure of the specific identity of the ac-
3 tive substance has been denied by the Ad-
4 ministrator; or

5 “(iii) the time period for protection
6 against disclosure of the specific identity of
7 the active substance has expired.”;

8 (3) in subsection (e)—

9 (A) by striking “Any person” and inserting
10 the following:

11 “(1) IN GENERAL.—Any person”; and

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

13 “(2) APPLICABILITY.—Any person may submit
14 to the Administrator information reasonably sup-
15 porting the conclusion that a chemical substance or
16 mixture presents, will present, or does not present a
17 substantial risk of injury to human health and the
18 environment.”; and

19 (4) in subsection (f), by striking “For purposes
20 of this section, the” and inserting the following: “In
21 this section:

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

24 “(A) that has been manufactured or proc-
25 essed for a nonexempt commercial purpose at

1 any point during the 10-year period ending on
2 the date of enactment of the Chemical Safety
3 Improvement Act;

4 “(B) that is added to the list published
5 under subsection (b)(1) after that date of en-
6 actment; or

7 “(C) for which a notice is received under
8 subsection (b)(5)(C).

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

13 “(3) MANUFACTURE; PROCESS.—The”.

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

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

17 (1) in subsection (a)—

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

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”; 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 “section 6(d) or section 7”;
7 and

8 (C) in paragraph (3), by striking “section
9 6 or 7” and inserting “section 6(d) or 7”; and
10 (2) in subsection (d), in the first sentence, by
11 striking “Health, Education, and Welfare” and in-
12 serting “Health and Human Services”.

13 **SEC. 12. RESEARCH, DEVELOPMENT, COLLECTION, DIS-**
14 **SEMINATION, AND UTILIZATION OF DATA.**

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

19 **SEC. 13. EXPORTS.**

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

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

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

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

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

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

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

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

16 “(4) TESTING.—The Administrator may re-
17 quire testing under section 4 of any chemical sub-
18 stance or mixture exempted from this Act under
19 paragraph (1) for the purpose of determining wheth-
20 er the chemical substance or mixture presents an
21 unreasonable risk of harm to human health within
22 the United States or to the environment of the
23 United States.”;

24 (2) by striking subsection (b) and inserting the
25 following:

1 “(b) NOTICE.—

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

5 “(A) a chemical substance or a mixture
6 containing a chemical substance that the Ad-
7 ministrator has determined under section 5 is
8 not likely to meet the safety standard and for
9 which a prohibition or restriction has been pro-
10 posed or established under that section;

11 “(B) a chemical substance or a mixture
12 containing a chemical substance that the Ad-
13 ministrator has determined under section 6
14 does not meet the safety standard and for
15 which a prohibition or restriction has been pro-
16 posed or established under that section;

17 “(C) a chemical substance for which the
18 United States is obligated by treaty to provide
19 export notification;

20 “(D) a chemical substance or mixture sub-
21 ject to a prohibition or restriction pursuant to
22 a regulation, order, or consent agreement in ef-
23 fect under this Act; or

1 “(E) a chemical substance or mixture for
2 which the submission of information is required
3 under section 4.

4 “(2) REGULATIONS.—

5 “(A) IN GENERAL.—The Administrator
6 shall promulgate regulations to carry out para-
7 graph (1).

8 “(B) CONTENTS.—The regulations pro-
9 mulgated pursuant to subparagraph (A) shall—

10 “(i) include such exemptions as the
11 Administrator determines to be appro-
12 priate, which may include exemptions iden-
13 tified under section 5(h); and

14 “(ii) indicate whether, or to what ex-
15 tent, the regulations apply to articles con-
16 taining a chemical substance or mixture
17 described in paragraph (1).

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

21 “(A) for a chemical substance or mixture
22 described in subparagraph (A), (B), or (D) of
23 paragraph (1), a notice of the determination,
24 regulation, order, consent agreement, require-
25 ment, or designation;

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

5 “(C) for a chemical substance or mixture
6 described in paragraph (1)(E), a notice of avail-
7 ability of the information on the chemical sub-
8 stance or mixture submitted to the Adminis-
9 trator.”; and

10 (3) in subsection (c)—

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

12 (B) by redesignating paragraphs (4)
13 through (6) as paragraphs (3) through (5), re-
14 spectively.

15 **SEC. 14. IMPORTS.**

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

18 **“SEC. 13. IMPORTS.**

19 “(a) REFUSAL OF ENTRY.—

20 “(1) IN GENERAL.—The Secretary of Homeland
21 Security shall refuse entry into the customs territory
22 of the United States (as defined in general note 2
23 to the Harmonized Tariff Schedule of the United
24 States) any chemical substance, mixture, or article

1 containing a chemical substance or mixture offered
2 for such entry, if—

3 “(A) the Administrator—

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

7 “(ii) has promulgated a regulation
8 pursuant to section 6(d) banning the
9 chemical substance or mixture, as of the
10 effective date of the regulation;

11 “(B) the chemical substance—

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

14 “(ii) is not exempt from any require-
15 ment to be included on that list by this
16 title or a regulation promulgated by the
17 Administrator pursuant to this title; or

18 “(C) the chemical substance, mixture, or
19 any article containing the chemical substance or
20 mixture is offered for entry in violation of—

21 “(i) a regulation, consent agreement,
22 or order in effect under this Act; or

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

25 “(2) PROCEDURE.—

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

6 “(i) shall notify the consignee of the
7 entry of the refusal;

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

10 “(iii) shall cause the disposal or stor-
11 age of the chemical substance or mixture
12 under such regulations as the Secretary
13 may prescribe, if the chemical substance or
14 mixture has not been exported by the con-
15 signee during the 90-day period beginning
16 on the date of receipt of the notice of the
17 refused entry.

18 “(B) EXCEPTION.—

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

24 “(I) executes a bond for the
25 amount of the full invoice of the

1 chemical substance or mixture (as set
2 forth in the customs entry); and

3 “(II) pays a duty on the chemical
4 substance or mixture.

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

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

22 “(b) CERTIFICATION.—

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

1 shall certify to the Secretary of Homeland Security
2 that—

3 “(A) after reasonable inquiry and to the
4 best knowledge and belief of the person, the
5 chemical substance or mixture is in compliance
6 with any applicable regulation, consent agree-
7 ment, or order under section 5 or 6; and

8 “(B) the chemical substance—

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

11 “(ii) is exempt from any requirement
12 to be included on that list by this title or
13 a regulation promulgated by the Adminis-
14 trator pursuant to this title.

15 “(2) ARTICLES.—

16 “(A) IN GENERAL.—The Administrator, by
17 regulation, may require certification under
18 paragraph (1) for an article containing a chem-
19 ical substance or mixture that is subject to reg-
20 ulation under section 5 or 6.

21 “(B) REQUIREMENT.—The regulation
22 under subparagraph (A) shall identify, with rea-
23 sonable specificity, the types of articles, includ-
24 ing parts or components of articles, that will be
25 subject to the certification requirement.

1 “(C) FACTORS FOR CONSIDERATION.—In
2 determining the need for and content of a cer-
3 tification regulation under this paragraph, the
4 Administrator shall take into consideration—

5 “(i) the utility of the certification to
6 enforcement of the applicable regulation,
7 consent agreement, or order under section
8 5 or 6;

9 “(ii) the contribution of imported arti-
10 cles to the potential risk presented by ex-
11 posure to the chemical substance or mix-
12 ture subject to regulation under section 5
13 or 6;

14 “(iii) the impact on commerce and po-
15 tential for the certification to impede or
16 disrupt import of articles;

17 “(iv) the frequency or duration of the
18 certification requirement; and

19 “(v) specification of the concentration
20 of a chemical substance in an article that
21 would subject the article to the certifi-
22 cation requirement.

23 “(3) REASONABLE INQUIRY.—

24 “(A) IN GENERAL.—For purposes of a cer-
25 tification under paragraph (1), reasonable in-

1 quiry shall include good faith reliance by an im-
2 porter on—

3 “(i) a safety data sheet or similar dec-
4 laration provided by a supplier that docu-
5 ments the specific identity of the chemical
6 substance or the specific identities of all
7 chemical substances in a mixture; or

8 “(ii) for chemical substances or mix-
9 tures claimed by the supplier as confiden-
10 tial, or not otherwise disclosed by the sup-
11 plier, a certification by the supplier that
12 the imported chemical substance or mix-
13 ture satisfies the applicable certification re-
14 quirements under paragraph (1).

15 “(B) ARTICLES.—For purposes of a cer-
16 tification under paragraph (2), reasonable in-
17 quiry shall include good faith reliance by an im-
18 porter on a certification by the supplier that the
19 imported article satisfies the applicable certifi-
20 cation requirements in a regulation promul-
21 gated pursuant to paragraph (2).

22 “(4) INFORMATION REGARDING IDENTITY.—
23 For purposes of this subsection, the Administrator
24 shall provide publicly accessible information regard-
25 ing the identity of a chemical substance or mixture

1 subject to regulation under this Act that would be
2 readily understood in import transactions.

3 “(c) NOTICE.—A person offering a chemical sub-
4 stance for entry into the customs territory of the United
5 States shall notify the Secretary of Homeland Security
6 if—

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

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

13 “(3) the chemical substance or chemical sub-
14 stance in a mixture—

15 “(A) is the subject of a safety assessment
16 and safety determination conducted pursuant to
17 section 6; and

18 “(B) has been found not to meet the safety
19 standard.

20 “(d) REGULATIONS.—

21 “(1) IN GENERAL.—The Secretary of Homeland
22 Security, after consultation with the Administrator,
23 shall promulgate regulations to carry out this sec-
24 tion.

1 “(2) APPLICATION.—The regulations under
2 paragraph (1) may modify the application of any re-
3 quirement of this section, as appropriate for the effi-
4 cient and effective implementation of this Act.”.

5 **SEC. 15. CONFIDENTIAL INFORMATION.**

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

8 **“SEC. 14. CONFIDENTIAL INFORMATION.**

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

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

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

18 “(b) INFORMATION GENERALLY PROTECTED FROM
19 DISCLOSURE.—The following information specific to, and
20 submitted by, a manufacturer, processor, or distributor
21 that meets the requirements of subsection (d) shall be pre-
22 sumed to be protected from disclosure, subject to the con-
23 dition that nothing in this Act prohibits the disclosure of
24 any such information through discovery, subpoena, other

1 court order, or any other judicial process otherwise allowed
2 under applicable Federal or State law:

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

6 “(2) Marketing and sales information.

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

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

11 “(5) Specific information regarding the use,
12 function, or application of a chemical substance or
13 mixture in a process, mixture, or product.

14 “(6) Specific production or import volumes of
15 the manufacturer and specific aggregated volumes
16 across manufacturers, if the Administrator deter-
17 mines that disclosure of the specific aggregated vol-
18 umes would reveal confidential information.

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

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

4 “(B) the claim has not subsequently been
5 withdrawn or found by the Administrator not to
6 warrant protection as confidential information
7 under subsection (e), (f)(2), or (g).

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

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

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

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

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

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

1 “(aa) testing is required
2 under section 4; or

3 “(bb) a notification is re-
4 quired under section 5; or

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

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

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

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

19 “(2) CERTAIN REQUESTS.—If a request is made
20 to the Administrator under section 552(a) of title 5,
21 United States Code, for information that is de-
22 scribed in paragraph (1) that is not described in
23 paragraph (1)(B), the Administrator may not deny
24 the request on the basis of section 552(b)(4) of title
25 5, United States Code.

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

4 “(A) For information submitted after the
5 date of enactment of the Chemical Safety Im-
6 provement Act, the specific identity of a chem-
7 ical substance as of the date on which the
8 chemical substance is first offered for commer-
9 cial distribution, if the person submitting the
10 information does not meet the requirements of
11 subsection (d).

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

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

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

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

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

13 “(5) LIMITATION.—Except as provided in para-
14 graph (1)(B), the specific identity of any chemical
15 substance that is not on the confidential portion of
16 the list published under section 8(b)(1) or subse-
17 quently added to the confidential portion of the list
18 pursuant to this section shall not be eligible for pro-
19 tection from disclosure.

20 “(6) BAN OR PHASE-OUT.—If the Adminis-
21 trator promulgates a regulation pursuant to section
22 6(d) that establishes a ban or phase-out of the man-
23 ufacture, processing, or distribution in commerce of
24 a chemical substance—

1 “(A) any protection from disclosure pro-
2 vided under this section with respect to infor-
3 mation relating to the chemical substance shall
4 no longer apply; and

5 “(B) the Administrator promptly shall
6 make the information public.

7 “(d) REQUIREMENTS FOR CONFIDENTIALITY
8 CLAIMS.—

9 “(1) ASSERTION OF CLAIMS.—

10 “(A) IN GENERAL.—A person seeking to
11 protect any information submitted under this
12 Act from disclosure (including information de-
13 scribed in subsection (b)) shall assert to the Ad-
14 ministrator a claim for protection concurrent
15 with submission of the information, in accord-
16 ance with such regulations regarding a claim
17 for protection from disclosure as the Adminis-
18 trator has promulgated or may promulgate pur-
19 suant to this title.

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

23 “(i) taken reasonable measures to pro-
24 tect the confidentiality of the chemical
25 identity;

1 “(ii) determined that the information
2 is not required to be disclosed or otherwise
3 made available to the public under any
4 other Federal law in connection with 1 or
5 more uses subject to this Act;

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

10 “(iv) a reasonable basis to believe that
11 the information is not readily discoverable
12 through reverse engineering.

13 “(C) SPECIFIC CHEMICAL IDENTITY.—In
14 the case of a claim under subparagraph (A) for
15 protection against disclosure of a specific chem-
16 ical identity, the claim shall include a struc-
17 turally descriptive generic name for the chem-
18 ical substance that the Administrator may dis-
19 close to the public, subject to the conditions
20 that—

21 “(i) the generic name shall—

22 “(I) conform with guidance pre-
23 scribed by the Administrator under
24 paragraph (3)(A); and

1 “(II) describe the chemical struc-
2 ture of the substance as specifically as
3 practicable while protecting those fea-
4 tures of the chemical structure—

5 “(aa) that are considered to
6 be confidential; and

7 “(bb) the disclosure of which
8 would be likely to harm the com-
9 petitive position of the person.

10 “(2) ADDITIONAL REQUIREMENTS FOR CON-
11 FIDENTIALITY CLAIMS.—Except for information de-
12 scribed in paragraphs (1) through (7) of subsection
13 (b), a person asserting a claim to protect informa-
14 tion from disclosure under this Act shall substan-
15 tiate the claim, in accordance with the regulations
16 promulgated and guidance issued by the Adminis-
17 trator.

18 “(3) GUIDANCE.—The Administrator shall de-
19 velop guidance regarding—

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

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

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

8 “(e) EXCEPTIONS TO PROTECTION FROM DISCLO-
9 SURE.—Information described in subsection (a) shall be
10 disclosed if—

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

14 “(A) under any law for the protection of
15 human health or the environment; or

16 “(B) for a specific law enforcement pur-
17 pose;

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

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

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

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

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

10 “(A) 1 or more applicable agreements with
11 the Administrator that conform with the guid-
12 ance issued under subsection (d)(3)(B) ensure
13 that the recipient will take appropriate meas-
14 ures, and has adequate authority, to maintain
15 the confidentiality of the information in accord-
16 ance with procedures comparable to the proce-
17 dures used by the Administrator to safeguard
18 the information; and

19 “(B) the Administrator notifies the person
20 that submitted the information that the infor-
21 mation has been disclosed to the State or polit-
22 ical subdivision of a State;

23 “(5) a health or environmental professional em-
24 ployed by a Federal or State agency or a treating
25 physician or nurse in a nonemergency situation pro-

1 provides a written statement of need and agrees to sign
2 a written confidentiality agreement with the Admin-
3 istrator, subject to the conditions that—

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

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

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

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

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

16 “(ii) 1 or more individuals being diag-
17 nosed or treated have been exposed to the
18 chemical substance concerned, or an envi-
19 ronmental release or exposure has oc-
20 curred; and

21 “(C) the confidentiality agreement shall
22 provide that the person will not use the infor-
23 mation for any purpose other than the health or
24 environmental needs asserted in the statement
25 of need, except as otherwise may be authorized

1 by the terms of the agreement or by the person
2 submitting the information to the Adminis-
3 trator, except that nothing in this Act prohibits
4 the disclosure of any such information through
5 discovery, subpoena, other court order, or any
6 other judicial process otherwise allowed under
7 applicable Federal or State law;

8 “(6) in the event of an emergency, a treating
9 physician, nurse, agent of a poison control center,
10 public health or environmental official of a State or
11 political subdivision of a State, or first responder
12 (including any individual duly authorized by a Fed-
13 eral agency, State, or political subdivision of a State
14 who is trained in urgent medical care or other emer-
15 gency procedures, including a police officer, fire-
16 fighter, or emergency medical technician) requests
17 the information, subject to the conditions that—

18 “(A) the treating physician, nurse, agent,
19 public health or environmental official of a
20 State or a political subdivision of a State, or
21 first responder shall have a reasonable basis to
22 suspect that—

23 “(i) a medical or public health or en-
24 vironmental emergency exists;

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

4 “(iii) 1 or more individuals being di-
5 agnosed or treated have likely been ex-
6 posed to the chemical substance concerned,
7 or a serious environmental release of or ex-
8 posure to the chemical substance con-
9 cerned has occurred;

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

16 “(i) provide a written statement of
17 need; and

18 “(ii) agree to sign a confidentiality
19 agreement; and

20 “(C) the written confidentiality agreement
21 or statement of need shall be submitted as soon
22 as practicable, but not necessarily before the in-
23 formation is disclosed;

24 “(7) the Administrator determines that disclo-
25 sure is relevant in a proceeding under this Act, sub-

1 make the information available to the pub-
2 lic; or

3 “(ii) the Administrator otherwise be-
4 comes aware that the need for protection
5 from disclosure can no longer be substan-
6 tiated, in which case the Administrator
7 shall take the actions described in sub-
8 section (g)(2).

9 “(B) EXTENSIONS.—

10 “(i) IN GENERAL.—Not later than the
11 date that is 60 days before the expiration
12 of the period described in subparagraph
13 (A), the Administrator shall provide to the
14 person that asserted the claim a notice of
15 the impending expiration of the period.

16 “(ii) STATEMENT.—

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

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1 “(II) ACTION BY ADMINIS-
2 TRATOR.—Not later than the date
3 that is 30 days after the date of re-
4 ceipt of a statement under subclause
5 (I), the Administrator shall—

6 “(aa) review the request;

7 “(bb) make a determination
8 regarding whether the informa-
9 tion for which the request is
10 made continues to meet the rel-
11 evant criteria established under
12 this section; and

13 “(cc)(AA) grant an exten-
14 sion of not more than 10 years;
15 or

16 “(BB) deny the claim.

17 “(C) NO LIMIT ON NUMBER OF EXTEN-
18 SIONS.—There shall be no limit on the number
19 of extensions granted under subparagraph (B),
20 if the Administrator determines that the rel-
21 evant statement under subparagraph
22 (B)(ii)(I)—

23 “(i) establishes the need to extend the
24 period; and

1 “(ii) meets the requirements estab-
2 lished by the Administrator.

3 “(2) REVIEW AND RESUBSTANTIATION.—

4 “(A) DISCRETION OF ADMINISTRATOR.—

5 The Administrator may review, at any time, a
6 claim for protection against disclosure under
7 subsection (a) for information submitted to the
8 Administrator regarding a chemical substance
9 and require any person that has claimed protec-
10 tion for that information, whether before, on, or
11 after the date of enactment of the Chemical
12 Safety Improvement Act, to withdraw or re-
13 assert and substantiate or resubstantiate the
14 claim in accordance with this section—

15 “(i) after the chemical substance is
16 identified as a high-priority substance
17 under section 4A;

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

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

23 “(iv) in limited circumstances, if the
24 Administrator determines that disclosure
25 of certain information currently protected

1 from disclosure would assist the Adminis-
2 trator in conducting safety assessments
3 and safety determinations under sub-
4 sections (b) and (c) of section 6 or promul-
5 gating regulations pursuant to section
6 6(d), subject to the condition that the in-
7 formation shall not be disclosed unless the
8 claimant withdraws the claim or the Ad-
9 ministrator determines that the informa-
10 tion does not meet the requirements of
11 subsection (d).

12 “(B) REVIEW REQUIRED.—The Adminis-
13 trator shall review a claim for protection from
14 disclosure under subsection (a) for information
15 submitted to the Administrator regarding a
16 chemical substance and require any person that
17 has claimed protection for that information,
18 whether before, on, or after the date of enact-
19 ment of the Chemical Safety Improvement Act,
20 to withdraw or reassert and substantiate or re-
21 substantiate the claim in accordance with this
22 section—

23 “(i) as necessary to comply with a re-
24 quest for information received by the Ad-

1 administrator under section 552 of title 5,
2 United States Code;

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

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

10 “(C) ACTION BY RECIPIENT.—If the Ad-
11 ministrator makes a request under subpara-
12 graph (A) or (B), the recipient of the request
13 shall—

14 “(i) reassert and substantiate or re-
15 substantiate the claim; or

16 “(ii) withdraw the claim.

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

24 “(3) UNIQUE IDENTIFIER.—The Administrator
25 shall—

1 “(A)(i) develop a system to assign a
2 unique identifier to each specific chemical iden-
3 tity for which the Administrator approves a re-
4 quest for protection from disclosure, other than
5 a specific chemical identity or structurally de-
6 scriptive generic term; and

7 “(ii) apply that identifier consistently to all
8 information relevant to the applicable chemical
9 substance;

10 “(B) annually publish and update a list of
11 chemical substances, referred to by unique iden-
12 tifier, for which claims to protect the specific
13 chemical identity from disclosure have been ap-
14 proved, including the expiration date for each
15 such claim;

16 “(C) ensure that any nonconfidential infor-
17 mation received by the Administrator with re-
18 spect to such a chemical substance during the
19 period of protection from disclosure—

20 “(i) is made public; and

21 “(ii) identifies the chemical substance
22 using the unique identifier; and

23 “(D) for each claim for protection of spe-
24 cific chemical identity that has been denied by
25 the Administrator on expiration of the period

1 for appeal under subsection (g)(3), that has ex-
2 pired, or that has been withdrawn by the sub-
3 mitter, provide public access to the specific
4 chemical identity clearly linked to all noncon-
5 fidential information received by the Adminis-
6 trator with respect to the chemical substance.

7 “(g) DUTIES OF ADMINISTRATOR.—

8 “(1) DETERMINATION.—

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

17 “(B) DENIAL OR MODIFICATION.—

18 “(i) IN GENERAL.—Except as pro-
19 vided in subsections (c) and (f), the Ad-
20 ministrator shall deny a claim to protect a
21 chemical identity from disclosure only if
22 the person that has submitted the claim
23 fails to meet the requirements of sub-
24 sections (a) and (d).

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

7 “(C) SUBSETS.—The Administrator
8 shall—

9 “(i) except for claims described in
10 subsection (b)(7), review all claims under
11 this section for the protection against dis-
12 closure of the specific identity of a chem-
13 ical substance; and

14 “(ii) review a representative subset,
15 comprising at least 25 percent, of all other
16 claims for protection against disclosure.

17 “(D) EFFECT OF FAILURE TO ACT.—The
18 failure of the Administrator to make a decision
19 regarding a claim for protection against disclo-
20 sure or extension under this section shall not be
21 the basis for denial or elimination of a claim for
22 protection against disclosure.

23 “(2) NOTIFICATION.—

24 “(A) IN GENERAL.—Except as provided in
25 subparagraph (B) and subsections (c), (e), and

1 (f), if the Administrator denies or modifies a
2 claim under paragraph (1), the Administrator
3 shall notify, in writing and by certified mail, the
4 person that submitted the claim of the intent of
5 the Administrator to release the information.

6 “(B) RELEASE OF INFORMATION.—

7 “(i) IN GENERAL.—Except as pro-
8 vided in clause (ii), the Administrator shall
9 not release information under this sub-
10 section until the date that is 30 days after
11 the date on which the person that sub-
12 mitted the request receives notification
13 under subparagraph (A).

14 “(ii) EXCEPTIONS.—

15 “(I) IN GENERAL.—For informa-
16 tion under paragraph (3) or (8) of
17 subsection (e), the Administrator shall
18 not release that information until the
19 date that is 15 days after the date on
20 which the person that submitted the
21 claim receives a notification, unless
22 the Administrator determines that re-
23 lease of the information is necessary
24 to protect against an imminent and
25 substantial harm to human health or

1 the environment, in which case no
2 prior notification shall be necessary.

3 “(II) NO NOTIFICATION.—For
4 information under paragraph (1), (2),
5 (6), (7), (9), or (10) of subsection (e),
6 no prior notification shall be nec-
7 essary.

8 “(3) APPEALS.—

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

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

20 “(ii) the United States District Court
21 for the District of Columbia.

22 “(B) NO DISCLOSURE.—The Adminis-
23 trator shall not disclose any information that is
24 the subject of an appeal under this section be-

1 fore the date on which the applicable court
2 rules on an action under subparagraph (A).

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

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

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

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

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

22 “(i) by virtue of that employment or
23 official position has obtained possession of,
24 or has access to, material the disclosure of
25 which is prohibited by subsection (a); and

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

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

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

17 “(i) APPLICABILITY.—

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

22 “(A) to require the substantiation or re-
23 substantiation of a claim for the protection
24 from disclosure of information submitted to the
25 Administrator under this Act before the date of

1 enactment of the Chemical Safety Improvement
2 Act; or

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

7 “(2) PRIOR ACTIONS.—Nothing in this Act pre-
8 vents the Administrator from reviewing, requiring
9 substantiation or resubstantiation for, or approving,
10 modifying or denying any claim for the protection
11 from disclosure of information before the effective
12 date of such regulations applicable to those claims as
13 the Administrator may promulgate after the date of
14 enactment of the Chemical Safety Improvement
15 Act.”.

16 **SEC. 16. PROHIBITED ACTS.**

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

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

21 “(A) any regulation promulgated, consent
22 agreement entered into, or order issued under
23 section 4;

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

1 “(C) any regulation promulgated, consent
2 agreement entered into, or order issued under
3 section 5 or 6; or

4 “(D) any requirement of, or any regulation
5 promulgated or order issued pursuant to title
6 II;”.

7 **SEC. 17. PENALTIES.**

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

10 (1) in subsection (a)(1)—

11 (A) in the first sentence—

12 (i) by inserting “this Act or a regula-
13 tion or order promulgated or issued pursu-
14 ant to this Act, including” after “a provi-
15 sion of”; and

16 (ii) by striking “\$25,000” and insert-
17 ing “\$37,500”; and

18 (B) in the second sentence, by striking“
19 violation of section 15 or 409” and inserting
20 “violation of this Act”; and

21 (2) in subsection (b)—

22 (A) by striking “Any person who” and in-
23 serting the following:

24 “(1) IN GENERAL.—Any person that”;

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

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

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

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

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

16 “(B) ORGANIZATIONS AND ENTITIES.—An
17 **[organization or entity]** that commits a viola-
18 tion described in subparagraph (A) shall be
19 subject on conviction to a fine of not more than
20 \$1,000,000 for each violation.

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

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

4 “(B) knowledge possessed by another indi-
5 vidual may not be attributed to the defendant.”.

6 **SEC. 18. PREEMPTION.**

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

10 “(a) IN GENERAL.—

11 “(1) ESTABLISHMENT OR ENFORCEMENT.—Ex-
12 cept as provided in subsections (c) and (d), no State
13 or political subdivision of a State may establish or
14 continue to enforce **【**any of the following: **【***Legis.*
15 *Counsel note: this phrase and the colon have been in-*
16 *serted here and in subsection (b) to comply with for-*
17 *matting conventions regarding the use below of provi-*
18 *sions with headers.***】】**

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

1 “(i) a rule promulgated by the Admin-
2 istrator;

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

5 “(iii) an order issued by the Adminis-
6 trator.

7 “(B) CHEMICAL SUBSTANCES FOUND TO
8 MEET THE SAFETY STANDARD OR RE-
9 STRICTED.—A statute or administrative action
10 to prohibit or restrict the manufacture, proc-
11 essing, or distribution in commerce or use of a
12 chemical substance—

13 “(i) for a substance found to meet the
14 safety standard and consistent with the
15 scope of the determination made under
16 section 6; **[or]**

17 “(ii) for a substance found not to
18 meet the safety standard, after the effec-
19 tive date of the rule issued under section
20 6(d) for the substance, consistent with the
21 scope of the determination made by the
22 Administrator.

23 “(C) SIGNIFICANT NEW USE.—A statute or
24 administrative action requiring the notification
25 of a use of a chemical substance that the Ad-

1 administrator has specified as a significant new
2 use and for which the Administrator has re-
3 quired notification pursuant to a rule promul-
4 gated under section 5.

5 “(2) EFFECTIVE DATE FOR CERTAIN PREEMP-
6 TION.—Under this subsection, Federal preemption
7 of State statutes and administrative actions applica-
8 ble to specific substances shall be consistent with the
9 scope of the determination made by the Adminis-
10 trator and shall not occur until the date of the Ad-
11 ministrator’s determination that the substance meets
12 the safety standard or until the date on which com-
13 pliance with the rule issued under section 6(d) is re-
14 quired.

15 “(b) NEW STATUTES OR ADMINISTRATIVE ACTIONS
16 CREATING PROHIBITIONS OR RESTRICTIONS.—Except as
17 provided in subsections (c) and (d), no State or political
18 subdivision of a State may establish (after the date of en-
19 actment of the Chemical Safety Improvement Act) **any**
20 of the following: **】**

21 “(1) HIGH PRIORITY.—A statute or administra-
22 tive action prohibiting or restricting the manufac-
23 ture, processing, distribution in commerce or use of
24 a chemical substance that is a high-priority sub-
25 stance identified under section 4A, as of the date on

1 which the Administrator commences a safety assess-
2 ment under section 6.

3 “(2) LOW PRIORITY.—A statute or administra-
4 tive action prohibiting or restricting the manufac-
5 ture, processing, distribution in commerce or use of
6 a chemical substance that is a low-priority substance
7 identified under section 4A, as of the date on which
8 the Administrator designates the substance as a low
9 priority.

10 “(c) EXCEPTIONS.—

11 “(1) **【IN GENERAL】**.—Subsections (a) and (b)
12 shall not apply to a requirement, prohibition, or re-
13 striction of a State or a political subdivision of a
14 State that— **【Legis. Counsel note: Generic header**
15 *was added here and in paragraph (3) to ensure con-*
16 *sistency with paragraph (2), which was given a head-*
17 *er in client specs】*

18 “(A) is adopted under the authority of any
19 other Federal law;

20 “(B) implements a reporting, monitoring,
21 or information collection requirement not other-
22 wise required by the Administrator under this
23 Act or required under any other Federal law; or

24 “(C) is adopted pursuant to authority
25 under a law of the State or political subdivision

1 of the State related to water quality, air qual-
2 ity, or waste treatment or disposal that—

3 “(i) does not impose a restriction on
4 the manufacture, processing, distribution
5 in commerce, or use of a chemical sub-
6 stance; and

7 “(ii) is not otherwise required by or
8 inconsistent with an action by the Admin-
9 istrator under section 5 or 6.

10 “(2) NO PREEMPTION OF STATE STATUTES
11 AND ADMINISTRATIVE ACTIONS.—Nothing in this
12 Act, nor any amendment made by this Act, nor any
13 regulation, requirement, standard of performance,
14 safety determination, or scientific assessment imple-
15 mented pursuant to this Act, shall affect the right
16 of a State or a political subdivision of a State to
17 adopt or enforce any regulation, requirement, stand-
18 ard of performance, safety determination, scientific
19 assessment, or any protection for public health or
20 the environment that—

21 “(A) is adopted or authorized to comply
22 with any other Federal law;

23 “(B) implements reporting, monitoring, or
24 information collection requirement not other-

1 wise required by the Administrator under this
2 Act or required under any other Federal law; or

3 “(C) is adopted pursuant to authority
4 under a law of the State or political subdivision
5 of the State related to water quality, air qual-
6 ity, or waste treatment or disposal that does
7 not impose a restriction on the manufacture,
8 processing, distribution in commerce, or use of
9 a chemical substance and is not otherwise re-
10 quired by or inconsistent with an action by the
11 Administrator under section 5 or 6.

12 “(3) **[RULE OF CONSTRUCTION]**.—Nothing in
13 this section shall be construed as requiring the Ad-
14 ministrator to modify or withdraw, any rule or order
15 under section 5 or 6 of this Act, or as modifying the
16 effect of this section as enacted prior to the effective
17 date of the Chemical Safety Improvement Act on
18 any rule or order promulgated or issued under this
19 Act prior to the effective date of the Chemical Safety
20 Improvement Act.

21 “(d) **PRESERVATION OF CERTAIN STATE LAW.**—
22 Nothing in this section shall be construed to preempt or
23 otherwise affect any warning requirement relating to con-
24 sumer products or substances that is established pursuant
25 to State law that was in effect on August 31, 2003, unless

1 a rule, consent agreement, or order is promulgated under
2 section 6 imposing a warning requirement, which shall
3 preempt a chemical specific State warning requirement
4 consistent with the scope of the Administrator’s deter-
5 mination under section 6.

6 “(e) STATE WAIVERS.—

7 “(1) IN GENERAL.—Upon application of a State
8 or political subdivision of a State, the Administrator
9 may provide a waiver from subsection (a) and sub-
10 section (b)(1), regarding a statute or administrative
11 action of that State or political subdivision of the
12 State that relates to the effects or exposure to any
13 chemical substance under the intended or reasonably
14 anticipated conditions of use if—

15 “(A)(i) the State or political subdivision of
16 the State determines it cannot wait until the
17 end of the period specified in the established
18 schedule and deadline for the completion of a
19 full safety assessment and determination estab-
20 lished under section 3A; and

21 “(ii) the Administrator determines that—

22 “(I) compelling State or local condi-
23 tions warrant granting the waiver to pro-
24 tect human health or the environment;

1 “(II) compliance with the proposed re-
2 quirement of the State or political subdivi-
3 sion of the State will not unduly burden
4 interstate and foreign commerce in the
5 manufacture, processing, distribution in
6 commerce, or use of a chemical substance;

7 “(III) compliance with the proposed
8 requirement of the State or political sub-
9 division of the State would not cause a vio-
10 lation of any applicable Federal law, rule,
11 or order; and

12 “(IV) based on the judgment of the
13 Administrator, the proposed requirement
14 of the State or political subdivision of the
15 State is consistent with sound objective sci-
16 entific practices, the weight of the evi-
17 dence, and the best available science;

18 “(B)(i) the Administrator finds a safety
19 assessment or determination has been unrea-
20 sonably delayed; and

21 “(ii) the State certifies that—

22 “(I) the State has a compelling local
23 interest to protect human health or the en-
24 vironment;

1 “(II) compliance with the proposed re-
2 quirement of the State will not unduly bur-
3 den interstate commerce in the manufac-
4 ture, processing, distribution in commerce,
5 or use of a chemical substance;

6 “(III) compliance with the proposed
7 requirement would not cause a violation of
8 any applicable Federal law, rule, or order;
9 and

10 “(IV) the proposed requirement is
11 grounded in reasonable scientific concern;
12 or

13 “(C)(i) the State has contracted with the
14 National Academy of Sciences to assess the
15 hazard, use and exposure, and risk of a chem-
16 ical substance;

17 “(ii) the report complies with the require-
18 ments of the Federal Advisory Committee Act
19 Amendments of 1997; and

20 “(iii) based on the best available evidence
21 described in the report of the National Academy
22 of Sciences, the State establishes a requirement
23 relating to the effects of or exposure to a chem-
24 ical substance.

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

4 “(A) not later than 180 days after the date
5 on which an application under paragraph (1)(A)
6 is submitted; and

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

10 “(3) NOTICE AND COMMENT.—The application
11 of a State or political subdivision of the State shall
12 be subject to public notice and comment.

13 “(4) FINAL AGENCY ACTION.—The decision of
14 the Administrator on the application of a State or
15 political subdivision of the State shall be—

16 “(A) considered to be a final agency ac-
17 tion; and

18 “(B) subject to judicial review.

19 “(5) DURATION OF WAIVERS.—A waiver—

20 “(A) granted under paragraph (1)(A) shall
21 remain in effect unless the waiver is found to
22 be in conflict with a completed safety assess-
23 ment and determination; and

24 “(B) granted under [subparagraph (B) or
25 (C) of paragraph (2)] shall remain in effect

1 until such time as the safety assessment and
2 determination is completed.

3 “(6) JUDICIAL REVIEW.—

4 “(A) IN GENERAL.—Not later than 60
5 days after the date on which the Administrator
6 makes a determination on an application of a
7 State or political subdivision of the State under
8 paragraph (1), any person may file a petition
9 for judicial review in the United States Court of
10 Appeals for the District of Columbia Circuit,
11 which shall have exclusive jurisdiction over the
12 determination.

13 “(B) JUDICIAL REVIEW OF
14 PRIORITIZATION SCREENING DECISION.—Not
15 later than 60 days after the date on which the
16 Administrator makes a decision on a rec-
17 ommendation made under section 4A(c) to des-
18 ignate a chemical substance as a low priority,
19 the Governor of a State or a State agency with
20 responsibility for protecting health and the envi-
21 ronment that submitted the recommendation, as
22 applicable, may file a petition for judicial review
23 in the United States Court of Appeals for the
24 District of Columbia Circuit, which shall have
25 exclusive jurisdiction over the determination.

1 “(7) SAVINGS.—

2 “(A) NO PREEMPTION OF COMMON LAW
3 OR STATUTORY CAUSES OF ACTION FOR CIVIL
4 RELIEF OR CRIMINAL CONDUCT.—Nothing in
5 this Act, nor any amendment made by this Act,
6 nor any regulation, requirement, standard of
7 performance, safety determination, or scientific
8 assessment implemented pursuant to this Act,
9 shall be construed to preempt, displace, or sup-
10 plant any state or Federal common law rights
11 or any state or Federal statute creating a rem-
12 edy for civil relief, including those for civil dam-
13 age, or a penalty for a criminal conduct.

14 “(B) CLARIFICATION OF NO PREEMP-
15 TION.—Notwithstanding any other provision in
16 this Act, nothing in this Act, nor any amend-
17 ments made by this Act, shall preempt or pre-
18 clude any cause of action for personal injury,
19 wrongful death, property damage, or other in-
20 jury based on negligence, strict liability, prod-
21 ucts liability, failure to warn, or any other legal
22 theory of liability under any state, maritime, or
23 Federal common law or statutory theory.

24 “(C) NO EFFECT ON PRIVATE REM-
25 EDIES.—

1 “(i) Nothing in this Act, nor any
2 amendments made by this Act, nor any
3 rules, regulations, requirements, safety as-
4 sessments, safety determinations, scientific
5 assessments, or orders issued pursuant to
6 this Act shall be interpreted as, in either
7 the plaintiff’s or defendant’s favor, disposi-
8 tive in any civil action.

9 “(ii) This Act does not affect the au-
10 thority of any court to make a determina-
11 tion in an adjudicatory proceeding under
12 applicable State or Federal law with re-
13 spect to the admission into evidence or any
14 other use of this Act or rules, regulations,
15 requirements, standards of performance,
16 safety assessments, scientific assessments,
17 or orders issued pursuant to this Act.”.

18 **SEC. 19. JUDICIAL REVIEW.**

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

21 (1) in subsection (a)—

22 (A) in paragraph (1)—

23 (i) in subparagraph (A), by striking
24 “section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e),

1 or 8, or under title II or IV” and inserting

2 “section 4(a), 5(d)(4), 6(d), or 8”; and

3 (ii) in subparagraph (B), by striking

4 “an order issued under subparagraph (A)

5 or (B) of section 6(b)(1)” and inserting

6 **【**“a regulation promulgated pursuant to

7 section 6(d)”**】**; and

8 (B) in paragraph (2), in the first sentence,

9 by striking “paragraph (1)(A)” and inserting

10 “paragraph (1)”;

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

12 (2) in subsection (c)(1)—

13 (A) in subparagraph (B)—

14 (i) in clause (i)—

15 (I) by striking “section 4(a),

16 5(b)(4), 6(a), or 6(e)” and inserting

17 “section 4(a), 5(d)(4), or 6(d)”;

18 (II) by striking “evidence in the

19 rulemaking record (as defined in sub-

20 section (a)(3)) taken as a whole;” and

21 inserting “evidence (including any

22 matter) in the rulemaking record,

23 taken as a whole; and”;

1 (ii) by striking clauses (ii) and (iii)
2 and the matter following clause (iii) and
3 inserting the following:

4 “(ii) the court may not review the
5 contents and adequacy of any statement of
6 basis and purpose required by section
7 553(c) of title 5, United States Code, to be
8 incorporated in the regulation, except as
9 part of the rulemaking record, taken as a
10 whole.”; and

11 **[(B) by striking subparagraph (C).]**

12 **SEC. 20. CITIZENS’ PETITIONS.**

13 Section 21 of the Toxic Substances Control Act (15
14 U.S.C. 2620) is amended—

15 (1) in subsection (a), by striking “an order
16 under section 5(e) or 6(b)(2)” and inserting “an
17 order under section 4 or 5(d)”;

18 (2) in subsection (b)—

19 (A) in paragraph (1), by striking “an
20 order under section 5(e), 6(b)(1)(A), or
21 6(b)(1)(B)” and inserting “an order under sec-
22 tion 4 or 5(d)”;

23 (B) in paragraph (4), by striking subpara-
24 graph (B) and inserting the following:

25 “(B) DE NOVO PROCEEDING.—

1 “(i) IN GENERAL.—In an action
2 under subparagraph (A) to initiate a pro-
3 ceeding to promulgate a regulation pursu-
4 ant to section 4, 5(d), 6(b), 6(c), 6(d), or
5 8 or an order issued under section 4 or
6 5(d), the petitioner shall be provided an
7 opportunity to have the petition considered
8 by the court in a de novo proceeding.

9 “(ii) DEMONSTRATION.—

10 “(I) IN GENERAL.—The court in
11 a de novo proceeding under this sub-
12 paragraph shall order the Adminis-
13 trator to initiate the action requested
14 by the petitioner if the petitioner dem-
15 onstrates to the satisfaction of the
16 court by a preponderance of the evi-
17 dence that—

18 “(aa) in the case of a peti-
19 tion to initiate a proceeding for
20 the issuance of a regulation or
21 order under section 4, the infor-
22 mation available to the Adminis-
23 trator is insufficient for the Ad-
24 ministrator to perform an action
25 described in section 4 or 6(d);

1 “(bb) in the case of a peti-
2 tion to issue an order under sec-
3 tion 5(d), there is a reasonable
4 basis to conclude that the chem-
5 ical substance is not likely to
6 meet the safety standard;

7 “(cc) in the case of a peti-
8 tion to initiate a proceeding for
9 the issuance of a regulation
10 under section 6(d), there is a rea-
11 sonable basis to conclude that the
12 chemical substance will not meet
13 the safety standard; or

14 “(dd) in the case of a peti-
15 tion to initiate a proceeding for
16 the issuance of a regulation
17 under section 8, there is a rea-
18 sonable basis to conclude that the
19 regulation is necessary to protect
20 human health or the environment
21 from an unreasonable risk of
22 harm to human health or the en-
23 vironment.

24 “(II) DEFERMENT.—The court
25 in a de novo proceeding under this

1 subparagraph may permit the Admin-
2 istrator to defer initiating the action
3 requested by the petitioner until such
4 time as the court prescribes, if the
5 court finds that—

6 “(aa) the extent of the risk
7 to human health or the environ-
8 ment alleged by the petitioner is
9 less than the extent of risks to
10 human health or the environment
11 with respect to which the Admin-
12 istrator is taking action under
13 this Act; and

14 “(bb) there are insufficient
15 resources available to the Admin-
16 istrator to take the action re-
17 quested by the petitioner.”.

18 **SEC. 21. EMPLOYMENT EFFECTS.**

19 Section 24(b)(2)(B)(ii) of the Toxic Substances Con-
20 trol Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by
21 striking “section 6(c)(3),” and inserting “the applicable
22 requirements of this Act;”.

23 **SEC. 22. STUDIES.**

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

1 **SEC. 23. ADMINISTRATION.**

2 Section 26(e) of the Toxic Substances Control Act
3 (15 U.S.C. 2625(e)) is amended by striking “Health, Edu-
4 cation, and Welfare” each place it appears and inserting
5 “Health and Human Services”.

6 **SEC. 24. DEVELOPMENT AND EVALUATION OF TEST METH-**
7 **ODS.**

8 Section 27(a) of the Toxic Substances Control Act
9 (15 U.S.C. 2626(a)) is amended in the first sentence by
10 striking “Health, Education, and Welfare” and inserting
11 “Health and Human Services”.

12 **SEC. 25. STATE PROGRAMS.**

13 Section 28 of the Toxic Substances Control Act (15
14 U.S.C. 2627) is amended—

15 (1) in subsection (b)(1)—

16 (A) in subparagraphs (A) through (D), by
17 striking the comma at the end of each subpara-
18 graph and inserting a semicolon; and

19 (B) in subparagraph (E), by striking “,
20 and” and inserting “; and”; and

21 (2) by striking subsections (c) and (d).

22 **SEC. 26. AUTHORIZATION OF APPROPRIATIONS.**

23 Section 29 of the Toxic Substances Control Act (15
24 U.S.C. 2628) is repealed.

1 **SEC. 27. ANNUAL REPORT.**

2 Section 30 of the Toxic Substances Control Act (15
3 U.S.C. 2629) is amended by striking paragraph (2) and
4 inserting the following:

5 “(2)(A) the number of notices received during
6 each year under section 5; and

7 “(B) the number of the notices described in
8 subparagraph (A) for chemical substances subject to
9 a regulation, testing consent agreement, or order
10 under section 4;”.

11 **SEC. 28. EFFECTIVE DATE.**

12 Section 31 of the Toxic Substances Control Act (15
13 U.S.C. 2601 note; Public Law 94–469) is amended by
14 striking “Except as provided in section 4(f), this” and in-
15 serting “This”.