

114TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mrs. BOXER (for herself and Mr. MARKEY) introduced the following bill;
which was read twice and referred to the Committee on

A BILL

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

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

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

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Alan Reinstein and Trevor Schaefer Toxic Chemical Pro-
6 tection Act”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. References.

TITLE I—AMENDMENTS TO THE TOXIC SUBSTANCES CONTROL
ACT

2

- Sec. 101. Findings, policy, and intent.
- Sec. 102. Definitions.
- Sec. 103. Policies, procedures and guidance.
- Sec. 104. Testing of chemical substances or mixtures.
- Sec. 105. Prioritization screening.
- Sec. 106. New chemicals and significant new uses.
- Sec. 107. Safety assessments and determinations.
- Sec. 108. Imminent hazards.
- Sec. 109. Information collection and reporting.
- Sec. 110. Relationship to other Federal laws.
- Sec. 111. Research, development, collection, dissemination, and utilization of data.
- Sec. 112. Exports.
- Sec. 113. Imports.
- Sec. 114. Confidential information.
- Sec. 115. Prohibited acts.
- Sec. 116. Penalties.
- Sec. 117. Preemption.
- Sec. 118. Judicial review.
- Sec. 119. Citizens' petitions.
- Sec. 120. Studies.
- Sec. 121. Administration.
- Sec. 122. Development and evaluation of test methods.
- Sec. 123. State programs.
- Sec. 124. Authorization of appropriations.
- Sec. 125. Annual report.

TITLE II—STRENGTHENING PROTECTIONS FOR CHILDREN AND
COMMUNITIES FROM DISEASE CLUSTERS

- Sec. 201. Purposes.
- Sec. 202. Definitions.
- Sec. 203. Guidelines for environmental investigations of disease clusters.
- Sec. 204. Enhanced support for environmental investigations of disease clusters.
- Sec. 205. Federal reports to Congress.
- Sec. 206. Authorization of appropriations.
- Sec. 207. Effect on other law.

TITLE III—COMMUNITY DISEASE CLUSTER TECHNICAL
ASSISTANCE GRANTS

- Sec. 301. Community disease cluster technical assistance grants.
- Sec. 302. Authorization of appropriations.

1 SEC. 2. REFERENCES.

2 Except as otherwise expressly provided, wherever in
3 this Act an amendment or repeal is expressed in terms
4 of an amendment to, or repeal of, a section or other provi-
5 sion, the reference shall be considered to be made to a

1 section or other provision of the Toxic Substances Control
2 Act (15 U.S.C. 2601 et seq.).

3 **TITLE I—AMENDMENTS TO THE**
4 **TOXIC SUBSTANCES CON-**
5 **TROL ACT**

6 **SEC. 101. FINDINGS, POLICY, AND INTENT.**

7 Section 2(a) (15 U.S.C. 2601(a)) is amended—

8 (1) In paragraph (2)—

9 (A) by striking “injury” and inserting
10 “harm”; and

11 (B) by striking “and” at the end;

12 (2) by redesignating paragraph (3) as para-
13 graph (6); and

14 (3) by inserting after paragraph (2) the fol-
15 lowing:

16 “(3) reform of this Act shall be administered to
17 protect the health of children, pregnant women, the
18 elderly, workers, consumers, the general public and
19 the environment from the risks of harmful exposures
20 to chemical substances and mixtures;

21 “(4) reform of this Act shall not displace or
22 supplant common law rights of action or remedies
23 for civil relief;

24 “(5) reform of this Act shall be administered to
25 ensure that appropriate information on chemical

1 substances and mixtures should be available to pub-
2 lic health officials and first responders in the event
3 of an emergency; and”.

4 **SEC. 102. DEFINITIONS.**

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

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

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

12 “(7) INFORMATION.—Except in section 14, the
13 term ‘information’ means any qualitative, quan-
14 titative or descriptive facts, data, analysis or assess-
15 ment related to chemical hazards, use, or exposure
16 (including the nature and extent of exposure to a
17 chemical substance), including from health and safe-
18 ty studies.

19 “(8) INTENDED OR REASONABLY FORESEEABLE
20 CONDITIONS OF USE.—The term ‘intended or rea-
21 sonably foreseeable conditions of use’ means the cir-
22 cumstances under which a chemical substance is in-
23 tended, reasonably known, or reasonably anticipated
24 to be manufactured, processed, distributed in com-
25 merce, used, disposed of, and released into the envi-

1 ronment, including reasonably foreseeable but unin-
2 tended exposure conditions from unplanned releases
3 into the environment.”;

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

6 “(12) POTENTIALLY EXPOSED OR SUSCEPTIBLE
7 POPULATION.—The term ‘potentially exposed or sus-
8 ceptible population’ means a group or groups of in-
9 dividuals within the general population who may
10 be—

11 “(A) differentially exposed to chemical sub-
12 stances under the intended or reasonably fore-
13 seeable conditions of use; or

14 “(B) more susceptible to adverse health
15 consequences from chemical exposures than the
16 general population, which when identified by
17 the Administrator may include such groups as
18 infants, children, pregnant women, workers,
19 and the elderly.”; and

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

22 “(15) PUBLICLY AVAILABLE INFORMATION.—
23 The term ‘publicly available information’ means in-
24 formation that is generally accessible and available
25 to the general public or in the public domain, includ-

1 ing information that has been published in periodi-
2 cals, books, print, or electronic or other media avail-
3 able for general distribution to any member of the
4 public.

5 “(16) SAFETY ASSESSMENT.—The term ‘safety
6 assessment’ means an assessment of the risk posed
7 by a chemical substance under the intended or rea-
8 sonably foreseeable conditions of use, integrating
9 hazard, use, and exposure information about the
10 chemical substance.

11 “(17) SAFETY DETERMINATION.—The term
12 ‘safety determination’ means a determination by the
13 Administrator as to whether a chemical substance
14 meets the safety standard under the intended or rea-
15 sonably foreseeable conditions of use.

16 “(18) SAFETY STANDARD.—The term ‘safety
17 standard’ means a standard that ensures with rea-
18 sonable certainty, without taking into consideration
19 cost or other non-risk factors, that no harm to
20 human health or the environment will result from
21 exposure to a chemical substance under the intended
22 or reasonably foreseeable conditions of use, including
23 no harm to the general population or to any poten-
24 tially exposed or susceptible subpopulation that the
25 Administrator has identified as relevant to the safety

1 assessment and determination for a chemical sub-
2 stance.”.

3 **SEC. 103. POLICIES, PROCEDURES AND GUIDANCE.**

4 The Toxic Substances Control Act (15 U.S.C. 2601
5 et seq.) is amended by adding after section 3 the following:

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

7 “(a) DEADLINE.—Not later than 2 years after the
8 date of enactment of the Alan Reinstein and Trevor
9 Schaefer Toxic Chemical Protection Act, the Adminis-
10 trator shall, after providing an opportunity for public no-
11 tice and comment, develop the policies, procedures and
12 guidance required by this section. As used in this section,
13 the term ‘guidance’ includes any significant written guid-
14 ance of general applicability prepared by the Adminis-
15 trator.

16 “(b) USE OF SCIENCE.—In establishing any policies,
17 procedures, and guidance, on the use of science in making
18 decisions under this section and sections 4, 4A, 5, and
19 6, the Administrator shall have the goal of making the
20 basis of decisions clear to the public. The policies, proce-
21 dures and any guidance issued under this subsection shall
22 describe how the Administrator will ensure that—

23 “(1) decisions by the Administrator—

24 “(A) are based on the best available
25 science; and

1 “(B) take into account the extent to
2 which—

3 “(i) assumptions and methods used to
4 develop information considered by the Ad-
5 ministrator are clearly and completely de-
6 scribed and documented;

7 “(ii) variability and uncertainty in
8 such information are evaluated and charac-
9 terized; and

10 “(iii) the information has been subject
11 to independent peer review;

12 “(2) to the extent practicable and where appro-
13 priate, the use of peer review, standardized test de-
14 sign and methods, consistent data evaluation proce-
15 dures, and appropriate laboratory practices will be
16 encouraged;

17 “(3) the names of the organizations or individ-
18 uals funding the generation and assessment of infor-
19 mation and the degree of control they had over the
20 generation, assessment, and dissemination of infor-
21 mation (including control over the design of the
22 work and the publication of information) will be
23 made clear; and

24 “(4) decisions by the Administrator follow the
25 applicable recommendations in relevant National

1 Academy of Sciences reports, including the reports
2 titled *Science and Decisions: Advancing Risk Assess-*
3 *ment, Phthalates and Cumulative Risk Assessment:*
4 *The Task Ahead, Review of EPA’s Integrated Risk In-*
5 *formation System (IRIS) Process, Review of the*
6 *Formaldehyde Assessment in the National Toxicology*
7 *Program 12th Report on Carcinogens, and Review of*
8 *the Styrene Assessment in the National Toxicology*
9 *Program 12th Report on Carcinogens.*

10 “(c) EXISTING EPA POLICIES, PROCEDURES AND
11 GUIDANCE.—The policies, procedures, and guidance de-
12 scribed in subsections (a) and (b) shall incorporate, as ap-
13 propriate, existing relevant hazard, exposure, and risk as-
14 sessment guidelines and methodologies, data evaluation
15 and quality criteria, testing methodologies and other rel-
16 evant guidelines and policies previously issued by the Ad-
17 ministrator.

18 “(d) REVIEW.—Not less than 5 years after the date
19 of enactment of this Act, and not less frequently than
20 every 5 years thereafter, the Administrator shall—

21 “(1) review the adequacy of any policies, proce-
22 dures, and guidance developed under this section, in-
23 cluding procedures for assessing and determining
24 risk under this Act; and

1 “(2) after providing an opportunity for public
2 notice and comment, revise the policies, procedures,
3 and guidance if necessary to reflect new scientific
4 developments or understandings.

5 “(e) SOURCES OF INFORMATION.—In making any de-
6 cision with respect to a chemical substance under sections
7 4, 4A, 5, and 6, the Administrator shall consider informa-
8 tion on the hazards and exposures of a chemical substance
9 under the intended or reasonably foreseeable conditions of
10 use that is reasonably available to the Administrator, in-
11 cluding information that is—

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

17 “(A) manufacturers and processors of a
18 substance;

19 “(B) the public;

20 “(C) other Federal agencies and depart-
21 ments; or

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

1 “(2) submitted to a governmental body in any
2 jurisdiction under a governmental requirement relat-
3 ing to the protection of human health and the envi-
4 ronment; or

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

9 “(f) TESTING OF CHEMICAL SUBSTANCES AND MIX-
10 TURES.—

11 “(1) IN GENERAL.—The Administrator shall es-
12 tablish policies and procedures for the testing of
13 chemical substances or mixtures under section 4. A
14 goal of the policies and procedures shall be to make
15 the basis of decisions clear to the public.

16 “(2) CONTENTS.—The policies and procedures
17 established under paragraph (1) shall—

18 “(A) address how and when the exposure
19 level or exposure potential of a chemical sub-
20 stance would factor into decisions to require
21 new testing, provided that the Administrator
22 shall not interpret the lack of exposure informa-
23 tion as a lack of exposure or exposure potential
24 and that lack of information on exposure or ex-

1 posure potential shall not, by itself, be a reason
2 not to require testing;

3 “(B) describe how the Administrator will
4 determine that additional testing is needed to
5 carry out this Act, including testing related to
6 potentially exposed or susceptible populations
7 and testing related to the accumulation of
8 chemical substances in the human body;

9 “(C) require the Administrator to consult
10 with the Director of the National Institute for
11 Occupational Safety and Health prior to pre-
12 scribing epidemiologic studies of employees; and

13 “(D) prior to adopting a requirement for
14 testing using mammals, require the Adminis-
15 trator to consider, as appropriate and to the ex-
16 tent practicable, reasonably available—

17 “(i) toxicity information;

18 “(ii) computational toxicology and
19 bioinformatics;

20 “(iii) high-throughput screening meth-
21 ods and their prediction models; and

22 “(iv) scientifically reliable and rel-
23 evant alternatives to tests on mammals
24 that would provide equivalent information.

1 “(3) TIERED TESTING.—Except as provided in
2 subparagraph (C), the Administrator shall employ a
3 tiered screening and testing process, in which the re-
4 sults of screening level tests or assessments of avail-
5 able information inform the decision as to whether
6 1 or more additional tests are necessary.

7 “(A) SCREENING LEVEL.—The screening
8 level tests required for a chemical substance or
9 mixture may include tests for hazard (which
10 may include in silico, in vitro, and in vivo tests),
11 environmental and biological fate and transport,
12 and measurements or modeling of exposure, as
13 appropriate. Screening level tests shall be
14 used—

15 “(i) to screen chemical substances or
16 mixtures for potential adverse effects; and

17 “(ii) to inform the decision of the Ad-
18 ministrator whether additional testing is
19 necessary.

20 “(B) ADDITIONAL TESTING.—If the Ad-
21 ministrator determines under subparagraph (A)
22 that additional testing is necessary to provide
23 more definitive information for prioritization or
24 safety assessments and safety determinations,
25 the Administrator may require more advanced

1 tests for potential human health or environ-
2 mental effects or exposure.

3 “(C) ADVANCED TESTING WITHOUT
4 SCREENING.—The Administrator may require
5 more advanced testing without conducting
6 screening-level testing when other information
7 available to the Administrator justifies the ad-
8 vanced test, pursuant to policies or procedures
9 developed by the Administrator under this sub-
10 section.

11 “(g) SAFETY ASSESSMENTS AND SAFETY DETER-
12 MINATIONS.—

13 “(1) SCHEDULE.—The Administrator shall in-
14 form the public regarding the schedule for the com-
15 pletion of each safety assessment and safety deter-
16 mination as soon as possible after designation as a
17 high priority substance pursuant to section 4A. The
18 time allotted may be different for different chemi-
19 cals, provided that all schedules shall comply with
20 the deadlines established under section 6.

21 “(2) POLICIES AND PROCEDURES FOR SAFETY
22 ASSESSMENTS AND SAFETY DETERMINATIONS.—The
23 Administrator shall establish policies and procedures
24 on how the Administrator shall carry out section 6.
25 A goal of the policies and procedures shall be to

1 make the basis of decisions clear to the public. At
2 a minimum, the policies and procedures shall—

3 “(A) describe—

4 “(i) how the Administrator will iden-
5 tify informational needs and seek such in-
6 formation from the public;

7 “(ii) what information (including
8 draft safety assessments) may be sub-
9 mitted by interested persons, including
10 States; and

11 “(iii) the criteria by which that infor-
12 mation will be evaluated;

13 “(B) require the Administrator, in each
14 safety assessment and safety determination,
15 to—

16 “(i) identify the substance’s intended
17 or reasonably foreseeable conditions of use
18 based on information provided by its man-
19 ufacturers and processors or otherwise
20 available to the Administrator;

21 “(ii) identify all potentially exposed or
22 susceptible populations that the Adminis-
23 trator determines are pertinent to the sub-
24 stance;

1 effects of exposure to the chemical sub-
2 stance and other chemicals posing similar
3 hazards; and

4 “(C) establish a timely and transparent
5 process for evaluating whether new information
6 submitted or obtained after the date of a final
7 safety assessment or safety determination war-
8 rants reconsideration of the assessment or de-
9 termination.

10 “(h) RELEASE OF SAFETY ASSESSMENTS.—Subject
11 to section 14, the Administrator shall —

12 “(1) make available to the public a nontechnical
13 summary and the final version of each safety assess-
14 ment and safety determination;

15 “(2) provide public notice and an opportunity
16 for comment on each proposed safety assessment
17 and safety determination; and

18 “(3) make public in a final safety assessment
19 and safety determination the list of studies consid-
20 ered by the Administrator in carrying out the safety
21 assessment and safety determination, as well as the
22 list of policies and procedures that were followed in
23 carrying out the safety assessment and safety deter-
24 mination.

1 “(i) CONSULTATION WITH SCIENCE ADVISORY COM-
2 MITTEE ON CHEMICALS.—

3 “(1) IN GENERAL.—Not later than 1 year after
4 the date of enactment of the Alan Reinstein and
5 Trevor Schaefer Toxic Chemical Protection Act, the
6 Administrator shall establish a Science Advisory
7 Committee on Chemicals (referred to in this sub-
8 section as the ‘Committee’) to provide independent
9 advice and expert consultation, upon the request of
10 the Administrator, with respect to the scientific and
11 technical aspects of issues relating to the implemen-
12 tation of this title.

13 “(2) COMPOSITION OF COMMITTEE.—The Com-
14 mittee shall be composed of representatives of such
15 science, government, labor, public health, public in-
16 terest, industry, and other groups as the Adminis-
17 trator deems advisable, including, at a minimum,
18 representatives that have specific scientific expertise
19 in the relationship of chemical exposures to women,
20 children, and other potentially exposed or susceptible
21 populations.

22 “(3) MEETINGS.—The Administrator shall con-
23 vene the Committee on a schedule the Administrator
24 determines appropriate, but not less frequently than
25 once every 2 years.

1 (A) by striking “rule” each place it ap-
2 pears and inserting “rule, testing consent
3 agreement, or order”;

4 (B) by striking “under subsection (a)”
5 each place it appears and inserting “under this
6 subsection”; and

7 (C) in paragraph (1)(B), by striking “rule-
8 making”;

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

10 (A) by striking “from cancer, gene
11 mutations, or birth defects”;

12 (B) by striking “unreasonable” each place
13 it appears and inserting “significant”; and

14 (C) by striking the last sentence; and

15 (4) by striking subsections (a) through (d) and
16 inserting the following:

17 “(a) DEVELOPMENT OF NEW INFORMATION ON
18 CHEMICAL SUBSTANCES AND MIXTURES.—

19 “(1) IN GENERAL.—The Administrator may re-
20 quire the development of new information related to
21 a chemical substance or mixture in accordance with
22 this section if the Administration determines that
23 the information is needed—

24 “(A) to perform a safety assessment or
25 make a safety determination under section 6;

1 “(B) to implement a requirement imposed
2 in a consent agreement or order issued under
3 section 5(c)(4);

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

5 “(D) at the request of the implementing
6 authority under any other Federal law.

7 “(2) TESTING FOR PRIORITIZATION PUR-
8 POSES.—The Administrator may require the devel-
9 opment of new information for the purposes of sec-
10 tion 4A, provided that any such testing shall not be
11 based on a set of uniform minimum information re-
12 quirements for all or large groups of chemical sub-
13 stances. Use of this authority shall be limited to
14 cases where the Administrator determines additional
15 information is needed to establish the priority of a
16 chemical substance.

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

21 “(A) promulgating a rule;

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

24 “(C) issuing an order.

25 “(4) CONTENTS.—

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

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

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

9 “(iii) to the extent practicable, test
10 protocols and methodologies for the devel-
11 opment of information for the chemical
12 substance or mixture, including specific
13 reference to reliable nonmammal test pro-
14 cedures; and

15 “(iv) specification of the period within
16 which persons required to conduct the test-
17 ing shall submit to the Administrator the
18 information developed in accordance with
19 the procedures described in clause (iii).

20 “(B) DURATION.—The period described in
21 subparagraph (A)(iv) shall not be of an unrea-
22 sonable duration.

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

1 subparagraph (A), the Administrator shall con-
2 sider—

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 needed to
8 perform the testing.

9 “(b) STATEMENT OF NEED.—

10 “(1) IN GENERAL.—In promulgating a rule, en-
11 tering into a testing consent agreement, or issuing
12 an order for development of additional information
13 (including information on exposure or exposure po-
14 tential) under this section, the Administrator shall—

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

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

22 “(C) explain the basis for any decision that
23 requires the use of mammals.

24 “(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 issuance of an order instead of
5 promulgating a rule or entering into a testing
6 consent agreement.

7 “(B) CONTENTS.—The statement de-
8 scribed in subparagraph (A) shall contain a dis-
9 cussion 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 MAMMALS.—

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

1 mals in testing of chemical substances or mixtures,
2 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 mammals
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 where testing of
16 a chemical substance would provide reliable
17 and useful information on others in the
18 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 animal-based studies and emerging
24 methods and models; and

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

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

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

19 “(B) beginning on the date that is 5 years
20 after the date of enactment of the Alan
21 Reinstein and Trevor Schaefer Toxic Chemical
22 Protection Act and every 5 years thereafter,
23 submit to Congress a report that describes the
24 progress made in implementing this subsection

1 and goals for future alternative test methods
2 implementation; and

3 “(C) to the extent practicable, fund and
4 carry out research, development, performance
5 assessment, and translational studies to accel-
6 erate the development of test methods and test-
7 ing strategies that reduce, refine, or replace the
8 use of mammals in any safety assessment or de-
9 termination made under section 6.

10 “(d) TESTING REQUIREMENTS.—

11 “(1) IN GENERAL.—The Administrator may re-
12 quire the following persons to develop information:

13 “(A) Manufacturers and processors of the
14 chemical substance or mixture.

15 “(B) Persons who begin to manufacture or
16 process such chemical substance or mixture—

17 “(i) after the effective date of the
18 rule, testing consent agreement, or order;
19 but

20 “(ii) subject to paragraph (3), not
21 later than 180 days after the completion of
22 the period for submitting information spec-
23 ified under subsection (a)(4)(A)(iv).

24 “(2) DESIGNATION.—The Administrator may
25 permit 2 or more of the persons identified in sub-

1 paragraphs (A) and (B) of paragraph (1) to des-
2 ignate a person or a qualified third party—

3 “(A) to develop the information; and

4 “(B) to submit the information on behalf
5 of the persons making the designation.

6 “(3) EXEMPTIONS.—

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

14 “(B) FAIR AND EQUITABLE REIMBURSE-
15 MENT TO DESIGNEE.—

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

24 “(ii) ARBITRATION.—If the applicant
25 and a person designated under paragraph

1 (2) cannot reach agreement on the amount
2 of fair and equitable reimbursement, the
3 amount shall be determined by arbitration.

4 “(C) TERMINATION.—If, after granting an
5 exemption under this paragraph, the Adminis-
6 trator determines that no person has complied
7 with the rule, testing consent agreement, or
8 order, the Administrator shall—

9 “(i) by order terminate the exemption;
10 and

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

15 “(e) TRANSPARENCY.—Subject to section 14, the Ad-
16 ministrators shall make available to the public all testing
17 consent agreements and orders under this section.”.

18 (b) CONFORMING AMENDMENTS.—Section
19 104(i)(5)(A) of the Comprehensive Environmental Re-
20 sponse, Compensation, and Liability Act of 1980 (42
21 U.S.C. 9604(i)(5)(A)) is amended by striking “section
22 4(e)” and inserting “section 4(f)”.

23 **SEC. 105. PRIORITIZATION SCREENING.**

24 The Toxic Substances Control Act (15 U.S.C. 2601
25 et seq.) is amended by adding after section 4 the following:

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

2 “(a) PRIORITIZATION SCREENING.—

3 “(1) IN GENERAL.—Not later than 1 year after
4 the date of enactment of the Alan Reinstein and
5 Trevor Schaefer Toxic Chemical Protection Act, the
6 Administrator shall by rule establish a screening
7 process and criteria for identifying existing chemical
8 substances that are—

9 “(A) a high priority for a safety assess-
10 ment and safety determination under section 6,
11 to be known as ‘high-priority substances’; and

12 “(B) a low priority for a safety assessment
13 and safety determination, to be known as ‘low-
14 priority substances’.

15 “(2) INITIAL LIST OF HIGH PRIORITY SUB-
16 STANCES.—Prior to promulgation of the rule estab-
17 lished under paragraph (1) and not later than 6
18 months after the date of enactment of the Alan
19 Reinstein and Trevor Schaefer Toxic Chemical Pro-
20 tection Act, the Administrator shall consider and
21 publish an initial list of high priority substances,
22 which shall contain not less than 15 chemical sub-
23 stances, and pursuant to sections 6(a) and 6(b)(2),
24 initiate or continue safety assessments and safety
25 determinations for such substances.

1 “(3) ADDITIONS TO PRIORITY LIST.—Starting 1
2 year after publication of the initial priority list under
3 paragraph (2) and at 1 year intervals thereafter for
4 the following 4 years, the Administrator shall add at
5 least 15 high-priority substances to the list and, pur-
6 suant to sections 6(a) and 6(b)(2), initiate or con-
7 tinue safety assessments and safety determinations
8 for those substances.

9 “(4) WORKPLAN AND ACTION PLAN CHEMI-
10 CALS.—The Administration may list as high-priority
11 substances under paragraphs (2) and (3) those
12 chemical substances or categories of chemical sub-
13 stances that are included in the Administrator’s
14 March 2012 Workplan (as updated in October 2014
15 and by subsequent updates) or are the subject of
16 Existing Chemical Action Plans published by the
17 Administrator before the date of enactment of the
18 Alan Reinstein and Trevor Schaefer Toxic Chemical
19 Protection Act without providing further justifica-
20 tion for listing or meeting the requirements of this
21 section.

22 “(5) IMPLEMENTATION.—

23 “(A) CONSIDERATION OF ACTIVE AND IN-
24 ACTIVE SUBSTANCES.—

1 “(i) CONSIDERATION OF ACTIVE SUB-
2 STANCES.—In implementing the process
3 described in paragraph (1), the Adminis-
4 trator shall consider active substances, as
5 determined under section 8, which may in-
6 clude substances on the interim list of ac-
7 tive substances established under that sec-
8 tion.

9 “(ii) CONSIDERATION OF INACTIVE
10 SUBSTANCES.—In implementing the proc-
11 ess described in paragraph (1), the Admin-
12 istrator may consider inactive substances,
13 as determined under section 8, that the
14 Administrator determines—

15 “(I)(aa) have not been subject to
16 a regulatory or other enforceable ac-
17 tion by the Administrator to ban or
18 phase out the substance; and

19 “(bb) have the potential for high
20 hazard and widespread exposure; or

21 “(II)(aa) have been subject to a
22 regulatory or other enforceable action
23 by the Administrator to ban or phase
24 out the substance; and

1 “(bb) there is the potential for
2 residual high hazards or widespread
3 exposures not otherwise addressed by
4 the regulatory or other action.

5 “(iii) REPOPULATION.—Upon the
6 completion of a safety determination under
7 section 6 for a chemical substance, the Ad-
8 ministrators shall remove the substance
9 from the list of high-priority substances.
10 The Administrator shall add not less than
11 1 chemical substance to the list of high-
12 priority substances for each chemical sub-
13 stance removed from the list, until a safety
14 assessment and safety determination is
15 completed for all active substances, except
16 that not less than 3 chemical substances
17 shall be added for each chemical substance
18 removed from the list, subject to section
19 21, when fees are in place.

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

22 “(i) IN GENERAL.—In addition to the
23 decisions required by paragraphs (1) and
24 (2), not later than 6 months after the ef-
25 fective date of the final rule under para-

1 graph (1), the Administrator shall begin
2 the prioritization screening process.

3 “(ii) DECISIONS ON SUBSTANCES SUB-
4 JECT TO TESTING FOR PRIORITIZATION
5 PURPOSES.—Not later than 120 days after
6 receipt of the information complying with a
7 rule, testing consent agreement, or order
8 issued under section 4(a)(2), the Adminis-
9 trator shall designate the substance as ei-
10 ther a high or low priority.

11 “(iii) CONSIDERATION.—The Admin-
12 istrator shall screen substances, taking
13 into consideration the requirement to meet
14 the deadlines under section 6 of this Act.

15 “(iv) ANNUAL GOAL.—The Adminis-
16 trator shall publish an annual goal for the
17 number of substances to be subject to the
18 prioritization screening process.

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

1 “(D) PUBLICATION OF LIST OF CHEMICAL
2 SUBSTANCES.—Not less frequently than annu-
3 ally, the Administrator shall—

4 “(i) publish a list of chemical sub-
5 stances being considered in the
6 prioritization screening process and their
7 status in the prioritization process, includ-
8 ing those substances for which a
9 prioritization decision has been deferred;
10 and

11 “(ii) publish a list of those substances
12 designated as high-priority and low-priority
13 substances and the basis for the designa-
14 tions.

15 “(6) CRITERIA.—The criteria described in para-
16 graph (1) shall include—

17 “(A) the recommendation of a Governor of
18 a State or a State agency with responsibility for
19 protecting health or the environment from
20 chemical substances appropriate for
21 prioritization screening, and the recommenda-
22 tions of the public;

23 “(B) the hazard of the chemical substance
24 (or category of substances), including specific

1 scientific classifications and designations by au-
2 thoritative governmental entities;

3 “(C) the intended or reasonably foreseeable
4 conditions of use of a chemical substance or sig-
5 nificant changes in the intended or reasonably
6 foreseeable conditions of use of the chemical
7 substance;

8 “(D) evidence and indicators of exposure
9 and potential exposure to humans or the envi-
10 ronment from the chemical substance including
11 potentially exposed or susceptible populations;

12 “(E) the volume of a chemical substance
13 manufactured or processed, and past and an-
14 ticipated future changes in volume;

15 “(F) whether the volume of a chemical
16 substance as reported under a regulation issued
17 under section 8(a) has significantly increased or
18 decreased since a previous report or since the
19 date on which a notice has been submitted
20 under section 5(a) for that chemical substance;

21 “(G) the availability of information about
22 potential hazards and exposures needed for con-
23 ducting a safety assessment or determination,
24 provided that limited availability of relevant in-

1 formation shall not be a sufficient basis for fail-
2 ing to designate a substance as a high priority;

3 “(H) the potential threat the chemical sub-
4 stance poses to drinking water supplies, based
5 on hazard, exposure, or exposure potential (in-
6 cluding whether the chemical substance is
7 stored near sources of drinking water);

8 “(I) the extent to which a chemical sub-
9 stance accumulates in the human body; and

10 “(J) other relevant criteria identified by
11 the Administrator.

12 “(b) PRIORITIZATION SCREENING PROCESS AND DE-
13 CISIONS.—

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

17 “(A) identify the chemicals being consid-
18 ered for prioritization;

19 “(B) request interested persons to supply
20 information on the substances being considered;

21 “(C) apply the criteria identified in sub-
22 section (a)(5); and

23 “(D) subject to paragraph (4) and using
24 the information available to the Administrator
25 at the time of the decision, identify a chemical

1 substance as a high-priority substance or a low-
2 priority substance.

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

5 “(A) shall identify as a high-priority sub-
6 stance a chemical substance that the Adminis-
7 trator determines has, or has the potential for,
8 significant hazard and significant or substantial
9 exposure;

10 “(B) may identify as a high-priority sub-
11 stance a chemical substance that the Adminis-
12 trator determines has, or has the potential for,
13 significant hazard or significant or substantial
14 exposure;

15 “(C) may identify as a high-priority sub-
16 stance an inactive substance, as determined
17 under section 8(b), that the Administrator de-
18 termines warrants a safety assessment and de-
19 termination under section 6; and

20 “(D) may identify as a high-priority sub-
21 stance a chemical substance that accumulates
22 in the body.

23 “(3) IDENTIFICATION OF LOW-PRIORITY SUB-
24 STANCES.—The Administrator shall identify as a

1 low-priority substance a chemical substance if the
2 Administrator—

3 “(A) concludes that sufficient hazard and
4 exposure information is available for an in-
5 formed evaluation of the substance’s risks to
6 human health and the environment;

7 “(B) determines, based on a review of the
8 information available, that the substance is like-
9 ly to meet the safety standard under the in-
10 tended or reasonably foreseeable conditions of
11 use; and

12 “(C) identifies the information on which
13 the determination is based and describes the
14 Administrator’s analysis of this information.

15 “(4) DEFERRING A DECISION.—If the Adminis-
16 trator determines that additional information is
17 needed to establish the priority of a chemical sub-
18 stance, the Administrator may defer the
19 prioritization screening decision for a reasonable pe-
20 riod to—

21 “(A) allow for the submission and evalua-
22 tion of additional information by an interested
23 person; or

1 “(B) require the development of informa-
2 tion pursuant to a rule, testing consent agree-
3 ment, or order issued under section 4(a)(2).

4 “(5) DEADLINES FOR SUBMISSION OF INFOR-
5 MATION.—If the Administrator requests the develop-
6 ment or submission of information under this sec-
7 tion, the Administrator shall establish a deadline for
8 submission of such information, which deadline shall
9 be of reasonable duration.

10 “(6) NOTICE AND COMMENT.—Except as pro-
11 vided in subsection (a)(4), the Administrator shall
12 publish the proposed decisions made under para-
13 graphs (2), (3) and (4) and the basis for the deci-
14 sions, and provide an opportunity for public com-
15 ment.

16 “(7) REVISION BASED ON NEW INFORMA-
17 TION.—The Administrator may, at any time, revise
18 the designation of a chemical substance as a high-
19 priority or a low-priority substance based on new in-
20 formation made available to the Administrator after
21 the date of the determination under paragraph (2)
22 or (3), following the procedures in this section.

23 “(8) REVIEW.—Not less frequently than once
24 every 5 years after the date on which the process
25 under this subsection is established, the Adminis-

1 trator shall review the process on the basis of experi-
2 ence and consider the resources available to effi-
3 ciently and effectively screen and prioritize sub-
4 stances, and if necessary modify the prioritization
5 screening process in a manner that complies with
6 this Act.

7 “(9) EFFECT.—Subject to section 18, a deci-
8 sion by the Administrator under this subsection with
9 respect to a chemical substance shall not be con-
10 strued to affect the manufacture, processing, dis-
11 tribution, use, or disposal of the chemical substance,
12 or regulation of those activities.

13 “(c) FINAL AGENCY ACTION.—Except for the des-
14 ignation of a substance as low priority under subsection
15 (b)(3), any action by the Administrator under this section
16 shall not be—

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

18 “(2) subject to judicial review.”.

19 **SEC. 106. NEW CHEMICALS AND SIGNIFICANT NEW USES.**

20 Section 5 (15 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) in subsection (a)(1), in the matter following
25 subparagraph (B)—

1 (A) by striking “subsection (d)” and in-
2 serting “subsection (b)”; and

3 (B) by striking “and such person complies
4 with any applicable requirement of subsection
5 (b)”;

6 (3) by striking subsection (b);

7 (4) by redesignating subsection (d) as sub-
8 section (b) and moving the subsection so as to ap-
9 pear after subsection (a);

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

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

13 “(1) IN GENERAL.—The notice required under
14 subsection (a) shall include, with respect to a chem-
15 ical substance—

16 “(A) the information required by sections
17 720.45 and 720.50 of title 40, Code of Federal
18 Regulations (or successor regulations); and

19 “(B) information regarding intended or
20 reasonably foreseeable conditions of use and
21 reasonably foreseeable exposures.”;

22 (B) in paragraph (2)—

23 (i) in the matter preceding subpara-
24 graph (A), by striking “or of data under
25 subsection (b)”;

1 (ii) in subparagraph (A), by adding
2 “and” after the semicolon at the end;
3 (iii) in subparagraph (B), by striking
4 “; and” and inserting a period; and
5 (iv) by striking subparagraph (C); and
6 (C) in paragraph (3), by striking “, (b),”;
7 (6) by striking subsection (e) and inserting the
8 following:

9 “(c) REVIEW OF NOTICE.—

10 “(1) INITIAL REVIEW.—

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

15 “(i) conduct an initial review of the
16 notice;

17 “(ii) as needed, develop a profile of
18 the relevant chemical substance and the
19 potential for exposure to humans and the
20 environment; and

21 “(iii) make any necessary determina-
22 tion under paragraph (3).

23 “(B) EXTENSION.—Except as provided in
24 paragraph (5), the Administrator may extend
25 the period described in subparagraph (A) for

1 good cause for 1 or more periods, the total of
2 which shall be not more than 90 days.

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

6 “(A) any relevant information identified in
7 subsection (b)(1); and

8 “(B) any other relevant information avail-
9 able to, or submitted to, the Administrator.

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

14 “(A) the relevant chemical substance or a
15 significant new use is not likely to meet the
16 safety standard, in which case the Adminis-
17 trator shall take appropriate action under para-
18 graph (5);

19 “(B) the relevant chemical substance or
20 significant new use is likely to meet the safety
21 standard, in which case the Administrator shall
22 allow the review period to expire without addi-
23 tional restrictions; or

24 “(C) additional information is necessary in
25 order to make a determination under subpara-

1 graph (A) or (B), in which case the Adminis-
2 trator shall take appropriate action under para-
3 graph (5).

4 “(4) RESTRICTIONS.—

5 “(A) IN GENERAL.—If the Administrator
6 makes a determination under paragraph (3)(A)
7 or (C) with respect to a notice submitted under
8 subsection (a), the Administrator shall before
9 the end of the applicable period for review
10 under paragraph (1) and by consent agreement
11 or order, as appropriate, prohibit or restrict the
12 manufacture, processing, use, distribution in
13 commerce, or disposal (as applicable) of the
14 chemical substance, or of the substance for a
15 significant new use without compliance with the
16 restrictions specified in the consent agreement
17 or order that the Administrator determines are
18 sufficient to ensure that the chemical substance
19 or significant new use is likely to meet the safe-
20 ty standard.

21 “(B) RULEMAKING.—Not later than 90
22 days after issuing a consent agreement or order
23 under subparagraph (A), the Administrator
24 shall—

1 “(i) consider whether to promulgate a
2 rule under subsection (a)(2) that identifies
3 as a significant new use any manufac-
4 turing, processing, use, distribution in
5 commerce, or disposal of the chemical sub-
6 stance, or of the chemical substance for a
7 new use that is not in compliance with the
8 restrictions imposed by the consent agree-
9 ment or order; and

10 “(ii)(I) initiate such rulemaking; or

11 “(II) publish a statement of the Ad-
12 ministrators’ reasons for not initiating
13 such action.

14 “(C) INCLUSIONS.—A prohibition, restric-
15 tion, or requirement under subparagraph (A)
16 shall include, as appropriate, 1 or more of the
17 following requirements:

18 “(i) A requirement that a chemical
19 substance or mixture or article containing
20 the substance be marked with, or accom-
21 panied by, clear and adequate warnings
22 and instructions with respect to use, dis-
23 tribution in commerce, or disposal, or any
24 combination of those activities, with the
25 form and content of the warnings and in-

1 instructions to be prescribed by the Adminis-
2 trator.

3 “(ii) A requirement that manufactur-
4 ers or processors, as applicable, of the
5 chemical substance or mixture make and
6 retain records of the processes used to
7 manufacture or process the chemical sub-
8 stance.

9 “(iii) A requirement that manufactur-
10 ers or processors, as applicable, monitor or
11 conduct such additional tests as are rea-
12 sonably necessary to address potential
13 risks from the manufacture, processing,
14 distribution in commerce, use, or disposal
15 of the chemical substance, subject to sec-
16 tion 4.

17 “(iv) A restriction on the quantity of
18 the chemical substance or a mixture or ar-
19 ticle containing the substance that may be
20 manufactured, processed, or distributed in
21 commerce.

22 “(v) A restriction on the quantity of
23 the chemical substance or a mixture or ar-
24 ticle containing the substance that may be

1 manufactured, processed, or distributed in
2 commerce—

3 “(I) for a particular use; or

4 “(II) for a particular use in a
5 concentration in excess of a level spec-
6 ified by the Administrator in the con-
7 sent agreement or order imposing the
8 requirement.

9 “(vi) A prohibition or other regulation
10 of the manufacture, processing, or dis-
11 tribution in commerce of the chemical sub-
12 stance or a mixture or article containing
13 the substance for a significant new use.

14 “(vii) A prohibition or other regula-
15 tion of any manner or method of commer-
16 cial use of the chemical substance or a
17 mixture or article containing the sub-
18 stance.

19 “(viii) A prohibition or other regula-
20 tion of any manner or method of disposal
21 of or environmental release of the chemical
22 substance or a mixture or article con-
23 taining the substance, by its manufacturer
24 or processor or by any other person who

1 uses, or disposes of it, for commercial pur-
2 poses.

3 “(ix) A prohibition or other appro-
4 priate restriction or requirement on the
5 manufacture, processing, or distribution in
6 commerce of the chemical substance or a
7 mixture or article containing the sub-
8 stance.

9 “(x) A prohibition or other appro-
10 priate restriction or requirement on the
11 manufacture, processing, or distribution in
12 commerce of the chemical substance or a
13 mixture or article containing the substance
14 for a particular use.

15 “(D) RULE OF CONSTRUCTION.—The re-
16 quirement, warning, or instruction required
17 under subparagraph (C) does not establish a
18 uniform national standard for the purpose of
19 supplanting, displacing, or preempting State
20 law.

21 “(E) WORKPLACE EXPOSURES.—The Ad-
22 ministrator shall consult with the Assistant Sec-
23 retary of Labor for Occupational Safety and
24 Health prior to adopting any prohibition or re-

1 restriction adopted under this subsection to ad-
2 dress workplace exposures.

3 “(5) ADDITIONAL INFORMATION.—If the Ad-
4 ministrator determines under paragraph (3)(C) that
5 additional information is needed in order to conduct
6 a review under this subsection, the Administrator—

7 “(A) shall provide an opportunity for the
8 submitter of the notice to submit such addi-
9 tional information;

10 “(B) may, by agreement with the sub-
11 mitter, extend the review period for a reason-
12 able time to allow the development and submis-
13 sion of the additional information;

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

18 “(D) shall, after receiving information the
19 Administrator finds supports the determination
20 under paragraph (3), promptly make the deter-
21 mination.

22 “(6) REGULATION PENDING DEVELOPMENT OF
23 INFORMATION.—Subject to paragraph (4)(B), the
24 Administrator may permit manufacture for commer-
25 cial purposes to commence pending receipt of the ad-

1 ditional information, subject to compliance with any
2 restrictions under paragraph (4) determined by the
3 Administrator to be sufficient to ensure that the
4 chemical substance is likely to meet the safety stand-
5 ard.

6 “(7) COMMENCEMENT OF MANUFACTURE.—
7 Subject to paragraphs (4), (5), and (6), at the end
8 of the applicable period for review under paragraph
9 (1)(A) the submitter of a notice under subsection (a)
10 may commence manufacture for commercial pur-
11 poses a chemical substance, or a chemical substance
12 for a significant new use.”;

13 (7) by striking subsections (e) through (g) and
14 inserting the following:

15 “(d) NOTICE OF COMMENCEMENT.—

16 “(1) IN GENERAL.—Not later than 30 days
17 after the date on which a manufacturer or processor
18 that has submitted a notice under subsection (a)
19 commences nonexempt commercial manufacture of a
20 chemical substance, the manufacturer or processor
21 shall submit to the Administrator a notice of com-
22 mencement that identifies—

23 “(A) the name of the manufacturer or
24 processor;

1 “(B) the initial date of nonexempt com-
2 mercial manufacture; and

3 “(C) additional information specified in
4 section 720.102(c)(1) of title 40, Code of Fed-
5 eral Regulations (or successor regulations).

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

11 “(e) FURTHER EVALUATION.—The Administrator
12 may screen a chemical substance under section 4A or re-
13 quire testing under section 4 at any time after the Admin-
14 istrator receives—

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

17 “(2) new information regarding the chemical
18 substance.

19 “(f) TRANSPARENCY.—Subject to section 14, the Ad-
20 ministrator shall make available to the public all notices,
21 determinations, consent agreements, rules and orders of
22 the Administrator issued under this section.”;

23 (8) by redesignating subsections (h) and (i) as
24 subsections (g) and (h), respectively;

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

1 (A) in paragraph (1), in the matter pre-
2 ceding subparagraph (A), by striking “or (b)”;

3 (B) by striking paragraph (2);

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

7 (D) in paragraph (2) (as so redesignated),
8 by striking “subsections (a) and (b)” and in-
9 serting “subsection (a)”;

10 (E) in paragraph (3) (as so redesignated),
11 in the first sentence, by striking “will not
12 present an unreasonable risk of injury to health
13 or the environment” and inserting “will meet
14 the safety standard”;

15 (F) in paragraph (4) (as so redesignated),
16 by striking “subsections (a) and (b)” and in-
17 serting “subsection (a)”;

18 (G) in paragraph (5) (as so redesignated),
19 in the first sentence, by striking “paragraph (1)
20 or (5)” and inserting “paragraph (1) or (4),”;
21 and

22 (10) by inserting after subsection (h) (as so re-
23 designated) the following:

24 “(i) PRIOR ACTIONS.—Nothing in this section re-
25 quires the Administrator to modify or withdraw any rule

1 or order promulgated under section 5 of this title prior
2 to the enactment of the Alan Reinstein and Trevor Schae-
3 fer Toxic Chemical Protection Act.”.

4 **SEC. 107. SAFETY ASSESSMENTS AND DETERMINATIONS.**

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

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

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

9 (2) by redesignating subsection (b) as sub-
10 section (m) and moving the subsection so as to ap-
11 pear after subsection (l) (as added by paragraph
12 (6));

13 (3) in subsection (m) (as so redesignated), by
14 striking “unreasonable” each place it appears and
15 inserting “significant”;

16 (4) by striking subsections (a), (c) and (d) and
17 inserting in lieu thereof the following, and by red-
18 ignating subsection (b) as subsection (i):

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

20 “(1) shall conduct a safety assessment and
21 make a safety determination of each high-priority
22 substance designated under section 4A in accordance
23 with subsections (b) and (c);

24 “(2) shall, when a safety determination con-
25 cludes that a substance does not meet the safety

1 standard, establish restrictions pursuant to sub-
2 section (d);

3 “(3) shall complete a safety assessment and
4 safety determination not later than 2 years after the
5 date on which a substance is designated as a high
6 priority;

7 “(4) shall promulgate a final rule pursuant to
8 subsection (d) not later than 2 years after the date
9 on which the safety determination is completed; and

10 “(5) may extend any deadline under this sub-
11 section for a reasonable period of time after an ade-
12 quate public justification, subject to the condition
13 that the aggregate length of all extensions of dead-
14 lines under paragraphs (3) and (4) of this sub-
15 section and any deferrals under subsection (c)(2)
16 does not exceed 2 years.

17 “(b) SAFETY ASSESSMENTS AND DETERMINA-
18 TIONS.—

19 “(1) IN GENERAL.—The Administrator shall
20 conduct a risk-based safety assessment and make a
21 risk-based safety determination of each high-priority
22 substance.

23 “(2) ALREADY INITIATED ASSESSMENTS.—

24 “(A) IN GENERAL.—Nothing in this Act
25 prevents the Administrator from initiating safe-

1 ty assessments and safety determinations of
2 chemical substances, or from continuing or
3 completing safety assessments and safety deter-
4 minations initiated prior to the date of enact-
5 ment of the Alan Reinstein and Trevor Schaefer
6 Toxic Chemical Protection Act, prior to the
7 date on which the policies and procedures the
8 Administrator is directed to establish under sec-
9 tion 3A and 4A are effective.

10 “(B) INTEGRATION.—As policies and pro-
11 cedures under section 3A and 4A are estab-
12 lished, the Administrator shall integrate them
13 into ongoing assessments and determinations to
14 the maximum extent practicable.

15 “(3) ACTIONS COMPLETED PRIOR TO COMPLE-
16 TION OF POLICIES AND PROCEDURES.—Nothing in
17 this Act requires the Administrator to revise or with-
18 draw a completed safety assessment, safety deter-
19 mination, or rule merely because such action was
20 completed prior to the completion of a policy or pro-
21 cedure established under section 3A or 4A, and the
22 validity of such assessment, determination, or rule
23 shall not be determined based on the content of such
24 policy or procedure.

25 “(c) SAFETY DETERMINATIONS.—

1 “(1) IN GENERAL.—Based on a review of the
2 information before the Administrator, including
3 draft safety assessments, if any, submitted by inter-
4 ested persons, the Administrator shall determine
5 that—

6 “(A) the relevant chemical substance meets
7 the safety standard;

8 “(B) the relevant chemical substance does
9 not meet the safety standard, in which case the
10 Administrator shall by rule under subsection
11 (d) impose restrictions necessary to assure that
12 the substance meets the safety standard under
13 the intended or reasonably foreseeable condi-
14 tions of use, or, where the safety standard can-
15 not be met with the application of restrictions,
16 to ban or phase out the substance, as appro-
17 priate; or

18 “(C) additional information is necessary in
19 order to make a safety determination under
20 subparagraph (A) or (B), in which case the Ad-
21 ministrator shall take appropriate action under
22 paragraph (2).

23 “(2) ADDITIONAL INFORMATION.—If the Ad-
24 ministrator determines that additional information is
25 needed in order to carry out a safety assessment and

1 safety determination for a high-priority substance,
2 the Administrator—

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

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

10 “(C) may defer, for a reasonable period
11 that complies with the deadlines in subsection
12 (a), a safety assessment and determination
13 until after receipt of the information; and

14 “(D) in compliance with the deadlines in
15 subsection (a), shall, upon receipt of informa-
16 tion the Administrator finds supports the as-
17 sessment and determination, make a determina-
18 tion under paragraph (1).

19 “(3) DEADLINE FOR SUBMISSION OF INFORMA-
20 TION.—When requesting the development or submis-
21 sion of information under this section the Adminis-
22 trator shall establish a deadline for the submission
23 of such information, which deadline shall be of rea-
24 sonable duration and shall comply with the deadlines
25 under subsection (a).

1 “(d) RULE.—

2 “(1) IMPLEMENTATION.—If the Administrator
3 makes a determination under subsection (c)(1)(B)
4 with respect to a chemical substance, the Adminis-
5 trator shall promulgate a rule establishing restric-
6 tions necessary to ensure that the chemical sub-
7 stance meets the safety standard.

8 “(2) SCOPE.—A rule promulgated under this
9 subsection—

10 “(A) may—

11 “(i) apply to a mixture or article con-
12 taining the chemical substance, as appro-
13 priate; and

14 “(ii) exempt a replacement part man-
15 ufactured prior to the applicable compli-
16 ance deadline; and

17 “(B) shall include dates by which compli-
18 ance is mandatory, which shall be as soon as
19 feasible and may vary for different affected per-
20 sons, as the Administrator determines to be ap-
21 propriate, but which shall be no later than 2
22 years after the date on which the rule is pro-
23 mulgated.

24 “(3) WORKPLACE EXPOSURES.—The Adminis-
25 trator shall consult with the Assistant Secretary of

1 Labor for Occupational Safety and Health prior to
2 adopting any prohibition or restriction adopted
3 under this subsection to address workplace expo-
4 sures.

5 “(4) RESTRICTIONS.—A restriction under para-
6 graph (1) shall include, as appropriate, 1 or more of
7 the following requirements:

8 “(A) A requirement that a chemical sub-
9 stance or a mixture or article containing the
10 substance be marked with, or accompanied by,
11 clear and adequate warnings and instructions
12 with respect to use, distribution in commerce,
13 or disposal, or any combination of those activi-
14 ties, with the form and content of the warnings
15 and instructions to be prescribed by the Admin-
16 istrator.

17 “(B) A requirement that manufacturers
18 and processors of the chemical substance or a
19 mixture or article containing the substance—

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

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

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

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

7 “(C) A restriction on the quantity of the
8 chemical substance or a mixture or article con-
9 taining the substance that may be manufac-
10 tured, processed, or distributed in commerce.

11 “(D) A requirement to ban or phase out or
12 other regulation on the manufacture, proc-
13 essing, distribution in commerce, use, or dis-
14 posal of the chemical substance or a mixture or
15 article containing the substance—

16 “(i) for a particular use;

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

20 “(iii) for all uses.

21 “(E) A restriction on the quantity of the
22 chemical substance or mixture or article con-
23 taining the substance that may be manufac-
24 tured, processed, or distributed in commerce—

25 “(i) for a particular use; or

1 “(ii) for a particular use at a con-
2 centration in excess of a level specified by
3 the Administrator.

4 “(F) A requirement to restrict, ban, or
5 phase out or other regulation of any manner or
6 method of commercial use or environmental re-
7 lease of the chemical substance or mixture or
8 article containing the substance.

9 “(G) A requirement to restrict, ban, or
10 phase out or other regulation of any manner or
11 method of disposal of the chemical substance or
12 any mixture or article containing the chemical
13 substance, by its manufacturer or processor or
14 by any person who uses, or disposes of it, for
15 commercial purposes, provided that such a re-
16 quirement may not require any person to take
17 any action that would be in violation of any law
18 or requirement of, or in effect for, a State or
19 political subdivision, and that such a require-
20 ment shall require each person subject to the
21 requirement to notify each State and political
22 subdivision in which a required disposal may
23 occur of such disposal.

24 “(H) A requirement directing manufactur-
25 ers or processors of the chemical substance or

1 mixture or article containing the substance to
2 give notice of significant risks of harm (without
3 taking into consideration cost or other non-risk
4 factors) to distributors in commerce of the
5 chemical substance and, to the extent reason-
6 ably ascertainable, to other persons in the chain
7 of commerce in possession of the chemical sub-
8 stance or mixture, and to give public notice of
9 such significant risks of harm.

10 “(5) RULE OF CONSTRUCTION.—The require-
11 ment, warning, or instruction, under paragraph (4)
12 does not establish a uniform national standard for
13 the purpose of supplanting, displacing, or pre-
14 empting State law.

15 “(6) ANALYSIS FOR RULEMAKING.—

16 “(A) IN GENERAL.—Where the Adminis-
17 trator determines that a rule under paragraph
18 (1) is likely to have an annual effect on the
19 economy of more than \$100,000,000, then
20 when deciding which restrictions to impose
21 under paragraph (3) as part of developing a
22 rule under paragraph (1) to ensure that a
23 chemical substance meets the safety standard,
24 the Administrator shall consider, to the extent
25 practicable based on reasonably available infor-

1 mation, the quantifiable and non-quantifiable
2 costs and benefits of the proposed regulatory
3 action and of the primary alternative regulatory
4 action or actions that the Administrator deter-
5 mines will ensure that the substance meets the
6 safety standard. As part of the analysis, the
7 Administrator shall review such technically and
8 economically feasible alternative or alternatives
9 to the chemical substance that the Adminis-
10 trator determines are relevant to the rule-
11 making;

12 “(B) PUBLIC DISCLOSURE OF ANALYSIS.—
13 When proposing a rule under paragraph (1),
14 the Administrator shall make publicly available
15 any analysis conducted under subparagraph
16 (A).

17 “(C) CONSIDERATION OF ANALYSIS.—
18 When making final a rule under paragraph (1),
19 the Administrator shall include a statement de-
20 scribing how the analysis considered under sub-
21 paragraph (A) was taken into account.

22 “(7) EXEMPTIONS.—

23 “(A) IN GENERAL.—The Administrator, as
24 part of a rulemaking under this subsection—

1 “(i) may exempt a use of a chemical
2 substance from any restriction in a rule
3 promulgated under paragraph (1) if the
4 Administrator determines, based on rea-
5 sonably available information, that the rule
6 cannot be complied with without—

7 “(I) harming national security;

8 “(II) causing significant disrup-
9 tion in the national economy due to
10 the lack of availability of a chemical
11 substance for the exempted use; or

12 “(III) interfering with a critical
13 or essential use for which no tech-
14 nically and economically feasible safer
15 alternative is available, considering
16 hazard and exposure; and

17 “(ii) may exempt a particular use of a
18 chemical substance from a restriction in a
19 rule issued under paragraph (1) if avail-
20 able information demonstrates that the
21 risks to health or the environment from
22 continued use of the substance are sub-
23 stantially lower than the risks to health or
24 the environment of replacing that use of

1 the substance with reasonably available al-
2 ternatives.

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

9 “(C) CONSIDERATION OF ANALYSIS.—
10 When making final a rule under paragraph (1)
11 that includes an exemption under this para-
12 graph, the Administrator shall include a state-
13 ment describing how the analysis was taken
14 into account.

15 “(D) CONDITIONS.—As part of a rule
16 issued under paragraph (1), the Administrator
17 shall include conditions in any exemption estab-
18 lished under this paragraph, including reason-
19 able recordkeeping, monitoring, and reporting
20 requirements, to the extent that the Adminis-
21 trator determines the conditions are necessary
22 to protect human health and the environment
23 while achieving the purposes of the exemption.

24 “(E) DURATION.—

1 “(i) IN GENERAL.—The Administrator
2 shall, as part of a rule under paragraph
3 (1) that contains an exemption under this
4 paragraph, set a time limit on any exemp-
5 tion not to exceed 5 years.

6 “(ii) EXTENSION.—The Administrator
7 may, by rule, extend, modify, or eliminate
8 the exemption when the Administrator de-
9 termines, on the basis of reasonably avail-
10 able information and after adequate public
11 justification, the exemption warrants ex-
12 tension or is no longer necessary.

13 “(iii) CONSIDERATION FOR EXTEN-
14 SION.—The Administrator shall issue ex-
15 emptions and establish time periods under
16 this subparagraph by considering factors
17 determined by the Administrator as rel-
18 evant to the goals of fostering innovation
19 and the development of alternatives that
20 meet the safety standard.

21 “(iv) EXCEPTION FOR RULE REQUIR-
22 ING BAN OR PHASE OUT.—Any renewal of
23 an exemption in the case of a rule requir-
24 ing the ban or phase out of a chemical
25 substance shall not exceed 5 years.

1 “(e) IMMEDIATE EFFECT.—The Administrator may
2 declare a proposed rule under subsection (d) of this section
3 to be effective upon publication of the proposed rule in
4 the Federal Register and until the effective date of a final
5 action taken respecting such rule if—

6 “(1) the Administrator determines that—

7 “(A) the manufacture, processing, distribu-
8 tion in commerce, use, or disposal of the chem-
9 ical substance or mixture subject to such pro-
10 posed rule or any combination of such activities
11 is likely to result in a significant risk of serious
12 or widespread injury (without taking into con-
13 sideration cost or other non-risk factors) to
14 health or the environment before such effective
15 date; and

16 “(B) making the proposed rule effective is
17 necessary to protect the public interest; and

18 “(2) in the case of a proposed rule to prohibit
19 the manufacture, processing, or distribution of a
20 chemical substance or mixture because of the risk
21 determined under paragraph (1)(A), a court has in
22 an action under section 7 of this title granted relief
23 with respect to the risk associated with the sub-
24 stance or mixture.

25 “(f) EXPEDITED ACTION ON PBTs.—

1 “(1) LIST OF PBTS.—In addition to carrying
2 out section 4A, not later than 180 days after the
3 date of enactment of the Alan Reinstein and Trevor
4 Schaefer Toxic Chemical Protection Act, the Admin-
5 istrator shall publish a list of chemical substances
6 that the Administrator determines are persistent,
7 bio-accumulative, and toxic and have the potential
8 for high or widespread exposure (referred to in this
9 subsection as ‘PBTs’).

10 “(2) USE AND EXPOSURE ASSESSMENT.—

11 “(A) IN GENERAL.—Not later than 60
12 days after publishing the PBT list required
13 under paragraph (1), the Administrator shall
14 require by order the submission by manufactur-
15 ers or processors of chemical substances in-
16 cluded in the list of any additional information
17 the Administrator determines to be necessary to
18 conduct an expedited assessment of the in-
19 tended, known, or reasonably foreseeable uses
20 of, and exposures to, such chemical substances.

21 “(B) PUBLICATION.—Not later than 1
22 year after receiving the information which man-
23 ufacturers and processors are required to sub-
24 mit under subparagraph (A), the Administrator
25 shall complete and publish an identification and

1 assessment of the intended or reasonably fore-
2 seeable conditions of use of, and exposures to,
3 substances on the PBT list.

4 “(3) EXPOSURE REDUCTION.—

5 “(A) RULE.—As soon as practicable, but
6 not later than 2 years after the date on which
7 the Administrator completes the use and expo-
8 sure assessment required under paragraph (2),
9 the Administrator shall impose, by rule, restric-
10 tions that the Administrator determines to be
11 necessary to achieve the maximum practicable
12 reduction in human or environmental exposure
13 to chemical substances included in the PBT
14 list.

15 “(B) CONTENTS OF RULES.—A rule pro-
16 mulgated under subparagraph (A) may include
17 any of the restrictions on manufacturing, proc-
18 essing, use, distribution in commerce, and dis-
19 posal described in subsection (d)(4) which the
20 Administrator determines are necessary to
21 achieve maximum practicable reduction in expo-
22 sure to the listed PBT substance.

23 “(C) EFFECTIVE DATE.—A rule promul-
24 gated under subparagraph (A) shall include an
25 effective date in accordance with subsection

1 (d)(2)(B) and may be made effective upon pub-
2 lication of a proposed rule in accordance with
3 subsection (f).

4 “(4) EXEMPTIONS.—

5 “(A) SCOPE AND BASIS.—A rule imposing
6 a restriction on a listed PBT substance in ac-
7 cordance with subparagraph (3) may exempt a
8 use of the substance from such restriction upon
9 a showing satisfactory to the Administrator
10 that the use meets the exemption criteria in
11 subsection (d)(7).

12 “(B) CONDITIONS.—The Administrator
13 shall include conditions in any exemption estab-
14 lished under this paragraph, including reason-
15 able recordkeeping, monitoring, and reporting
16 requirements, to the extent necessary to protect
17 health or the environment while achieving the
18 purposes of the exemption.

19 “(C) DURATION.—An exemption estab-
20 lished under this paragraph shall be in effect
21 for a period determined by the Administrator
22 but not to exceed 5 years and, after public no-
23 tice and an opportunity for comment, may be
24 renewed by the Administrator for 1 or more pe-
25 riods not exceeding a total of 5 years by order

1 following submission of an application justifying
2 the continuing need for the exemption and con-
3 taining such information as the Administrator
4 may require.

5 “(g) REPORT ON PUBLIC BUILDINGS.—Not later
6 than 6 months after the date of enactment of the Alan
7 Reinstein and Trevor Schaefer Toxic Chemical Protection
8 Act, the Administrator shall submit to Congress a report
9 on how data on exposure in public buildings will be gath-
10 ered to carry out subsection (f) and on what testing is
11 necessary to protect the public from exposures to chemical
12 substances identified under subsection (f) in public build-
13 ings.

14 “(h) FINAL AGENCY ACTION.—Under this section—

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

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

1 final agency action on the date of promulgation of
2 the final rule.”;

3 (5) by redesignating subsections (e) and (f) as
4 subsections (i) and (j), respectively; and

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

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

7 (B) by redesignating paragraph (5) as
8 paragraph (4); and

9 (7) by inserting after subsection (j)(as so redesi-
10 gnated) the following:

11 “(k) PRIOR ACTIONS.—Nothing in this section shall
12 be construed as requiring the Administrator to modify or
13 withdraw any rule or order promulgated under section 6
14 of this title promulgated prior to the enactment of the
15 Alan Reinstein and Trevor Schaefer Toxic Chemical Pro-
16 tection Act.”.

17 “(l) ASBESTOS.—

18 “(1) LISTING.—The Administrator shall include
19 all forms of asbestos as 1 high-priority chemical sub-
20 stance under section 4A(a)(2) in accordance with
21 section 4A(a)(4).

22 “(2) SCHEDULE.—Notwithstanding paragraphs
23 (3), (4) and (5) of subsection (a), the Administrator
24 shall—

1 “(A) complete a safety assessment and
2 safety determination of all forms of asbestos
3 not later than 2 years after the date of enact-
4 ment of the Alan Reinstein and Trevor Schaefer
5 Toxic Chemical Protection Act; and

6 “(B) promulgate a final rule not later than
7 3 years after the date of enactment of that
8 Act.”.

9 **SEC. 108. IMMINENT HAZARDS.**

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

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

13 “(a) CIVIL ACTIONS.—

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

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

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

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

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

7 “(A) the existence of—

8 “(i) a decision by the Administrator
9 under section 4, 5(c)(6), 6(c)(2) or 6(h); or

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

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

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

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

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

22 **SEC. 109. INFORMATION COLLECTION AND REPORTING.**

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

24 (1) in subsection (a), by adding at the end the
25 following:

1 “(4) REGULATIONS.—

2 “(A) DEADLINE.—

3 “(i) IN GENERAL.—Not later than 2
4 years after the date of enactment of the
5 Alan Reinstein and Trevor Schaefer Toxic
6 Chemical Protection Act, the Adminis-
7 trator shall promulgate rules requiring the
8 maintenance of records and the reporting
9 of information known by, or reasonably as-
10 certainable by, the person making the re-
11 port, including rules requiring processors
12 to report information, so that the Adminis-
13 trator has the information necessary to
14 carry out sections 4 and 6.

15 “(ii) PRIOR REGULATIONS.—In car-
16 rying out this subparagraph, the Adminis-
17 trator may modify, as appropriate, the reg-
18 ulations promulgated prior to the date of
19 enactment of the Alan Reinstein and
20 Trevor Schaefer Toxic Chemical Protection
21 Act.

22 “(B) CONTENTS.—The rules promulgated
23 under subparagraph (A)—

1 “(i) may impose different reporting
2 and record retention requirements on man-
3 ufacturers and processors;

4 “(ii) shall include the level of detail
5 necessary to be reported, including the
6 manner by which use and exposure infor-
7 mation may be reported; and

8 “(iii) shall require reporting of infor-
9 mation or maintenance of records where
10 the Administrator determines the submis-
11 sion of reports would assist in the effective
12 implementation of this Act.

13 “(C) ADMINISTRATION.—In implementing
14 this paragraph, the Administrator shall take
15 measures to—

16 “(i) limit the potential for duplication
17 in reporting requirements;

18 “(ii) minimize the impact of the rules
19 on small manufacturers and processors;
20 and

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

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

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

7 “(3) CHEMICAL SUBSTANCES IN COMMERCE.—

8 “(A) RULE.—

9 “(i) IN GENERAL.—Not later than 1
10 year after the date of enactment of the
11 Alan Reinstein and Trevor Schaefer Toxic
12 Chemical Protection Act, the Adminis-
13 trator shall by rule require manufacturers
14 and processors to notify the Administrator,
15 not later than 180 days after the date of
16 promulgation of the rule, of each chemical
17 substance on the list published under para-
18 graph (1) that the manufacturer or proc-
19 essor, as applicable, has manufactured or
20 processed for a nonexempt commercial pur-
21 pose during the 10-year period prior to the
22 date of enactment of the Alan Reinstein
23 and Trevor Schaefer Toxic Chemical Pro-
24 tection Act.

1 “(ii) CONSIDERATION AS ACTIVE SUB-
2 STANCE.—The Administrator shall con-
3 sider chemical substances for which notices
4 are received under clause (i) to be active
5 substances and shall, pursuant to para-
6 graph (4)(C), designate the chemical sub-
7 stance as an active substance on the list
8 published under paragraph (1).

9 “(B) CONFIDENTIAL CHEMICAL SUB-
10 STANCES.—

11 “(i) IN GENERAL.—The Administrator
12 shall maintain the list under paragraph
13 (1), which shall include a confidential por-
14 tion and a nonconfidential portion con-
15 sistent with this section and section 14;

16 “(ii) EXISTING CLAIM OF CONFIDEN-
17 TIALITY.—The rule promulgated under
18 subparagraph (A) shall require a manufac-
19 turer or processor that is submitting a no-
20 tice pursuant to subparagraph (A) for a
21 chemical substance on the confidential por-
22 tion of the list published under paragraph
23 (1) to indicate in the notice whether the
24 manufacturer or processor seeks to main-
25 tain any existing claim for protection

1 against disclosure of the specific identity of
2 the substance as confidential pursuant to
3 section 14.

4 “(iii) SUBSTANTIATION.—The rule
5 promulgated under subparagraph (A) shall
6 require the substantiation of a claim de-
7 scribed in clause (ii) pursuant to section
8 14 and in accordance with the review plan
9 described in subparagraph (C).

10 “(C) REVIEW PLAN AND REQUIRE-
11 MENTS.—

12 “(i) IN GENERAL.—Not later than 1
13 year after the date on which the Adminis-
14 trator compiles the initial list of active sub-
15 stances pursuant to subparagraph (A), the
16 Administrator shall develop a plan to re-
17 view all claims to protect the specific iden-
18 tity of a chemical substance on the con-
19 fidential portion of the list published under
20 paragraph (1) that is identified as an ac-
21 tive substance in a report submitted pursu-
22 ant to subparagraph (A) or identified as
23 active substances under paragraph (4)(A).

1 “(ii) CONTENTS.—The plan shall de-
2 scribe how the Administrator will carry out
3 the requirements of this subparagraph.

4 “(iii) REQUIREMENTS.—The Adminis-
5 trator shall —

6 “ (I) require, at a time deter-
7 mined by the Administrator, all man-
8 ufacturers or processors asserting a
9 claim under subparagraph (B) to sub-
10 stantiate each such claim unless the
11 manufacturer or processor has sub-
12 stantiated the claim in a submission
13 made to the Administrator within 5
14 years of the date of the Administra-
15 tor’s request;

16 “(II) in accordance with the re-
17 quirements of section 14, —

18 “(aa) review each substan-
19 tiation—

20 “(AA) submitted pursu-
21 ant to subclause (I) to deter-
22 mine if the claim warrants
23 protection from disclosure;
24 and

1 “(BB) submitted pre-
2 viously by a manufacturer or
3 processor and relied on in
4 lieu of the substantiation re-
5 quired pursuant to subclause
6 (I), if such substantiation
7 has not been previously re-
8 viewed by the Administrator,
9 to determine if the claim
10 warrants protection from
11 disclosure;

12 “(bb) approve, modify or
13 deny each claim; and

14 “(cc) except as provided in
15 this section and section 14, pro-
16 tect from disclosure information
17 for which the Administrator ap-
18 proves such a claim for a period
19 of 10 years unless—

20 “(AA) prior to the expi-
21 ration of the period, the per-
22 son notifies the Adminis-
23 trator that the person is
24 withdrawing the confiden-
25 tiality claim, in which case,

1 the Administrator shall
2 promptly make the informa-
3 tion available to the public;
4 or

5 “(BB) prior to the ex-
6 piration of the period, the
7 Administrator otherwise be-
8 comes aware that the need
9 for protection from dislo-
10 sure can no longer be sub-
11 stantiated, in which case the
12 Administrator shall take the
13 actions described in sub-
14 section (g)(2); and

15 “(III) encourage manufacturers
16 and processors that have previously
17 made claims to protect the specific
18 identities of chemical substances iden-
19 tified as inactive pursuant to para-
20 graph (4)(B) to review and either
21 withdraw or substantiate such claims.

22 “(D) TIMELINE FOR COMPLETION OF RE-
23 VIEWS.—

24 “(i) IN GENERAL.—The Administrator
25 shall complete reviews of all claims speci-

1 fied in subparagraph (C) not later than 5
2 years after the date on which the Adminis-
3 trator compiles the initial list of active sub-
4 stances pursuant to subparagraph (A).

5 “(ii) EXTENSION.—The Administrator
6 may extend the deadline for completion of
7 the reviews described in subparagraph (C)
8 for up to a maximum of 2 additional years,
9 after an adequate public justification, if
10 the Administrator finds the extension is
11 necessary based on the number of such
12 claims needing review and the available re-
13 sources.

14 “(iii) ANNUAL GOAL.—The Adminis-
15 trator shall publish an annual goal for the
16 number of reviews to be completed over the
17 course of implementation of the plan.

18 “(E) NO CONFIDENTIALITY FOR UNLISTED
19 CHEMICALS.—The specific identity of any chem-
20 ical that is not on the confidential portion of
21 the list published under paragraph (1) or subse-
22 quently added to the confidential portion of the
23 list pursuant to section 14 shall not be eligible
24 for protection from disclosure.

1 “(F) CERTIFICATION.—The Administrator
2 shall require a manufacturer or processor—

3 “(i) to certify the accuracy of each re-
4 port submitted or record maintained under
5 this section; and

6 “(ii) to retain documentation sup-
7 porting certification under clause (i) for a
8 period of 5 years beginning on the last day
9 of the submission period.

10 “(4) ACTIVE AND INACTIVE SUBSTANCES.—

11 “(A) ACTIVE SUBSTANCES.—For the pur-
12 poses of this section, the term ‘active substance’
13 means a chemical substance that—

14 “(i) has been manufactured or proc-
15 essed for a nonexempt commercial purpose
16 at any point during the 10-year period
17 prior to the date of enactment of the Alan
18 Reinstein and Trevor Schaefer Toxic
19 Chemical Protection Act; or

20 “(ii) that is added to the list pub-
21 lished under paragraph (1) after the date
22 of enactment of the Alan Reinstein and
23 Trevor Schaefer Toxic Chemical Protection
24 Act.

1 “(B) INACTIVE SUBSTANCES.—For pur-
2 poses of this section, the term ‘inactive sub-
3 stance’ means a chemical substance on the list
4 published under paragraph (1) that does not
5 meet any of the criteria in subparagraph (A).

6 “(C) LIST OF DESIGNATIONS.—The Ad-
7 ministrator shall maintain and keep current
8 designations of active and inactive substances
9 on the list published under paragraph (1).

10 “(D) UPDATE.—The Administrator shall
11 update the list of chemicals designated as active
12 as soon as practicable following the publication
13 of the most recent data reported under part
14 711 of title 40, Code of Federal Regulations,
15 and the rule promulgated under subsection
16 (a)(4).

17 “(E) CHANGE TO ACTIVE STATUS.—

18 “(i) IN GENERAL.—Any person who
19 intends to manufacture or process for a
20 nonexempt commercial purpose a chemical
21 substance that is designated as an inactive
22 substance shall notify the Administrator
23 not less than 90 days before the date on
24 which the substance is manufactured or
25 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 chemical substance on
6 the confidential portion of the list
7 published under paragraph (1) seeks
8 to maintain an existing claim for pro-
9 tection against disclosure of the spe-
10 cific identity of the 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) substantiate the claim.

16 “(II) NO CONFIDENTIALITY FOR
17 UNLISTED CHEMICALS.—The specific
18 identity of any inactive chemical that
19 is not on the confidential portion of
20 the list published under paragraph (1)
21 or subsequently added to the confiden-
22 tial portion of the list pursuant to sec-
23 tion 14 shall not be eligible for protec-
24 tion from disclosure.

1 “(iii) ACTIVE STATUS.—After receiv-
2 ing notification under clause (i), the Ad-
3 ministrators shall—

4 “(I) designate the chemical sub-
5 stance as an active substance;

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

13 “(III) except as provided in this
14 section and section 14, protect from
15 disclosure information for which the
16 Administrator approves a claim under
17 subclause (II) for a period of 10 years
18 unless—

19 “(aa) prior to the expiration
20 of the 10-year period, the person
21 notifies the Administrator that
22 the person is withdrawing the
23 confidentiality claim, in which
24 case, the Administrator shall

1 promptly make the information
2 available to the public; or

3 “(bb) prior to the expiration
4 of the 10-year period, the Admin-
5 istrator otherwise becomes aware
6 that the need for protection from
7 disclosure can no longer be sub-
8 stantiated, in which case the Ad-
9 ministrator shall take the actions
10 described in subsection (g)(2);
11 and

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

16 “(F) CATEGORY STATUS.—The list of inac-
17 tive chemical substances shall not be considered
18 a category for purposes of section 26(c).

19 “(5) INTERIM LIST OF ACTIVE SUBSTANCES.—
20 Prior to the promulgation of the rule required under
21 this subsection, the Administrator shall designate
22 those substances reported under Part 711 of title
23 40, Code of Federal Regulations, during the report-
24 ing period that most closely preceded the date of en-
25 actment of the Alan Reinstein and Trevor Schaefer

1 Toxic Chemical Protection Act, as the initial list of
2 active substances for the purposes of section 4A.

3 “(6) PUBLIC PARTICIPATION.—The Adminis-
4 trator shall make available to the public—

5 “(A) the specific identity of each chemical
6 substance on the nonconfidential portion of the
7 list published under paragraph (1) that the Ad-
8 ministrator has designated as an active sub-
9 stance;

10 “(B) the specific identity of each chemical
11 substance on the nonconfidential portion of the
12 list published under paragraph (1) that the Ad-
13 ministrator has designated as an inactive sub-
14 stance;

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

22 “(D) subject to section 14, the specific
23 identity of any active substance—

1 “(i) for which no claim of protection
2 against disclosure of the specific identity
3 pursuant to this subsection was received;

4 “(ii) for which a claim for protection
5 against disclosure of the specific identity of
6 the substance has been denied by the Ad-
7 ministrator; or

8 “(iii) for which the time period for
9 protection against disclosure of the specific
10 identity of the substance has expired; and

11 “(E) any substance previously classified as
12 an inactive substance that has been reclassified
13 as an active substance.”; and

14 (3) in subsection (e)—

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

17 “(1) IN GENERAL.—Any person”; and

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

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

1 **SEC. 110. RELATIONSHIP TO OTHER FEDERAL LAWS.**

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

3 (1) in subsection (a)—

4 (A) in the first sentence of paragraph

5 (1)—

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

10 (ii) by striking “such risk” the first
11 place it appears and inserting “the risk
12 posed by the substance or mixture”;

13 (B) in paragraph (2), in the matter fol-
14 lowing subparagraph (B), by striking “section 6
15 or 7” and inserting “subsections (b) or (c) of
16 section 6, or section 7”; and

17 (C) in paragraph (3), by striking “section
18 6 or 7” and inserting “section 6(d) or section
19 7”; and

20 (2) in subsection (d), in the first sentence, by
21 striking “Health, Education, and Welfare” and in-
22 serting “Health and Human Services”.

1 **SEC. 111. RESEARCH, DEVELOPMENT, COLLECTION, DIS-**
2 **SEMINATION, AND UTILIZATION OF DATA.**

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

6 **SEC. 112. EXPORTS.**

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

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

10 “(2) EXCEPTION.—Paragraph (1) shall not
11 apply to any chemical substance, mixture, or article
12 that the Administrator determines—

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

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

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

20 “(A) determine that paragraph (1) shall
21 not apply to the mixture or article if the Ad-
22 ministrator finds that the chemical substance as
23 contained in the mixture or article will meet the
24 safety standard; and

25 “(B) establish a threshold concentration of
26 the chemical substance in a mixture or article

1 at which paragraph (1) shall not apply if the
2 Administrator finds that at or below this con-
3 centration the substance as contained in the ar-
4 ticle or mixture will meet the safety standard.

5 “(4) TESTING.—The Administrator may re-
6 quire testing under section 4 of any chemical sub-
7 stance or mixture exempted from this Act by para-
8 graph (1) for the purpose of determining whether or
9 not the substance or mixture meets the safety stand-
10 ard within the United States.”;

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

13 “(b) NOTICE.—

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

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

24 “(B) a chemical substance or a mixture
25 containing a chemical substance that the Ad-

1 administrator has determined under section 6
2 does not meet the safety standard and for
3 which a notification, prohibition, or restriction
4 has been proposed or established under that
5 section;

6 “(C) a chemical substance for which the
7 United States is obligated by treaty to provide
8 export notification;

9 “(D) a chemical substance or mixture sub-
10 subject to a prohibition or restriction pursuant to
11 a rule, order, or consent agreement in effect
12 under this Act;

13 “(E) a chemical substance or mixture for
14 which the submission of information is required
15 under section 4; or

16 “(F) a chemical substance or mixture con-
17 taining a chemical substance with respect to
18 which an action is pending, or relief has been
19 granted under section 7.

20 “(2) REGULATIONS.—

21 “(A) IN GENERAL.—The Administrator
22 shall promulgate regulations to carry out para-
23 graph (1).

24 “(B) CONTENTS.—The regulations pro-
25 mulgated under subparagraph (A) shall include

1 any exemptions the Administrator determines
2 to be appropriate, which may include exemp-
3 tions identified under section 5(g).

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

7 “(A) for a chemical substance or mixture
8 described in paragraph (1)(E), a notice of avail-
9 ability of the information on the chemical sub-
10 stance or mixture submitted to the Adminis-
11 trator;

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

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

21 (3) in subsection (c)—

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

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

1 **SEC. 113. IMPORTS.**

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

4 **“SEC. 13. IMPORTS.**

5 “(a) REFUSAL OF ENTRY.—

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

13 “(A) the Administrator—

14 “(i) has determined under section 6(c)
15 that the chemical substance, mixture or ar-
16 ticle does not meet the safety standard;
17 and

18 “(ii) has promulgated a rule under
19 section 6(d) banning the chemical sub-
20 stance, mixture, or article, as of the effec-
21 tive date of the rule;

22 “(B) the chemical substance—

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

25 “(ii) is not exempt from any require-
26 ment to be included on the list under sec-

1 signee in the 90-day period beginning on
2 the date of receipt of the notice of the re-
3 fused entry.

4 “(B) EXCEPTION.—

5 “ (i) IN GENERAL.—The Secretary of
6 Homeland Security may, pending a review
7 by the Administrator, release to the con-
8 signee the chemical substance or mixture if
9 the consignee—

10 “ (I) executes a bond for the
11 amount of the full invoice of the
12 chemical substance or mixture (as set
13 forth in the customs entry); and

14 “ (II) pays a duty on the chemical
15 substance or mixture.

16 “(ii) ADMINISTRATION.—If a con-
17 signee fails to return a chemical substance
18 or mixture released to that consignee
19 under clause (i) for any cause to the cus-
20 tody of the Secretary of Homeland Secu-
21 rity when demanded, the consignee shall be
22 liable to the United States for liquidated
23 damages equal to the full amount of the
24 bond.

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

9 “(b) CERTIFICATION.—

10 “(1) IN GENERAL.—A person offering a chem-
11 ical substance or mixture subject to this Act for
12 entry into the customs territory of the United States
13 shall certify to the Secretary of Homeland Security
14 that the chemical substance or mixture is in compli-
15 ance with any applicable rule, consent agreement, or
16 order under section 5 or 6, and that the chemical
17 substance—

18 “(A) is included on the list under section
19 8(b)(1); or

20 “(B) is exempt from any requirement to be
21 included on the list under section 8(b)(1) by
22 this title or a rule issued by the Administrator
23 under this title.

24 “(2) ARTICLES.—The Administrator may, by
25 rule, require certification under paragraph (1) for an

1 article containing a chemical substance or mixture
2 that is subject to regulation under section 5 or 6.

3 “(3) CONTENT OF CERTIFICATION RULE.—In
4 determining the need for and content of a certifi-
5 cation rule under this subsection, the Administrator
6 may consider—

7 “(A) the utility of such certification to the
8 enforcement of the applicable rule, consent
9 agreement, or order under section 5 or 6;

10 “(B) the frequency of the certification re-
11 quirement; and

12 “(C) if applicable, specification of the con-
13 centration of a chemical substance in an article
14 that would subject the article to the certifi-
15 cation requirement.

16 “(4) PUBLIC INFORMATION.—For purposes of
17 this section, the Administrator shall provide publicly
18 accessible information on the identity of a chemical
19 substance or mixture subject to regulation under
20 this Act that would be readily understood in import
21 transactions.

22 “(c) NOTICE.—A person offering a chemical sub-
23 stance for entry into the customs territory of the United
24 States shall notify the Secretary of Homeland Security
25 if—

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

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

7 “(3) the chemical substance or chemical sub-
8 stance in a mixture is the subject of a safety assess-
9 ment and safety determination conducted pursuant
10 to section 6(d) and has been found not to meet the
11 safety standard.

12 “(d) RULES.—

13 “(1) IN GENERAL.—The Secretary of Homeland
14 Security, after consultation with the Administrator,
15 shall issue rules for the administration of this sec-
16 tion.

17 “(2) CONTENT.—A rule issued under para-
18 graph (1) may tailor the application of any require-
19 ment in this section, as appropriate for the efficient
20 and effective implementation of this Act.”.

21 **SEC. 114. CONFIDENTIAL INFORMATION.**

22 Section 14 (15 U.S.C. 2613) is amended—

23 (1) by striking the heading “**DISCLOSURE OF**
24 **DATA**” and inserting “**CONFIDENTIAL INFORMA-**
25 **TION**”;

1 (2) by striking subsection (c) and redesignating
2 subsection (b) as subsection (c);

3 (3) by striking subsection (a) and inserting the
4 following:

5 **“SEC. 14. CONFIDENTIAL INFORMATION.**

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

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

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

15 “(b) INFORMATION GENERALLY PROTECTED FROM
16 DISCLOSURE.—

17 “(1) IN GENERAL.—The information described
18 in paragraph (2) specific to and submitted by a
19 manufacturer, processor, or distributor that meets
20 the requirements of subsection (d) shall be protected
21 from disclosure, except that—

22 “(A) such information may be disclosed in
23 accordance with subsection (e);

1 “(B) such information is subject to the re-
2 view and substantiation requirements in sub-
3 section (f)(2); and

4 “(C) nothing in this Act shall operate to
5 prohibit the disclosure of such information
6 through discovery, subpoena, other court or-
7 ders, or any other judicial process otherwise al-
8 lowed under applicable state or Federal laws.

9 “(2) PROTECTED INFORMATION.—Information
10 subject to paragraph (1) shall include—

11 “(A) specific information describing the
12 processes used in manufacture or processing of
13 a chemical substance, mixture, or article;

14 “(B) marketing and sales plans and strate-
15 gies;

16 “(C) information identifying suppliers or
17 customers;

18 “(D) the percentages of the components of
19 a mixture;

20 “(E) specific information about the use,
21 function, or application of a chemical substance
22 or mixture in a process, mixture, or product;

23 “(F) specific production or import volumes
24 of the manufacturer, and specific aggregated
25 volumes across manufacturers if the Adminis-

1 trator determines that disclosure of the specific
2 aggregated volumes would reveal confidential
3 information; and

4 “(G) except as otherwise provided in this
5 section, the specific identity of a chemical sub-
6 stance prior to the date on which it was in-
7 cluded on the list under section 8(b)(1), includ-
8 ing the chemical name, molecular formula,
9 Chemical Abstracts Service number, and other
10 information that would identify a specific chem-
11 ical substance, if—

12 “(i) the specific identity was claimed
13 as confidential information at the time it
14 was submitted to the Administrator in a
15 notice under section 5;

16 “(ii) the claim has not subsequently
17 been withdrawn or found by the Adminis-
18 trator not to warrant protection as con-
19 fidential information under subsection (e),
20 (f)(2), or (g); and

21 “(iii) the substance is not an active
22 substance under section 8(b)(4) of this
23 Act.”;

24 (4) by striking the heading “DATA FROM
25 HEALTH AND SAFETY STUDIES” in subsection (c)

1 (as so redesignated) and inserting “INFORMATION
2 NOT PROTECTED FROM DISCLOSURE.—Notwith-
3 standing subsections (a) and (b), the following infor-
4 mation shall not be protected from disclosure:”;

5 (5) by inserting at the end of subsection (c) (as
6 so redesignated) the following:

7 “(3) OTHER INFORMATION NOT PROTECTED
8 FROM DISCLOSURE.—Information shall not be pro-
9 tected from disclosure under this section if it is—

10 “(A) for information submitted after the
11 date of enactment of the Alan Reinstein and
12 Trevor Schaefer Toxic Chemical Protection Act,
13 the specific identity of a chemical substance as
14 of the date on which it is included on the list
15 under section 8(b)(1), if the person submitting
16 the information does not meet the requirements
17 of subsection (d);

18 “(B) a safety assessment developed or a
19 safety determination made under section 6;

20 “(C) general information describing the
21 manufacturing volumes, expressed as specific
22 aggregated volumes or, when the Administrator
23 determines that disclosure of specific aggre-
24 gated volumes would reveal confidential infor-
25 mation, expressed in ranges; or

1 “(D) general descriptions of the processes
2 used in manufacture or processing and indus-
3 trial, commercial, or consumer functions and
4 uses of a chemical substance, mixture, or article
5 containing a chemical substance or mixture, in-
6 cluding information specific to an industry or
7 industry sector that would be customarily
8 shared with the general public or within an in-
9 dustry or industry sector.

10 “(4) EXCEPTION.—Information elements that
11 are otherwise eligible for protection under this sec-
12 tion that are contained in submissions of informa-
13 tion described in paragraph (1) shall be protected
14 from disclosure if the submitter complies with sub-
15 section (d), but information in such submissions de-
16 scribed in paragraph (1) that is not eligible for pro-
17 tection against disclosure shall be disclosed.

18 “(5) NO CONFIDENTIALITY FOR UNLISTED
19 CHEMICALS.—Except as provided in the second sen-
20 tence of paragraph (1), the specific identity of any
21 chemical that is not on the confidential portion of
22 the list published under section 8(b)(1) or subse-
23 quently added to the confidential portion of the list
24 pursuant to this section shall not be eligible for pro-
25 tection from disclosure.

1 “(6) BAN OR PHASE-OUT.—If the Adminis-
2 trator promulgates a rule pursuant to section 6(d)
3 that establishes a ban or phase out on the manufac-
4 ture, processing, or distribution in commerce of a
5 chemical substance, any protection from disclosure
6 provided under section 14 applicable for information
7 on the chemical substance shall no longer apply and
8 the Administrator shall promptly make the informa-
9 tion public.

10 “(d) REQUIREMENTS FOR CONFIDENTIALITY
11 CLAIMS.—

12 “(1) ASSERTION OF CLAIMS.—

13 “(A) IN GENERAL.—A person seeking to
14 protect any information submitted under this
15 Act from disclosure (including information de-
16 scribed in subsection (b)) shall assert a claim
17 for such protection to the Administrator at the
18 time of the submission of the information, pur-
19 suant to rules applicable to a claim for protec-
20 tion from disclosure that the Administrator has
21 promulgated under this title.

22 “(B) CONTENTS OF CLAIM.—An assertion
23 of a claim under subparagraph (A) shall include
24 a statement that the person has —

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

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

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

12 “(iv) a reasonable basis to believe that
13 the information is not readily otherwise
14 publicly available or discoverable through
15 reverse engineering.

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

1 “(i) the generic name conforms with
2 guidance prescribed by the Administrator
3 under paragraph (3)(A); and

4 “(ii) describes the chemical structure
5 of the substance as specifically as possible
6 while protecting those features of the
7 chemical structure that are considered con-
8 fidential and the disclosure of which would
9 potentially harm the competitive position
10 of the person.

11 “(2) ADDITIONAL REQUIREMENTS FOR CON-
12 FIDENTIALITY CLAIMS.—Except for information de-
13 scribed in subsection (b)(2), a person asserting a
14 claim to protect information from disclosure under
15 this Act shall, in accordance with the rules promul-
16 gated and guidance issued by the Administrator,
17 substantiate that the information meets the require-
18 ments for protection pursuant to section 552 of title
19 5, United States Code, under subsection (b)(4) of
20 that section.

21 “(3) GUIDANCE.—The Administrator shall de-
22 velop guidance on—

23 “(A) the determination of structurally de-
24 scriptive generic names, in the case of claims

1 for the protection against disclosure of specific
2 chemical identity; and

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

6 “(4) CERTIFICATION.—An authorized official of
7 the person described in paragraph (1)(A) shall cer-
8 tify that the statements and information included in
9 assertions and substantiations of claims for protec-
10 tion submitted under this subsection are true and
11 correct.

12 “(e) EXCEPTIONS TO PROTECTION FROM DISCLO-
13 SURE.—Information described in subsection (a) (including
14 information subject to subsection (b)) shall be disclosed
15 if—

16 “(1) the information is to be disclosed to an of-
17 ficer or employee of the United States in connection
18 with the official duties of that person under any law
19 for the protection of human health or the environ-
20 ment or for specific law enforcement purposes;

21 “(2) the information is to be disclosed to a con-
22 tractor with the United States and employees of that
23 contractor if, in the opinion of the Administrator,
24 the disclosure is necessary for the satisfactory per-
25 formance by the contractor of a contract with the

1 United States for the performance of work in con-
2 nection with this Act and under such conditions as
3 the Administrator shall specify;

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

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

11 “(A) 1 or more applicable agreements with
12 the Administrator that conform with the guid-
13 ance issued under subsection (d)(3)(B) ensure
14 that the recipient government will take appro-
15 priate steps, and has adequate authority, to
16 maintain the confidentiality of the information
17 in accordance with procedures comparable to
18 those which the Administrator uses to safe-
19 guard the information; and

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

24 “(5) a health or environmental professional em-
25 ployed by a Federal or State agency or a treating

1 physician or nurse in a nonemergency situation pro-
2 vides a written statement of need and agrees to sign
3 a written confidentiality agreement with the Admin-
4 istrator that conforms with the guidance issued
5 under subsection (d)(3)(B), subject to the conditions
6 that—

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

10 “(i) the information is necessary for
11 or will assist in diagnosis or treatment of
12 1 or more individuals or in responding to
13 an environmental release or exposure; and

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

19 “(B) the confidentiality agreement pro-
20 vides that the person will not use the informa-
21 tion for any purpose other than the health or
22 environmental needs asserted in the statement
23 of need, except as may otherwise be authorized
24 by the terms of the agreement or by the person
25 submitting the information to the Adminis-

1 trator, except that nothing in this Act shall op-
2 erate to prohibit the disclosure of such informa-
3 tion through discovery, subpoena, and other
4 court orders, or any other judicial process oth-
5 erwise allowed under applicable state or Federal
6 laws;

7 “(6) in the event of an emergency, a treating
8 physician, nurse, agent of a poison control center,
9 public health or environmental official of a State or
10 political subdivision of a State, or first responder re-
11 quests the information, subject to the conditions
12 that—

13 “(A) the treating physician, nurse, agent,
14 public health or environmental official of a
15 State or a political subdivision of a State, or
16 first responder has a reasonable basis to sus-
17 pect that—

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

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

23 “(iii) 1 or more individuals being di-
24 agnosed or treated have likely been ex-
25 posed to the chemical substance concerned,

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

4 “(B) if requested by the person submitting
5 the information to the Administrator, the treat-
6 ing physician, nurse, agent, public health or en-
7 vironmental official of a State or a political sub-
8 division of a State, or first responder provides
9 a written statement of need and agrees to sign
10 a confidentiality agreement as described in
11 paragraph (5); and

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

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

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

25 “(9) the information is publicly available; or

1 “(10) the information is required to be dis-
2 closed or otherwise made public under any other
3 Federal law.

4 “(f) DURATION OF PROTECTION FROM DISCLO-
5 SURE.—

6 “(1) IN GENERAL.—

7 “(A) INFORMATION PROTECTED FROM DIS-
8 CLOSURE.—Subject to paragraph (2) and ex-
9 cept as allowed under subsection (e), the Ad-
10 ministrator shall protect from disclosure infor-
11 mation that meets the requirements of sub-
12 section (d) for a period of 10 years, unless—

13 “(i) prior to the expiration of the 10-
14 year period, the person notifies the Admin-
15 istrator that the person is withdrawing the
16 confidentiality claim, in which case, the
17 Administrator shall promptly make the in-
18 formation available to the public;

19 “(ii) prior to the expiration of the 10-
20 year period, the Administrator otherwise
21 becomes aware that the need for protection
22 from disclosure can no longer be substan-
23 tiated, in which case the Administrator
24 shall take the actions described in sub-
25 section (g)(2); or

1 “(iii) the Administrator denies the
2 claim under subsection (g)(1).

3 “(B) EXTENSIONS.—

4 “(i) IN GENERAL.—Not less than 60
5 days prior to the expiration of the period
6 described in subparagraph (A), the Admin-
7 istrator shall provide notice of the impend-
8 ing expiration of the period to the person
9 who asserted the claim.

10 “(ii) SUBMISSION TO REASSERT A
11 CLAIM.—Not less than 30 days prior to ex-
12 piration of the period described in subpara-
13 graph (A), the person reasserting the claim
14 shall submit a statement substantiating, in
15 accordance with subsection (d)(2), the
16 need to extend the period.

17 “(iii) REVIEW.—Not later than 30
18 days of receipt of the statement described
19 in clause (ii), the Administrator shall

20 “(I) review the request and make
21 a determination as to whether the in-
22 formation for which the request is
23 made continues to meet the relevant
24 criteria established in this section; and

1 “(II)(aa) grant an extension not
2 to exceed 10 years; or

3 “(bb) deny the claim.

4 “(C) LIMIT ON NUMBER OF EXTEN-
5 SIONS.—There shall be no limit on the number
6 of extensions granted under subparagraph (B)
7 as long as the Administrator finds that the sub-
8 stantiation establishes the need to extend the
9 period and meets the requirements established
10 by the Administrator, and that the length of
11 any extension does not exceed 10 years.

12 “(2) REVIEW AND RESUBSTANTIATION.—

13 “(A) IN GENERAL.—The Administrator
14 may at any time review a claim for protection
15 against disclosure under subsection (a) for in-
16 formation submitted to the Administrator on a
17 chemical substance (including information de-
18 scribed in subsection (b)(2)), and may require
19 any person who has claimed protection for that
20 information, whether before or after the date of
21 enactment of the Alan Reinstein and Trevor
22 Schaefer Toxic Chemical Protection Act, to
23 withdraw or reassert and substantiate or re-
24 substantiate the claim in conformance with the
25 requirements of this section—

1 “(i) after the chemical substance is
2 identified as a high-priority substance
3 under section 4A;

4 “(ii) for any chemical substance for
5 which the Administrator has made a deter-
6 mination under section 6(c)(1)(B) or (C);

7 “(iii) for any inactive chemical sub-
8 stance identified pursuant to section
9 8(b)(4);

10 “(iv) if the Administrator determines
11 that disclosure of certain information cur-
12 rently protected from disclosure would as-
13 sist the Administrator in conducting safety
14 assessments and determinations under sec-
15 tion 6(b) and (c) or promulgating rules
16 under section 6(d);

17 “(v) if necessary to comply with a re-
18 quest for information the Administrator re-
19 ceives pursuant to section 552 of title 5,
20 United States Code;

21 “(vi) if information available to the
22 Administrator provides a basis that the re-
23 quirements of subsection (b)(4) of section
24 552 of title 5, United States Code, are no
25 longer met; or

1 “(vii) for information contained in a
2 notice of substantial risk submitted under
3 section 8(e).

4 “(B) RESUBSTANTIATION.—If the Admin-
5 istrator makes a request under subparagraph
6 (A), the person receiving the request shall—

7 “(i) resubstantiate the claim; or

8 “(ii) withdraw the claim.

9 “(C) EXTENSION.—Protection from disclo-
10 sure of the information subject to a claim that
11 is reviewed and approved by the Administrator
12 under this paragraph shall be extended for a
13 period of 10 years from the date of approval,
14 subject to any subsequent request by the Ad-
15 ministrator under this paragraph.

16 “(3) UNIQUE IDENTIFIER.—The Administrator
17 shall—

18 “(A) develop a system to assign a unique
19 identifier to each specific chemical identity for
20 which the Administrator approves a request for
21 protection from disclosure, other than a specific
22 chemical identity or structurally descriptive ge-
23 neric term, and apply such identifier consist-
24 ently to all information relevant to such sub-
25 stance;

1 “(B) annually publish and update a list of
2 substances for which claims to protect specific
3 chemical identity from disclosure have been ap-
4 proved, referred to by unique identifier, includ-
5 ing the expiration date for each such claim;

6 “(C) ensure that any nonconfidential infor-
7 mation received by the Administrator with re-
8 spect to such a substance during the period of
9 protection from disclosure is made public and
10 identifies the substance using the unique identi-
11 fier; and

12 “(D) for each claim for protection of spe-
13 cific chemical identity that has been denied by
14 the Administrator, upon expiration of the pe-
15 riod for appeal under subsection (g)(3), that
16 has expired, or that has been withdrawn by the
17 submitter, provide public access to the specific
18 chemical identity clearly linked to all noncon-
19 fidential information received by the Adminis-
20 trator with respect to the substance.

21 “(g) DUTIES OF THE ADMINISTRATOR.—

22 “(1) DETERMINATION.—

23 “(A) IN GENERAL.—Except as provided in
24 subsection (b), the Administrator shall, subject
25 to subparagraph (C), not later than 90 days

1 after the receipt of a claim under subsection
2 (d), and not later than 30 days after the receipt
3 of a request for extension of a claim under sub-
4 section (f), review and approve, modify, or deny
5 the claim or request.

6 “(B) DENIAL OR MODIFICATION.—

7 “(i) IN GENERAL.—Except as pro-
8 vided in subsections (e) and (f), the Ad-
9 ministrator shall deny a claim to protect a
10 chemical identity from disclosure only if
11 the person who has submitted the claim
12 fails to meet the requirements of sub-
13 sections (a) and (d).

14 “(ii) REASONS FOR DENIAL OR MODI-
15 FICATION.—The Administrator shall pro-
16 vide to the person who has submitted the
17 claim a written statement of the reasons
18 for the denial or modification of the claim.

19 “(C) SUBSETS.—The Administrator
20 shall—

21 “(i) except for claims described in
22 subsection (b)(7), review all claims under
23 this section for the protection against dis-
24 closure of the specific identity of a chem-
25 ical substance; and

1 “(ii) review a representative subset,
2 comprising at least 25 percent, of all other
3 claims for protection against disclosure.

4 “(D) EFFECT OF FAILURE TO ACT.—The
5 failure of the Administrator to make a decision
6 on a claim for protection against disclosure or
7 extension under this section shall not be the
8 basis for denial or elimination of a claim for
9 protection against disclosure.

10 “(2) NOTIFICATION.—

11 “(A) IN GENERAL.—Except as provided in
12 subparagraph (B) and subsections (c), (e), and
13 (f), if the Administrator denies or modifies a
14 claim under paragraph (1), the Administrator
15 shall notify, in writing and by certified mail, the
16 person who submitted the claim of the intent of
17 the Administrator to release the information.

18 “(B) RELEASE OF INFORMATION.—

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

1 “(ii) EXCEPTIONS.—

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

15 “(II) NO NOTIFICATION.—For
16 information under paragraph (1), (2),
17 (6), (7), (9) or (10) of subsection (e),
18 no prior notification is necessary.

19 “(3) APPEALS.—

20 “(A) IN GENERAL.—A person who receives
21 a notification under paragraph (2) may, if the
22 person believes disclosure of the information is
23 prohibited under subsection (a), before the date
24 on which the information is to be released,

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

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

7 “(ii) the United States District Court
8 for the District of Columbia.

9 “(B) NO DISCLOSURE.—The Adminis-
10 trator shall not disclose any information that is
11 the subject of an appeal under this section prior
12 to the date on which the applicable court rules
13 on an action under subparagraph (A).

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

18 “(h) CRIMINAL PENALTY FOR WRONGFUL DISCLO-
19 SURE.—

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

24 “(A) by virtue of that employment or offi-
25 cial position has obtained possession of, or has

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

3 “(B) knowing that disclosure of that mate-
4 rial is prohibited by subsection (a), willfully dis-
5 closes the material in any manner to any person
6 not entitled to receive that material, shall be
7 guilty of a misdemeanor and fined under title
8 18, United States Code, imprisoned for not
9 more than 1 year, or both.

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

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

21 “(i) APPLICABILITY.—

22 “(1) Except as otherwise provided by this sec-
23 tion, section 8, or any other Federal law, the Admin-
24 istrator shall have no authority—

1 “(A) to require the substantiation or re-
2 substantiation of a claim for the protection
3 from disclosure of information submitted to the
4 Administrator under this Act prior to the date
5 of enactment of the Alan Reinstein and Trevor
6 Schaefer Toxic Chemical Protection Act; or

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

11 “(2) PRIOR ACTIONS.—Nothing in this Act pre-
12 vents the Administrator from reviewing, requiring
13 substantiation or resubstantiation for, or approving,
14 modifying or denying any claim for the protection
15 from disclosure of information prior to the effective
16 date of rules applicable to such claims that the Ad-
17 ministrator may promulgate after the date of enact-
18 ment of the Alan Reinstein and Trevor Schaefer
19 Toxic Chemical Protection Act.

20 “(j) DEFINITION OF FIRST RESPONDER.—For the
21 purposes of this section, the term ‘first responder’ means
22 a person duly authorized by a State or political subdivision
23 of a State or a Federal agency, trained in urgent medical
24 care or other emergency procedures, including a police of-
25 ficer, firefighter, or emergency medical technician.”.

1 **SEC. 115. PROHIBITED ACTS.**

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

4 “(1) fail or refuse to comply with—

5 “(A) any rule promulgated, consent agree-
6 ment entered into, or order issued under section
7 4;

8 “(B) any requirement prescribed by section
9 5 or 6;

10 “(C) any rule promulgated, consent agree-
11 ment entered into, or order issued under section
12 5 or 6;

13 “(D) any requirement of title II or any
14 rule promulgated or order issued under title II;
15 or

16 “(E) any requirement of title VI or any
17 rule promulgated or order issued under title
18 VI;”.

19 **SEC. 116. PENALTIES.**

20 Section 16 (15 U.S.C. 2615) is amended—

21 (1) in subsection (a)—

22 (A) in paragraph (1)—

23 (i) in the first sentence—

24 (I) by inserting “this Act or a
25 rule or order promulgated or issued

1 pursuant to this Act, as described in”
2 after “a provision of”; and

3 (II) by striking “\$25,000” and
4 inserting “\$37,500”; and

5 (ii) in the second sentence, by striking
6 “violation of section 15 or 409” and in-
7 serting “violation of this Act”; and

8 (2) in subsection (b)—

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

11 “(1) IN GENERAL.—Any person”;

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

14 (C) by striking “\$25,000” and inserting
15 “\$50,000”; and

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

17 “(2) IMMINENT DANGER OF DEATH OR SERIOUS
18 BODILY INJURY.—Any person who knowingly or will-
19 fully violates any provision of this Act, and who
20 knows at the time of the violation that the violation
21 places another person in imminent danger of death
22 or serious bodily injury shall be subject, upon convic-
23 tion, to a fine of not more than \$250,000, imprison-
24 ment for not more than 15 years, or both. Any per-
25 son committing such violation which is an organiza-

1 tion shall, upon conviction under this paragraph, be
2 subject to a fine of not more than \$1,000,000 for
3 each violation.

4 “(3) KNOWLEDGE OF IMMINENT DANGER OR
5 INJURY.—In determining whether a defendant knew
6 that the violation placed another person in imminent
7 danger of death or serious bodily injury, the defend-
8 ant is responsible only for actual awareness or ac-
9 tual belief possessed, and knowledge possessed by
10 another person that is not the defendant may not be
11 attributed to the defendant.”.

12 **SEC. 117. PREEMPTION.**

13 Section 18 (15 U.S.C. 2617) is amended—

14 (1) in paragraph (a)(1), by striking “(1) Except
15 as provided in paragraph (2), nothing” and inserting
16 “Nothing”;

17 (2) by striking paragraph (a)(2); and

18 (3) by striking subsection (b) and inserting the
19 following:

20 “(b) SAVINGS.—

21 “(1) NO PREEMPTION OF COMMON LAW OR
22 STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF
23 OR CRIMINAL CONDUCT.—Nothing in this Act, nor
24 any amendment made by this Act, nor any regula-
25 tion, requirement, standard of performance, safety

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

7 “(2) CLARIFICATION OF NO PREEMPTION.—
8 Notwithstanding any other provision in this Act,
9 nothing in this Act, nor any amendments made by
10 this Act, shall preempt or preclude any cause of ac-
11 tion for personal injury, wrongful death, property
12 damage, or other injury based on negligence, strict
13 liability, products liability, failure to warn, or any
14 other legal theory of liability under any state, mari-
15 time, or Federal common law or statutory theory.

16 “(3) NO EFFECT ON PRIVATE REMEDIES.—

17 “(A) IN GENERAL.—Nothing in this Act,
18 nor any amendments made by this Act, nor any
19 rules, regulations, requirements, safety assess-
20 ments, safety determinations, scientific assess-
21 ments, or orders issued pursuant to this Act
22 shall be interpreted as, in either the plaintiff’s
23 or defendant’s favor, dispositive in any civil ac-
24 tion.

1 “(B) NO EFFECT ON AUTHORITY OF
2 COURT.—This Act does not affect the authority
3 of any court to make a determination in an ad-
4 judicatory proceeding under applicable State or
5 Federal law with respect to the admission into
6 evidence or any other use of this Act or rules,
7 regulations, requirements, standards of per-
8 formance, safety assessments, scientific assess-
9 ments, or orders issued pursuant to this Act.

10 “(4) NO PREEMPTION OF STATE LAWS.—Noth-
11 ing in this Act, nor any amendment made by this
12 Act, nor any regulation, requirement, standard of
13 performance, safety determination, or scientific as-
14 sessment implemented pursuant to this Act, shall af-
15 fect the right of a State or a political subdivision of
16 a State to adopt or enforce any regulation, require-
17 ment, standard of performance, safety determina-
18 tion, scientific assessment, or any protection for
19 public health or the environment that is different
20 from, or in addition to, any regulation, requirement,
21 standard of performance, safety determination, or
22 scientific assessment implemented pursuant to this
23 Act.”.

24 **SEC. 118. JUDICIAL REVIEW.**

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

1 (1) in subsection (a)—

2 (A) in subparagraph (1)(A), by striking
3 “section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8,
4 or under title II or IV” and inserting “section
5 4(a), 5(c)(4), 6(d), or 8”;

6 (B) in subparagraph (1)(B), by striking
7 “subparagraph (A)” and inserting “paragraph
8 (1)”; and

9 (C) by striking paragraph (3); and
10 (2) in subsection (c)—

11 (A) in subparagraph (1)(B), by striking
12 clauses (i) and (ii) and the last sentence of the
13 subparagraph;

14 (B) by redesignating paragraph (1)(B)(iii)
15 as paragraph (1)(B)(i); and

16 (C) in paragraph (1)(B)(i) as so redesign-
17 ated), by striking “(I) any statement required
18 to be made pursuant to section 6(c)(1) of this
19 title, or (II)”.

20 **SEC. 119. CITIZENS’ PETITIONS.**

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

22 (1) in subsection (a), by striking “an order
23 under section 5(e)” and inserting “an order under
24 section 4, 5(c),”; and

25 (2) in subsection (b)—

1 (A) in paragraph (1), by striking “an
2 order under section 5(e)” and inserting “an
3 order under section 4, 5(c),”; and

4 (B) in paragraph (4), by striking subpara-
5 graph (B) and inserting the following:

6 “(B) DE NOVO PROCEEDING.—

7 “(i) IN GENERAL.—In an action
8 under subparagraph (A) to initiate a pro-
9 ceeding to issue a rule under section 4,
10 5(c), 6(d), or 8 or an order issued under
11 section 4 or 5(c), the petitioner shall be
12 provided an opportunity to have the peti-
13 tion considered by the court in a de novo
14 proceeding.

15 “(ii) DEMONSTRATION.—

16 “(I) IN GENERAL.—The court
17 shall order the Administrator to ini-
18 tiate the action requested by the peti-
19 tioner if the petitioner demonstrates
20 to the satisfaction of the court by a
21 preponderance of the evidence that—

22 “(aa) in the case of a peti-
23 tion to initiate a proceeding for
24 the issuance of a rule or order
25 under section 4, the information

1 available to the Administrator is
2 insufficient for the Administrator
3 to perform an action described in
4 section 4, 4A, or 6(b);

5 “(bb) in the case of a peti-
6 tion to issue an order under sec-
7 tion 5(c), there is a reasonable
8 basis to conclude that the sub-
9 stance is not likely to meet the
10 safety standard;

11 “(cc) in the case of a peti-
12 tion to initiate a proceeding for
13 the issuance of a rule under sec-
14 tion 6(d), there is a reasonable
15 basis to conclude that the sub-
16 stance will not meet the safety
17 standard; or

18 “(dd) in the case of a peti-
19 tion to initiate a proceeding for
20 the issuance of a rule under sec-
21 tion 8, there is a reasonable basis
22 to conclude that the rule is nec-
23 essary to require reporting or
24 recordkeeping to obtain informa-
25 tion relevant to determining

1 whether a substance or mixture
2 may fail to meet the safety
3 standard.

4 “(II) DEFERMENT.—The court
5 may permit the Administrator to defer
6 initiating the action requested by the
7 petitioner until such time as the court
8 prescribes if the court finds that—

9 “(aa) the extent of the risk
10 to human health or the environ-
11 ment alleged by the petitioner is
12 less than the extent of risks to
13 human health or the environment
14 with respect to which the Admin-
15 istrator is taking action under
16 this Act; and

17 “(bb) there are insufficient
18 resources available to the Admin-
19 istrator to take the action re-
20 quested by the petitioner.”.

21 **SEC. 120. STUDIES.**

22 Section 25 (15 U.S.C. 2624) is repealed.

23 **SEC. 121. ADMINISTRATION.**

24 Section 26(e) (15 U.S.C. 2625(e)) is amended—

1 (1) by striking “Health, Education, and Wel-
2 fare” each place it appears and inserting “Health
3 and Human Services”; and

4 (2) by striking subsection (b) and inserting—
5 “(b) FEES.—

6 “(1) IN GENERAL.—The Administrator shall,
7 by rule, require manufacturers of chemical sub-
8 stances to pay reasonable fees to defray the costs of
9 administering this title, including but not limited to
10 costs resulting from—

11 “(A) issuing rules and orders to conduct
12 testing under section 4 and reviewing data sub-
13 mitted under these requirements;

14 “(B) developing the priority list and desig-
15 nating substances as high-priority under section
16 4A;

17 “(C) reviewing notices submitted under
18 section 5;

19 “(D) conducting safety assessments and
20 making safety determinations under section 6;

21 “(E) promulgating rules and issuing orders
22 to restrict chemical substances under section 6;

23 “(F) promulgating rules and issuing orders
24 to report information and data and maintain
25 records under section 8; and

1 “(G) reviewing confidentiality claims under
2 section 14.

3 “(2) APPORTIONMENT.—

4 “(A) IN GENERAL.—The Administrator
5 shall apportion fees among individual manufac-
6 turers in relation to the costs of administering
7 this title which are attributable to each manu-
8 facturer’s production or importation of chemical
9 substances subject to action under sections 4,
10 4A, 5, 6 and 8.

11 “(B) MULTIPLE MANUFACTURERS.—If
12 there is more than 1 manufacturer of such sub-
13 stance, the Administrator shall provide for the
14 sharing of fees in proportion to each manufac-
15 turer’s contribution to total production of such
16 substance, unless there is some other basis for
17 apportionment that better reflects consider-
18 ations of hazard and exposure.

19 “(3) SMALL BUSINESS CONCERNS.—The rule
20 promulgated under paragraph (1) may set separate
21 fees for manufacturers of chemical substances that
22 are small business concerns based on their ability to
23 pay.

24 “(4) LIMITATION.—Fees collected under this
25 subsection shall only be used to defray the costs of

1 administering this title and not for any other pur-
2 pose.”.

3 “(5) LEVEL OF FEES.—The Administrator shall
4 ensure that fees are set at a level sufficient to enable
5 the Administrator to perform all of the responsibil-
6 ities described in paragraph (1) and add not less
7 than 3 chemical substances to the list of high-pri-
8 ority substances for each chemical substance re-
9 moved from the list under section 4A(a)(5)(iii) and
10 to complete safety assessments and determinations
11 and any necessary rulemaking for these high-priority
12 substances in accordance with section 6(a).”.

13 **SEC. 122. DEVELOPMENT AND EVALUATION OF TEST METH-**
14 **ODS.**

15 Section 27(a) (15 U.S.C. 2626(a)) is amended by
16 striking “Health, Education, and Welfare” and inserting
17 “Health and Human Services”.

18 **SEC. 123. STATE PROGRAMS.**

19 Section 28 (15 U.S.C. 2627) is amended by striking
20 subsections (c) and (d).

21 **SEC. 124. AUTHORIZATION OF APPROPRIATIONS.**

22 Section 29 (15 U.S.C. 2628) is repealed.

23 **SEC. 125. ANNUAL REPORT.**

24 Section 30 (15 U.S.C. 2629) is amended by striking
25 paragraph (2) and inserting the following:

1 “(2)(A) the number of notices received during
2 each year under section 5; and

3 “(B) the number of the notices described in
4 subparagraph (A) for chemical substances subject to
5 a rule, testing consent agreement, or order under
6 section 4;”.

7 **TITLE II—STRENGTHENING PRO-**
8 **TECTIONS FOR CHILDREN**
9 **AND COMMUNITIES FROM**
10 **DISEASE CLUSTERS**

11 **SEC. 201. PURPOSES.**

12 The purposes of this title are—

13 (1) to provide to the Administrator the author-
14 ity to help conduct investigations into the potential
15 for environmental pollutants or toxic substances to
16 cause disease clusters;

17 (2) to ensure that the Administrator has the
18 authority to undertake actions to help address exist-
19 ing and potential environmental pollution and toxic
20 substances that may contribute to the creation of
21 disease clusters; and

22 (3) to enable the Administrator to integrate and
23 work in conjunction with other Federal, State, and
24 local agencies, institutions of higher education, and

1 the public in investigating and helping to address
2 the possible causes of disease clusters.

3 **SEC. 202. DEFINITIONS.**

4 In this title:

5 (1) ADMINISTRATOR.—The term “Adminis-
6 trator” means the Administrator of the Environ-
7 mental Protection Agency.

8 (2) AGENCY.—The term “Agency” means the
9 Environmental Protection Agency.

10 (3) DIRECTOR.—The term “Director” means
11 the Director of the National Institute of Environ-
12 mental Health Sciences.

13 (4) DISEASE CLUSTER.—The term “disease
14 cluster” means—

15 (A) the occurrence of a greater-than-ex-
16 pected number of cases of a particular disease
17 within a group of individuals, a geographical
18 area, or a period of time; or

19 (B) the occurrence of a particular disease
20 in such number of cases, or meeting such other
21 criteria, as the Administrator, in consultation
22 with the Administrator of the Agency for Toxic
23 Substances and Disease Registry and the Direc-
24 tor, may determine.

1 (5) ENVIRONMENTAL POLLUTANTS OR TOXIC
2 SUBSTANCES.—The term “environmental pollutants
3 or toxic substances” includes the substances de-
4 scribed in paragraph (7).

5 (6) FEDERAL AGENCY.—The term “Federal
6 agency” means—

7 (A) any department, agency, or other in-
8 strumentality of the Federal Government;

9 (B) any independent agency or establish-
10 ment of the Federal Government (including any
11 Government corporation); and

12 (C) the Government Printing Office.

13 (7) POTENTIAL CAUSES OF A DISEASE CLUS-
14 TER.—The term “potential causes of a disease clus-
15 ter” includes environmental and public health fac-
16 tors that could increase the possibility of disease
17 clusters, including environmental pollutants or toxic
18 substances and sources of those pollutants and sub-
19 stances, including—

20 (A) emissions of air pollutants that are
21 regulated under the Clean Air Act (42 U.S.C.
22 7401 et seq.);

23 (B) water pollutants that are regulated
24 under the Federal Water Pollution Control Act
25 (33 U.S.C. 1251 et seq.);

1 (C) a contaminant, as that term is defined
2 in section 1401 of the Safe Drinking Water Act
3 (42 U.S.C. 300f);

4 (D) a hazardous substance, as that term is
5 defined in section 101 of the Comprehensive
6 Environmental Response, Compensation, and
7 Liability Act (42 U.S.C. 9601);

8 (E) solid waste and hazardous waste, as
9 those terms are defined in section 1004 of the
10 Solid Waste Disposal Act (42 U.S.C. 6903);

11 (F) a chemical substance, as that term is
12 defined in section 3 of the Toxic Substances
13 Control Act (15 U.S.C. 2602);

14 (G) a substance that is regulated under
15 the Emergency Planning and Community
16 Right-To-Know Act of 1986 (42 U.S.C. 11001
17 et seq.); and

18 (H) any other form of environmental pollu-
19 tion or toxic substance that is a known or po-
20 tential cause of an adverse health effect, includ-
21 ing a developmental, reproductive, neurotoxic,
22 or carcinogenic effect.

23 (8) REGIONAL RESPONSE CENTER.—The term
24 “Regional Response Center” means a Regional Dis-

1 ease Cluster Information and Response Center es-
2 tablished under section 204.

3 (9) RESPONSE TEAM.—The term “Response
4 Team” means a Regional Disease Cluster Informa-
5 tion and Response Team established under section
6 204.

7 (10) SECRETARY.—The term “Secretary”
8 means the Secretary of Health and Human Services.

9 **SEC. 203. GUIDELINES FOR ENVIRONMENTAL INVESTIGA-**
10 **TIONS OF DISEASE CLUSTERS.**

11 (a) ESTABLISHMENT.—

12 (1) IN GENERAL.—The Administrator, in con-
13 sultation with the Administrator of the Agency for
14 Toxic Substances and Disease Registry, the Sec-
15 retary, and the Director, shall develop, publish, and
16 periodically update guidelines that describe a sys-
17 tematic, integrated approach that uses the best
18 available science to investigate—

19 (A) 1 or more suspected or potential dis-
20 ease clusters;

21 (B) environmental pollutants or toxic sub-
22 stances associated with 1 or more suspected or
23 potential disease clusters; or

24 (C) potential causes of 1 or more disease
25 clusters.

1 (2) COORDINATION.—The Administrator shall
2 ensure that the Office of Children’s Health Protec-
3 tion, in consultation with appropriate advisory com-
4 mittees, such as the Children’s Health Protection
5 Advisory Committee, has a prominent role on behalf
6 of the Agency in developing and updating guidelines
7 under paragraph (1).

8 (b) REQUIREMENTS.—Guidelines developed under
9 this section shall include—

10 (1) definitions of key concepts and actions;

11 (2) disease cluster identification and reporting
12 protocols;

13 (3) standardized methods of reviewing and cat-
14 egorizing data, including from health surveillance
15 systems and disease cluster reports;

16 (4) guidance for using, in a health-protective
17 way, an appropriate epidemiological, statistical, or
18 other approach for the circumstances of an inves-
19 tigation;

20 (5) procedures for peer review of key documents
21 by individuals who have no direct or indirect conflict
22 of interest; and

23 (6) a description of roles and responsibilities of
24 the Administrator and the Administrator of the
25 Agency for Toxic Substances and Disease Registry

1 in conducting investigations described in those
2 guidelines, in accordance with this title.

3 (c) TIMING.—

4 (1) IN GENERAL.—Draft guidelines developed
5 under this section shall be available for public review
6 and comment for a period of not less than 60 days.

7 (2) FINAL GUIDELINES.—Not later than 1 year
8 after the date of enactment of this Act, the Adminis-
9 trator, in consultation with the Administrator of the
10 Agency for Toxic Substances and Disease Registry,
11 the Secretary, and the Director, shall publish in the
12 Federal Register final guidelines under this section.

13 **SEC. 204. ENHANCED SUPPORT FOR ENVIRONMENTAL IN-**
14 **VESTIGATIONS OF DISEASE CLUSTERS.**

15 (a) ESTABLISHMENT OF REGIONAL DISEASE CLUS-
16 TER INFORMATION AND RESPONSE CENTERS AND
17 TEAMS.—

18 (1) ESTABLISHMENT.—

19 (A) IN GENERAL.—The Administrator, in
20 consultation with the Administrator of the
21 Agency for Toxic Substances and Disease Reg-
22 istry, the Secretary, and the Director, and other
23 appropriate Federal agencies, shall establish
24 and operate Regional Disease Cluster Informa-

1 tion and Response Centers and Regional Dis-
2 ease Cluster Information and Response Teams.

3 (B) PRINCIPAL RESPONSIBILITY.—The Ad-
4 ministrator shall be principally responsible for
5 directing, coordinating, and approving Federal
6 efforts and assistance authorized under this
7 section.

8 (2) COORDINATION.—

9 (A) IN GENERAL.—The Administrator
10 shall ensure that the Office of Children’s
11 Health Protection, in consultation with appro-
12 priate advisory committees, such as the Chil-
13 dren’s Health Protection Advisory Committee,
14 has a prominent role on behalf of the Agency
15 in establishing and operating the Regional Re-
16 sponse Centers and the Response Teams.

17 (B) GRANTS AND COOPERATIVE AGREE-
18 MENTS.—

19 (i) IN GENERAL.—The Administrator
20 shall provide support (including research,
21 program implementation, and operational
22 support activities) to individuals on Re-
23 sponse Teams described in subsection (b)
24 and Community Disease Cluster Advisory
25 Committees described in subsection (c)

1 through grants and cooperative agreements
2 with institutions of higher education that
3 have programs or individuals with dem-
4 onstrated expertise in research, training,
5 studies, and technical assistance.

6 (ii) AUTHORIZATION OF APPROPRIA-
7 TIONS.—There are authorized to be appro-
8 priated to carry out this subparagraph
9 such sums as are necessary.

10 (3) TIMING.—Not later than 1 year after the
11 date of enactment of this Act, the Administrator
12 shall establish at least—

13 (A) 2 Regional Response Centers; and

14 (B) 2 Response Teams.

15 (b) RESPONSE TEAMS.—

16 (1) MEMBERSHIP.—Each Response Team shall
17 include individuals who—

18 (A) have expertise in epidemiology,
19 toxicogenomics, molecular biology, toxicology,
20 pollution control requirements, data analysis,
21 environmental health and disease surveillance,
22 exposure assessment, pediatric health, commu-
23 nity outreach and involvement, and other rel-
24 evant fields; and

1 (B) have no direct or indirect conflict of
2 interest.

3 (2) LEADERSHIP.—Each Response Team shall
4 have—

5 (A) an individual who is the leader of the
6 Response Team and who reports to the Admin-
7 istrator, the Administrator of the Agency for
8 Toxic Substances and Disease Registry, and the
9 Director; and

10 (B) an individual who has the skills or ex-
11 perience necessary to carry out community out-
12 reach and involvement activities, including—

13 (i) the establishment of Community
14 Disease Cluster Advisory Committees
15 under subsection (c); and

16 (ii) the facilitation of activities of
17 those Committees.

18 (3) ACTIVITIES.—

19 (A) IN GENERAL.—The Administrator, in
20 consultation with the Administrator of the
21 Agency for Toxic Substances and Disease Reg-
22 istry and the Director, shall establish the scope
23 of activities for Response Teams to ensure that
24 the activities are consistent with achieving the
25 purposes of this title.

1 (B) REQUIREMENTS.—The activities of the
2 Response Teams shall include—

3 (i) making guidelines, protocols, data,
4 and other relevant information and exper-
5 tise available to State and local officials
6 and the public to assist in efforts—

7 (I) to investigate suspected or po-
8 tential disease clusters, environmental
9 pollutants or toxic substances associ-
10 ated with those disease clusters, and
11 potential causes of disease clusters;
12 and

13 (II) to address potential causes
14 of disease clusters;

15 (ii) responding rapidly to a petition
16 described in subparagraph (C) from any
17 person, including a State or local official,
18 regarding the need—

19 (I) to investigate suspected or po-
20 tential disease clusters, environmental
21 pollutants or toxic substances associ-
22 ated with those disease clusters, and
23 potential causes of disease clusters;
24 and

1 (II) to address the potential
2 causes of disease clusters;

3 (iii) providing the best available envi-
4 ronmental sampling and laboratory equip-
5 ment to collect, analyze, and interpret
6 monitoring, health surveillance, and other
7 relevant information at scales and
8 timelines appropriate to an action;

9 (iv) involving community members, in
10 accordance with established scientific
11 methods and norms (including the preser-
12 vation of the confidentiality of individuals),
13 in—

14 (I) investigations of suspected or
15 potential disease clusters, environ-
16 mental pollutants or toxic substances
17 associated with those disease clusters,
18 or potential causes of disease clusters,
19 including through—

20 (aa) environmental exposure
21 assessments;

22 (bb) biomonitoring activities;

23 and

1 (cc) community-based
2 participatory research initiatives;
3 and

4 (II) other efforts to address the
5 potential causes of disease clusters;

6 (v) working with State and local agen-
7 cies—

8 (I) to help make the use and
9 management of integrated environ-
10 mental health data consistent and
11 timely; and

12 (II) to fill data gaps; and

13 (vi) investigating suspected or poten-
14 tial disease clusters, environmental pollut-
15 ants or toxic substances associated with
16 those disease clusters, and potential causes
17 of disease clusters, and addressing the po-
18 tential causes of disease clusters that the
19 Administrator determines State and local
20 officials need assistance in investigating or
21 addressing, or that the Administrator de-
22 termines should be investigated or ad-
23 dressed.

24 (C) PETITION.—

1 (i) IN GENERAL.—Any person, includ-
2 ing a State or local official, may submit a
3 petition referred to in subparagraph (B)(ii)
4 to the Administrator, the Administrator of
5 the Agency for Toxic Substances and Dis-
6 ease Registry, and the Director that re-
7 quests that a Response Team conduct an
8 investigation or take other action to ad-
9 dress the potential causes of disease clus-
10 ters in accordance with this title.

11 (ii) REQUIREMENTS.—Each petition
12 submitted under clause (i) shall clearly de-
13 scribe the basis for the requested investiga-
14 tion or action, including any data sup-
15 porting the request.

16 (iii) CONSIDERATION.—The Adminis-
17 trator, in consultation with the Adminis-
18 trator of the Agency for Toxic Substances
19 and Disease Registry and the Director,
20 shall establish criteria for the consideration
21 of petitions submitted under this section
22 using health-protective factors, including—

23 (I) evidence of the release of en-
24 vironmental pollutants or toxic sub-
25 stances;

1 (II) the locations in which there
2 appear to be potentially significant
3 health threats from the potential
4 causes of disease clusters;

5 (III) cases in which existing data
6 appear to be inadequate to fully as-
7 sess the potential risks to public
8 health; and

9 (IV) such other factors as the
10 Administrator determines are nec-
11 essary.

12 (iv) RESPONSE.—Not later than 60
13 days after the date of receipt of a petition
14 under clause (iii), the Administrator, in
15 consultation with the Administrator of the
16 Agency for Toxic Substances and Disease
17 Registry and the Director, shall provide a
18 written response that describes—

19 (I) the investigation or actions
20 that will be undertaken in response to
21 the petition, including the timeline
22 and basis for the investigation or ac-
23 tions; and

24 (II) the reasons for any denial or
25 deferral in providing such a response.

1 (v) TIMING OF ISSUANCE OF CRI-
2 TERIA.—

3 (I) IN GENERAL.—The Adminis-
4 trator, in consultation with the Ad-
5 ministrator of the Agency for Toxic
6 Substances and Disease Registry and
7 the Director, shall provide for public
8 notice of draft criteria established
9 under this subparagraph for a period
10 of not less than 60 days.

11 (II) FINAL CRITERIA.—Not later
12 than 1 year after the date of enact-
13 ment of this Act, the Administrator,
14 in consultation with the Administrator
15 of the Agency for Toxic Substances
16 and Disease Registry and the Direc-
17 tor, shall publish in the Federal Reg-
18 ister final criteria required under this
19 subparagraph.

20 (4) USE OF PUBLICLY AVAILABLE REPORTS.—
21 Response Team investigations and actions shall—

22 (A) include publicly available reports pre-
23 pared by the Response Team that contain state-
24 ments of facts, findings, and recommendations
25 for actions, to the extent appropriate; and

1 (B) be prepared in a manner that pre-
2 serves the confidentiality of individuals.

3 (5) TRANSPARENCY AND ACCOUNTABILITY.—

4 Response Team activities shall include measures to
5 ensure—

6 (A) transparency and accountability to po-
7 tentially affected individuals, State and local of-
8 ficials, the public, and other persons and agen-
9 cies, while preserving the confidentiality of indi-
10 viduals;

11 (B) that consistent, accurate, and mean-
12 ingful information is provided to potentially af-
13 fected individuals, State and local officials, the
14 public, and other persons and agencies through
15 the use of comprehensive, community-based
16 communications plans; and

17 (C) accountability to meeting goals and
18 timetables.

19 (6) DATABASE.—

20 (A) IN GENERAL.—The Administrator, in
21 consultation with the Administrator of the
22 Agency for Toxic Substances and Disease Reg-
23 istry, the Secretary, and the Director, shall
24 compile and regularly update information in a
25 comprehensive electronic database that—

- 1 (i) is publicly accessible through the
2 Internet;
- 3 (ii) provides a centralized location for
4 information relating to—
- 5 (I) disease cluster reports and in-
6 vestigations;
- 7 (II) environmental pollutants or
8 toxic substances that are associated
9 with suspected or potential disease
10 clusters;
- 11 (III) illnesses associated with
12 suspected or potential disease clusters,
13 including locally generated informa-
14 tion;
- 15 (IV) systematic tracking of envi-
16 ronmental pollutants or toxic sub-
17 stances and illnesses associated with
18 suspected or potential disease clusters;
- 19 (V) actions to help address the
20 potential causes of disease clusters;
21 and
- 22 (VI) any other information that
23 the Administrator determines to be
24 necessary; and

1 (iii) facilitates the rapid reporting and
2 analysis of information described in clause
3 (ii).

4 (B) CONFIDENTIALITY.—A database de-
5 scribed in subparagraph (A) shall be main-
6 tained in a manner that preserves the confiden-
7 tiality of individuals.

8 (c) COMMUNITY DISEASE CLUSTER ADVISORY COM-
9 MITTEES.—

10 (1) IN GENERAL.—The Administrator shall es-
11 tablish Community Disease Cluster Advisory Com-
12 mittees to provide oversight, guidance, and advice
13 relating to—

14 (A) the investigation of suspected and po-
15 tential disease clusters;

16 (B) the investigation of environmental pol-
17 lutants or toxic substances associated with sus-
18 pected or potential disease clusters;

19 (C) the investigation of potential causes of
20 disease clusters;

21 (D) efforts to address the potential causes
22 of disease clusters; and

23 (E) the most effective means of ensuring
24 outreach to and involvement of community
25 members.

1 (2) MEMBERSHIP.—Membership on Community
2 Disease Cluster Advisory Committees shall be com-
3 prised of representatives that include—

4 (A) individuals who are or may be im-
5 pacted by a suspected or potential disease clus-
6 ter, and the designee of such an individual who
7 may participate with or in the place of such an
8 individual;

9 (B) State or local government health or
10 environmental agencies;

11 (C) at least 2 individuals, appointed by the
12 Administrator in consultation with the Adminis-
13 trator of the Agency for Toxic Substances and
14 Disease Registry and the Director, with dem-
15 onstrated knowledge of the activities described
16 in paragraph (1); and

17 (D) other appropriate individuals, as deter-
18 mined by the Administrator, in consultation
19 with the Administrator of the Agency for Toxic
20 Substances and Disease Registry and the Direc-
21 tor.

22 (3) PROHIBITION.—No member of a Committee
23 may have any direct or indirect conflict of interest.

24 (4) TECHNICAL ASSISTANCE.—

1 (A) IN GENERAL.—The Administrator, in
2 consultation with the Administrator of the
3 Agency for Toxic Substances and Disease Reg-
4 istry and the Director, may make grants avail-
5 able to any group of individuals that may be af-
6 fected by a suspected or potential disease clus-
7 ter.

8 (B) USE OF FUNDS.—Grants made avail-
9 able under subparagraph (A) may be used to
10 facilitate active involvement in all aspects of
11 Committee activities and to assist Committee
12 members in obtaining technical assistance in in-
13 terpreting information with regard to—

14 (i) the investigation of—

15 (I) suspected or potential disease
16 clusters;

17 (II) environmental pollutants or
18 toxic substances that are associated
19 with suspected or potential disease
20 clusters; and

21 (III) the potential causes of dis-
22 ease clusters;

23 (ii) addressing the potential causes of
24 disease clusters;

1 (iii) understanding the health con-
2 cerns associated with suspected or poten-
3 tial disease clusters; and

4 (iv) understanding other scientific and
5 technical issues relating to the activities of
6 a Regional Response Team and Commu-
7 nity Disease Cluster Advisory Committee,
8 including the potential need for and inter-
9 pretation of any biomonitoring of individ-
10 uals in the area.

11 (d) ENVIRONMENTAL RESEARCH AND ANALYSIS.—

12 The Administrator, in consultation with the Administrator
13 of the Agency for Toxic Substances and Disease Registry,
14 the Secretary, and the Director, shall use available au-
15 thorities and programs to compile, research, and analyze
16 information generated by actions authorized under this
17 section, including by—

18 (1) using those authorities to test environ-
19 mental pollutants or toxic substances identified
20 under subsection (b)(6); and

21 (2) incorporating environmental pollutants or
22 toxic substances identified under subsection (b)(6) in
23 appropriate national biomonitoring initiatives.

1 **SEC. 205. FEDERAL REPORTS TO CONGRESS.**

2 (a) IN GENERAL.—Not later than 1 year after the
3 date of enactment of this Act and annually thereafter, the
4 Administrator, in consultation with the Administrator of
5 the Agency for Toxic Substances and Disease Registry,
6 the Secretary, and the Director, shall prepare a report
7 that describes—

8 (1) the status of activities under this title to in-
9 vestigate and address the suspected and potential
10 causes of disease clusters;

11 (2) environmental pollutants or toxic substances
12 that are associated with suspected or potential dis-
13 ease clusters;

14 (3) the potential causes of disease clusters; and

15 (4) ways to address the potential causes of
16 those disease clusters.

17 (b) REQUIREMENTS.—The report shall include a de-
18 scription of—

19 (1) outreach activities to State and local offi-
20 cials and communities;

21 (2) actions that the Administrator has taken to
22 prioritize the testing of environmental pollutants or
23 toxic substances;

24 (3) actions that the Administrator has taken to
25 include environmental pollutants or toxic substances

1 identified under section 204(b)(7) in appropriate na-
2 tional biomonitoring initiatives;

3 (4) actions that the Administrator is taking or
4 plans to take to address problems in implementing
5 this title;

6 (5) actions that the Secretary is taking or plans
7 to take to address problems in implementing this
8 title;

9 (6) actions that the Administrator of the Agen-
10 cy for Toxic Substances and Disease Registry has
11 undertaken or is considering taking with respect to
12 any disease clusters under subparagraphs (D) and
13 (E) of section 104(i)(1) of Comprehensive Environ-
14 mental Response, Compensation, and Liability Act
15 (42 U.S.C. 9604(i)(1)) and other provisions of that
16 section;

17 (7) actions that the Director is taking or plans
18 to take to address problems in implementing this
19 title; and

20 (8) other relevant information.

21 (c) SUBMISSION AND AVAILABILITY.—The Adminis-
22 trator shall—

23 (1) submit the report under this subsection
24 to—

1 (A) the Committees on Environment and
2 Public Works and Health, Education, Labor,
3 and Pensions of the Senate; and

4 (B) the Committee on Energy and Com-
5 merce of the House of Representatives; and

6 (2) make the report available to the public.

7 **SEC. 206. AUTHORIZATION OF APPROPRIATIONS.**

8 There are authorized to be appropriated such sums
9 as are necessary to carry out this title.

10 **SEC. 207. EFFECT ON OTHER LAW.**

11 Nothing in this title modifies, limits, or otherwise af-
12 fects the application of, or obligation to comply with, any
13 law, including any environmental or public health law.

14 **TITLE III—COMMUNITY DISEASE**
15 **CLUSTER TECHNICAL ASSIST-**
16 **ANCE GRANTS**

17 **SEC. 301. COMMUNITY DISEASE CLUSTER TECHNICAL AS-**
18 **SISTANCE GRANTS.**

19 (a) IN GENERAL.—The Administrator of the Envi-
20 ronmental Protection Agency (referred to in this title as
21 the “Administrator”), in coordination with the Secretary
22 of Health and Human Services (referred to in this title
23 as the “Secretary”) may award grants in accordance with
24 this title to any individual or group of individuals that may

1 be affected by a reported community-based disease clus-
2 ter—

3 (1) to pay the Federal share of the technical as-
4 sistance described in subsection (d);

5 (2) to protect public health and the environ-
6 ment;

7 (3) to promote healthy and safe environments;
8 and

9 (4) to prevent and address harmful exposures
10 to hazardous substances.

11 (b) APPLICATION.—

12 (1) IN GENERAL.—To be eligible for a grant
13 under this title, an individual or group of individuals
14 shall submit to the Administrator and the Secretary
15 an application that contains a description of the—

16 (A) need for technical assistance, including
17 the need to procure independent technical advi-
18 sors to help grant recipients interpret the infor-
19 mation described in subsection (d);

20 (B) expected outputs, including results, ef-
21 fects, or consequences that will occur from the
22 technical assistance; and

23 (C) expected outcomes, including activity,
24 effort, or associated work products that will be

1 produced or provided over a period of time or
2 by a specific date.

3 (2) RESPONSE.—Not later than 120 days after
4 the date on which an application is submitted under
5 paragraph (1), the Administrator and the Secretary
6 shall respond to each applicant in writing and de-
7 scribe whether the application is approved, denied,
8 or will be considered after the applicant modifies the
9 application.

10 (3) CRITERIA.—The Administrator, in coordi-
11 nation with the Secretary, shall develop criteria that,
12 if satisfied, would result in the Administrator and
13 the Secretary accepting an application submitted
14 under paragraph (1).

15 (c) AMOUNT.—

16 (1) IN GENERAL.—Except as provided in para-
17 graph (2), each grant awarded under this title shall
18 not exceed \$50,000.

19 (2) WAIVER.—The Administrator, in coordina-
20 tion with the Secretary, may waive the limitation de-
21 scribed in paragraph (1) if the waiver is necessary
22 to provide the technical assistance described in sub-
23 section (d).

1 (d) USE OF FUNDS.—Grants awarded under this title
2 shall be used to obtain technical assistance in interpreting
3 information regarding—

4 (1) investigating reported community-based dis-
5 ease clusters associated with 1 or more hazardous
6 chemicals;

7 (2) the potential hazardous chemicals associated
8 with a reported community-based disease cluster;

9 (3) providing individuals or groups of individ-
10 uals with community-based tools to educate the indi-
11 viduals on the mitigation of hazardous chemicals as-
12 sociated with reported community-based disease
13 clusters; or

14 (4) other scientific and technical issues related
15 to reported community-based disease clusters.

16 (e) NUMBER OF GRANTS.—No individual or group of
17 individuals shall be awarded more than 1 grant under this
18 title.

19 (f) NON-FEDERAL SHARE.—

20 (1) IN GENERAL.—Except as provided in para-
21 graph (2), the non-Federal share for each grant
22 awarded under this title is 20 percent.

23 (2) WAIVER.—The Administrator, in coordina-
24 tion with the Secretary, may waive the non-Federal
25 share described in paragraph (1) if—

1 (A) the recipient of the grant demonstrates
2 financial need; and

3 (B) the waiver is necessary to provide the
4 technical assistance described in subsection (d).

5 (g) RENEWAL OF GRANT.—

6 (1) IN GENERAL.—Any grant awarded under
7 this title may be renewed to facilitate technical as-
8 sistance to any group of individuals that may be af-
9 fected by a reported community-based disease clus-
10 ter.

11 (2) CONDITIONS.—Each renewal of a grant
12 awarded under this title is subject to the same con-
13 ditions that apply to an initial grant.

14 (h) REPORTS.—Any recipient of a grant awarded
15 under this title shall submit to the Administrator and the
16 Secretary a report that describes the progress in address-
17 ing the needs and achieving the outputs and outcomes de-
18 scribed in subsection (b).

19 **SEC. 302. AUTHORIZATION OF APPROPRIATIONS.**

20 For each of fiscal years 2016 through 2021, there
21 are authorized to be appropriated to the Administrator
22 and the Secretary from any funds made available to the
23 Administrator and the Secretary for the purpose of pro-
24 viding community members with technical assistance and
25 engagement on environmental health issues from the Haz-

1 arduous Substance Superfund established under section
2 9507 of the Internal Revenue Code of 1986 such sums
3 as are necessary to carry out section 301.