

[DISCUSSION DRAFT]

FEBRUARY 27, 2014

113TH CONGRESS
2D SESSION

H. R. _____

To provide for the safe and efficient flow of chemicals in interstate and foreign commerce.

IN THE HOUSE OF REPRESENTATIVES

M____ introduced the following bill; which was referred to the
Committee on _____

A BILL

To provide for the safe and efficient flow of chemicals in interstate and foreign commerce.

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

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

5 (a) SHORT TITLE.—This Act may be cited as the
6 “Chemicals in Commerce Act”.

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

- Sec. 1. Short title; table of contents; references.
- Sec. 2. Findings and purpose.
- Sec. 3. Definitions.
- Sec. 4. Testing of chemical substances and mixtures.
- Sec. 5. New chemicals and significant new uses.
- Sec. 6. Existing chemicals.
- Sec. 7. Imminent hazards.
- Sec. 8. Information collection and reporting.
- Sec. 9. Relationship to other Federal laws.
- Sec. 10. Research, development, collection, dissemination, and utilization of data.
- Sec. 11. Inspections and subpoenas.
- Sec. 12. Exports.
- Sec. 13. Imports.
- Sec. 14. Confidential information.
- Sec. 15. Prohibited acts.
- Sec. 16. Penalties.
- Sec. 17. Preemption.
- Sec. 18. Judicial review.
- Sec. 19. Citizens' petitions.
- Sec. 20. National security.
- Sec. 21. Studies.
- Sec. 22. Policies, procedures, and guidance.
- Sec. 23. Technical amendment.
- Sec. 24. State Programs.
- Sec. 25. Authorization of appropriations.
- Sec. 26. Annual report.
- Sec. 27. Preservation of authority.

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

7 **SEC. 2. FINDINGS AND PURPOSE.**

8 (a) AMENDMENT.—Section 2 (15 U.S.C. 2601) is
9 amended to read as follows:

10 **“SEC. 2. FINDINGS AND PURPOSE.**

11 “(a) FINDINGS.—Congress finds that—

1 “(1) chemicals in commerce should be safe for
2 their intended use;

3 “(2) unmanaged risks of chemical substances in
4 commerce may pose a danger to human health and
5 the environment;

6 “(3) public confidence in the Federal chemical
7 regulatory program is important;

8 “(4) chemical regulation should reflect modern
9 science, technology, and knowledge; and

10 “(5) innovation in the development of new
11 chemical substances should be encouraged to reduce
12 risk, provide improved products, stimulate the econ-
13 omy, create jobs, and protect interstate commerce.

14 “(b) PURPOSE.—The purpose of this Act is to pro-
15 mote uniform protections to human health and the envi-
16 ronment through regulating chemical substances in com-
17 merce while minimizing undue burdens on commerce.”.

18 (b) TABLE OF CONTENTS AMENDMENT.—The item
19 relating to section 2 in the table of contents is amended
20 to read as follows:

“Sec. 2. Findings and purpose.”.

21 **SEC. 3. DEFINITIONS.**

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

23 (1) by redesignating paragraphs (2) through
24 (6), (7) through (9), (10), (11), and (12) through

1 (14) as paragraphs (3) through (7), (9) through
2 (11), (13), (14), and (17) through (19), respectively;
3 (2) by inserting after paragraph (1) the fol-
4 lowing:

5 “(2) BEST AVAILABLE SCIENCE.—The term
6 ‘best available science’ means science that—

7 “(A) maximizes the quality, objectivity,
8 and integrity of information, including statis-
9 tical information;

10 “(B) uses studies conducted in accordance
11 with sound and objective scientific practices;

12 “(C) applies scientifically valid, relevant,
13 publicly available information;

14 “(D) enables assessment of the risks and
15 uncertainties in the scientific basis for deci-
16 sions; and

17 “(E) applies information that meets the in-
18 formation quality criteria established by the Ad-
19 ministrator under section 26(i).”;

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

22 “(8) INTENDED CONDITIONS OF USE.—The
23 term ‘intended conditions of use’ means the cir-
24 cumstances under which a chemical substance is in-
25 tended or reasonably anticipated to be manufac-

1 tured, processed, distributed in commerce, and
2 used.”;

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

5 “(12) POTENTIALLY EXPOSED SUBPOPULA-
6 TION.—The term ‘potentially exposed subpopulation’
7 means a group or groups of individuals within the
8 general population who may be differentially exposed
9 to a chemical substance under the intended condi-
10 tions of use or who may be susceptible to more seri-
11 ous health consequences from chemical substance ex-
12 posures than the general population, which where
13 appropriate may include infants, children, pregnant
14 women, workers, and the elderly.”; and

15 (5) by inserting after paragraph (14) (as so re-
16 designated) the following:

17 “(15) PUBLICLY AVAILABLE INFORMATION.—
18 The term ‘publicly available information’ includes in-
19 formation that has been published in periodicals,
20 books, or print, electronic, or other media readily ac-
21 cessible to any member of the public.

22 “(16) SAFETY DETERMINATION.—The term
23 ‘safety determination’ means a safety determination
24 made under section 6(b).”.

1 **SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIX-**
2 **TURES.**

3 (a) IN GENERAL.—Section 4 (15 U.S.C. 2603) is
4 amended to read as follows:

5 **“SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIX-**
6 **TURES.**

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

9 “(1) IN GENERAL.—Except as otherwise pro-
10 vided in this section, the Administrator may require
11 manufacturers and processors to develop new hazard
12 and exposure information related to a chemical sub-
13 stance or mixture in accordance with this section if
14 the Administrator determines that the information is
15 needed—

16 “(A) to perform a safety determination;

17 “(B) to ensure compliance with—

18 “(i) a rule, consent agreement, or
19 order issued under section 5(c)(5); or

20 “(ii) a rule under section 6(f);

21 “(C) pursuant to section 12(a)(2); or

22 “(D) for the implementation of another
23 Federal statute, as determined by the Federal
24 agency implementing such statute, if such infor-
25 mation is necessary to meet the regulatory test-
26 ing needs of that agency.

1 “(2) FORM.—The Administrator may carry out
2 paragraph (1) by—

3 “(A) promulgating a rule;

4 “(B) entering into a consent agreement; or

5 “(C) issuing an order.

6 “(3) AVAILABLE INFORMATION.—Before pro-
7 mulgating a rule, entering into a consent agreement,
8 or issuing an order under this subsection, the Ad-
9 ministrator shall consider available information, in-
10 cluding exposure potential and screening level haz-
11 ard and exposure information.

12 “(4) CONTENTS.—

13 “(A) IN GENERAL.—A rule promulgated,
14 consent agreement entered into, or order issued
15 under paragraph (2)—

16 “(i) shall identify the chemical sub-
17 stance or mixture for which information is
18 required and those persons required to de-
19 velop that information;

20 “(ii) may include protocols and meth-
21 odologies for the development of informa-
22 tion for the chemical substance or mixture,
23 including, if available, specific reference to
24 reliable nonanimal test procedures; and

1 “(iii) shall provide a reasonable period
2 within which persons required to develop
3 the information shall submit the informa-
4 tion to the Administrator.

5 “(B) CONSIDERATIONS.—In determining
6 the procedures and period to be required under
7 subparagraph (A), the Administrator shall con-
8 sider—

9 “(i) the relative costs of the various
10 test protocols and methodologies that may
11 be required; and

12 “(ii) the reasonably foreseeable avail-
13 ability of facilities and personnel needed to
14 perform the testing.

15 “(5) SCREENING LEVEL HAZARD AND EXPO-
16 SURE INFORMATION.—If the available information
17 under paragraph (3) is not sufficient to make a de-
18 termination under subsection (a)(1), to assist the
19 Administrator in planning requirements for addi-
20 tional testing under this subsection, the Adminis-
21 trator may, by rule, consent agreement, or order, re-
22 quire the development of screening level information
23 on a chemical substance or mixture (which may in-
24 clude scientifically reliable and relevant in silico, in
25 vitro, and in vivo tests).

1 “(6) ADDITIONAL TESTING DEVELOPMENT.—If,
2 after reviewing screening level information obtained
3 under paragraph (5), the Administrator determines
4 that additional information development is nec-
5 essary, the Administrator shall require under para-
6 graph (1) the development of such information for
7 specific endpoints using scientifically valid ap-
8 proaches.

9 “(b) STATEMENT OF NEED.—

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

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

16 “(B) explaining why information reason-
17 ably available to the Administrator is inad-
18 equate to meet that need, including a reference,
19 as appropriate, to the information identified in
20 paragraph (2)(B); and

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

23 “(2) EXPLANATION OF AN ORDER.—

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

1 trator shall explain why good cause exists for
2 issuing an order instead of promulgating a rule
3 or entering into a consent agreement.

4 “(B) CONTENTS.—The explanation de-
5 scribed in subparagraph (A) shall detail—

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

10 “(ii) the extent to which the Adminis-
11 trator has obtained or attempted to obtain
12 the information required to be developed
13 under the order through voluntary submis-
14 sions;

15 “(iii) the extent to which the Adminis-
16 trator anticipates using—

17 “(I) available information for
18 structurally related chemical sub-
19 stances;

20 “(II) valid structure-activity rela-
21 tionship models; or

22 “(III) nonanimal test alter-
23 natives; and

24 “(iv) safety determinations on other
25 chemical substances or mixtures, and the

1 information relied on in such determina-
2 tions, to the extent relevant to the chem-
3 ical substances or mixtures that would be
4 the subject of the order.

5 “(c) REDUCTION OF TESTING ON VERTEBRATE ANI-
6 MALS.—

7 “(1) IN GENERAL.—In carrying out this title,
8 the Administrator shall minimize the use of
9 vertebrate animals in testing of chemical substances
10 or mixtures by—

11 “(A) encouraging and facilitating, to the
12 extent practicable—

13 “(i) the use of integrated and tiered
14 testing and assessment strategies; and

15 “(ii) test methods that eliminate or
16 reduce the use of vertebrate animals while
17 providing test information of high scientific
18 quality;

19 “(B) grouping 2 or more chemical sub-
20 stances or mixtures into scientifically appro-
21 priate categories in cases in which testing of a
22 chemical substance or mixture would provide re-
23 liable and useful test information on others in
24 the category; and

1 “(C) before adopting a requirement for
2 testing using vertebrate animals, considering
3 the sufficiency of—

4 “(i) available toxicity information;

5 “(ii) computational toxicology and
6 bioinformatics;

7 “(iii) high through-put screening
8 methods and their prediction models;

9 “(iv) scientifically reliable and rel-
10 evant alternatives to vertebrate animal
11 tests; and

12 “(v) available vertebrate animal-based
13 studies.

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

19 “(A) after providing public notice and an
20 opportunity for public comment, develop a plan
21 to promote the development and implementation
22 of alternative test methods and testing strate-
23 gies to generate information used in safety de-
24 terminations that can reduce, refine, or replace
25 the use of vertebrate animals, including toxicity

1 pathway-based risk assessment, in vitro studies,
2 systems biology, computational toxicology,
3 bioinformatics, and high throughput screening;
4 and

5 “(B) subject to the availability of appro-
6 priations, carry out research, development, per-
7 formance assessment, and translational studies
8 to accelerate the development of test methods
9 and testing strategies that reduce, refine, or re-
10 place the use of vertebrate animals for purposes
11 of this title.

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

19 “(A) there is sufficient information to sup-
20 port a conclusion that a chemical substance or
21 mixture has, or does not have, a particular
22 property;

23 “(B) because of one or more physical or
24 chemical properties of the chemical substance

1 or mixture or other toxicokinetic consider-
2 ations—

3 “(i) the chemical substance or mixture
4 cannot be absorbed; or

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

7 “(C) the chemical substance or mixture,
8 when tested on vertebrate animals at certain
9 concentrations, causes severe tissue corrosion,
10 severe irritation, or significant pain or distress.

11 “(4) REPORTS.—Not later than 5 years after
12 the date of enactment of the Chemicals in Commerce
13 Act, and every 5 years thereafter, the Administrator
14 shall submit to Congress a report that describes the
15 progress made in implementing this subsection.

16 “(d) REQUIREMENT TO DEVELOP INFORMATION.—

17 “(1) LIMITATION.—The Administrator may not
18 require persons who begin to manufacture or process
19 a chemical substance or mixture more than 180 days
20 after the end of the period provided for that chem-
21 ical substance or mixture under subsection
22 (a)(4)(A)(iii) to develop information related to the
23 chemical substance or mixture under subsection (a).

24 “(2) DESIGNATION.—If 2 or more manufactur-
25 ers or processors designate one of themselves or a

1 third party to develop information required by the
2 Administrator under subsection (a), the Adminis-
3 trator shall require any other manufacturer or proc-
4 essor seeking to use the information so developed in
5 order to meet the requirements of subsection (a) to
6 provide fair and equitable reimbursement for such
7 information development.

8 “(3) ARBITRATION.—In the case of a dispute
9 among the parties described in paragraph (2) re-
10 garding the amount that constitutes fair and equi-
11 table reimbursement under such paragraph, such
12 dispute shall be resolved by arbitration according
13 to—

14 “(A) the terms of any applicable contract
15 among the parties; or

16 “(B) if no such contract exists, regulations
17 developed by the Administrator.

18 “(e) INFORMATION AVAILABILITY.—Subject to sec-
19 tion 14, the Administrator shall make available to the pub-
20 lic consent agreements entered into, orders issued, and in-
21 formation submitted under this section.

22 “(f) CONSULTATION.—Prior to requiring the develop-
23 ment of information from epidemiologic studies of work-
24 ers, or applying such information, the Administrator shall

1 consult with the Director of the National Institute for Oc-
2 cupational Safety and Health.

3 “(g) EXPEDITED CONSIDERATION.—

4 “(1) IN GENERAL.—Upon the receipt of any in-
5 formation submitted under this title that provides a
6 reasonable basis to conclude that a chemical sub-
7 stance or mixture presents or will present a signifi-
8 cant risk of serious or widespread harm to human
9 health, the Administrator shall, within the 180-day
10 period beginning on the date of the receipt of such
11 information—

12 “(A) initiate appropriate action under sec-
13 tion 5, 6, or 7 to prevent or reduce such risk;
14 or

15 “(B) publish in the Federal Register a
16 finding that such information does not support
17 a conclusion that the chemical substance or
18 mixture presents such a risk.

19 “(2) EXTENSION.—For good cause shown the
20 Administrator may extend such period for an addi-
21 tional period of not more than 90 days. The Admin-
22 istrator shall publish in the Federal Register notice
23 of any such extension and the reasons therefor.”.

24 (b) CONFORMING AMENDMENT.—Section
25 104(i)(5)(A) of the Comprehensive Environmental Re-

1 sponse, Compensation, and Liability Act of 1980 (42
2 U.S.C. 9604(i)(5)(A)) is amended by striking “Before as-
3 suring the initiation of such program, the Administrator
4 of ATSDR shall consider recommendations of the Inter-
5 agency Testing Committee established under section 4(e)
6 of the Toxic Substances Control Act on the types of re-
7 search that should be done.”.

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

9 (a) AMENDMENT.—Section 5 (15 U.S.C. 2604) is
10 amended to read as follows:

11 **“SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.**

12 **“(a) NOTICE REQUIREMENT.—**

13 **“(1) IN GENERAL.—**Unless a person submits,
14 not later than 90 days before manufacturing or
15 processing begins, a notice to the Administrator of
16 that person’s intent to manufacture a new chemical
17 substance or manufacture or process a chemical sub-
18 stance for a new use that the Administrator has de-
19 termined, in accordance with paragraph (2), is a sig-
20 nificant new use, such person may not—

21 **“(A) manufacture a new chemical**
22 **substance; or**

23 **“(B) manufacture or process a chem-**
24 **ical substance for a use which the Admin-**

1 istrator has determined, in accordance with
2 paragraph (2), is a significant new use.

3 “(2) DETERMINATION OF SIGNIFICANT NEW
4 USE.—A determination by the Administrator that a
5 use of a chemical substance is a significant new use,
6 with respect to which notification is required under
7 paragraph (1), shall be made by a rule promulgated
8 after a consideration of all relevant factors, includ-
9 ing information on—

10 “(A) the projected volume of manufac-
11 turing and processing of the chemical substance
12 for that use;

13 “(B) the extent to which a use changes the
14 type or form of exposure of human beings or
15 the environment to the chemical substance;

16 “(C) the extent to which a use increases
17 the magnitude and duration of exposure of
18 human beings or the environment to the chem-
19 ical substance; and

20 “(D) the intended conditions of use.

21 “(3) ARTICLES.—The Administrator may deter-
22 mine that the use of a chemical substance as part
23 of an article is a significant new use under this sec-
24 tion, but only where the Administrator—

1 “(A) identifies specific types of articles
2 that are, or likely will be, in United States com-
3 merce; and

4 “(B) determines that—

5 “(i) an unreasonable risk of harm to
6 human health or the environment may re-
7 sult from exposure to a chemical substance
8 in the article; and

9 “(ii) placing requirements on the arti-
10 cles is required because such risk cannot
11 be addressed adequately through require-
12 ments placed on the chemical substance.

13 “(b) CONTENT OF NOTICE; PUBLICATION IN THE
14 FEDERAL REGISTER.—

15 “(1) IN GENERAL.—The notice required by sub-
16 section (a)(1) shall include, with respect to a chem-
17 ical substance or significant new use—

18 “(A) the information required by sections
19 720.45 and 720.50 of title 40, Code of Federal
20 Regulations (or successor regulations); and

21 “(B) information regarding intended condi-
22 tions of use and any reasonably anticipated ex-
23 posure.

24 “(2) FEDERAL REGISTER PUBLICATION.—Sub-
25 ject to section 14, not later than 5 business days

1 after the date of the receipt of a notice under sub-
2 section (a)(1), the Administrator shall publish in the
3 Federal Register—

4 “(A) the identity of the chemical substance
5 for which such notice has been received by the
6 Administrator; and

7 “(B) the intended conditions of use of such
8 chemical substance as identified by the manu-
9 facturer or processor.

10 “(3) PUBLICLY ACCESSIBLE LISTS.—The Ad-
11 ministrator shall maintain publicly accessible lists
12 of—

13 “(A) each chemical substance for which
14 notice has been received under subsection (a)(1)
15 and for which the review period prescribed by
16 subsection (c) has not expired; and

17 “(B) each chemical substance for which
18 such review period has expired since the last
19 publication of such list.

20 “(c) REVIEW AND DETERMINATION.—

21 “(1) REVIEW.—

22 “(A) IN GENERAL.—Except as provided in
23 subparagraph (B), not later than 90 days after
24 the date of receipt of a notice submitted under
25 subsection (a)(1), the Administrator shall—

1 “(i) conduct a review of the notice;

2 “(ii) to the extent the Administrator
3 considers necessary, develop a profile of
4 the chemical substance and the potential
5 for exposure to humans and the environ-
6 ment;

7 “(iii) if the Administrator considers it
8 necessary to conduct a review under clause
9 (i) or to make a determination under para-
10 graph (3), request additional information
11 pursuant to paragraph (2)(B); and

12 “(iv) make a determination under
13 paragraph (3).

14 “(B) EXTENSION OF REVIEW.—The Ad-
15 ministrator may extend the period described in
16 subparagraph (A) for good cause for one or
17 more periods. Except as provided in paragraph
18 (2)(B), the cumulative total of any such exten-
19 sions shall not exceed 90 days.

20 “(2) INFORMATION.—

21 “(A) PREVIOUSLY SUBMITTED INFORMA-
22 TION.—In conducting a review under paragraph
23 (1)(A), the Administrator shall take into con-
24 sideration any relevant information submitted

1 under subsection (a) or otherwise available to
2 the Administrator.

3 “(B) ADDITIONAL INFORMATION.—If the
4 Administrator determines that additional infor-
5 mation (including information on exposure or
6 exposure potential) is needed in order to con-
7 duct a review and make a determination under
8 this subsection, the Administrator—

9 “(i) shall provide an opportunity for
10 the submitter of the notice to submit such
11 additional information;

12 “(ii) may, by agreement with the sub-
13 mitter, extend the review period no longer
14 than necessary to allow for the develop-
15 ment and submission of the additional in-
16 formation;

17 “(iii) shall promptly make a deter-
18 mination under paragraph (3) upon receipt
19 of the information; and

20 “(iv) may take action under para-
21 graph (5) pending receipt of the additional
22 information, which may, as appropriate,
23 permit the submitter of the notice to file a
24 notice of commencement under subsection
25 (d).

1 “(3) DETERMINATIONS.—Before the end of the
2 applicable period for review under paragraph (1) or
3 (2)(B), and based on the information described in
4 paragraph (2), the Administrator shall determine
5 that exposure to the chemical substance under the
6 intended conditions of use—

7 “(A) is likely to result in an unreasonable
8 risk of harm to human health or the environ-
9 ment, in which case the Administrator shall
10 take appropriate action under paragraph (5); or

11 “(B) is not likely to result in an unreason-
12 able risk of harm to human health or the envi-
13 ronment, in which case the Administrator shall
14 allow the review period to expire without impos-
15 ing restrictions on the chemical substance.

16 “(4) COMMERCIAL PRODUCTION.—At the end of
17 the applicable review period specified under para-
18 graph (1) or (2)(B), the submitter of a notice under
19 subsection (a)(1) may submit a notice of commence-
20 ment under subsection (d), unless the Adminis-
21 trator—

22 “(A) determines under paragraph (3)(A)
23 that exposure to the chemical substance under
24 the intended conditions of use is likely to result

1 in an unreasonable risk of harm to human
2 health or the environment; and

3 “(B) imposes a requirement or restriction
4 under paragraph (5) that prohibits the manu-
5 facture of the chemical substance.

6 “(5) REQUIREMENTS AND RESTRICTIONS.—If,
7 before the end of the applicable review period under
8 paragraph (1) or (2)(B), the Administrator makes a
9 determination under paragraph (3)(A), the Adminis-
10 trator shall, by rule, consent agreement, or order,
11 impose one or more of the following requirements or
12 restrictions on the manufacturer or processor:

13 “(A) A requirement or restriction that the
14 chemical substance be marked with, or accom-
15 panied by, clear and adequate warnings and in-
16 structions with respect to distribution in com-
17 merce or use, or any combination of those ac-
18 tivities, with the form and content of the warn-
19 ings and instructions to be prescribed by the
20 Administrator.

21 “(B) A requirement or restriction that
22 manufacturers or processors of the chemical
23 substance—

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

4 “(ii) monitor specific uses of or expo-
5 sures to the chemical substance; or

6 “(iii) subject to section 4, develop ad-
7 ditional information that is reasonably nec-
8 essary to address potential risks from the
9 manufacture, processing, distribution in
10 commerce, or use of the chemical sub-
11 stance.

12 “(C) A restriction on the quantity of the
13 chemical substance that may be manufactured,
14 processed, or distributed in commerce.

15 “(D) A requirement to restrict or ban the
16 manufacture, processing, or distribution in com-
17 merce of the chemical substance—

18 “(i) for a particular use;

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

22 “(iii) for all uses.

23 “(E) A restriction on the quantity of the
24 chemical substance that may be manufactured,
25 processed, or distributed in commerce—

1 “(i) for a particular use; or

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

5 “(F) A requirement to restrict or ban a
6 method of commercial use of the chemical sub-
7 stance.

8 “(G) A requirement directing manufactur-
9 ers or processors of the chemical substance to
10 give notice of unreasonable risks of harm to dis-
11 tributors in commerce of the chemical substance
12 and, to the extent reasonably ascertainable, to
13 other persons in the chain of commerce in pos-
14 session of the chemical substance.

15 “(d) NOTICE OF COMMENCEMENT.—

16 “(1) IN GENERAL.—A person who has sub-
17 mitted a notice under subsection (a)(1) and com-
18 mences manufacture of a new chemical substance
19 shall, for a purpose not exempt under subsection (f),
20 submit a notice of commencement to the Adminis-
21 trator—

22 “(A) not later than 30 days after the date
23 on which the person commenced manufacture;
24 and

1 “(B) which identifies the name of the man-
2 ufacturer and the initial date of such manufac-
3 ture.

4 “(2) WITHDRAWAL.—A person who has sub-
5 mitted a notice under subsection (a)(1), but has not
6 commenced manufacture, may withdraw the notice.

7 “(e) ADDITIONAL EVALUATION.—The Administrator
8 may initiate action under section 6 with respect to a chem-
9 ical substance for which a notice has been submitted under
10 subsection (a)(1) at any time after the Administrator,
11 after publication of the chemical substance on the list re-
12 quired by section 8(b), becomes aware of new information
13 regarding the chemical substance that provides a reason-
14 able basis to conclude that a determination made with re-
15 spect to the chemical substance under subsection (c)(3)
16 should be reconsidered.

17 “(f) EXEMPTIONS.—

18 “(1) EXPERIMENTATION, RESEARCH, AND
19 ANALYSIS.—

20 “(A) GENERAL RULE.—Except as provided
21 in subparagraph (B), the requirements of sub-
22 section (a)(1) shall not apply with respect to
23 the manufacturing or processing of any chem-
24 ical substance that is manufactured or proc-
25 essed, or proposed to be manufactured or proc-

1 essed, only in small quantities (as defined by
2 the Administrator by rule) solely for purposes
3 of—

4 “(i) scientific experimentation or anal-
5 ysis; or

6 “(ii) chemical research on, or analysis
7 of, such chemical substance or another
8 chemical substance, including such re-
9 search or analysis for the development of a
10 product.

11 “(B) NOTICE REQUIREMENT.—A manufac-
12 turer or processor exempted under subpara-
13 graph (A) shall notify all persons engaged in
14 such experimentation, research, or analysis, in
15 such form and manner as the Administrator
16 may prescribe, of any risk to health which the
17 manufacturer, the processor, or the Adminis-
18 trator has reason to believe may be associated
19 with such chemical substance.

20 “(2) TEST MARKETING.—

21 “(A) IN GENERAL.—The Administrator
22 may, upon request, exempt any person from
23 any requirement of subsection (a) in order to
24 permit the person to manufacture or process a

1 chemical substance for test marketing pur-
2 poses—

3 “(i) upon a showing by the person
4 satisfactory to the Administrator that the
5 manufacture, processing, distribution in
6 commerce, and use of the chemical sub-
7 stance, and that any combination of such
8 activities, for such test marketing purposes
9 is not likely to result in an unreasonable
10 risk of harm to human health or the envi-
11 ronment; and

12 “(ii) under such restrictions as the
13 Administrator considers appropriate.

14 “(B) PUBLICATION OF RECEIPT.—Imme-
15 diately upon receipt of a request under subpara-
16 graph (A), the Administrator shall publish in
17 the Federal Register notice of the receipt of
18 such request. The Administrator shall give in-
19 terested persons an opportunity to comment
20 upon any such request and shall, within 45
21 days of its receipt, either approve or deny the
22 request. The Administrator shall publish in the
23 Federal Register notice of the approval or de-
24 nial of such a request.

1 “(3) LIKELIHOOD OF RISK.—The Adminis-
2 trator may, upon request and by rule or order, ex-
3 empt a person who commences manufacture of a
4 new chemical substance or manufacture or proc-
5 essing of a chemical substance for a significant new
6 use from all or part of the requirements of this sec-
7 tion if under prescribed conditions the Administrator
8 determines that the manufacture, processing, dis-
9 tribution in commerce, and use of such chemical
10 substance, and any combination of such activities
11 under such prescribed conditions, is not likely to re-
12 sult in an unreasonable risk of harm to human
13 health or the environment. A rule promulgated
14 under this paragraph (and any substantive amend-
15 ment to, or repeal of, such a rule)—

16 “(A) shall be promulgated in accordance
17 with section 553 of title 5, United States Code
18 (without regard to any reference in such section
19 to sections 556 and 557 of such title); and

20 “(B) shall be subject to public notice and
21 an opportunity for public comment.

22 “(4) TEMPORARY EXISTENCE.—The Adminis-
23 trator may, by rule, make the requirements of sub-
24 section (a) inapplicable with respect to the manufac-
25 turing or processing of any chemical substance—

1 “(A) which exists temporarily as a result
2 of a chemical reaction in the manufacturing or
3 processing of a mixture or another chemical
4 substance; and

5 “(B) to which there is no, and will not be,
6 human or environmental exposure.

7 “(5) BYPRODUCTS.—The Administrator shall,
8 by rule, make the requirements of subsection (a) in-
9 applicable to the manufacture or processing of any
10 byproduct chemical substance produced without a
11 separate commercial intent during the manufacture,
12 processing, use, or disposal of another chemical sub-
13 stance or mixture if—

14 “(A) such byproduct chemical substance is
15 not used for commercial purposes; or

16 “(B) the only intended commercial purpose
17 of the byproduct chemical substance is for—

18 “(i) burning as a fuel;

19 “(ii) disposing as a waste, including in
20 a landfill or for enriching soil; or

21 “(iii) extracting, by reaction or other-
22 wise, a chemical substance to recycle or re-
23 claim.

24 “(g) MIXTURES.—A combination of chemical sub-
25 stances physically combined without a chemical reaction

1 shall not be considered a new chemical substance for pur-
2 poses of this section.”.

3 (b) TABLE OF CONTENTS AMENDMENT.—The item
4 relating to section 5 in the table of contents is amended
5 to read as follows:

“Sec. 5. New chemicals and significant new uses.”.

6 **SEC. 6. EXISTING CHEMICALS.**

7 (a) AMENDMENTS.—Section 6 (15 U.S.C. 2605) is
8 amended—

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

11 **“SEC. 6. EXISTING CHEMICALS.”;**

12 (2) by redesignating subsections (e) and (f) as
13 subsections (i) and (j), respectively;

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

16 **“(a) ASSIGNING PRIORITIES FOR SAFETY DETER-**
17 **MINATIONS.—**

18 **“(1) IN GENERAL.—**Not later than 1 year after
19 the date of enactment of the Chemicals in Commerce
20 Act, the Administrator shall, after providing public
21 notice and an opportunity for public comment, es-
22 tablish a risk-based process for designating, based
23 on the weight of the best available science, chemical
24 substances as either high priority or low priority. In
25 making such designations, the Administrator—

1 “(A) shall identify as high priority a chem-
2 ical substance that has the potential for high
3 hazard and high exposure;

4 “(B) may identify as high priority a chem-
5 ical substance that has the potential for high
6 hazard or high exposure; and

7 “(C) shall identify as low priority a chem-
8 ical substance that is not likely to result in an
9 unreasonable risk of harm to human health or
10 the environment under the intended conditions
11 of use.

12 “(2) TIMELY COMPLETION.—The Administrator
13 shall designate a priority for all chemical substances
14 identified as active under section 8 as soon as fea-
15 sible, taking into account the ability of the Adminis-
16 trator to schedule and complete safety determina-
17 tions under this section. The Administrator may
18 defer designation of a priority in order to provide in-
19 terested persons an opportunity to submit additional
20 information not previously made available to the Ad-
21 ministrator.

22 “(3) PUBLICATION OF LIST.—The Adminis-
23 trator shall publish, and update from time to time,
24 a list of chemical substances—

1 “(A) identifying those under consideration
2 for designation as high or low priority;

3 “(B) identifying those that have been des-
4 ignated as a high or low priority at the time a
5 designation has been made under paragraph
6 (1); and

7 “(C) indicating those for which a safety
8 determination has been completed.

9 “(4) FACTORS FOR ASSIGNING PRIORITIES.—
10 The factors used by the Administrator to assign pri-
11 orities shall include—

12 “(A) the hazard and exposure potential of
13 a chemical substance, including specific sci-
14 entific classifications and designations by au-
15 thoritative governmental entities;

16 “(B) the specific uses and exposures that
17 are significant to the risk of harm to human
18 health and the environment and the intended
19 conditions of use, or changes in the conditions
20 of use, of chemical substances;

21 “(C) evidence and indicators of exposure to
22 humans or the environment from a chemical
23 substance;

24 “(D) the volume of a chemical substance
25 manufactured or processed;

1 “(E) whether the volume of a chemical
2 substance as reported under a regulation issued
3 under section 8(a) has significantly increased or
4 decreased since a previous report or since the
5 date on which a notice has been submitted
6 under section 5(a) for that chemical substance;

7 “(F) the availability of information about
8 potential hazards and exposures needed for con-
9 ducting a safety determination, with limited
10 availability of relevant information to be a fac-
11 tor in designating a chemical substance as a
12 high priority; and

13 “(G) the extent of Federal or State regula-
14 tion of a chemical substance or the extent of
15 the impact of State regulation of that chemical
16 substance on the United States, with existing
17 Federal or State regulation as a factor in desig-
18 nating a chemical substance as a low priority.

19 “(5) EFFECT OF LOW-PRIORITY DESIGNA-
20 TION.—Chemical substances designated by the Ad-
21 ministrator as a low priority shall not be subject to
22 a safety determination, and unless redesignated as a
23 high priority, shall be considered not likely to result
24 in an unreasonable risk of harm to human health or

1 the environment under the intended conditions of
2 use.

3 “(6) NOTICE AND COMMENT.—The Administra-
4 tor’s proposed priority designations under this sub-
5 section shall be subject to public notice and an op-
6 portunity for public comment.

7 “(7) REVISION BASED ON NEW INFORMA-
8 TION.—The Administrator may revise the priority
9 designation of a chemical substance based on consid-
10 eration of new information.

11 “(8) PROCESS REVIEW.—The Administrator
12 shall periodically review and if necessary modify the
13 process of assigning priorities to chemical substances
14 under this subsection based upon experience and re-
15 sources available to efficiently and effectively
16 prioritize chemical substances.

17 “(9) LIMITATION.—Except as provided in sec-
18 tion 18, a designation by the Administrator under
19 this subsection of a chemical substance as a high
20 priority shall not affect the manufacture, processing,
21 distribution, use, or disposal of the chemical sub-
22 stance, or regulation of those activities.

23 “(10) FINAL AGENCY ACTION.—A designation
24 by the Administrator under this subsection of a
25 chemical substance as a high priority shall not be

1 considered to be a final agency action subject to ju-
2 dicial review.

3 “(b) MAKING SAFETY DETERMINATIONS.—The Ad-
4 ministrator shall make a safety determination, based on
5 the best available science related to health and environ-
6 mental considerations, and in accordance with the weight
7 of the scientific evidence, regarding whether—

8 “(1) a chemical substance designated as a high
9 priority will not result in an unreasonable risk of
10 harm to human health or the environment under the
11 intended conditions of use;

12 “(2) a chemical substance designated as a high
13 priority will result in an unreasonable risk of harm
14 to human health or the environment under the in-
15 tended conditions of use, in which case, the Adminis-
16 trator shall impose one or more of the restrictions
17 identified in subsection (f)(3); or

18 “(3) additional information is necessary in
19 order to make a determination under paragraph (1)
20 or (2).

21 “(c) REQUIREMENTS FOR DETERMINATION.—In
22 making a safety determination the Administrator shall—

23 “(1) afford greater weight to scientific evidence
24 that meets the criteria established by the Adminis-
25 trator under section 26(i);

1 “(2) use the best available science, and inte-
2 grate and assess information on hazards, exposures,
3 and risks;

4 “(3) analyze exposure to the chemical substance
5 for the specific uses that are significant to the risk
6 of harm and subsets of exposure (including informa-
7 tion on potentially exposed subpopulations), and the
8 duration, intensity, frequency, and number of expo-
9 sures under the intended conditions of use of the
10 chemical substance;

11 “(4) describe the weight of the scientific evi-
12 dence for observed biological effects and risks, in-
13 cluding the appropriate modes of action;

14 “(5) incorporate reference parameters that may
15 be appropriate with regard to a specific chemical
16 substance (such as a margin of exposure); and

17 “(6) consider whether the weight of the evi-
18 dence of the best available science supports the iden-
19 tification of threshold doses of a chemical substance
20 below which no adverse effects can be expected to
21 occur.

22 “(d) ADDITIONAL INFORMATION.—If the Adminis-
23 trator determines pursuant to subsection (b)(3) that addi-
24 tional information is needed in order to make a safety de-
25 termination, the Administrator—

1 “(1) shall provide an opportunity for interested
2 persons to submit the additional information;

3 “(2) may promulgate a rule, enter into a con-
4 sent agreement, or issue an order under section 4 to
5 require the development of the information;

6 “(3) may defer, for a reasonable period, the
7 safety determination until after receipt of the infor-
8 mation; and

9 “(4) shall, upon receipt of the information,
10 make a safety determination under subsection (b)(1)
11 or (2).

12 “(e) PUBLICATION.—In making a safety determina-
13 tion, the Administrator shall publish a statement that in-
14 cludes—

15 “(1) such safety determination; and

16 “(2) a summary of the analysis performed pur-
17 suant to subsection (c) in support of that determina-
18 tion.

19 “(f) RULE.—

20 “(1) IMPLEMENTATION.—If the Administrator
21 determines under subsection (b)(2) that a chemical
22 substance will result in an unreasonable risk of
23 harm to human health or the environment under the
24 intended conditions of use, the Administrator shall

1 promulgate a rule, in accordance with this sub-
2 section.

3 “(2) SCOPE.—A rule promulgated under this
4 subsection—

5 “(A) may—

6 “(i) as appropriate, apply to mixtures
7 containing the chemical substance; or

8 “(ii) apply to articles, but only where
9 the Administrator—

10 “(I) identifies specific types of
11 articles that are, or likely will be, in
12 United States commerce; and

13 “(II) determines that ensuring
14 that no unreasonable risk of harm to
15 human health or the environment will
16 result from exposure to the chemical
17 substance requires placing require-
18 ments on such articles that cannot be
19 addressed adequately through require-
20 ments placed on chemical substances
21 or mixtures; and

22 “(B) shall—

23 “(i) exempt replacement parts for ar-
24 ticles manufactured prior to the applicable
25 compliance deadline; and

1 “(ii) include dates by which compli-
2 ance is mandatory, which may vary for dif-
3 ferent affected persons, as the Adminis-
4 trator determines to be appropriate.

5 “(3) RESTRICTION.—A rule promulgated under
6 this subsection shall include, as appropriate, one or
7 more of the following:

8 “(A) A requirement that a chemical sub-
9 stance be marked with, or accompanied by,
10 clear and adequate warnings and instructions
11 with respect to distribution in commerce, or
12 use, or any combination of those activities, with
13 the form and content of the warnings and in-
14 structions to be prescribed by the Adminis-
15 trator.

16 “(B) A requirement that manufacturers
17 and processors of the chemical substance—

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

21 “(ii) monitor specific uses of or expo-
22 sures to the chemical substance; or

23 “(iii) subject to section 4, develop ad-
24 ditional information that is reasonably nec-

1 essary to ensure compliance with this sec-
2 tion.

3 “(C) A restriction on the quantity of the
4 chemical substance that may be manufactured,
5 processed, or distributed in commerce.

6 “(D) A requirement to restrict, ban, or
7 phase out the manufacture, processing, or dis-
8 tribution in commerce of the chemical sub-
9 stance—

10 “(i) for a particular use;

11 “(ii) for a particular use at a con-
12 centration in excess of a level specified by
13 the Administrator; or

14 “(iii) for all uses.

15 “(E) A restriction on the quantity of the
16 chemical substance that may be manufactured,
17 processed, or distributed in commerce—

18 “(i) for a particular use; or

19 “(ii) for a particular use at a con-
20 centration in excess of a level specified by
21 the Administrator.

22 “(F) A requirement to restrict, ban, or
23 phase out a method of commercial use of the
24 chemical substance;

1 “(G) A requirement directing manufactur-
2 ers or processors of the chemical substance to
3 give notice of unreasonable risks of harm to dis-
4 tributors in commerce of the chemical substance
5 and, to the extent reasonably ascertainable, to
6 other persons in the chain of commerce in pos-
7 session of the chemical substance.

8 “(4) LIMITATIONS.—When imposing require-
9 ments or restrictions on a chemical substance under
10 this subsection, the Administrator shall—

11 “(A) determine that—

12 “(i) such requirements or restrictions
13 are proportional to the risks of the chem-
14 ical substance that are addressed in the
15 safety determination;

16 “(ii) such requirements or restrictions
17 will result in net benefits; and

18 “(iii) requirements or restrictions im-
19 posed on uses of the chemical substance
20 are cost-effective in ensuring that the
21 chemical substance will not result in an
22 unreasonable risk of harm to human health
23 or the environment under the intended
24 conditions of use, compared to alternative

1 requirements or restrictions that the Ad-
2 ministrator may reasonably adopt;

3 “(B) impose requirements or restrictions
4 that prohibit or substantially prevent specific
5 uses of the chemical substance only when tech-
6 nically and economically feasible alternatives
7 that materially reduce risk to human health or
8 the environment compared to the use proposed
9 to be prohibited or substantially prevented are
10 available and likely to be used as a substitute
11 for the use proposed to be prohibited or sub-
12 stantially prevented; and

13 “(C) provide for a reasonable transition
14 period for implementation.

15 “(g) FINAL AGENCY ACTION.—

16 “(1) DETERMINATION OF NO UNREASONABLE
17 RISK.—A determination under subsection (b)(1) that
18 a chemical substance will not result in an unreason-
19 able risk of harm to human health or the environ-
20 ment under the intended conditions of use shall be
21 considered a final agency action.

22 “(2) DETERMINATION OF UNREASONABLE
23 RISK.—A determination under subsection (b)(2) that
24 a chemical substance will result in an unreasonable
25 risk of harm to human health or the environment

1 under the intended conditions of use shall be consid-
2 ered a final agency action on the date of publication
3 of the final rule promulgated under subsection (f).”;
4 and

5 (4) in subsection (i) (as so redesignated by
6 paragraph (2) of this subsection)—

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

8 (B) by redesignating paragraph (5) as
9 paragraph (4).

10 (b) TABLE OF CONTENTS AMENDMENT.—The item
11 relating to section 6 in the table of contents is amended
12 to read as follows:

“Sec. 6. Existing chemicals.”.

13 **SEC. 7. IMMINENT HAZARDS.**

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

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

17 “(a) CIVIL ACTIONS.—

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

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

24 “(B) relief (as authorized by subsection
25 (b)) against any person who manufactures,

1 processes, distributes in commerce, uses, or dis-
2 poses of an imminently hazardous chemical sub-
3 stance or mixture or any article containing such
4 chemical substance or mixture; or

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

8 “(2) RULE, ORDER, OR OTHER PROCEEDING.—
9 The Administrator may commence a civil action
10 under this subsection notwithstanding—

11 “(A) the existence of—

12 “(i) a decision by the Administrator
13 under section 5(c)(3), 6(a), or 6(b); or

14 “(ii) a rule, consent agreement, or
15 order, as applicable, under section 4(a)(2),
16 5(c)(5), or 6(f); or

17 “(B) the pendency of any administrative or
18 judicial proceeding under any provision of this
19 Act.”;

20 (2) in subsection (d), by striking “section 6(a)”
21 and inserting “section 6(f)”; and

22 (3) in subsection (f)—

23 (A) in the first sentence, by striking “and
24 unreasonable risk of serious or widespread in-
25 jury to health or the environment” and insert-

1 ing “risk of serious or widespread harm to
2 human health or the environment”; and
3 (B) by striking “such injury” and inserting
4 “such harm”.

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

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

7 (1) in subsection (a), by adding at the end the
8 following:

9 “(4) REQUIREMENTS.—Not later than 2 years after
10 the date of enactment of the Chemicals in Commerce Act,
11 the Administrator shall promulgate rules establishing re-
12 porting requirements for manufacturers and processors as
13 necessary to carry out section 6.

14 “(5) GUIDANCE.—The Administrator shall develop
15 guidance relating to the information required to be re-
16 ported under this subsection that—

17 “(A) includes the level of detail necessary to be
18 reported; and

19 “(B) describes the manner by which manufac-
20 turers and processors may voluntarily report use and
21 exposure information.

22 “(6) NONAPPLICABILITY.—This subsection shall not
23 apply to—

24 “(A) a chemical substance extracted, by reac-
25 tion or otherwise, from another chemical substance

1 for the purpose of recycling or reclaiming such ex-
2 tracted chemical substance; or

3 “(B) a combination of chemical substances
4 physically combined without a chemical reaction.”;

5 (2) in subsection (b)—

6 (A) in paragraph (1), by adding at the end
7 the following: “The Administrator shall estab-
8 lish and maintain a confidential portion and a
9 nonconfidential portion of the list published
10 under this paragraph, consistent with section
11 14. Chemical substances on each such portion
12 of the list shall be identified as either active or
13 inactive, as designated under paragraph (5).”;
14 and

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

17 “(3) NOMENCLATURE.—The Administrator shall de-
18 velop guidance that—

19 “(A) permits the continued use of Class 2 no-
20 menclature in use on date of enactment of the
21 Chemical in Commerce Act;

22 “(B) permits the continued use of the Soap and
23 Detergent Association Nomenclature System, pub-
24 lished in March 1978 by the Administrator in sec-
25 tion 1 of addendum III of the document entitled

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

6 “(C) treats as being included on the list pub-
7 lished under paragraph (1), under the Chemical Ab-
8 stracts Service numbers for the respective categories,
9 all components of—

10 “(i) cement, Portland, chemicals, CAS No.
11 65997-15-1;

12 “(ii) cement, alumina, chemicals, CAS No.
13 65997-16-2;

14 “(iii) glass, oxide, chemicals, CAS No.
15 65997-17-3;

16 “(iv) frits, chemicals, CAS No. 65997-18-
17 4;

18 “(v) steel manufacture, chemicals, CAS
19 No. 65997-19-5; and

20 “(vi) ceramic materials and wares, chemi-
21 cals, CAS No. 66402-68-4;

22 “(D) if guidance in effect before the guidance
23 developed under this paragraph allowed for multiple
24 nomenclature conventions—

1 “(i) permits the continued use of the no-
2 menclature conventions for chemical substances;
3 and

4 “(ii) includes new guidance that establishes
5 equivalency between the nomenclature conven-
6 tions for chemical substances on the list pub-
7 lished under paragraph (1); and

8 “(E) for any chemical substance appearing mul-
9 tiple times on the list under different Chemical Ab-
10 stracts Service numbers, includes guidance recog-
11 nizing the multiple listings as a single chemical sub-
12 stance.

13 “(4) CHEMICAL SUBSTANCES IN COMMERCE.—

14 “(A) RULE.—

15 “(i) IN GENERAL.—The Administrator, by
16 rule, shall require manufacturers and may re-
17 quire processors to notify the Administrator
18 when the manufacturer or processor, as applica-
19 ble, has manufactured or processed a chemical
20 substance that has been placed on the list
21 under paragraph (1) during the 5-year period
22 prior to the date of enactment of the Chemicals
23 in Commerce Act.

24 “(ii) PROCEDURE FOR NOTICE OF ACTIVE
25 AND INACTIVE CHEMICAL SUBSTANCES.—A rule

1 under this subparagraph shall establish a proce-
2 dure for any person to notify the Administrator
3 of a chemical substance that the Administrator
4 should identify as active or inactive under para-
5 graph (5).

6 “(B) GUIDANCE.—Before issuing a final rule
7 under subparagraph (A), the Administrator shall
8 make publicly available guidance relating to the rule
9 for chemical substances on the confidential portion
10 of the list under paragraph (1), including guidance
11 on the use of—

12 “(i) accession numbers;

13 “(ii) premanufacture notice case numbers,
14 if applicable; and

15 “(iii) generic names.

16 “(C) CONFIDENTIAL CHEMICAL SUBSTANCES.—
17 The rule issued under subparagraph (A) shall re-
18 quire a manufacturer or processor submitting a no-
19 tice including information relating to a chemical sub-
20 stance to indicate whether the manufacturer or proc-
21 essor claims the information as confidential pursu-
22 ant to section 14.

23 “(D) PRESERVATION OF RECORDS.—The rule
24 issued under subparagraph (A) shall require a man-
25 ufacturer or processor to retain a record supporting

1 the accuracy of the information submitted to the Ad-
2 ministrator by the manufacturer or processor for a
3 period of 5 years beginning on the last day of the
4 submission period.

5 “(E) APPLICABILITY.—Nothing in this para-
6 graph requires the resubstantiation of a claim for
7 protection against disclosure for information sub-
8 mitted to the Administrator prior to the date of en-
9 actment of the Chemicals in Commerce Act.

10 “(5) ACTIVE AND INACTIVE SUBSTANCES.—

11 “(A) ACTIVE SUBSTANCES.—For purposes of
12 this paragraph, the term ‘active substance’ means a
13 chemical substance—

14 “(i) that has been manufactured or proc-
15 essed (other than a chemical substance de-
16 scribed in section 720.30 of title 40, Code of
17 Federal Regulations (or successor regulations),
18 or a chemical substance manufactured or proc-
19 essed only as part of an article) at any point
20 during—

21 “(I) in the case of a chemical sub-
22 stance manufactured or processed before
23 the date of enactment of the Chemicals in
24 Commerce Act, the 5-year period ending
25 on such date of enactment; and

1 “(II) in the case of a chemical sub-
2 stance first manufactured or processed on
3 or after the date of enactment of the
4 Chemicals in Commerce Act, the 4-year pe-
5 riod ending on the date on which the most
6 recent data was reported under part 711
7 of title 40, Code of Federal Regulations (or
8 successor regulations);

9 “(ii) that is added to the list published
10 under paragraph (1) after the date of enact-
11 ment of the Chemicals in Commerce Act;

12 “(iii) for which a person has notified the
13 Administrator pursuant to subparagraph (C)
14 that such person intends to manufacture or
15 process a chemical substance that is designated
16 as an inactive substance; or

17 “(iv) that has been reported under part
18 711 of title 40, Code of Federal Regulations (or
19 successor regulations) after the date of enact-
20 ment of the Chemicals in Commerce Act.

21 “(B) INACTIVE SUBSTANCES.—For purposes of
22 this paragraph, the term ‘inactive substance’ means
23 a chemical substance on the list published under
24 paragraph (1) that has not been manufactured or
25 processed at any point during—

1 “(i) in the case of a chemical substance
2 manufactured or processed before the date of
3 enactment of the Chemicals in Commerce Act,
4 the 5-year period ending on such date of enact-
5 ment; and

6 “(ii) in the case of a chemical substance
7 first manufactured or processed on or after the
8 date of enactment of the Chemicals in Com-
9 merce Act, the 4-year period ending on the date
10 on which the most recent data were reported
11 under part 711 of title 40, Code of Federal
12 Regulations (or successor regulations).

13 “(C) CHANGE TO ACTIVE STATUS.—

14 “(i) IN GENERAL.—Any person who in-
15 tends to manufacture or process a chemical
16 substance that is identified as an inactive sub-
17 stance shall notify the Administrator before the
18 date on which the chemical substance is manu-
19 factured or processed.

20 “(ii) UPDATE OF STATUS.—On receiving
21 notification under clause (i), the Administrator
22 shall designate the chemical substance as an ac-
23 tive substance and amend the list under para-
24 graph (1) accordingly.

1 “(6) INFORMATION ON LIST.—The Administrator
2 shall include on the list published under paragraph (1)—

3 “(A) the accession number, generic name, and,
4 if applicable, premanufacture notice case number for
5 each active or inactive substance, in the case of a
6 chemical substance on the confidential portion of the
7 list published under paragraph (1); and

8 “(B) the specific identity of any active or inac-
9 tive substance for which no such claim of confiden-
10 tiality was received under paragraph (4)(C), subject
11 to the condition that, before revealing the specific
12 identity of the chemical substance, the Adminis-
13 trator shall—

14 “(i) publish, if applicable, the accession
15 number, generic name, and premanufacture no-
16 tice case number for that chemical substance;
17 and

18 “(ii) provide an opportunity for any per-
19 son—

20 “(I) to certify to the Administrator
21 that the person intends to manufacture or
22 process the chemical substance at any
23 point in the subsequent 4-year period; and

1 “(II) to claim confidentiality for the
2 specific identity of the chemical sub-
3 stance.”; and

4 (3) in subsection (e), by striking “injury to
5 health or the environment” and inserting “harm to
6 human health or the environment”.

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

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

9 (1) in subsection (a)—

10 (A) in the first sentence of paragraph

11 (1)—

12 (i) by striking “the manufacture,
13 processing, distribution in commerce, use,
14 or disposal of a chemical substance or mix-
15 ture, or that any combination of such ac-
16 tivities, presents or will present an unrea-
17 sonable risk of injury to health or the envi-
18 ronment” and inserting “a chemical sub-
19 stance or mixture is likely to result in an
20 unreasonable risk of harm to human health
21 or the environment under the intended
22 conditions of use”; and

23 (ii) by striking “such risk” the first
24 place it appears and inserting “the risk
25 posed by the manufacture, processing, dis-

1 tribution in commerce, or use of the chem-
2 ical substance or mixture”;

3 (B) in paragraph (2), in the matter fol-
4 lowing subparagraph (B), by striking “section 6
5 or 7” and inserting “section 6(f) or 7”; and

6 (C) in paragraph (3), by striking “section
7 6 or 7” and inserting “section 6(f) or 7”;
8 (2) in subsection (b)—

9 (A) by inserting “(1)” before “The” in the
10 first sentence; and

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

12 “(2) In determining whether to initiate action under
13 section 6(f), the Administrator shall compare—

14 “(A) the estimated costs of complying with ac-
15 tions taken under this title with the estimated costs
16 of proceeding instead under other law or laws ad-
17 ministered by the Administrator; and

18 “(B) the efficiency of actions under this title
19 and under such other law or laws to protect against
20 the risk being addressed.”; and

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

1 **SEC. 10. 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. 11. INSPECTIONS AND SUBPOENAS.**

7 Section 11(b)(2)(B) (15 U.S.C. 2610(b)(2)(B)) is
8 amended by inserting “or marketing” after “sales”.

9 **SEC. 12. EXPORTS.**

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

11 (1) in subsection (a)—

12 (A) in paragraph (1)—

13 (i) by striking “chemical substance,
14 mixture, or to an article containing a
15 chemical substance or mixture,” and in-
16 serting “chemical substance or mixture”;
17 and

18 (ii) by striking “substance, mixture or
19 article” each place it appears and inserting
20 “substance or mixture”; and

21 (B) in paragraph (2)—

22 (i) by striking “substance, mixture or
23 article” both places it appears and insert-
24 ing “substance or mixture” and

25 (ii) by striking “unreasonable risk of
26 injury to health” both places it appears

1 and inserting “unreasonable risk of harm
2 to human health”;

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

5 “(b) NOTICE.—

6 “(1) REGULATED SUBSTANCES.—

7 “(A) IN GENERAL.—The Administrator
8 may require a person to notify the Adminis-
9 trator that the person is exporting or intends to
10 export to a foreign country a chemical sub-
11 stance or mixture for which for which the Ad-
12 ministrator has—

13 “(i) imposed a requirement or restric-
14 tion under section 5(c)(5); or

15 “(ii) promulgated a rule under section
16 6(f).

17 “(B) FREQUENCY.—The Administrator
18 shall require notice from a person under sub-
19 paragraph (A) no more frequently than annu-
20 ally after the first notice submitted by that per-
21 son for the chemical substance or mixture.

22 “(C) NOTICE TO GOVERNMENT OF RECEIV-
23 ING COUNTRY.—Upon receipt of a notification
24 under this paragraph, the Administrator may
25 notify the government of the country to which

1 the chemical substance or mixture is being ex-
2 ported.

3 “(2) TREATY OBLIGATIONS.—

4 “(A) IN GENERAL.—The Administrator
5 shall require a person to notify the Adminis-
6 trator that the person is exporting or intends to
7 export to a foreign country a chemical sub-
8 stance or mixture, or an article containing such
9 chemical substance or mixture, for which the
10 United States is obligated by treaty to provide
11 export notification.

12 “(B) CONTENTS.—Such notice shall in-
13 clude all information necessary to enable the
14 United States to satisfy obligations under the
15 applicable treaty.

16 “(C) FREQUENCY.—The Administrator
17 shall require notice from a person under sub-
18 paragraph (A) no more frequently than annu-
19 ally after the first notice submitted by that per-
20 son for the chemical substance or mixture.”;
21 and

22 (3) in subsection (c)—

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

1 (B) by redesignating paragraphs (4)
2 through (6) as paragraphs (3) through (5), re-
3 spectively.

4 **SEC. 13. IMPORTS.**

5 (a) AMENDMENT.—Section 13 (15 U.S.C. 2612) is
6 amended to read as follows:

7 **“SEC. 13. IMPORTS.**

8 **“(a) NOTICE.—**

9 **“(1) IN GENERAL.—**A person offering a chem-
10 ical substance or mixture described in paragraph (2)
11 for entry into the customs territory of the United
12 States shall certify to the Secretary of Homeland Se-
13 curity that, after reasonable inquiry and to the best
14 knowledge and belief of the person, the chemical
15 substance or mixture is—

16 **“(A) in compliance with any applicable**
17 **rule, consent agreement, or order under section**
18 **5 or 6; and**

19 **“(B) included on the list under section**
20 **8(b) or exempt from any requirement to be in-**
21 **cluded on that list.**

22 **“(2) COVERED CHEMICAL SUBSTANCES AND**
23 **MIXTURES.—**The chemical substances or mixtures
24 referred to in paragraph (1) are those that are or
25 contain a chemical substance that is either—

1 “(A) designated as a high priority under
2 section 6(a);

3 “(B) subject to prohibitions or restrictions
4 under section 5(c)(5); or

5 “(C) subject to requirements or restric-
6 tions under a rule promulgated under section
7 6(f).

8 “(b) REFUSAL OF ENTRY.—

9 “(1) IN GENERAL.—The Secretary of Homeland
10 Security shall refuse entry into the customs territory
11 of the United States (as defined in general note 2
12 to the Harmonized Tariff Schedule of the United
13 States) any chemical substance or mixture offered
14 for such entry if the chemical substance or mixture
15 is intended to be imported for a use that would vio-
16 late a rule, consent agreement, or order in effect
17 under this title.

18 “(2) PROCEDURE.—

19 “(A) IN GENERAL.—Except as provided in
20 subparagraph (B), if a chemical substance or
21 mixture is refused entry under paragraph (1),
22 the Secretary of Homeland Security—

23 “(i) shall notify the consignee of the
24 refusal of entry;

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

3 “(iii) shall cause the disposal or stor-
4 age of the chemical substance or mixture
5 under such rules as the Administrator may
6 prescribe, consistent with other applicable
7 Federal law, if the chemical substance or
8 mixture has not been removed from the
9 United States in the 90-day period begin-
10 ning on the date of receipt of the notice of
11 the refusal of entry provided under clause
12 (i).

13 “(B) EXCEPTION.—

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

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

23 “(II) pays any applicable duty on
24 the chemical substance or mixture.

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

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

18 “(c) RULES.—The Secretary of Homeland Security,
19 after consultation with the Administrator, shall issue rules
20 for the administration of this section.”.

21 (b) TABLE OF CONTENTS AMENDMENT.—The item
22 relating to section 13 in the table of contents is amended
23 to read as follows:

 “Sec. 13. Imports.”.

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

2 (a) AMENDMENT.—Section 14 (15 U.S.C. 2613) is
3 amended to read as follows:

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

5 “(a) IN GENERAL.—Except as provided in subsection
6 (d), the Administrator shall not disclose information ob-
7 tained by the Administrator under this title that is—

8 “(1) information exempt from disclosure under
9 section 552(b)(4) of title 5, United States Code;

10 “(2) specific information describing the manu-
11 facture, processing, or distribution in commerce of a
12 chemical substance, mixture, or article;

13 “(3) marketing and sales information;

14 “(4) information on the identity of constituents
15 in a mixture and the respective percentages of those
16 constituents;

17 “(5) specific information about the use, func-
18 tion, or application of a chemical substance or mix-
19 ture in a process, mixture, or product;

20 “(6) information on specific production or im-
21 port volumes of a manufacturer and specific volumes
22 aggregated across manufacturers if disclosure of
23 that aggregated data could reveal information identi-
24 fied in paragraphs (1) through (6); or

25 “(7) the specific identity of a chemical sub-
26 stance, including the chemical name, molecular for-

1 mula, Chemical Abstracts Service number, or other
2 information that would identify a specific chemical
3 substance, if the specific identity is claimed under
4 subsection (b) as confidential information and the
5 claim has not subsequently been withdrawn or found
6 by the Administrator not to warrant protection as
7 confidential information under this section.

8 “(b) REQUIREMENTS FOR CERTAIN CONFIDEN-
9 TIALITY CLAIMS.—A person seeking protection from dis-
10 closure of information under this section shall—

11 “(1) claim such information as confidential by
12 identifying such information to the Administrator;
13 and

14 “(2) in the case of information described in
15 paragraph (8) of subsection (a), submit—

16 “(A) written documentation justifying why
17 the information qualifies for such protection, in-
18 cluding documentation establishing that—

19 “(i) the submitting person takes rea-
20 sonable measures to protect the confiden-
21 tiality of the information;

22 “(ii) the information is not required
23 to be disclosed, or otherwise made avail-
24 able, to the public under any other Federal

1 law in connection with one or more uses
2 subject to this title;

3 “(iii) disclosure of the information is
4 likely to cause meaningful harm to the
5 competitive position of the person; and

6 “(iv) the information is not reasonably
7 believed to be readily discoverable through
8 reverse engineering;

9 “(B) the time period for which the person
10 claims protection from disclosure of the infor-
11 mation, which may be renewed upon request
12 not later than 30 days before the expiration of
13 the period; and

14 “(C) a generic name for the chemical sub-
15 stance that the Administrator may disclose to
16 the public, subject to the condition that the ge-
17 neric name discloses a maximum amount of in-
18 formation on the structure of the chemical sub-
19 stance while protecting those features of such
20 structure that are considered confidential and
21 the disclosure of which would potentially harm
22 the competitive position of the person.

23 “(c) GUIDANCE.—The Administrator shall develop
24 guidance on the determination of generic names for con-
25 fidential chemical identities.

1 “(d) EXCEPTIONS TO PROTECTION FROM DISCLO-
2 SURE.—

3 “(1) IN GENERAL.—In accordance with sub-
4 section (l), subsection (a) shall not apply to—

5 “(A) health and safety information—

6 “(i) relating to a chemical substance
7 or mixture that has been offered for com-
8 mercial distribution as of the date on
9 which the information is to be disclosed; or

10 “(ii) that is developed pursuant to a
11 requirement under section 4, 5, or 6;

12 “(B) health and safety information sub-
13 mitted to the Administrator in connection with
14 a notice of substantial risk required under sec-
15 tion 8(e);

16 “(C) general information describing the
17 manufacturing volumes, expressed in ranges,
18 that would not reveal information protected as
19 confidential under this section; and

20 “(D) general descriptions of industrial,
21 commercial, or consumer functions and uses of
22 a chemical substance or mixture that are cus-
23 tomarily shared with the general public or with-
24 in the industry to which the person submitting
25 the information belongs, and would not reveal

1 information protected as confidential under this
2 section.

3 “(2) LIMITED INFORMATION SHARING.—The
4 Administrator may share information otherwise pro-
5 tected from disclosure by this section only as follows:

6 “(A) To an officer or employee of the
7 United States—

8 “(i) to carry out that person’s official
9 duties; or

10 “(ii) for specific law enforcement pur-
11 poses under this or any other Act.

12 “(B) To a contractor with the United
13 States and employees of that contractor if, in
14 the opinion of the Administrator, the disclosure
15 is necessary for the satisfactory performance by
16 the contractor of a contract with the United
17 States for the performance of work in connec-
18 tion with this title and under such conditions as
19 the Administrator shall specify.

20 “(C) To a State, upon written request, for
21 the purpose of development, administration, or
22 enforcement of a law, if—

23 “(i) the recipient agrees in writing to
24 take appropriate steps, and has adequate
25 authority, to maintain the confidentiality

1 of the information in accordance with pro-
2 cedures as stringent as those the Adminis-
3 trator uses to safeguard the information;
4 and

5 “(ii) the Administrator notifies a per-
6 son claiming protection of the information
7 that the information will be disclosed to a
8 State.

9 “(D) To a person who is a health profes-
10 sional employed by a Federal or State agency,
11 or a treating physician or nurse, in a non-
12 emergency situation if such person—

13 “(i) states in writing to the Adminis-
14 trator that the person has a reasonable
15 basis to believe that disclosure of the infor-
16 mation will assist in diagnosis or treatment
17 of any person exposed to the chemical sub-
18 stance; and

19 “(ii) agrees in writing not to use the
20 information for any purpose other than the
21 diagnosis and treatment referred to in
22 clause (i).

23 “(E) To a treating physician, nurse, or
24 agent of a poison control center, or any other
25 person such a physician, nurse, or agent deter-

1 mines is necessary to aid in diagnosis or treat-
2 ment described in clause (i), if—

3 “(i) such physician, nurse, or agent
4 states that the requested information is
5 necessary for, or will assist in, emergency
6 or first-aid diagnosis or treatment and a
7 person being diagnosed or treated has like-
8 ly been exposed to the chemical substance;
9 and

10 “(ii) each person receiving the pro-
11 tected information agrees in writing as
12 soon as practicable, but not necessarily
13 prior to receiving the information, not to
14 use the information concerned for any pur-
15 pose other than the diagnosis or treatment
16 referred to in clause (i).

17 “(3) PROHIBITION.—No person who receives in-
18 formation under paragraph (2) may use such infor-
19 mation for any purpose not specified in such para-
20 graph, nor disclose such information to any person
21 not authorized to receive such information.

22 “(4) USE OF INFORMATION BY THE ADMINIS-
23 TRATOR.—Subsection (a) shall not apply to the ex-
24 tent that the Administrator determines that infor-
25 mation disclosure is necessary—

1 “(A) to protect health or the environment
2 from an imminent and substantial risk of harm;
3 or

4 “(B) in a proceeding under this title, sub-
5 ject to the condition that the disclosure is made
6 in such a manner as to preserve confidentiality
7 to the extent practicable without impairing the
8 proceeding.

9 “(e) DURATION OF PROTECTION FROM DISCLO-
10 SURE.—The Administrator shall protect from disclosure
11 information as required under this section unless—

12 “(1) the person claiming confidentiality of such
13 information under subsection (b) notifies the Admin-
14 istrator that the person is withdrawing the confiden-
15 tiality claim, in which case the Administrator shall
16 promptly make the information available to the pub-
17 lic; or

18 “(2) the Administrator finds that—

19 “(A) the time period described in sub-
20 section (b)(2)(B) has expired;

21 “(B) the information has been publicly dis-
22 closed through some other means; or

23 “(C) the information no longer meets the
24 criteria for protection under this section.

25 “(f) REESTABLISHMENT OF CONFIDENTIALITY.—

1 “(1) IN GENERAL.—Except as provided in para-
2 graph (2), the Administrator may require a person
3 who has claimed information as confidential under
4 subsection (b) to reestablish such claim.

5 “(2) LIMITATION.—The Administrator may not
6 under paragraph (1) require reestablishment of a
7 claim for protection from disclosure of information if
8 such claim was submitted to the Administrator
9 under this title prior to the date of enactment of the
10 Chemicals in Commerce Act, unless the Adminis-
11 trator has a reasonable basis to conclude that the
12 claim does not meet the requirements of this section
13 for protection from disclosure.

14 “(g) DETERMINATION BY THE ADMINISTRATOR.—
15 The Administrator shall—

16 “(1) approve a claim of confidentiality received
17 under subsection (b); or

18 “(2) if the person who has submitted the claim
19 fails to meet the requirements of this section, ap-
20 prove the claim with conditions or deny the claim.

21 “(h) NOTICE AND EXPLANATION.—If the Adminis-
22 trator takes action under subsection (g)(2), makes a find-
23 ing under subsection (e)(2), shares information under sub-
24 section (d)(2)(C) or (D), or discloses information pursuant
25 to a determination under subsection (d)(4)(A), the Admin-

1 istrator shall provide to the person who has claimed con-
2 fidentiality of information under subsection (b) a written
3 statement of the release, or the Administrator’s intent to
4 release or otherwise condition the protection, of the infor-
5 mation and the reasons for taking such action.

6 “(i) TIMING OF RELEASE OF INFORMATION.—

7 “(1) IN GENERAL.—Except as provided in this
8 section, the Administrator may not release informa-
9 tion otherwise protected from disclosure until 30
10 days after the date on which the person who sub-
11 mitted the claim of confidentiality receives notifica-
12 tion under subsection (h).

13 “(2) EXCEPTIONS.—

14 “(A) IN GENERAL.—The Administrator
15 may not share information identified in sub-
16 section (d)(2)(A)(i) until 15 days after the date
17 on which the person who submitted the claim of
18 confidentiality receives a notification under sub-
19 section (h), unless the Administrator deter-
20 mines that release of the information is nec-
21 essary to protect against an imminent and sub-
22 stantial harm to human health or the environ-
23 ment, in which case no prior notification is nec-
24 essary.

1 “(B) NO NOTIFICATION.—For information
2 identified in subsection (d)(2)(A)(ii) or (E), or
3 (d)(4)(A) or (B), no prior notification is nec-
4 essary.

5 “(j) SUBSETS.—If it is not feasible for the Adminis-
6 trator to review each claim received under subsection (b),
7 the Administrator shall review a subset of all submitted
8 information protection claims selected on a statistically
9 valid basis.

10 “(k) JUDICIAL REVIEW.—

11 “(1) IN GENERAL.—A decision by the Adminis-
12 trator under subsection (g)(2) is subject to review
13 and injunctive relief in a district court of the United
14 States located in the district in which the person
15 seeking protection of the information from disclosure
16 resides, or the United States District Court for the
17 District of Columbia.

18 “(2) STAY.—Except as provided in subsection
19 (d), the Administrator shall disclose no information
20 included in claim of confidentiality made under sub-
21 section (b) during the pendency of judicial review
22 under this subsection.

23 “(l) SEPARABILITY OF INFORMATION.—In carrying
24 out this title, the Administrator shall separate information
25 as necessary to ensure that—

1 “(1) no information that is eligible for protec-
2 tion under this section is disclosed with information
3 not protected under this section; and

4 “(2) all information required to be disclosed
5 under this title is disclosed.

6 “(m) ADMINISTRATION.—In carrying out this sec-
7 tion, the Administrator shall employ the procedures in
8 part 2 of title 40, Code of Federal Regulations (or suc-
9 cessor regulations).”.

10 (b) TABLE OF CONTENTS AMENDMENT.—The item
11 relating to section 14 in the table of contents is amended
12 to read as follows:

“Sec. 14. Confidential information.”.

13 **SEC. 15. PROHIBITED ACTS.**

14 Section 15(1) (15 U.S.C. 2614(1)) is amended by
15 striking “(A) any rule” and all that follows through “or
16 (D)” and inserting “any requirement of this title or any
17 rule, order, or consent agreement issued or entered into
18 under this title, or”.

19 **SEC. 16. PENALTIES.**

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

21 (1) in subsection (a)(1)—

22 (A) in the first sentence—

23 (i) by striking “section 15 or 409”

24 and inserting “this title, or who otherwise

1 violates this Act, except as provided in sec-
2 tion 207(b),”; and

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

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

8 (2) in subsection (a)(2)(A), by striking “of sec-
9 tion 15 or 409” and inserting “described in para-
10 graph (1)”; and

11 (3) in subsection (b)—

12 (A) by striking “Any person” and inserting
13 the following:

14 “(1) IN GENERAL.—Any person”;

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

17 (C) by striking “\$25,000” and inserting
18 “\$50,000”; and

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

20 “(2) IMMINENT DANGER OF DEATH OR SERIOUS
21 BODILY INJURY.—Any person who knowingly or will-
22 fully violates any provision of this Act and who
23 knows, at the time of the violation, that the violation
24 places another person in imminent danger of death
25 or serious bodily injury shall be subject, upon convic-

1 tion, to a fine of not more than \$250,000, imprison-
2 ment for not more than 5 years, or both.”.

3 **SEC. 17. PREEMPTION.**

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

6 “(a) IN GENERAL.—Except as otherwise provided in
7 this section, no State or local government may establish
8 or continue in force a law or regulation that, for the pur-
9 pose of regulating chemical substances, mixtures, or arti-
10 cles for intended conditions of use—

11 “(1) requires the development or submission of
12 information—

13 “(A) that the Administrator has required
14 under section 4, 5, or 6; or

15 “(B) relating to a chemical substance, mix-
16 ture, or article and its intended conditions of
17 use with respect to which the Administrator has
18 completed a safety determination;

19 “(2) prohibits or restricts the manufacture,
20 processing, distribution in commerce, or use of a
21 chemical substance, mixture, or article for its in-
22 tended conditions of use if—

23 “(A) the Administrator has—

24 “(i) determined under section
25 5(c)(3)(B) that the chemical substance,

1 mixture, or article for its intended condi-
2 tions of use is not likely to result in an un-
3 reasonable risk of harm to human health
4 or the environment;

5 “(ii) determined under section 6(b)(1)
6 that the chemical substance, mixture, or
7 article will not result in an unreasonable
8 risk of harm to human health or the envi-
9 ronment under the intended conditions of
10 use;

11 “(iii) promulgated a rule, entered into
12 a consent order, or issued an order under
13 section 5(c)(5) or 6(f) with respect to the
14 chemical substance, mixture, or article for
15 its intended conditions of use; or

16 “(iv) designated the chemical sub-
17 stance as a low priority substance under
18 section 6(a); or

19 “(B) the review period under section
20 5(c)(1) with respect to the chemical substance,
21 mixture, or article for its intended conditions of
22 use has expired;

23 “(3) requires the notification of a use of a
24 chemical substance, mixture, or article with respect

1 to which the Administrator has required notification
2 pursuant to section 5;

3 “(4) includes any requirement with respect to a
4 chemical substance, mixture, or article, or its in-
5 tended conditions of use, with respect to which the
6 Administrator, before the date of enactment of the
7 Chemicals in Commerce Act, has promulgated a
8 rule, entered into a consent agreement, issued an
9 order, or allowed the expiration of a significant new
10 use review period under section 5 or 6; or

11 “(5) in the case of a law or regulation that was
12 not in effect on the date of enactment of the Chemi-
13 cals in Commerce Act and regulates a chemical sub-
14 stance, takes effect on or after the date the Adminis-
15 trator identifies that chemical substance as a low
16 priority under section 6(a).

17 “(b) EXCEPTIONS.—Subsection (a) shall not apply to
18 a law or regulation that is adopted or authorized pursuant
19 to any other Federal law.

20 “(c) DAMAGES OR EQUITABLE RELIEF.—Nothing in
21 this section preempts any cause of action under State law
22 for damages or equitable relief alleging personal injury,
23 death, or property damage arising from exposure to a
24 chemical substance or mixture.”.

1 **SEC. 18. JUDICIAL REVIEW.**

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

3 (1) in subsection (a)—

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

6 “(1) FILING OF PETITION.—

7 “(A) IN GENERAL.—Not later than 60
8 days after the date of the promulgation of a
9 rule under section 4, 5(c)(5), 6(f), or 8 or title
10 II or IV or an order under section 4 or 5(c)(5),
11 any person may file a petition for judicial re-
12 view of the rule or order in the United States
13 Court of Appeals for—

14 “(i) the District of Columbia Circuit;

15 “(ii) the circuit in which the person
16 resides; or

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

19 “(B) EXCLUSIVE JURISDICTION OF
20 COURTS OF APPEALS.—The courts of appeals of
21 the United States shall have exclusive jurisdic-
22 tion of any action to obtain judicial review
23 (other than in an enforcement proceeding)
24 under subparagraph (A).”;

25 (B) in paragraph (2)—

1 (i) by inserting “ADMINISTRATIVE
2 RULES.—” before “Copies of any petition”;
3 and

4 (ii) by striking “paragraph (1)(A)”
5 and inserting “paragraph (1)”; and
6 (C) in paragraph (3)—

7 (i) by inserting “DEFINITION.—” be-
8 fore “For purposes of”;

9 (ii) by amending subparagraph (B) to
10 read as follows:

11 “(B) in the case of a rule or order under
12 section 4, the statement issued under section
13 4(b), in the case of a rule or order under sec-
14 tion 5(c)(5), the determination required under
15 section 5(c)(3), in the case of rule under section
16 6(f), the statement published under section
17 6(e), and in the case of a rule under title IV,
18 the finding required for the issuance of such a
19 rule;”.

20 (iii) by striking subparagraph (C);
21 and

22 (iv) by redesignating subparagraphs
23 (D) and (E) as subparagraphs (C) and
24 (D), respectively; and

1 (2) in subsection (c)(1), by striking subpara-
2 graphs (B) and (C) and inserting the following:

3 “(B) APPLICABILITY OF SECTION 706 OF
4 TITLE 5, UNITED STATES CODE.—Section 706
5 of title 5, United States Code, shall apply to re-
6 view of a rule, order, or final agency action
7 under this section, except that—

8 “(i) in the case of a rule under section
9 4, 5(c)(5), or 6(f) or an order under sec-
10 tion 4 or 5(c)(5)—

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

15 “(II) the court shall hold as un-
16 lawful and set aside the rule if the
17 court finds that the rule is not sup-
18 ported by substantial evidence in the
19 rulemaking record; and

20 “(ii) the court shall not review the
21 contents and adequacy of the statement of
22 basis and purpose required by section
23 553(c) of title 5, United States Code, to be
24 incorporated in the rule except as part of

1 a review of the rulemaking record taken as
2 a whole.”.

3 **SEC. 19. CITIZENS’ PETITIONS.**

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

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

9 (2) in subsection (b)—

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

14 (B) by striking subparagraph (B) of para-
15 graph (4) and inserting the following:

16 “(B) DE NOVO PROCEEDING.—

17 “(i) IN GENERAL.—In an action
18 under subparagraph (A) to initiate a pro-
19 ceeding to issue a rule under section 4,
20 6(f), or 8 or an order issued under section
21 4 or 5(c), the petitioner shall be provided
22 an opportunity to have the petition consid-
23 ered by the court in a de novo proceeding.

24 “(ii) DEMONSTRATION.—

1 “(I) IN GENERAL.—The court
2 shall order the Administrator to ini-
3 tiate the action requested by the peti-
4 tioner if the petitioner demonstrates
5 to the satisfaction of the court by a
6 preponderance of the evidence that—

7 “(aa) in the case of a peti-
8 tion to initiate a proceeding for
9 the issuance of a rule or order
10 under section 4, the information
11 available to the Administrator is
12 insufficient for the Administrator
13 to perform an action described in
14 section 4(a)(1);

15 “(bb) in the case of a peti-
16 tion to issue an order under sec-
17 tion 5(c), there is a reasonable
18 basis to conclude that the chem-
19 ical substance is likely to result
20 in an unreasonable risk of harm
21 to human health or the environ-
22 ment under the intended condi-
23 tions of use;

24 “(cc) in the case of a peti-
25 tion to initiate a proceeding for

1 the issuance of a rule under sec-
2 tion 6(f), there is a reasonable
3 basis to conclude that the chem-
4 ical substance or mixture will re-
5 sult in an unreasonable risk of
6 harm to human health or the en-
7 vironment under the intended
8 conditions of use; or

9 “(dd) in the case of a peti-
10 tion to initiate a proceeding for
11 the issuance of a rule under sec-
12 tion 8, there is a reasonable basis
13 to conclude that the rule is nec-
14 essary to protect human health
15 or the environment from an un-
16 reasonable risk of harm.

17 “(II) DEFERMENT.—The court
18 may permit the Administrator to defer
19 initiating the action requested by the
20 petitioner, until such time as the
21 court prescribes, if the court finds
22 that—

23 “(aa) the extent of the risk
24 to human health or the environ-
25 ment alleged by the petitioner is

1 less than the extent of those risks
2 to human health or the environ-
3 ment with respect to which the
4 Administrator is otherwise taking
5 action under this title; and

6 “(bb) there are insufficient
7 resources available to the Admin-
8 istrator to take the action re-
9 quested by the petitioner.”.

10 **SEC. 20. NATIONAL SECURITY.**

11 (a) AMENDMENT.—Section 22 (15 U.S.C. 2621) is
12 amended to read as follows:

13 **“SEC. 22. NATIONAL SECURITY.**

14 “(a) WAIVER.—The Administrator shall waive com-
15 pliance with any provision of this Act upon a determina-
16 tion by the President that the waiver is necessary in the
17 interest of national security. Upon the issuance of such
18 a waiver, the Administrator shall publish in the Federal
19 Register a notice that the waiver was granted for national
20 security purposes, unless the President directs the Admin-
21 istrator to omit such publication because the publication
22 itself would be contrary to the interests of national secu-
23 rity.

24 “(b) CONSULTATION.—The Administrator shall con-
25 sult periodically with the President or the President’s des-

1 ignee to discuss how implementation of this Act could af-
2 fect national security.”.

3 (b) TABLE OF CONTENTS AMENDMENT.—The item
4 relating to section 22 in the table of contents is amended
5 to read as follows:

“Sec. 22. National security.”.

6 **SEC. 21. STUDIES.**

7 Section 25 (15 U.S.C. 2624) and the item relating
8 thereto in the table of contents are repealed.

9 **SEC. 22. POLICIES, PROCEDURES, AND GUIDANCE.**

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

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

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

15 “(h) POLICIES, PROCEDURES, AND GUIDANCE.—Not
16 later than 1 year after the date of enactment of the
17 Chemicals in Commerce Act, the Administrator shall, after
18 providing public notice and an opportunity for public com-
19 ment, establish all policies, procedures, and guidance nec-
20 essary to implement the amendments made to this title
21 by the Chemicals in Commerce Act. Such policies, proce-
22 dures, and guidance shall employ and rely upon the best
23 available science and the best available risk assessment
24 principles and methodologies.

25 “(i) INFORMATION QUALITY.—

1 “(1) IN GENERAL.—The Administrator shall es-
2 tablish scientifically sound criteria for evaluating the
3 quality and reliability of all information, regardless
4 of the affiliation or funding source of the person or
5 organization generating or providing the informa-
6 tion, that the Administrator considers under section
7 4, 5, or 6.

8 “(2) VALIDITY.—The policies, procedures, and
9 guidance developed under subsection (h) shall estab-
10 lish criteria to—

11 “(A) ensure that information considered by
12 the Administrator under this title is of high
13 quality, reliable, and, where available, produced
14 according to validated methods or processes;

15 “(B) address the strengths and limitations
16 of test design and the reliability of test methods
17 and protocols; and

18 “(C) maximize the quality, objectivity, util-
19 ity, and integrity of the information.

20 “(3) STANDARD PRACTICES TO ENSURE QUAL-
21 ITY.—The Administrator shall—

22 “(A) require, to the extent practicable, the
23 use of good laboratory practices, scientifically
24 reliable test methods, standardized protocols,
25 consistent data evaluation procedures, and

1 other methods to ensure that information devel-
2 oped or submitted pursuant to this title is of
3 high scientific quality; and

4 “(B) in using information for decisions
5 under sections 4, 5, and 6, describe the quality
6 of, limitations on, and basis for reliance on such
7 information.

8 “(j) BEST AVAILABLE SCIENCE.—In making a deci-
9 sion with respect to a chemical substance or mixture under
10 section 4, 5, or 6, the Administrator shall use the best
11 available science.

12 “(k) GUIDANCE.—The Administrator shall provide
13 public notice and opportunity for public comment for any
14 significant written guidance of general applicability pre-
15 pared by the Administrator under this title.”.

16 **SEC. 23. TECHNICAL AMENDMENT.**

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

20 **SEC. 24. STATE PROGRAMS.**

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

23 **SEC. 25. AUTHORIZATION OF APPROPRIATIONS.**

24 Section 29 (15 U.S.C. 2628) and the item relating
25 thereto in the table of contents are repealed.

1 **SEC. 26. ANNUAL REPORT.**

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

4 “(2)(A) the number of notices received under
5 section 5; and

6 “(B) the number of the notices described in
7 subparagraph (A) for chemical substances subject to
8 a rule, consent agreement, or order under section
9 4;”.

10 **SEC. 27. PRESERVATION OF AUTHORITY.**

11 Except as specifically provided in this Act or the
12 amendments made by this Act, nothing in this Act or the
13 amendments made by this Act shall amend, alter, or af-
14 fect—

15 (1) the authority of the Administrator under
16 the Toxic Substances Control Act as in effect before
17 the date of enactment of this Act; or

18 (2) the continued application or validity of any
19 action taken by the Administrator under the Toxic
20 Substances Control Act before the date of enactment
21 of this Act.