### [DISCUSSION DRAFT]

April 22, 2014

113TH CONGRESS 2D Session



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 the6 "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. Development of information regarding 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' civil actions.
- Sec. 20. Citizens' petitions.
- Sec. 21. National security.
- Sec. 22. Studies.
- Sec. 23. Policies, procedures, and guidance.
- Sec. 24. Technical amendment.
- Sec. 25. State Programs.
- Sec. 26. Authorization of appropriations.
- Sec. 27. Annual report.
- Sec. 28. Preservation of authority.

(c) REFERENCES.—Except as otherwise expressly
 provided, wherever in this Act an amendment or repeal
 is expressed in terms of an amendment to, or repeal of,
 a section or other provision, the reference shall be consid ered to be made to a section or other provision of the Toxic
 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 $(7)$ through
24	(9), $(10)$ , $(11)$ , and $(12)$ through $(14)$ as paragraphs

(8) through (10), (12), (13), and (15) through (17),
 respectively;

3 (2) by inserting after paragraph (6) the fol-4 lowing:

5 "(7) INTENDED CONDITIONS OF USE.—The 6 term 'intended conditions of use' means the cir-7 cumstances under which a chemical substance is in-8 tended or reasonably anticipated to be manufac-9 tured, processed, distributed in commerce, used, and 10 disposed of.";

(3) by inserting after paragraph (10) (as so re-designated) the following:

13 ((11))POTENTIALLY EXPOSED SUBPOPULA-14 TION.—The term 'potentially exposed subpopulation' 15 means a group or groups of individuals within the 16 general population who the Administrator has rea-17 son to believe may be differentially exposed to a 18 chemical substance under the intended conditions of 19 use or who may be susceptible to more serious ad-20 verse health consequences from chemical substance 21 exposures than the general population, which where 22 appropriate may include infants, children, pregnant 23 women, workers, and the elderly."; and

24 (4) by inserting after paragraph (13) (as so re-25 designated) the following:

 "(14) RISK EVALUATION.—The term 'risk evaluation' means a risk evaluation conducted under section 6(b).".
 SEC. 4. DEVELOPMENT OF INFORMATION REGARDING
 CHEMICAL SUBSTANCES AND MIXTURES.
 (a) IN GENERAL.—Section 4 (15 U.S.C. 2603) is

7 amended to read as follows:

# 8 "SEC. 4. DEVELOPMENT OF INFORMATION REGARDING 9 CHEMICAL SUBSTANCES AND MIXTURES.

10 "(a) Development of New Information on
11 Chemical Substances and Mixtures.—

12 "(1) IN GENERAL.—Except as otherwise pro-13 vided in this title, the Administrator may require 14 manufacturers and processors to develop new hazard 15 and exposure information related to a chemical sub-16 stance or mixture in accordance with this section if 17 the Administrator decides that the information is 18 needed—

19 "(A) for priority designation purposes pur20 suant to section 6(a)(1)(D);

21 "(B) to perform a risk evaluation under
22 section 6(b);

23	"(C) to ensure compliance with—
24	"(i) a rule, consent agreement, or
25	order issued under section $5(c)(5)$ ; or

1	"(ii) a rule under section 6(c);
2	"(D) pursuant to section $12(a)(2)$ ; or
3	"(E) for the implementation of another
4	Federal statute, as determined by the Federal
5	agency implementing such statute, if such infor-
6	mation is necessary to meet the regulatory test-
7	ing needs of that agency.
8	"(2) FORM.—The Administrator may carry out
9	paragraph (1) by—
10	"(A) promulgating a rule;
11	"(B) entering into a consent agreement; or
12	"(C) issuing an order.
13	"(3) AVAILABLE INFORMATION.—Before pro-
14	mulgating a rule, entering into a consent agreement,
15	or issuing an order under this subsection, the Ad-
16	ministrator shall consider available information, in-
17	cluding exposure potential and screening level haz-
18	ard and exposure information.
19	"(4) CONTENTS.—
20	"(A) IN GENERAL.—A rule promulgated,
21	consent agreement entered into, or order issued
22	under paragraph (2)—
23	"(i) shall identify the chemical sub-
24	stance or mixture for which information is

1	required and those persons required to de-
2	velop that information;
3	"(ii) may include protocols and meth-
4	odologies for the development of informa-
5	tion for the chemical substance or mixture,
6	including, if available, specific reference to
7	reliable nonanimal test procedures; and
8	"(iii) shall provide a reasonable period
9	within which persons required to develop
10	the information shall submit the informa-
11	tion to the Administrator.
12	"(B) CONSIDERATIONS.—In determining
13	the procedures and period to be required under
14	subparagraph (A), the Administrator shall con-
15	sider—
16	"(i) the costs of the test protocols and
17	methodologies that may be required; and
18	"(ii) the reasonably foreseeable avail-
19	ability of facilities and personnel needed to
20	perform the testing.
21	"(5) Screening level hazard and expo-
22	SURE INFORMATION.—If the Administrator finds
23	that the available information under paragraph $(3)$
24	is not sufficient to make a determination under
25	paragraph (1), to assist the Administrator in plan-

1 ning requirements for additional testing under this 2 subsection, the Administrator may, by rule, consent 3 agreement, or order, require the development of screening level information on a chemical substance 4 5 or mixture (which may include scientifically reliable 6 and relevant in silico, in vitro, and in vivo tests). 7 "(6) Additional testing development.—If, 8 after reviewing the available information under para-9 graph (3) and any screening level information ob-10 tained under paragraph (5), the Administrator de-11 termines that such information is not sufficient to 12 make a determination under paragraph (1) and that

additional information development is necessary, the
Administrator shall require under paragraph (1) the
development of such information for specific
endpoints using scientifically valid approaches.

17 "(b) Statement of Need.—

18 "(1) IN GENERAL.—In promulgating a rule, en19 tering into a consent agreement, or issuing an order
20 for development of additional information under this
21 section, the Administrator shall issue a statement—
22 "(A) identifying the need intended to be

met by the rule, consent agreement, or order;

24 "(B) explaining why information reason-25 ably available to the Administrator is inad-

1	equate to meet that need, including a reference,
2	as appropriate, to the information identified in
3	paragraph $(2)(B)$ ; and
4	"(C) explaining the basis for a decision
5	that requires the use of vertebrate animals.
6	"(2) Explanation of an order.—
7	"(A) IN GENERAL.—If the Administrator
8	issues an order under this section, the Adminis-
9	trator shall explain why good cause exists for
10	issuing an order instead of promulgating a rule
11	or entering into a consent agreement.
12	"(B) CONTENTS.—The explanation de-
13	scribed in subparagraph (A) shall detail—
14	"(i) information that is readily acces-
15	sible to the Administrator, including infor-
16	mation submitted under any other provi-
17	sion of law;
18	"(ii) the extent to which the Adminis-
19	trator has obtained or attempted to obtain
20	the information required to be developed
21	under the order through voluntary submis-
22	sions;
23	"(iii) the extent to which the Adminis-
24	trator anticipates using—

	10
1	"(I) available information for
2	structurally related chemical sub-
3	stances;
4	"(II) valid structure-activity rela-
5	tionship models; or
6	"(III) nonanimal test alter-
7	natives; and
8	"(iv) risk evaluations on other chem-
9	ical substances or mixtures, and the infor-
10	mation relied on in such determinations, to
11	the extent relevant to the chemical sub-
12	stances or mixtures that would be the sub-
13	ject of the order.
14	"(c) Reduction of Testing on Vertebrate Ani-
15	MALS.—
16	"(1) IN GENERAL.—In carrying out this title,
17	the Administrator shall minimize the use of
18	vertebrate animals in testing of chemical substances
19	or mixtures by—
20	"(A) encouraging and facilitating, to the
21	extent practicable—
22	"(i) the use of integrated and tiered
23	testing and assessment strategies; and
24	"(ii) test methods that eliminate or
25	reduce the use of vertebrate animals while

1	providing test information of high scientific
2	quality;
3	"(B) grouping 2 or more chemical sub-
4	stances or mixtures into scientifically appro-
5	priate categories in cases in which testing of a
6	chemical substance or mixture would provide re-
7	liable and useful test information on others in
8	the category; and
9	"(C) before adopting a requirement for
10	testing using vertebrate animals, considering
11	the sufficiency of—
12	"(i) available toxicity information;
13	"(ii) computational toxicology and
14	bioinformatics;
15	"(iii) high through-put screening
16	methods and their prediction models;
17	"(iv) scientifically reliable and rel-
18	evant alternatives to vertebrate animal
19	tests; and
20	"(v) available vertebrate animal-based
21	studies.
22	"(2) Implementation of alternative test-
23	ING METHODS.—To promote development and timely
24	incorporation of new testing methods that are not

based on vertebrate animals, the Administrator
 shall—

3 "(A) after providing public notice and an 4 opportunity for public comment, develop a plan 5 to promote the development and implementation 6 of alternative test methods and testing strate-7 gies to generate information used in risk eval-8 uations that can reduce, refine, or replace the 9 use of vertebrate animals, including toxicity 10 pathway-based risk assessment, in vitro studies, 11 systems biology, computational toxicology, 12 bioinformatics, and high throughput screening; 13 and

"(B) subject to the availability of appropriations, carry out research, development, performance assessment, and translational studies
to accelerate the development of test methods
and testing strategies that reduce, refine, or replace the use of vertebrate animals for purposes
of this title.

21 "(3) CRITERIA FOR MODIFYING OR WAIVING
22 ANIMAL TESTING REQUIREMENTS.—On request from
23 a manufacturer or processor that is required to con24 duct testing on vertebrate animals of a chemical sub25 stance or mixture under this section, the Adminis-

1	trator may modify or waive the requirement if the
2	Administrator determines that—
3	"(A) there is sufficient information to sup-
4	port a conclusion that a chemical substance or
5	mixture has, or does not have, a particular
6	property;
7	"(B) because of one or more physical or
8	chemical properties of the chemical substance
9	or mixture or other toxicokinetic consider-
10	ations—
11	"(i) the chemical substance or mixture
12	cannot be absorbed; or
13	"(ii) testing for a specific endpoint is
14	technically not practicable to conduct; or
15	"(C) the chemical substance or mixture,
16	when tested on vertebrate animals at certain
17	concentrations, causes such animals severe tis-
18	sue corrosion, severe irritation, or significant
19	pain or distress.
20	"(4) REPORTS.—Not later than 5 years after
21	the date of enactment of the Chemicals in Commerce
22	Act, and every 5 years thereafter, the Administrator
23	shall submit to Congress a report that describes the
24	progress made in implementing this subsection.
25	"(d) FAIR AND EQUITABLE REIMBURSEMENT.—

1	"(1) Designation.—If 2 or more manufactur-
2	ers or processors designate one of themselves or a
3	third party to develop information required by the
4	Administrator under subsection (a), the Adminis-
5	trator shall require any other manufacturer or proc-
6	essor seeking to use the information so developed in
7	order to meet the requirements of subsection (a) to
8	provide fair and equitable reimbursement for such
9	information development.
10	"(2) ARBITRATION.—In the case of a dispute
11	among the parties described in paragraph $(1)$ re-
12	garding the amount that constitutes fair and equi-
13	table reimbursement under such paragraph, such
14	dispute shall be resolved by arbitration according
15	to—
16	"(A) the terms of any applicable contract
17	among the parties; or
18	"(B) if no such contract exists, regulations
19	developed by the Administrator.
20	"(e) INFORMATION AVAILABILITY.—Subject to sec-
21	tion 14, the Administrator shall make available to the pub-
22	lic consent agreements entered into, orders issued, and in-
23	formation submitted under this section.
24	"(f) CONSULTATION.—Prior to requiring the develop-
25	ment of information from epidemiologic studies of work-

ers, or applying such information, the Administrator shall
 consult with the Director of the National Institute for Oc cupational Safety and Health.

4 "(g) Expedited Consideration.—

5 "(1) IN GENERAL.—Upon the receipt of any in-6 formation submitted under this title that provides a 7 reasonable basis to conclude that a chemical sub-8 stance or mixture presents or will present a signifi-9 cant risk of serious or widespread harm to human 10 health, the Administrator shall, within the 180-day 11 period beginning on the date of the receipt of such 12 information-

13 "(A) initiate appropriate action under sec14 tion 5, 6, or 7 to prevent or reduce such risk;
15 or

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

20 "(2) EXTENSION.—For good cause shown the
21 Administrator may extend such period for an addi22 tional period of not more than 90 days. The Admin23 istrator shall publish in the Federal Register notice
24 of any such extension and the reasons therefor.".

1 (b) CONFORMING AMENDMENT.—Section 2 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42) 3 U.S.C. 9604(i)(5)(A)) is amended by striking "Before as-4 suring the initiation of such program, the Administrator 5 of ATSDR shall consider recommendations of the Inter-6 7 agency Testing Committee established under section 4(e) 8 of the Toxic Substances Control Act on the types of research that should be done.". 9

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

"Sec. 4. Development of information regarding chemical substances and mixtures.".

#### 13 SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.

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

#### 16 "SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.

17 "(a) NOTICE REQUIREMENT.—

18 "(1) IN GENERAL.—Unless a person submits,
19 not later than 90 days before manufacturing or
20 processing begins, a notice to the Administrator of
21 that person's intent to manufacture a new chemical
22 substance or manufacture or process a chemical sub23 stance for a new use that the Administrator has de-

1	termined, in accordance with paragraph (2), is a sig-
2	nificant new use, such person may not—
3	"(A) manufacture a new chemical
4	substance; or
5	"(B) manufacture or process a chem-
6	ical substance for a use which the Admin-
7	istrator has determined, in accordance with
8	paragraph (2), is a significant new use.
9	"(2) DETERMINATION OF SIGNIFICANT NEW
10	USE.—A determination by the Administrator that a
11	use of a chemical substance is a significant new use,
12	with respect to which notification is required under
13	paragraph (1), shall be made by a rule promulgated
14	after a consideration of all relevant factors, includ-
15	ing information on—
16	"(A) the projected volume of manufac-
17	turing and processing of the chemical substance
18	for that use;
19	"(B) the extent to which a use changes the
20	type or form of exposure of human beings or
21	the environment to the chemical substance;
22	"(C) the extent to which a use increases
23	the magnitude and duration of exposure of
24	human beings or the environment to the chem-
25	ical substance; and

1	"(D) the intended conditions of use.
2	"(3) ARTICLES.—The Administrator may deter-
3	mine that the use of a chemical substance as part
4	of an article is a significant new use under this sec-
5	tion, but only where the Administrator—
6	"(A) identifies specific types of articles
7	that are, or likely will be, in United States com-
8	merce; and
9	"(B) determines that—
10	"(i) an unreasonable risk of harm to
11	human health or the environment may re-
12	sult from exposure to a chemical substance
13	in the article; and
14	"(ii) placing requirements on the arti-
15	cles is required because such risk cannot
16	be addressed adequately through require-
17	ments placed on the chemical substance.
18	"(b) Content of Notice; Publication in the
19	Federal Register.—
20	"(1) IN GENERAL.—The notice required by sub-
21	section $(a)(1)$ shall include, with respect to a chem-
22	ical substance or significant new use—
23	"(A) the information required by sections
24	720.45 and 720.50 of title 40, Code of Federal
25	Regulations (or successor regulations); and

1	"(B) information regarding intended condi-
2	tions of use and any reasonably anticipated ex-
3	posure.
4	"(2) FEDERAL REGISTER PUBLICATION.—Sub-
5	ject to section 14, not later than 5 business days
6	after the date of the receipt of a notice under sub-
7	section $(a)(1)$ , the Administrator shall publish in the
8	Federal Register—
9	"(A) the identity of the chemical substance
10	for which such notice has been received by the
11	Administrator; and
12	"(B) the intended conditions of use of such
13	chemical substance as identified by the manu-
14	facturer or processor.
15	"(3) Publicly accessible lists.—The Ad-
16	ministrator shall maintain publicly accessible lists
17	of—
18	"(A) each chemical substance for which
19	notice has been received under subsection $(a)(1)$
20	and for which the review period prescribed by
21	subsection (c) has not expired; and
22	"(B) each chemical substance for which
23	such review period has expired since the last
24	publication of such list.
25	"(c) Review and Determination.—

1	"(1) REVIEW.—
2	"(A) IN GENERAL.—Except as provided in
3	subparagraph (B), not later than 90 days after
4	the date of receipt of a notice submitted under
5	subsection (a)(1), the Administrator shall—
6	"(i) conduct a review of the notice;
7	"(ii) to the extent the Administrator
8	considers necessary, develop a profile of
9	the chemical substance and the potential
10	for exposure to humans and the environ-
11	ment;
12	"(iii) if the Administrator considers it
13	necessary for the review under clause (i) or
14	to make a determination under paragraph
15	(3), request additional information pursu-
16	ant to paragraph $(2)(B)$ ; and
17	"(iv) make a determination under
18	paragraph (3).
19	"(B) EXTENSION OF REVIEW.—The Ad-
20	ministrator may extend the period described in
21	subparagraph (A) for good cause for one or
22	more periods. Except as provided in paragraph
23	(2)(B), the cumulative total of any such exten-
24	sions shall not exceed 90 days.
25	"(2) INFORMATION.—

1	"(A) Previously submitted informa-
2	TION.—In conducting a review under paragraph
3	(1)(A), the Administrator shall take into con-
4	sideration any relevant information submitted
5	under subsection (a) or otherwise available to
6	the Administrator.
7	"(B) Additional information.—If the
8	Administrator determines that additional infor-
9	mation (including information on exposure or
10	exposure potential) is needed in order to con-
11	duct a review and make a determination under
12	this subsection, the Administrator—
13	"(i) shall provide an opportunity for
14	the submitter of the notice to submit such
15	additional information;
16	"(ii) may, by agreement with the sub-
17	mitter, extend the review period no longer
18	than necessary to allow for the develop-
19	ment and submission of the additional in-
20	formation;
21	"(iii) shall promptly make a deter-
22	mination under paragraph (3) upon receipt
23	of the information; and
24	"(iv) may take action under para-
25	graph (5) pending receipt of the additional

1	information, which may, as appropriate,
2	permit the submitter of the notice to file a
3	notice of commencement under subsection
4	(d).
5	"(3) Determinations.—Before the end of the
6	applicable period for review under paragraph $(1)$ or
7	(2)(B), and based on the information described in
8	paragraph (2), the Administrator shall determine
9	that exposure to the chemical substance under the
10	intended conditions of use—
11	"(A) may present an unreasonable risk of
12	harm to human health or the environment, in
13	which case the Administrator shall take appro-
14	priate action under paragraph (5); or
15	"(B) does not warrant regulation under
16	paragraph (5), in which case the Administrator
17	shall allow the review period to expire without
18	imposing restrictions on the chemical substance.
19	"(4) Commercial production.—At the end of
20	the applicable review period specified under para-
21	graph $(1)$ or $(2)(B)$ , the submitter of a notice under
22	subsection $(a)(1)$ may commence manufacture for
23	commercial purposes unless the Administrator—
24	"(A) determines under paragraph $(3)(A)$
25	that exposure to the chemical substance under

the intended conditions of use may present an
 unreasonable risk of harm to human health or
 the environment; and

4 "(B) imposes a requirement or restriction
5 under paragraph (5) that prohibits the manu6 facture of the chemical substance.

"(5) REQUIREMENTS AND RESTRICTIONS.—If, 7 8 before the end of the applicable review period under 9 paragraph (1) or (2)(B), the Administrator makes a 10 determination under paragraph (3)(A), the Adminis-11 trator shall, by rule, consent agreement, or order, 12 impose on the manufacturer of a new chemical sub-13 stance, or on the manufacturer or processor of a 14 chemical substance for a significant new use, one or 15 more of the following requirements or restrictions, to 16 the extent necessary to protect adequately against 17 an unreasonable risk to human health and the envi-18 ronment:

"(A) A requirement or restriction that the
chemical substance be marked with, or accompanied by, clear and adequate warnings and instructions with respect to distribution in commerce, use, or disposal, or any combination of
those activities, with the form and content of

1	the warnings and instructions to be prescribed
2	by the Administrator.
3	"(B) A requirement or restriction that
4	manufacturers or processors of the chemical
5	substance—
6	"(i) make and retain records of the
7	processes used to manufacture or process
8	the chemical substance;
9	"(ii) monitor specific uses of or expo-
10	sures to the chemical substance; or
11	"(iii) subject to section 4, develop ad-
12	ditional information that is reasonably nec-
13	essary to address potential risks from the
14	manufacture, processing, distribution in
15	commerce, use, or disposal of the chemical
16	substance.
17	"(C) A restriction on the quantity of the
18	chemical substance that may be manufactured,
19	processed, or distributed in commerce.
20	"(D) A requirement to restrict or ban the
21	manufacture, processing, or distribution in com-
22	merce of the chemical substance—
23	"(i) for a particular use;

1	"(ii) for a particular use at a con-
2	centration in excess of a level specified by
3	the Administrator; or
4	"(iii) for all uses.
5	"(E) A restriction on the quantity of the
6	chemical substance that may be manufactured,
7	processed, or distributed in commerce—
8	"(i) for a particular use; or
9	"(ii) for a particular use at a con-
10	centration in excess of a level specified by
11	the Administrator.
12	"(F) A requirement to restrict or ban a
13	method of commercial use of the chemical sub-
14	stance.
15	"(G) A requirement to ban or phase out a
16	method of disposal of the chemical substance or
17	any article containing the chemical substance.
18	"(H) A requirement directing manufactur-
19	ers or processors of the chemical substance to
20	give notice of unreasonable risks of harm to dis-
21	tributors in commerce of the chemical substance
22	and, to the extent reasonably ascertainable, to
23	other persons in the chain of commerce in pos-
24	session of the chemical substance.
25	"(d) Notice of Commencement.—

1	"(1) IN GENERAL.—A person who has sub-
2	mitted a notice under subsection $(a)(1)$ and com-
3	mences manufacture of a new chemical substance
4	shall, for a purpose not exempt under subsection (e),
5	submit a notice of commencement to the Adminis-
6	trator—
7	"(A) not later than 30 days after the date
8	on which the person commenced manufacture;
9	and
10	"(B) which identifies the name of the man-
11	ufacturer and the initial date of such manufac-
12	ture.
13	"(2) WITHDRAWAL.—A person who has sub-
14	mitted a notice under subsection $(a)(1)$ , but has not
15	commenced manufacture, may withdraw the notice.
16	"(e) EXEMPTIONS.—
17	"(1) EXPERIMENTATION, RESEARCH, AND
18	ANALYSIS.—
19	"(A) GENERAL RULE.—Except as provided
20	in subparagraph (B), the requirements of sub-
21	section $(a)(1)$ shall not apply with respect to
22	the manufacturing or processing of any chem-
23	ical substance that is manufactured or proc-
24	essed, or proposed to be manufactured or proc-
25	essed, only in small quantities (as defined by

	2.
1	the Administrator by rule) solely for purposes
2	of—
3	"(i) scientific experimentation or anal-
4	ysis; or
5	"(ii) chemical research on, or analysis
6	of, such chemical substance or another
7	chemical substance, including such re-
8	search or analysis for the development of a
9	product.
10	"(B) NOTICE REQUIREMENT.—A manufac-
11	turer or processor exempted under subpara-
12	graph (A) shall notify all persons engaged in
13	such experimentation, research, or analysis, in
14	such form and manner as the Administrator
15	may prescribe, of any risk to health which the
16	manufacturer, the processor, or the Adminis-
17	trator has reason to believe may be associated
18	with such chemical substance.
19	"(2) Test marketing.—
20	"(A) IN GENERAL.—The Administrator
21	may, upon request, exempt any person from
22	any requirement of subsection (a) in order to
23	permit the person to manufacture or process a
24	chemical substance for test marketing pur-
25	poses—

1	"(i) upon a showing by the person
2	satisfactory to the Administrator that the
3	manufacture, processing, distribution in
4	commerce, use, and disposal of the chem-
5	ical substance, and that any combination
6	of such activities, for such test marketing
7	purposes is not likely to result in an unrea-
8	sonable risk of harm to human health or
9	the environment; and
10	"(ii) under such restrictions as the
11	Administrator considers appropriate.
12	"(B) PUBLICATION OF RECEIPT.—Imme-
13	diately upon receipt of a request under subpara-
14	graph (A), the Administrator shall publish in
15	the Federal Register notice of the receipt of
16	such request. The Administrator shall give in-
17	terested persons an opportunity to comment
18	upon any such request and shall, within 45
19	days of its receipt, either approve or deny the
20	request. The Administrator shall publish in the
21	Federal Register notice of the approval or de-
22	nial of such a request.
23	"(3) RISK-BASED EXEMPTION.—The Adminis-
24	trator may, upon request and by rule or order, ex-

25 empt a person who commences manufacture of a

1	new chemical substance or manufacture or proc-
2	essing of a chemical substance for a significant new
3	use from all or part of the requirements of this sec-
4	tion if under prescribed conditions the Administrator
5	determines that the manufacture, processing, dis-
6	tribution in commerce, use, or disposal of such
7	chemical substance, or any combination of such ac-
8	tivities under such prescribed conditions, will not
9	present an unreasonable risk of harm to human
10	health or the environment.
11	"(4) TEMPORARY EXISTENCE.—The Adminis-
12	trator may, by rule, make the requirements of sub-
13	section (a) inapplicable with respect to the manufac-
14	turing or processing of any chemical substance—
15	"(A) which exists temporarily as a result
16	of a chemical reaction in the manufacturing or
17	processing of a mixture or another chemical
18	substance; and
19	"(B) to which there is no, and will not be,
20	human or environmental exposure.
21	"(5) BYPRODUCTS.—The Administrator may,
22	by rule, make the requirements of subsection (a) in-
23	applicable to the manufacture or processing of any
24	byproduct chemical substance produced without a
25	separate commercial intent during the manufacture,

<ul> <li>2 stance or mixture if—</li> <li>3 "(A) such byproduct chemical substance</li> <li>4 not used for commercial purposes; or</li> <li>5 "(B) the only intended commercial purposes)</li> </ul>	is
4 not used for commercial purposes; or	is
5 "(B) the only intended commercial purpo	
	se
6 of the byproduct chemical substance is for—	
7 "(i) burning as a fuel;	
8 ''(ii) disposing as a waste, including	n
9 a landfill or for enriching soil; or	
10 "(iii) extracting, by reaction or othe	r-
11 wise, a chemical substance to recycle or 1	<b>)-</b>
12 claim.	
13 "(f) MIXTURES.—A combination of chemical su	)-
14 stances physically combined without a chemical reaction	n
15 shall not be considered a new chemical substance for pu	[°-
16 poses of this section.".	
17 (b) TABLE OF CONTENTS AMENDMENT.—The ite	n
18 relating to section 5 in the table of contents is amend	d
19 to read as follows:	
"Sec. 5. New chemicals and significant new uses.".	
20 SEC. 6. EXISTING CHEMICALS.	
<ul> <li>20 SEC. 0. EXISTING CHEMICALS.</li> <li>21 (a) AMENDMENTS.—Section 6 (15 U.S.C. 2605)</li> </ul>	is
	is
21 (a) AMENDMENTS.—Section 6 (15 U.S.C. 2605)	

#### 1 "SEC. 6. EXISTING CHEMICALS.";

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

4 (3) by striking subsections (a) through (d) and 5 inserting the following:

6 "(a) Assigning Priorities for Risk Evalua-7 tions.—

8 "(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Chemicals in Commerce 9 10 Act, the Administrator shall, after providing public 11 notice and an opportunity for public comment, es-12 tablish a risk-based process for obtaining available 13 information and designating chemical substances as 14 either high priority or low priority. In making such 15 designations, the Administrator—

16 "(A) notwithstanding subparagraph (C),
17 shall identify as high priority a chemical sub18 stance that has the potential for high hazard
19 and high exposure;

20 "(B) may identify as high priority a chem21 ical substance that has the potential for high
22 hazard or high exposure;

23 "(C) shall identify as low priority a chem24 ical substance that the Administrator has deter25 mined, based on available information, is not
26 likely to present a significant risk of harm to

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1 human health or the environment under the in-2 tended conditions of use; and

3 "(D) may require development of additional information, solely for purposes of desig-4 nating priorities under this subsection and only 6 if the Administrator determines that available information is not sufficient to make a priority 8 designation.

9 "(2) TIMELY COMPLETION.—The Administrator 10 shall designate a priority for all chemical substances 11 identified as active under section 8(b) as soon as 12 feasible, taking into account the ability of the Ad-13 ministrator to schedule and complete risk evalua-14 tions under this section. The Administrator may 15 defer designation of a priority in order to provide in-16 terested persons an opportunity to submit additional 17 information not previously made available to the Ad-18 ministrator.

19 "(3) Publication of list.—The Adminis-20 trator shall publish, and update from time to time, 21 a list of chemical substances—

22 "(A) identifying those under consideration 23 for designation as high or low priority;

24 "(B) identifying those that have been des-25 ignated as a high or low priority at the time a

1	designation has been made under paragraph
2	(1); and
3	"(C) indicating those for which a risk eval-
4	uation has been completed.
5	"(4) Factors for assigning priorities.—
6	The factors used by the Administrator to assign pri-
7	orities shall include—
8	"(A) the hazard and exposure potential of
9	a chemical substance, including specific sci-
10	entific classifications and designations by au-
11	thoritative governmental entities;
12	"(B) the specific uses and exposures that
13	are significant to the risk of harm to human
14	health and the environment and the intended
15	conditions of use, or changes in the conditions
16	of use, of chemical substances, including for po-
17	tentially exposed subpopulations;
18	"(C) evidence and indicators of exposure to
19	humans, including to potentially exposed sub-
20	populations, or the environment from a chem-
21	ical substance;
22	"(D) the volume of a chemical substance
23	manufactured or processed;
24	((E) whether the volume of a chemical
25	substance as reported under a regulation issued

1 under section 8(a) has significantly increased or 2 decreased since a previous report or since the 3 date on which a notice has been submitted 4 under section 5(a) for that chemical substance; 5 "(F) the adequacy of the available infor-6 mation about potential hazards and exposures 7 needed for conducting a risk evaluation; and 8 "(G) the extent of Federal or State regula-

9 tion of a chemical substance or the extent of 10 the impact of State regulation of that chemical 11 substance on the United States, with existing 12 Federal or State regulation as a factor in desig-13 nating a chemical substance as a low priority. 14 "(5) NOTICE AND COMMENT.—The Administra-15 tor's proposed priority designations under this sub-16 section shall be subject to public notice and an op-17 portunity for public comment.

18 "(6) REVISION BASED ON NEW INFORMA19 TION.—The Administrator may revise or assign a
20 priority designation of a chemical substance based
21 on consideration of new information.

"(7) PROCESS REVIEW.—The Administrator
shall periodically review and if necessary modify the
process of assigning priorities to chemical substances
under this subsection based upon experience and re-

1	sources available to efficiently and effectively
2	prioritize chemical substances.
3	"(8) CLARIFICATION.—Except as provided in
4	section 18, a designation by the Administrator under
5	this subsection of a chemical substance as a high
6	priority shall not affect the manufacture, processing,
7	distribution, use, or disposal of the chemical sub-
8	stance.
9	"(9) FINAL AGENCY ACTION.—A designation by
10	the Administrator under this subsection of a chem-
11	ical substance as a high priority shall not be consid-
12	ered to be a final agency action subject to judicial
13	review.
14	"(b) Evaluating Risk.—
15	"(1) High priority risk evaluation.—
16	"(A) IN GENERAL.—The Administrator
17	shall conduct a risk evaluation regarding wheth-
18	er a chemical substance designated as high pri-
19	ority presents or will present, in the absence of
20	regulation under subsection (c), a significant
21	risk of harm to human health or the environ-
22	ment under its intended conditions of use.
23	"(B) REQUIREMENTS.—In conducting a
24	risk evaluation under this paragraph, the Ad-
25	ministrator shall—

1	"(i) integrate and assess information
2	on hazards and exposures for the specific
3	uses that are relevant to the risk of harm
4	and to subsets of exposure (including in-
5	formation on potentially exposed sub-
6	populations);
7	"(ii) analyze the duration, intensity,
8	frequency, and number of exposures under
9	the intended conditions of use of the chem-
10	ical substance;
11	"(iii) describe the weight of the sci-
12	entific evidence for observed biological ef-
13	fects and risks, including the appropriate
14	modes of action;
15	"(iv) incorporate reference parameters
16	that may be appropriate with regard to a
17	specific chemical substance (such as a mar-
18	gin of exposure); and
19	"(v) consider whether the scientific in-
20	formation supports the identification of
21	threshold doses of a chemical substance
22	below which no adverse effects can be ex-
23	pected to occur.
24	"(C) DEADLINE.—Not later than 4 years
25	after the date on which the Administrator des-
ignates a chemical substance as high priority
 under subsection (a), the Administrator shall
 publish a determination resulting from a risk
 evaluation conducted under this paragraph for
 such chemical substance under its intended con ditions of use.

7 "(2) ALTERNATIVE RISK EVALUATION.—The 8 Administrator may conduct a risk evaluation regard-9 ing a chemical substance that is not designated as 10 a high priority substance under subsection (a), and 11 may determine, at any time, that the chemical sub-12 stance will not present, in the absence of regulation 13 under subsection (c), a significant risk of harm to 14 human health or the environment under one or more 15 specific conditions of use.

# 16 "(3) Factors for evaluating risk.—

17 "(A) FACTORS TO BE CONSIDERED.—In
18 evaluating whether a chemical substance pre19 sents or will present, in the absence of regula20 tion under subsection (c), a significant risk of
21 harm to human health or the environment
22 under its intended conditions of use, the Ad23 ministrator shall consider—

24 "(i) the nature, circumstances, sever25 ity, and magnitude of the risk;

1	"(ii) the likely impact of the risk on
2	potentially exposed subpopulations from
3	use of the chemical substance under its in-
4	tended conditions of use;
5	"(iii) whether harm has occurred from
6	the chemical substance under its intended
7	conditions of use; and
8	"(iv) the probability that harm will
9	occur from use of the chemical substance
10	under its intended conditions of use.
11	"(B) Factors not to be considered.—
12	In evaluating whether a chemical substance pre-
13	sents or will present, in the absence of regula-
14	tion under subsection (c), a significant risk of
15	harm to human health or the environment
16	under its intended conditions of use, the Ad-
17	ministrator may not consider the economic
18	costs or benefits of—
19	"(i) the intended uses of the chemical
20	substance; or
21	"(ii) reducing the exposure to the
22	chemical substance by rule under sub-
23	section (c).
24	"(4) Additional information.—If the Ad-
25	ministrator determines that additional information is

1	needed in order to complete a risk evaluation under
2	this subsection, the Administrator—
3	"(A) shall provide an opportunity for inter-
4	ested persons to submit the additional informa-
5	tion;
6	"(B) may promulgate a rule, enter into a
7	consent agreement, or issue an order under sec-
8	tion 4 to require the development of the infor-
9	mation;
10	"(C) may defer, for a reasonable period
11	and subject to subsection (d), the risk evalua-
12	tion until after receipt of the information; and
13	"(D) shall, upon receipt of the informa-
14	tion, complete a risk evaluation under this sub-
15	section.
16	"(5) Publication.—Upon completion of a risk
17	evaluation under this subsection, the Administrator
18	shall publish a statement that includes—
19	"(A) such risk evaluation; and
20	"(B) a summary of the analysis performed
21	in support of the risk evaluation.
22	"(6) REVIEW OF RISK EVALUATIONS.—The Ad-
23	ministrator may reconsider a risk evaluation con-
24	ducted under this subsection to take into account in-

40

1	formation not previously considered, or as the Ad-
2	ministrator otherwise considers necessary.
3	"(7) FINAL AGENCY ACTION.—

"(A) DETERMINATION OF NO SIGNIFICANT 4 RISK.—A determination under paragraph (1) or 6 (2) that a chemical substance will not present 7 a significant risk of harm to human health or 8 the environment under the intended conditions 9 of use shall be considered a final agency action.

10 "(B) DETERMINATION OF SIGNIFICANT 11 RISK.—A determination under paragraph (1) 12 that a chemical substance presents or will 13 present, in the absence of a regulation under 14 subsection (c), a significant risk of harm to 15 human health or the environment under the in-16 tended conditions of use shall be considered a 17 final agency action on the date of publication of 18 the final rule promulgated under subsection (c). 19 "(c) RULE.—

20 "(1) IMPLEMENTATION.—Not later than 3 21 years after determining under subsection (b) that a 22 chemical substance presents or will present, in the 23 absence of regulation under this subsection, a sig-24 nificant risk of harm to human health or the envi-25 ronment under the intended conditions of use, the

1	Administrator shall promulgate a rule, in accordance
2	with this subsection, with requirements or restric-
3	tions that the Administrator determines are nec-
4	essary to protect adequately against an unreasonable
5	risk of harm to human health or the environment
6	from the chemical substance under its intended con-
7	ditions of use.
8	"(2) SCOPE.—A rule promulgated under this
9	subsection—
10	"(A) may—
11	"(i) as appropriate, apply to mixtures
12	containing the chemical substance; or
13	"(ii) apply to articles, but only where
14	the Administrator—
15	"(I) identifies specific types of
16	articles that are, or likely will be, in
17	United States commerce; and
18	"(II) determines that ensuring
19	that no unreasonable risk of harm to
20	human health or the environment will
21	result from exposure to the chemical
22	substance requires placing require-
23	ments on such articles that cannot be
24	addressed adequately through require-

1	ments placed on chemical substances
2	or mixtures; and
3	"(B) shall—
4	"(i) exempt replacement parts for ar-
5	ticles manufactured prior to the applicable
6	compliance deadline or for use in vehicles;
7	and
8	"(ii) include dates by which compli-
9	ance is mandatory, which may vary for dif-
10	ferent affected persons, as the Adminis-
11	trator determines to be appropriate.
12	"(3) Requirements and restrictions.—A
13	rule promulgated under this subsection shall include,
14	as appropriate, one or more of the following:
15	"(A) A requirement that a chemical sub-
16	stance be marked with, or accompanied by,
17	clear and adequate warnings and instructions
18	with respect to distribution in commerce, use,
19	or disposal, or any combination of those activi-
20	ties, with the form and content of the warnings
21	and instructions to be prescribed by the Admin-
22	istrator.
23	"(B) A requirement that manufacturers
24	and processors of the chemical 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 ensure compliance with this sec-
9	tion.
10	"(C) A restriction on the quantity of the
11	chemical substance that may be manufactured,
12	processed, or distributed in commerce.
13	"(D) A requirement to restrict, ban, or
14	phase out the manufacture, processing, or dis-
15	tribution in commerce of the chemical sub-
16	stance—
17	"(i) for a particular use;
18	"(ii) for a particular use at a con-
19	centration in excess of a level specified by
20	the Administrator; or
21	"(iii) for all uses.
22	"(E) A restriction on the quantity of the
23	chemical substance that may be manufactured,
24	processed, or distributed in commerce—
25	"(i) for a particular use; or

1	"(ii) for a particular use at a con-
2	centration in excess of a level specified by
3	the Administrator.
4	"(F) A requirement to restrict, ban, or
5	phase out a method of commercial use of the
6	chemical substance;
7	"(G) A requirement to ban or phase out a
8	method of disposal of the chemical substance or
9	any article containing the chemical substance.
10	"(H) A requirement directing manufactur-
11	ers or processors of the chemical substance to
12	give notice of unreasonable risks of harm to dis-
13	tributors in commerce of the chemical substance
14	and, to the extent reasonably ascertainable, to
15	other persons in the chain of commerce in pos-
16	session of the chemical substance.
17	"(4) RISK MANAGEMENT STANDARDS.—When
18	imposing requirements or restrictions on a chemical
19	substance under this subsection, the Administrator
20	shall—
21	"(A) determine whether requirements or
22	restrictions imposed on uses of the chemical
23	substance are cost-effective in ensuring that the
24	chemical substance will not result in an unrea-
25	sonable risk of harm to human health or the

environment under the intended conditions of
 use;

3 "(B) provide for a reasonable transition
4 period for implementation; and

5 "(C) in deciding whether to prohibit or 6 substantially prevent a specific use of a chem-7 ical substance and in setting an appropriate transition period for such action, determine 8 9 whether technically and economically feasible al-10 ternatives that benefit human health or the en-11 vironment, compared to the use proposed to be 12 prohibited or substantially prevented, will be 13 reasonably available as a substitute when the 14 proposed prohibition or restriction takes effect.

15 "(d) EXTENSIONS.—If the Administrator determines that additional information is needed in order to conduct 16 17 a risk evaluation of a chemical substance under subsection 18 (b) or to promulgate a final rule regarding the chemical 19 substance under subsection (c), the Administrator may ex-20 tend the deadline required under subsection (b) or (c) as 21 necessary but not to exceed a cumulative period of 3 years. 22 "(e) GUIDANCE.—The Administrator shall, after pro-

22 (e) GUIDANCE.—The Administrator shan, after pro23 viding public notice and an opportunity for public com24 ment, establish guidance regarding how aggregate expo-

1	sure to a chemical substance will be taken into account
2	in carrying out this section."; and
3	(4) in subsection (f) (as so redesignated by
4	paragraph (2) of this subsection)—
5	(A) by striking paragraph (4); and
6	(B) by redesignating paragraph (5) as
7	paragraph (4).
8	(b) TABLE OF CONTENTS AMENDMENT.—The item
9	relating to section 6 in the table of contents is amended
10	to read as follows:
	"Sec. 6. Existing chemicals.".
11	SEC. 7. IMMINENT HAZARDS.
12	Section 7 (15 U.S.C. 2606) is amended—
13	(1) by striking subsection (a) and inserting the
14	following:
15	"(a) CIVIL ACTIONS.—
16	"(1) IN GENERAL.—The Administrator may
17	commence a civil action in an appropriate district
18	court of the United States for—
19	"(A) seizure of an imminently hazardous
20	chemical substance or mixture or any article
21	containing the chemical substance or mixture;
22	"(B) relief (as authorized by subsection
23	(b)) against any person who manufactures,
24	processes, distributes in commerce, uses, or dis-

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1	stance or mixture or any article containing such
2	chemical substance or mixture; or
3	"(C) both seizure described in subpara-
4	graph (A) and relief described in subparagraph
5	(B).
6	"(2) Rule, order, or other proceeding.—
7	The Administrator may commence a civil action
8	under this subsection notwithstanding—
9	"(A) the existence of—
10	"(i) a decision by the Administrator
11	under section $5(c)(3)$ , $6(a)$ , or $6(b)$ ; or
12	"(ii) a rule, consent agreement, or
13	order, as applicable, under section $4(a)(2)$ ,
14	5(c)(5), or $6(c)$ or title IV; or
15	"(B) the pendency of any administrative or
16	judicial proceeding under any provision of this
17	Act.";
18	(2) in subsection (d), by striking "section $6(a)$ "
19	and inserting "section 6(c)";
20	(3) in subsection (f)—
21	(A) in the first sentence, by striking "in-
22	jury to health or the environment" and insert-
23	ing "harm to human health or the environ-
24	ment"; and

1	(B) by striking "such injury" and inserting
2	"such harm".
3	SEC. 8. INFORMATION COLLECTION AND REPORTING.
4	Section 8 (15 U.S.C. 2607) is amended—
5	(1) in subsection (a)—
6	(A) in paragraph (3)(A)(ii)—
7	(i) in subclause (I), by striking "rule
8	proposed or promulgated under section 4,
9	5(b)(4), or 6, or an order in effect under
10	section 5(e)," and inserting "a proposed or
11	promulgated rule, a consent agreement, or
12	an order under section 4, 5, or 6;" and
13	(ii) in subclause (II), by striking "sec-
14	tion 5 or 7," and inserting "section 7;"
15	and
16	(B) by adding at the end the following:
17	"(4) REQUIREMENTS.—Not later than 2 years after
18	the date of enactment of the Chemicals in Commerce Act,
19	the Administrator shall promulgate rules establishing sep-
20	arate reporting requirements for manufacturers and proc-
21	essors as necessary to carry out sections 4 and 6.
22	"(5) GUIDANCE.—The Administrator shall develop
23	guidance relating to the information required to be re-
24	ported under this subsection that—

1	"(A) includes the level of detail necessary to be
2	reported; and
3	"(B) describes the manner by which manufac-
4	turers and processors may voluntarily report use and
5	exposure information.
6	"(6) NONAPPLICABILITY.—This subsection shall not
7	apply to—
8	"(A) a chemical substance extracted, by reac-
9	tion or otherwise, from another chemical substance
10	for the purpose of recycling or reclaiming such ex-
11	tracted chemical substance; or
12	"(B) a combination of chemical substances
13	physically combined without a chemical reaction.";
14	(2) in subsection (b)—
15	(A) in paragraph (1), by adding at the end
16	the following: "The Administrator shall estab-
17	lish and maintain a confidential portion and a
18	nonconfidential portion of the list published
19	under this paragraph, consistent with section
20	14. Chemical substances on each such portion
21	of the list shall be identified as either active or
22	inactive, as designated under paragraph (5).";
23	and
24	(B) by adding at the end the following new
25	paragraphs:

"(3) NOMENCLATURE.—The Administrator shall de velop guidance that—

3 "(A) permits the continued use of Class 2 no4 menclature in use on date of enactment of the
5 Chemical in Commerce Act;

6 "(B) permits the continued use of the Soap and 7 Detergent Association Nomenclature System, pub-8 lished in March 1978 by the Administrator in sec-9 tion 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and fur-10 11 ther described in the appendix A of volume I of the 12 1985 edition of the Toxic Substances Control Act 13 Substances Inventory (EPA Document No. EPA-14 560/7 - 85 - 002a;

"(C) treats as being included on the list published under paragraph (1), under the Chemical Abstracts Service numbers for the respective categories,
all components of—

19 "(i) cement, Portland, chemicals, CAS No.
20 65997–15–1;

21 "(ii) cement, alumina, chemicals, CAS No.
22 65997–16–2;
23 "(iii) glass, oxide, chemicals, CAS No.

24 65997-17-3;

"(iv) frits, chemicals, CAS No. 65997–18–
4;
"(v) steel manufacture, chemicals, CAS
No. 65997–19–5; and
"(vi) ceramic materials and wares, chemi-
cals, CAS No. 66402–68–4;
"(D) if guidance in effect before the guidance
developed under this paragraph allowed for multiple
nomenclature conventions, includes new guidance
that establishes equivalency between the nomen-
clature conventions for chemical substances on the
list published under paragraph (1); and
"(E) for any chemical substance appearing mul-
tiple times on the list under different Chemical Ab-
stracts Service numbers, includes guidance recog-
nizing the multiple listings as a single chemical sub-
stance.
"(4) Chemical Substances in Commerce.—
"(A) RULE.—
"(i) IN GENERAL.—The Administrator, by
rule, shall require manufacturers and may re-
quire processors to notify the Administrator
when the manufacturer or processor, as applica-
ble, has manufactured or processed a chemical
substance that has been placed on the list

under paragraph (1) during the 5-year period
 prior to the date of enactment of the Chemicals
 in Commerce Act.

4 "(ii) PROCEDURE FOR NOTICE OF ACTIVE 5 AND INACTIVE CHEMICAL SUBSTANCES.—A rule 6 under this subparagraph shall establish a proce-7 dure for any person to notify the Administrator 8 of a chemical substance that the Administrator 9 should identify as active or inactive under para-10 graph (5).

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

17 "(i) accession numbers;

18 "(ii) premanufacture notice case numbers,

19 if applicable; and

"(iii) generic names.

21 "(C) CONFIDENTIAL CHEMICAL SUBSTANCES.—
22 The rule issued under subparagraph (A) shall re23 quire a manufacturer or processor submitting a no24 tice including information relating to a chemical sub25 stance to indicate whether the manufacturer or proc-

essor claims the information as confidential pursu ant to section 14.

"(D) PRESERVATION OF RECORDS.—The rule
issued under subparagraph (A) shall require a manufacturer or processor to retain a record supporting
the accuracy of the information submitted to the Administrator by the manufacturer or processor for a
period of 5 years beginning on the last day of the
submission period.

"(E) APPLICABILITY.—Nothing in this paragraph requires the resubstantiation of a claim for
protection against disclosure for information submitted to the Administrator prior to the date of enactment of the Chemicals in Commerce Act.

15 "(5) ACTIVE AND INACTIVE SUBSTANCES.—

16 "(A) ACTIVE SUBSTANCES.—For purposes of
17 this subsection, the term 'active substance' means a
18 chemical substance—

"(i) that has been manufactured or processed (other than a chemical substance described in section 720.30 of title 40, Code of
Federal Regulations (or successor regulations),
or a chemical substance manufactured or processed only as part of an article) at any point
during—

1	((I) in the case of a chemical sub-
2	stance manufactured or processed before
3	the date of enactment of the Chemicals in
4	Commerce Act, the 5-year period ending
5	on such date of enactment; and
6	$((\Pi)$ in the case of a chemical sub-
7	stance first manufactured or processed on
8	or after the date of enactment of the
9	Chemicals in Commerce Act, the 4-year pe-
10	riod ending on the date on which the most
11	recent data was reported under part 711
12	of title 40, Code of Federal Regulations (or
13	successor regulations);
14	"(ii) that is added to the list published
15	under paragraph (1) after the date of enact-
16	ment of the Chemicals in Commerce Act;
17	"(iii) for which a person has notified the
18	Administrator pursuant to subparagraph (C)
19	that such person intends to manufacture or
20	process a chemical substance that is designated
21	as an inactive substance; or
22	"(iv) that has been reported under part
23	711 of title 40, Code of Federal Regulations (or
24	successor regulations) after the date of enact-
25	ment of the Chemicals in Commerce Act.

1	"(B) INACTIVE SUBSTANCES.—For purposes of
2	this subsection, the term 'inactive substance' means
3	a chemical substance on the list published under
4	paragraph (1) that has not been manufactured or
5	processed at any point during—
6	"(i) in the case of a chemical substance
7	manufactured or processed before the date of
8	enactment of the Chemicals in Commerce Act,
9	the 5-year period ending on such date of enact-
10	ment; and
11	"(ii) in the case of a chemical substance
12	first manufactured or processed on or after the
13	date of enactment of the Chemicals in Com-
14	merce Act, the 4-year period ending on the date
15	on which the most recent data were reported
16	under part 711 of title 40, Code of Federal
17	Regulations (or successor regulations).
18	"(C) Change to active status.—
19	"(i) IN GENERAL.—Any person who in-
20	tends to manufacture or process a chemical

tends to manufacture or process a chemical
substance that is identified as an inactive substance shall notify the Administrator before the
date on which the chemical substance is manufactured or processed.

1 "(ii) UPDATE OF STATUS.—On receiving 2 notification under clause (i), the Administrator 3 shall designate the chemical substance as an ac-4 tive substance and amend the list under para-5 graph (1) accordingly. 6 "(6) INFORMATION ON LIST.—The Administrator 7 shall include on the list published under paragraph (1)— "(A) the accession number, generic name, and, 8 9 if applicable, premanufacture notice case number for 10 each active or inactive substance, in the case of a

10 each active or inactive substance, in the case of a 11 chemical substance on the confidential portion of the 12 list published under paragraph (1); and

13 "(B) the specific identity of any active or inac-14 tive substance for which no such claim of confiden-15 tiality was received under paragraph (4)(C), subject 16 to the condition that, before revealing the specific 17 identity of the chemical substance, the Adminis-18 trator shall—

19 "(i) publish, if applicable, the accession
20 number, generic name, and premanufacture no21 tice case number for that chemical substance;
22 and

23 "(ii) provide an opportunity for any per24 son—

1	"(I) to certify to the Administrator
2	that the person intends to manufacture or
3	process the chemical substance at any
4	point in the subsequent 4-year period; and
5	"(II) to claim confidentiality for the
6	specific identity of the chemical sub-
7	stance.";
8	(3) in subsection (d), by striking "shall promul-
9	gate" and inserting "may promulgate";
10	(4) in subsection (e), by striking "injury to
11	health or the environment" and inserting "harm to
12	human health or the environment"; and
13	(5) by redesignating subsection (f) as sub-
14	section (g) and inserting after subsection (e) the fol-
15	lowing new subsection:
16	"(f) Administration.—In implementing this sec-
17	tion, the Administrator shall take measures to—
18	"(1) limit the potential for duplication in re-
19	porting requirements;
20	((2)) minimize the impact of the rules on small
21	manufacturers and processors; and
22	"(3) ensure that the rules impose reporting ob-
23	ligations only on the entities most likely to have in-
24	formation relevant to the effective enforcement of
25	this title.".

	58
1	SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.
2	Section 9 (15 U.S.C. 2608) is amended—
3	(1) in subsection (a)—
4	(A) in the first sentence of paragraph
5	(1)—
6	(i) by striking "the manufacture,
7	processing, distribution in commerce, use,
8	or disposal of a chemical substance or mix-
9	ture, or that any combination of such ac-
10	tivities, presents or will present an unrea-
11	sonable risk of injury to health or the envi-
12	ronment" and inserting "a chemical sub-
13	stance or mixture presents or will present
14	a significant risk of harm to human health
15	or the environment under the intended
16	conditions of use, based on an evaluation
17	of factors in accordance with section
18	6(b)(3),"; and
19	(ii) by striking "such risk" the first
20	place it appears and inserting "the risk
21	posed by the manufacture, processing, dis-
22	tribution in commerce, or use of the chem-

(B) in paragraph (2), in the matter following subparagraph (B), by striking "section 6
or 7" and inserting "section 6(c) or 7"; and

ical substance or mixture";

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1	(C) in paragraph (3), by striking "section
2	6 or 7" and inserting "section 6(c) or 7";
3	(2) in subsection (b)—
4	(A) by inserting "(1)" before "The" in the
5	first sentence; and
6	(B) by adding at the end the following:
7	((2) For purposes of this subsection, in determining
8	whether to initiate action under section 6(c), the Adminis-
9	trator shall compare—
10	"(A) the estimated costs of complying with ac-
11	tions taken under this title with the estimated costs
12	of proceeding instead under other law or laws ad-
13	ministered by the Administrator; and
15	•
14	"(B) the efficiency of actions under this title
14	"(B) the efficiency of actions under this title
14 15	"(B) the efficiency of actions under this title and under such other law or laws to protect against
14 15 16	"(B) the efficiency of actions under this title and under such other law or laws to protect against the risk being addressed."; and
14 15 16 17	<ul><li>"(B) the efficiency of actions under this title and under such other law or laws to protect against the risk being addressed."; and</li><li>(3) in subsection (d), in the first sentence, by</li></ul>
14 15 16 17 18	<ul> <li>"(B) the efficiency of actions under this title and under such other law or laws to protect against the risk being addressed."; and</li> <li>(3) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and in-</li> </ul>
14 15 16 17 18 19	<ul> <li>"(B) the efficiency of actions under this title and under such other law or laws to protect against the risk being addressed."; and</li> <li>(3) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and inserting "Health and Human Services".</li> </ul>
14 15 16 17 18 19 20	<ul> <li>"(B) the efficiency of actions under this title and under such other law or laws to protect against the risk being addressed."; and</li> <li>(3) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and inserting "Health and Human Services".</li> <li>SEC. 10. RESEARCH, DEVELOPMENT, COLLECTION, DIS-</li> </ul>
<ol> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> </ol>	<ul> <li>"(B) the efficiency of actions under this title and under such other law or laws to protect against the risk being addressed."; and</li> <li>(3) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and inserting "Health and Human Services".</li> <li>SEC. 10. RESEARCH, DEVELOPMENT, COLLECTION, DIS- SEMINATION, AND UTILIZATION OF DATA.</li> </ul>

	60
1	SEC. 11. INSPECTIONS AND SUBPOENAS.
2	Section $11(b)(2)(B)$ (15 U.S.C. $2610(b)(2)(B)$ ) is
3	amended by inserting "or marketing" after "sales".
4	SEC. 12. EXPORTS.
5	Section 12 (15 U.S.C. 2611) is amended—
6	(1) in subsection (a)—
7	(A) in paragraph (1)—
8	(i) by striking "chemical substance,
9	mixture, or to an article containing a
10	chemical substance or mixture," and in-
11	serting "chemical substance or mixture";
12	and
13	(ii) by striking "substance, mixture or
14	article" each place it appears and inserting
15	"substance or mixture"; and
16	(B) in paragraph (2)—
17	(i) by striking "substance, mixture or
18	article" both places it appears and insert-
19	ing "substance or mixture" and
20	(ii) by striking "unreasonable risk of
21	injury to health" both places it appears
22	and inserting "unreasonable risk of harm
23	to human health";
24	(2) by amending subsection (b) to read as fol-
25	lows:
26	"(b) NOTICE.—

1	"(1) Regulated substances.—
2	"(A) IN GENERAL.—The Administrator
3	may require a person to notify the Adminis-
4	trator that the person is exporting or intends to
5	export to a foreign country a chemical sub-
6	stance or mixture—
7	"(i) for which the Administrator
8	has—
9	"(I) imposed a requirement or
10	restriction under section $5(c)(5)$ ; or
11	"(II) promulgated a rule under
12	section $6(c)$ ; or
13	"(ii) for which relief has been granted
14	under section 7.
15	"(B) FREQUENCY.—The Administrator
16	shall require notice from a person under sub-
17	paragraph (A) no more frequently than annu-
18	ally after the first notice submitted by that per-
19	son for the chemical substance or mixture.
20	"(C) NOTICE TO GOVERNMENT OF RECEIV-
21	ING COUNTRY.—Upon receipt of a notification
22	under this paragraph, the Administrator may
23	notify the government of the country to which
24	the chemical substance or mixture is being ex-
25	ported.

"(2) TREATY OBLIGATIONS.—

2 "(A) IN GENERAL.—The Administrator 3 shall require a person to notify the Adminis-4 trator that the person is exporting or intends to 5 export to a foreign country a chemical sub-6 stance or mixture, or an article containing such 7 chemical substance or mixture, for which the 8 United States is obligated by treaty to provide 9 export notification.

"(B) CONTENTS.—Such notice shall include all information necessary to enable the
United States to satisfy obligations under the
applicable treaty.

14 "(C) FREQUENCY.—The Administrator
15 shall require notice from a person under sub16 paragraph (A) no more frequently than annu17 ally after the first notice submitted by that per18 son for the chemical substance or mixture.";
19 and

20 (3) in subsection (c) -

21 (A) by striking paragraph (3); and
22 (B) by redesignating paragraphs (4)
23 through (6) as paragraphs (3) through (5), re24 spectively.

#### 1 SEC. 13. IMPORTS.

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

#### 4 "SEC. 13. IMPORTS.

5 "(a) NOTICE.—A person offering a chemical sub-6 stance for entry into the customs territory of the United 7 States shall certify to the Secretary of Homeland Security 8 that, after reasonable inquiry and to the best knowledge 9 and belief of the person, the chemical substance is—

10 "(1) in compliance with any applicable rule,
11 consent agreement, or order under section 5 or 6;
12 and

"(2) included on the list under section 8(b) or
exempt from any requirement to be included on that
list.

16 "(b) Refusal of Entry.—

"(1) IN GENERAL.—The Secretary of Homeland 17 18 Security shall refuse entry into the customs territory 19 of the United States (as defined in general note 2) 20 to the Harmonized Tariff Schedule of the United 21 States) any chemical substance, mixture, or article 22 offered for such entry if the chemical substance, 23 mixture, or article is intended to be imported for a 24 use that would violate a rule, consent agreement, or 25 order in effect under this Act.

26 "(2) PROCEDURE.—

1	"(A) IN GENERAL.—Except as provided in
2	subparagraph (B), if a chemical substance or
3	mixture is refused entry under paragraph (1),
4	the Secretary of Homeland Security—
5	"(i) shall notify the consignee of the
6	refusal of entry;
7	"(ii) shall not release the chemical
8	substance or mixture to the consignee; and
9	"(iii) shall cause the disposal or stor-
10	age of the chemical substance or mixture
11	under such rules as the Administrator may
12	prescribe, consistent with other applicable
13	Federal law, if the chemical substance or
14	mixture has not been removed from the
15	United States in the 90-day period begin-
16	ning on the date of receipt of the notice of
17	the refusal of entry provided under clause
18	(i).
19	"(B) EXCEPTION.—
20	"(i) IN GENERAL.—The Secretary of
21	Homeland Security may, pending a review
22	by the Administrator, release to the con-
23	signee the chemical substance or mixture if
24	the consignee—

1	"(I) executes a bond for the
2	amount of the full invoice of the
3	chemical substance or mixture (as set
4	forth in the customs entry); and
5	"(II) pays any applicable duty on
6	the chemical substance or mixture.
7	"(ii) Administration.—If a con-
8	signee fails to return a chemical substance
9	or mixture released to that consignee
10	under clause (i) for any cause to the cus-
11	tody of the Secretary of Homeland Secu-
12	rity when demanded, the consignee shall be
13	liable to the United States for liquidated
14	damages equal to the full amount of the
15	bond.
16	"(C) Storage.—All charges for storage,
17	cartage, and labor on and for the disposal of a
18	chemical substance or mixture that is refused
19	entry or released under this subsection shall be
20	paid by the owner or consignee, and a default
21	on that payment shall constitute a lien against
22	any future entry made by the owner or con-
23	signee.

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

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

"Sec. 13. Imports.".

## 7 SEC. 14. CONFIDENTIAL INFORMATION.

8 (a) AMENDMENT.—Section 14 (15 U.S.C. 2613) is9 amended to read as follows:

### 10 "SEC. 14. CONFIDENTIAL INFORMATION.

"(a) IN GENERAL.—Subject to subsections (b) and
(d), the Administrator shall not disclose information obtained by the Administrator under this title that is—

14 "(1) information exempt from disclosure under
15 section 552(b)(4) of title 5, United States Code;

16 "(2) specific information describing the manu-17 facture, processing, distribution in commerce, or dis-

18 posal of a chemical substance, mixture, or article;

19 "(3) marketing and sales information;

20 "(4) information on the identity of constituents
21 in a mixture and the respective percentages of those
22 constituents;

23 "(5) specific information about the use, func24 tion, or application of a chemical substance or mix25 ture in a process, mixture, or article;

"(6) information on specific production or im port volumes of a manufacturer and specific volumes
 aggregated across manufacturers if disclosure of
 that aggregated data could reveal information identi fied in paragraphs (1) through (5); or

6 ((7) the specific identity of a chemical sub-7 stance, including the chemical name, molecular for-8 mula, Chemical Abstracts Service number, or other 9 information that would identify a specific chemical 10 substance, if the specific identity is claimed under 11 subsection (b) as confidential information and the 12 claim has not subsequently been withdrawn or found 13 by the Administrator not to warrant protection as 14 confidential information under this section.

15 "(b) REQUIREMENTS FOR CERTAIN CONFIDEN16 TIALITY CLAIMS.—A person seeking protection from dis17 closure of information under this section shall—

18 "(1) claim such information as confidential by
19 identifying such information to the Administrator;
20 and

21 "(2) in the case of information described in
22 paragraph (7) of subsection (a), submit—

23 "(A) written documentation justifying why
24 the information qualifies for such protection, in25 cluding documentation establishing that—

1	"(i) the submitting person takes rea-
2	sonable measures to protect the confiden-
3	tiality of the information;
4	"(ii) the information is not required
5	to be disclosed, or otherwise made avail-
6	able, to the public under any other Federal
7	law in connection with one or more uses
8	subject to this title;
9	"(iii) disclosure of the information is
10	likely to cause meaningful harm to the
11	competitive position of the person; and
12	"(iv) the information is not reasonably
13	believed to be readily discoverable through
14	reverse engineering;
15	"(B) the time period for which the person
16	claims protection from disclosure of the infor-
17	mation, which may be renewed upon request
18	not later than 30 days before the expiration of
19	the period; and
20	"(C) a generic name for the chemical sub-
21	stance, or a unique identifier that adequately
22	distinguishes the chemical substance, that the
23	Administrator may disclose to the public, sub-
24	ject to the condition that such generic name or
25	unique identifier discloses a maximum amount

1	of information on the structure of the chemical
2	substance while protecting those features of
3	such structure that are considered confidential
4	and the disclosure of which would potentially
5	harm the competitive position of the person.
6	"(c) GUIDANCE.—The Administrator shall develop
7	guidance on the determination of generic names and
8	unique identifiers for confidential chemical identities.
9	"(d) Exceptions to Protection From Disclo-
10	SURE.—
11	"(1) IN GENERAL.—In accordance with sub-
12	section (l), subsection (a) shall not apply to—
13	"(A) health and safety information—
14	"(i) relating to a chemical substance
15	or mixture that has been offered for com-
16	mercial distribution as of the date on
17	which the information is to be disclosed; or
18	"(ii) that is developed pursuant to a
19	requirement under section 4, 5, or 6;
20	"(B) health and safety information sub-
21	mitted to the Administrator in connection with
22	a notice of substantial risk required under sec-
23	tion $8(e);$
24	"(C) general information describing the
25	manufacturing volumes, expressed in ranges,

1	that would not reveal information protected as
2	confidential under this section; and
3	"(D) general descriptions of industrial,
4	commercial, or consumer functions and uses of

5 a chemical substance or mixture that are cus-6 tomarily shared with the general public or with-7 in the industry to which the person submitting 8 the information belongs, and would not reveal 9 information protected as confidential under this 10 section.

11 "(2) LIMITED INFORMATION SHARING.—The 12 Administrator may share information otherwise pro-13 tected from disclosure by this section only as follows: 14 "(A) To an officer or employee of the United States— 15 "(i) to carry out that person's official 16 17 duties; or 18 "(ii) for specific law enforcement pur-19 poses under this or any other Act.

20 "(B) To a contractor with the United
21 States and employees of that contractor if, in
22 the opinion of the Administrator, the disclosure
23 is necessary for the satisfactory performance by
24 the contractor of a contract with the United
25 States for the performance of work in connec-

1	tion with this title and under such conditions as
2	the Administrator shall specify.
3	"(C) To a State, upon written request, for
4	the purpose of development, administration, or
5	enforcement of a law, if—
6	"(i) the recipient agrees in writing to
7	take appropriate steps, and has adequate
8	authority, to maintain the confidentiality
9	of the information in accordance with pro-
10	cedures as stringent as those the Adminis-
11	trator uses to safeguard the information;
12	and
13	"(ii) the Administrator notifies a per-
14	son claiming protection of the information
15	that the information will be disclosed to a
16	State.
17	"(D) To a person who is a health profes-
18	sional employed by a Federal or State agency,
19	or a treating physician or nurse, in a non-
20	emergency situation if such person—
21	"(i) states in writing to the Adminis-
22	trator that the person has a reasonable
23	basis to believe that disclosure of the infor-
24	mation will assist in diagnosis or treatment

1	of any person exposed to the chemical sub-
2	stance; and
3	"(ii) agrees in writing not to use the
4	information for any purpose other than the
5	diagnosis and treatment referred to in
6	clause (i).
7	"(E) To a treating physician, nurse, or
8	agent of a poison control center, or any other
9	person such a physician, nurse, or agent deter-
10	mines is necessary to aid in diagnosis or treat-
11	ment described in clause (i), if—
12	"(i) such physician, nurse, or agent
13	states that the requested information is
14	necessary for, or will assist in, emergency
15	or first-aid diagnosis or treatment and a
16	person being diagnosed or treated has like-
17	ly been exposed to the chemical substance;
18	and
19	"(ii) each person receiving the pro-
20	tected information agrees in writing as
21	soon as practicable, but not necessarily
22	prior to receiving the information, not to
23	use the information concerned for any pur-
24	pose other than the diagnosis or treatment
25	referred to in clause (i).
1	"(3) Prohibition.—No person who receives in-
----	---
2	formation under paragraph (2) may use such infor-
3	mation for any purpose not specified in such para-
4	graph, nor disclose such information to any person
5	not authorized to receive such information.
6	"(4) Use of information by the adminis-
7	TRATOR.—Subsection (a) shall not apply to the ex-
8	tent that the Administrator determines that infor-
9	mation disclosure is necessary—
10	"(A) to protect health or the environment
11	from an unreasonable risk of harm; or
12	"(B) in a proceeding under this title, sub-
13	ject to the condition that the disclosure is made
14	in such a manner as to preserve confidentiality
15	to the extent practicable without impairing the
16	proceeding.
17	"(5) Health and safety information.—
18	For purposes of this subsection, the term 'health
19	and safety information' does not include information
20	described in subsection $(a)(7)$ .
21	"(e) DURATION OF PROTECTION FROM DISCLO-
22	SURE.—The Administrator shall protect from disclosure
23	information as required under this section unless—
24	((1) the person claiming confidentiality of such
25	information under subsection (b) notifies the Admin-

1	istrator that the person is withdrawing the confiden-
2	tiality claim, in which case the Administrator shall
3	promptly make the information available to the pub-
4	lic; or
5	"(2) the Administrator finds that—
6	"(A) the time period described in sub-
7	section $(b)(2)(B)$ has expired;
8	"(B) the information has been publicly dis-
9	closed through some other means; or
10	"(C) the information no longer meets the
11	criteria for protection under this section.
12	"(f) Reestablishment of Confidentiality.—
13	"(1) IN GENERAL.—Except as provided in para-
14	graph (2), the Administrator may require a person
15	who has claimed information as confidential under
16	subsection (b) to reestablish such claim.
17	"(2) LIMITATION.—The Administrator may not
18	under paragraph $(1)$ require reestablishment of a
19	claim for protection from disclosure of information if
20	such claim was submitted to the Administrator
21	under this title prior to the date of enactment of the
22	Chemicals in Commerce Act, unless the Adminis-
23	trator has a reasonable basis to conclude that the
24	claim does not meet the requirements of this section
25	for protection from disclosure.

"(g) DETERMINATION BY THE ADMINISTRATOR.—
 2 The Administrator shall—

3 "(1) approve a claim of confidentiality received
4 under subsection (b); or

5 "(2) if the person who has submitted the claim
6 fails to meet the requirements of this section, ap7 prove the claim with conditions or deny the claim.

8 "(h) NOTICE AND EXPLANATION.—If the Adminis-9 trator takes action under subsection (g)(2), makes a finding under subsection (e)(2), shares information under sub-10 paragraphs (C) or (D) of subsection (d)(2), or discloses 11 12 information pursuant to a determination under subsection (d)(4)(A), the Administrator shall provide to the person 13 who has claimed confidentiality of information under sub-14 15 section (b) a written statement of the release, or the Ad-16 ministrator's intent to release or otherwise condition the protection, of the information and the reasons for taking 17 18 such action.

19 "(i) TIMING OF RELEASE OF INFORMATION.—

"(1) IN GENERAL.—Except as provided in this
section, the Administrator may not release information otherwise protected from disclosure until 30
days after the date on which the person who submitted the claim of confidentiality receives notification under subsection (h).

1 "(2) EXCEPTIONS.—

2 "(A) IN GENERAL.—The Administrator may not share information identified in sub-3 4 paragraphs (A)(i) or (E) of subsection (d)(2)5 until 15 days after the date on which the per-6 son who submitted the claim of confidentiality 7 receives a notification under subsection (h), un-8 less the Administrator determines that release 9 of the information is necessary to protect 10 against an imminent and substantial harm to 11 human health or the environment, in which case 12 no prior notification is necessary.

"(B) NO NOTIFICATION.—For information
identified in subparagraphs (A)(ii) or (E) of
subsection (d)(2), or subparagraphs (A) or (B)
of subsection (d)(4), no prior notification is
necessary.

"(j) SUBSETS.—If it is not feasible for the Administrator to review each claim received under subsection (b),
the Administrator shall review a subset of all submitted
information protection claims selected on a statistically
valid basis.

23 "(k) JUDICIAL REVIEW.—

24 "(1) IN GENERAL.—A decision by the Adminis25 trator under subsection (g)(2) is subject to review

1	and injunctive relief in a district court of the United
2	States located in the district in which the person
3	seeking protection of the information from disclosure
4	resides, or the United States District Court for the
5	District of Columbia.
6	"(2) STAY.—Except as provided in subsection
7	(d), the Administrator shall disclose no information
8	included in claim of confidentiality made under sub-
9	section (b) during the pendency of judicial review
10	under this subsection.
11	"(1) Separability of Information.—In carrying
12	out this title, the Administrator shall separate information
13	as necessary to ensure that—
14	"(1) no information that is eligible for protec-
15	tion under this section is disclosed with information
16	not protected under this section; and
17	"(2) all information required to be disclosed
18	under this title is disclosed.
19	"(m) Administration.—In carrying out this sec-
20	tion, the Administrator shall employ the procedures in
21	part 2 of title 40, Code of Federal Regulations (or suc-
22	cessor regulations).".
23	(b) TABLE OF CONTENTS AMENDMENT.—The item
24	relating to section 14 in the table of contents is amended

25 to read as follows:

"Sec. 14. Confidential information.".

### 1 SEC. 15. PROHIBITED ACTS.

2 Section 15(1) (15 U.S.C. 2614(1)) is amended by
3 striking "(A) any rule" and all that follows through "or
4 (D)" and inserting "any requirement of this title or any
5 rule, order, or consent agreement issued or entered into
6 under this title, or".

## 7 SEC. 16. PENALTIES.

8	Section 16 (15 U.S.C. 2615) is amended—
9	(1) in subsection $(a)(1)$ —
10	(A) in the first sentence—
11	(i) by striking "section 15 or 409"
12	and inserting "this title, or who otherwise
13	violates this Act, except as provided in sec-
14	tion 207(b),"; and
15	(ii) by striking "\$25,000" and insert-
16	ing ''\$37,500''; and
17	(B) in the second sentence, by striking
18	"violation of section 15 or 409" and inserting
19	"violation of this Act";
20	(2) in subsection $(a)(2)(A)$ , by striking "of sec-
21	tion 15 or 409" and inserting "described in para-
22	graph (1)"; and
23	(3) in subsection (b)—
24	(A) by striking "Any person" and inserting
25	the following:
26	"(1) IN GENERAL.—Any person";

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1	(B) by striking "section 15 or 409" and
2	inserting "this Act";
3	(C) by striking "\$25,000" and inserting
4	"\$50,000"; and
5	(D) by adding at the end the following:
6	"(2) Imminent danger of death or serious
7	BODILY INJURY.—Any person who knowingly or will-
8	fully violates any provision of this Act and who
9	knows, at the time of the violation, that the violation
10	places another person in imminent danger of death
11	or serious bodily injury shall be subject, upon convic-
12	tion, to a fine of not more than \$250,000, imprison-
13	ment for not more than 5 years, or both.".
14	SEC. 17. PREEMPTION.
14 15	<b>SEC. 17. PREEMPTION.</b> Section 18 (15 U.S.C. 2617) is amended by striking
15	Section 18 (15 U.S.C. 2617) is amended by striking
15 16	Section 18 (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following:
15 16 17	Section 18 (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following: "(a) IN GENERAL.—Except as otherwise provided in
15 16 17 18	Section 18 (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following: "(a) IN GENERAL.—Except as otherwise provided in this section, no State or local government may—
15 16 17 18 19	Section 18 (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following: "(a) IN GENERAL.—Except as otherwise provided in this section, no State or local government may— "(1) establish or continue in force a law or reg-
15 16 17 18 19 20	Section 18 (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following: "(a) IN GENERAL.—Except as otherwise provided in this section, no State or local government may— "(1) establish or continue in force a law or reg- ulation to the extent that the law or regulation, for
<ol> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> </ol>	Section 18 (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following: "(a) IN GENERAL.—Except as otherwise provided in this section, no State or local government may— "(1) establish or continue in force a law or reg- ulation to the extent that the law or regulation, for the purpose of regulating chemical substances, mix-

1	"(i) that the Administrator has re-
2	quired for the chemical substance under
3	section 4, 5, or 6; or
4	"(ii) relating to a chemical substance,
5	mixture, or article and its intended condi-
6	tions of use with respect to which the Ad-
7	ministrator has completed a risk evalua-
8	tion;
9	"(B) prohibits or restricts the manufac-
10	ture, processing, distribution in commerce, or
11	use of a chemical substance, mixture, or article
12	for its intended conditions of use if—
13	"(i) the Administrator has—
14	"(I) determined under section
15	5(c)(3)(B) that the chemical sub-
16	stance, mixture, or article for its in-
17	tended conditions of use does not war-
18	rant regulation under section 5;
19	"(II) determined under section
20	6(b) that the chemical substance, mix-
21	ture, or article will not present a sig-
22	nificant risk of harm to human health
23	or the environment under the in-
24	tended conditions of use; or

1	"(III) promulgated a rule, en-
2	tered into a consent agreement, or
3	issued an order under section $5(c)(5)$
4	or $6(c)$ with respect to the chemical
5	substance, mixture, or article for its
6	intended conditions of use; or
7	"(ii) the review period under section
8	5(c)(1) with respect to the chemical sub-
9	stance, mixture, or article for its intended
10	conditions of use has expired;
11	"(C) requires the notification of a use of a
12	chemical substance, mixture, or article with re-
13	spect to which the Administrator has required
14	notification pursuant to section 5; or
15	"(D) includes any requirement with re-
16	spect to a chemical substance, mixture, or arti-
17	cle, or its intended conditions of use, with re-
18	spect to which and to the extent that the Ad-
19	ministrator, under section 5 or 6, before the
20	date of enactment of the Chemicals in Com-
21	merce Act, has promulgated a rule, entered into
22	a consent agreement, issued an order, or al-
23	lowed the expiration of a significant new use re-
24	view period; or

"(2) establish a law or regulation on or after
the date on which the Administrator identifies a
chemical substance as a low priority under section
6(a) to the extent that the law or regulation regulates that chemical substance for intended conditions
of use.

7 "(b) EXCEPTIONS.—Subsection (a) shall not apply to
8 a law or regulation that is adopted or authorized pursuant
9 to any other Federal law.

10 "(c) DAMAGES OR EQUITABLE RELIEF.—Nothing in
11 this section preempts any cause of action under State law
12 for damages or equitable relief alleging personal injury,
13 death, or property damage arising from exposure to a
14 chemical substance or mixture.".

#### 15 SEC. 18. JUDICIAL REVIEW.

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

17 (1) in subsection (a)—

18 (A) by striking paragraph (1) and insert-19 ing the following:

20 "(1) FILING OF PETITION.—

21 "(A) IN GENERAL.—Not later than 60
22 days after the date of the promulgation of a
23 rule under section 4, 5(c)(5), 6(c), or 8 or title
24 II or IV or an order under section 4 or 5(c)(5),
25 any person may file a petition for judicial re-

1	view of the rule or order in the United States
2	Court of Appeals for—
3	"(i) the District of Columbia Circuit;
4	"(ii) the circuit in which the person
5	resides; or
6	"(iii) the circuit in which the principal
7	place of business of the person is located.
8	"(B) EXCLUSIVE JURISDICTION OF
9	COURTS OF APPEALS.—The courts of appeals of
10	the United States shall have exclusive jurisdic-
11	tion of any action to obtain judicial review
12	(other than in an enforcement proceeding)
13	under subparagraph (A).";
14	(B) in paragraph (2)—
15	(i) by inserting "Administrative
16	RULES.—" before "Copies of any petition";
17	and
18	(ii) by striking "paragraph (1)(A)"
19	and inserting "paragraph (1)"; and
20	(C) in paragraph (3)—
21	(i) by inserting "DEFINITION.—" be-
22	fore "For purposes of";
23	(ii) by amending subparagraph (B) to
24	read as follows:

1	"(B) in the case of a rule or order under
2	section 4, the statement issued under section
3	4(b), in the case of a rule or order under sec-
4	tion $5(c)(5)$ , the determination required under
5	section $5(c)(3)$ , in the case of rule under section
6	6(c), the statement published under section
7	6(b)(5), and in the case of a rule under title IV,
8	the finding required for the issuance of such a
9	rule;".
10	(iii) by striking subparagraph (C);
11	and
12	(iv) by redesignating subparagraphs
13	(D) and (E) as subparagraphs (C) and
14	(D), respectively; and
15	(2) in subsection $(c)(1)$ , by striking subpara-
16	graphs (B) and (C) and inserting the following:
17	"(B) Applicability of section 706 of
18	TITLE 5, UNITED STATES CODE.—Section 706
19	of title 5, United States Code, shall apply to re-
20	view of a rule, order, or final agency action
21	under this section, except that—
22	"(i) in the case of a rule under section
23	4, $5(c)(5)$ , or $6(c)$ or an order under sec-
24	tion 4 or $5(c)(5)$ —

	$\cup 0$
1	"(I) the standard of review pre-
2	scribed in section $706(2)(E)$ of title 5,
3	United States Code, shall not apply;
4	and
5	"(II) the court shall hold as un-
6	lawful and set aside the rule if the
7	court finds that the rule is not sup-
8	ported by substantial evidence in the
9	rulemaking record; and
10	"(ii) the court shall not review the
11	contents and adequacy of the statement of
12	basis and purpose required by section
13	553(c) of title 5, United States Code, to be
14	incorporated in the rule except as part of
15	a review of the rulemaking record taken as
16	a whole.".
17	SEC. 19. CITIZENS' CIVIL ACTIONS.
18	Section 20(a)(1) (15 U.S.C. 2619(a)(1)) is amend-
19	ed—
20	(1) by striking "or 6" and inserting "6, or 8";
21	and
22	(2) by striking "section 5" and inserting "sec-
23	tion 4 or 5".
24	SEC. 20. CITIZENS' PETITIONS.
25	Section 21 (15 U.S.C. 2620) is amended—

1	(1) in subsection (a), by striking "section 4, 6,
2	or 8 or an order under section $5(e)$ or $6(b)(2)$ " and
3	inserting "section 4, 6(c), or 8 or an order under
4	section 4 or 5(c)";
5	(2) in subsection (b)—
6	(A) in paragraph (1), by striking "an
7	order under section $5(e)$ , $6(b)(1)(A)$ , or
8	6(b)(1)(B)" and inserting "an order under sec-
9	tion 4 or $5(c)$ "; and
10	(B) by striking subparagraph (B) of para-
11	graph (4) and inserting the following:
12	"(B) DE NOVO PROCEEDING.—
13	"(i) IN GENERAL.—In an action
14	under subparagraph (A) to initiate a pro-
15	ceeding to issue a rule under section 4,
16	6(c), or 8 or an order issued under section
17	4 or $5(c)$ , the petitioner shall be provided
18	an opportunity to have the petition consid-
19	ered by the court in a de novo proceeding.
20	"(ii) Demonstration.—
21	"(I) IN GENERAL.—The court
22	shall order the Administrator to ini-
23	tiate the action requested by the peti-
24	tioner if the petitioner demonstrates

to the satisfaction of the court by a
preponderance of the evidence that—
"(aa) in the case of a peti-
tion to initiate a proceeding for
the issuance of a rule or order
under section 4, the information
available to the Administrator is
insufficient for the Administrator
to perform an action described in
section $4(a)(1)$ ;
"(bb) in the case of a peti-
tion to issue an order under sec-
tion 5(c), there is a reasonable
basis to conclude that the chem-
ical substance is likely to result
in an unreasonable risk of harm
to human health or the environ-
ment under the intended condi-
tions of use;
"(cc) in the case of a peti-
tion to initiate a proceeding for
the issuance of a rule under sec-
tion $6(c)$ , there is a reasonable
basis to conclude that the chem-
ical substance or mixture will re-

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sult in an unreasonable risk of harm to human health or the environment under the intended conditions of use; or

"(dd) in the case of a peti-5 6 tion to initiate a proceeding for 7 the issuance of a rule under sec-8 tion 8, there is a reasonable basis 9 to conclude that the rule is nec-10 essary to protect human health 11 or the environment from an un-12 reasonable risk of harm.

13 "(II) DEFERMENT.—The court
14 may permit the Administrator to defer
15 initiating the action requested by the
16 petitioner, until such time as the
17 court prescribes, if the court finds
18 that—

19 "(aa) the extent of the risk
20 to human health or the environ21 ment alleged by the petitioner is
22 less than the extent of those risks
23 to human health or the environ24 ment with respect to which the

1	Administrator is otherwise taking
2	action under this title; and
3	"(bb) there are insufficient
4	resources available to the Admin-
5	istrator to take the action re-
6	quested by the petitioner."; and
7	(3) by adding at the end the following:
8	"(c) LIMITATION.—For purposes of this section, any
9	reference to a rule under section 4 shall not include a rule
10	under section $4(a)(1)(C)$ .".
11	SEC. 21. NATIONAL SECURITY.
12	(a) Amendment.—Section 22 (15 U.S.C. 2621) is
13	amended to read as follows:
14	"SEC. 22. NATIONAL SECURITY.

#### 14 "SEC. 22. NATIONAL SECURITY.

"(a) WAIVER.—The Administrator shall waive com-15 pliance with any provision of this Act upon a determina-16 17 tion by the President that the waiver is necessary in the interest of national security. Upon the issuance of such 18 a waiver, the Administrator shall publish in the Federal 19 20 Register a notice that the waiver was granted for national security purposes, unless the President directs the Admin-21 22 istrator to omit such publication because the publication 23 itself would be contrary to the interests of national secu-24 rity.

"(b) CONSULTATION.—The Administrator shall con sult periodically with the President or the President's des ignee to discuss how implementation of this Act could af fect national security.".

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

"Sec. 22. National security.".

#### 8 SEC. 22. STUDIES.

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

#### 11 SEC. 23. POLICIES, PROCEDURES, AND GUIDANCE.

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

- (1) by striking "Health, Education, and Welfare" each place it appears and inserting "Health
  and Human Services";
- 16 (2) in subsection (b), by striking "section 4 or
  17 5" and inserting "section 4, 5, or 6"; and

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

19 "(h) POLICIES, PROCEDURES, AND GUIDANCE.—Not 20 later than 1 year after the date of enactment of the 21 Chemicals in Commerce Act, the Administrator shall, after 22 providing public notice and an opportunity for public com-23 ment, establish all policies, procedures, and guidance nec-24 essary to implement the amendments made to this title 25 by the Chemicals in Commerce Act. 1 "(i) SCIENTIFIC STANDARDS.—In evaluating infor-2 mation from studies and tests, and in carrying out sec-3 tions 4, 5, and 6 to the extent that the Administrator 4 makes a decision based on science, the Administrator shall 5 consider, among other applicable factors—

- 6 "(1) the extent to which the scientific and tech7 nical procedures, measures, methods, or models em8 ployed to generate the information are reasonable
  9 for and consistent with the intended application;
- 10 "(2) the extent to which the information is rel11 evant for the Administrator's intended use;
- "(3) the degree of clarity and completeness with
  which the data, assumptions methods, quality assurance, sponsoring organizations, and analyses employed to generate the information are documented;
  "(4) the extent to which the variability and un-
- 17 certainty in the information or in the procedures,
  18 measures, methods, or models are evaluated and
  19 characterized; and
- 20 "(5) the extent of independent verification, vali21 dation, and peer review of the information or of the
  22 procedures, measures, methods, or models.

23 "(j) WEIGHT OF SCIENTIFIC EVIDENCE.—The Ad24 ministrator shall make decisions under sections 4, 5, and
25 6 based on the weight of the scientific evidence.

"(k) GUIDANCE.—The Administrator shall provide
 public notice and opportunity for public comment for any
 significant written guidance of general applicability pre pared by the Administrator under this title.".

## 5 SEC. 24. TECHNICAL AMENDMENT.

6 Section 27(a) (15 U.S.C. 2626(a)) is amended by
7 striking "Health, Education, and Welfare" and inserting
8 "Health and Human Services".

# 9 SEC. 25. STATE PROGRAMS.

Section 28 (15 U.S.C. 2627) is amended by strikingsubsections (c) and (d).

## 12 SEC. 26. AUTHORIZATION OF APPROPRIATIONS.

13 Section 29 (15 U.S.C. 2628) and the item relating14 thereto in the table of contents are repealed.

# 15 SEC. 27. ANNUAL REPORT.

16 Section 30 (15 U.S.C. 2629) is amended by striking17 paragraph (2) and inserting the following:

18 "(2)(A) the number of notices received under19 section 5; and

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

## 1 SEC. 28. PRESERVATION OF AUTHORITY.

Except as specifically provided in this Act or the
amendments made by this Act, nothing in this Act or the
amendments made by this Act shall amend, alter, or affect—

6 (1) the authority of the Administrator under
7 the Toxic Substances Control Act as in effect before
8 the date of enactment of this Act; or

9 (2) the continued application or validity of any
10 action taken by the Administrator under the Toxic
11 Substances Control Act before the date of enactment
12 of this Act.