113TH CONGRESS 1ST SESSION	S.	
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To reauthorize and modernize the Toxic Substances Control Act, and for other purposes.

## IN THE SENATE OF THE UNITED STATES

Mr. Lautenberg (for himself, Mr. Vitter, Mrs. Gillibrand, Mr. Crapo, Mr. Durbin, Mr. Alexander, Mr. Schumer, Mr. Inhofe, Mr. Udall of New Mexico, Ms. Collins, Ms. Landrieu, Mr. Rubio, Mr. Manchin, Mr. Boozman, Mr. Menendez, and Mr. Hoeven) introduced the following bill; which was read twice and referred to the Committee on

## A BILL

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

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS; REF-
- 4 ERENCES.
- 5 (a) Short Title.—This Act may be cited as the
- 6 "Chemical Safety Improvement Act".
- 7 (b) Table of Contents for
- 8 this Act is as follows:

- Sec. 1. Short title; table of contents; references.
- Sec. 2. Findings, policy, and intent.
- Sec. 3. Definitions.
- Sec. 4. Chemical assessment framework; prioritization screening; testing.
- Sec. 5. New chemicals and significant new uses.
- Sec. 6. Safety assessments and determinations.
- Sec. 7. Imminent hazards.
- Sec. 8. Information collection and reporting.
- Sec. 9. Relationship to other Federal laws.
- Sec. 10. Research, development, collection, dissemination, and utilization of data.
- Sec. 11. Exports.
- Sec. 12. Imports.
- Sec. 13. Confidential information.
- Sec. 14. Prohibited acts.
- Sec. 15. Preemption.
- Sec. 16. Judicial review.
- Sec. 17. Citizens' petitions.
- Sec. 18. Studies.
- Sec. 19. Administration.
- Sec. 20. Development and evaluation of test methods.
- Sec. 21. State programs.
- Sec. 22. Authorization of appropriations.
- Sec. 23. Annual report.
- 1 (c) References.—Except as otherwise expressly
- 2 provided, wherever in this Act an amendment or repeal
- 3 is expressed in terms of an amendment to, or repeal of,
- 4 a section or other provision, the reference shall be consid-
- 5 ered to be made to a section or other provision of the Toxic
- 6 Substances Control Act (15 U.S.C. 2601 et seq.).
- 7 SEC. 2. FINDINGS, POLICY, AND INTENT.
- 8 (a) Purposes.—The purposes of this Act are—
- 9 (1) to improve the safety of consumers in the
- 10 United States; and
- 11 (2) to ensure that risks from chemical sub-
- stances are adequately understood and managed by
- modernizing title I of the Toxic Substances Control
- 14 Act (15 U.S.C. 2601 et seq.).

1	(b) Findings, Policy, and Intent.—Section 2 (15
2	U.S.C. 2601) is amended by striking subsections (a)
3	through (c) and inserting the following:
4	"(a) FINDINGS.—Congress finds that—
5	"(1) chemicals should be safe for the intended
6	use of the chemicals;
7	"(2) the unmanaged risks of chemical sub-
8	stances may pose a danger to human health and the
9	environment;
10	"(3) public confidence in the Federal chemical
11	regulatory program has diminished over time;
12	"(4) scientific understanding of chemicals and
13	the possible risks of the chemicals has evolved great-
14	ly since 1976, requiring that Congress update the
15	law to ensure that chemical regulation in the United
16	States reflects modern science, technology and
17	knowledge;
18	"(5) this Act should be modernized to create a
19	robust Federal system for assessing and managing
20	chemical risks;
21	"(6) chemicals are used in diverse manufac-
22	turing industries and other valuable commercial, in-
23	stitutional, and consumer applications that have ben-
24	efitted society;

1	"(7) for the purposes of promoting uniform
2	protections through regulation of chemical sub-
3	stances in commerce, to minimize undue burdens on
4	commerce, and to minimize burdens on States, speci-
5	fied actions by the Administrator should preempt re-
6	quirements by States and political subdivisions of
7	States that relate to the effects of or exposure to a
8	chemical substance under the intended conditions of
9	use; and
10	"(8) innovation in the development of new
11	chemical substances, especially safer chemical sub-
12	stances, should be encouraged to reduce risk, provide
13	improved products, stimulate the economy, create
14	jobs, and protect interstate commerce.
15	"(b) Policy.—It is the policy of the United States
16	that—
17	"(1) this Act—
18	"(A) should protect the health of people
19	and the environment from the unmanaged risks
20	of chemical substances; and
21	"(B) should be modernized to build public
22	confidence in the ability of the Federal regu-
23	latory system to protect health and the environ-
24	ment, promote innovation, and sustain a glob-

1	ally competitive chemical industry in the United
2	States;
3	"(2) the Administrator—
4	"(A) should have the appropriate hazard,
5	use, and exposure information necessary to
6	make safety determinations;
7	"(B) should minimize the use of animal
8	testing through the use of scientifically reliable
9	and relevant test methods, where appropriate;
10	"(C) should encourage the use of best lab-
11	oratory practices to ensure high quality, rel-
12	evant, and reliable results from test methods
13	and studies;
14	"(D) should have the authority to share
15	confidential business information with States
16	and political subdivisions of the States, subject
17	to appropriate safeguards against inappropriate
18	disclosure;
19	"(E) should have the resources and tools
20	necessary to implement this Act; and
21	"(F) should implement this Act in a man-
22	ner that promotes transparency of information
23	and decisionmaking, protects substantiated con-
24	fidential business information, and promotes in-
25	novation, including innovation in chemical sub-

1 stances that have reduced hazard, exposure, 2 and risk patterns; 3 "(3) adequate data and information should be available with respect to the effect of and exposure 4 5 to chemical substances and mixtures on health and 6 the environment, to the extent necessary for safety 7 assessments and determinations, and that, where 8 necessary, the development of such test data and in-9 formation should be the primary responsibility of 10 those who manufacture or process such chemical 11 substances and mixtures; and 12 "(4) States have an important role in pro-13 tecting health and the environment from 14 unmanaged risks of chemical substances in commerce, particularly in recommending priorities for 15 16 Federal assessment and regulation, providing safety 17 assessment information, and fostering programs to 18 protect consumers. 19 "(c) Intent of Congress.—It is the intent of Con-20 gress that the Administrator shall— 21 "(1) rely on robust scientific evidence to imple-22 ment this Act in a way that balances the mutual 23 goals of promoting the safety of American con-24 sumers and preventing harm to American innova-25 tion, manufacturing, and the economy; and

1	"(2) implement this Act to protect the health of
2	the people of the United States and the environment
3	in such a manner as not to unduly impede commerce
4	or create unnecessary economic barriers to techno-
5	logical innovation, including safer chemistry.".
6	SEC. 3. DEFINITIONS.
7	Section 3 (15 U.S.C. 2602) is amended—
8	(1) by redesignating paragraphs (2) through
9	(6), (7) through (11), and (12) through (14) as
10	paragraphs (3) through (7), (9) through (13), and
11	(17) through (19), respectively;
12	(2) by inserting after paragraph (1) the fol-
13	lowing:
14	"(2) Best available science.—The term
15	'best available science' means science that—
16	"(A) maximizes the quality, objectivity,
17	and integrity of information, including statis-
18	tical information;
19	"(B) uses peer-reviewed and publically
20	available data; and
21	"(C) clearly documents and communicates
22	risks and uncertainties in the scientific basis for
23	decisions.";
24	(3) by inserting after paragraph (7) (as so re-
25	designated) the following:

1	(8) INTENDED CONDITIONS OF USE.—The
2	term 'intended conditions of use' means the cir-
3	cumstances under which a chemical substance is in-
4	tended or reasonably anticipated to be manufac-
5	tured, processed, distributed in commerce, used, and
6	disposed of."; and
7	(4) by inserting after paragraph (13) (as so re-
8	designated) the following:
9	"(14) Safety assessment.—The term 'safety
10	assessment' means a risk-based assessment of the
11	safety of a chemical substance that—
12	"(A) integrates hazard; use; and exposure
13	information about a chemical substance; and
14	"(B) includes—
15	"(i) an assessment of exposure under
16	the intended conditions of use; and
17	"(ii) reference parameters that may
18	be appropriate with regard to a specific
19	chemical substance (such as a margin of
20	exposure).
21	"(15) Safety Determination.—The term
22	'safety determination' means a determination by the
23	Administrator as to whether a chemical substance
24	meets the safety standard under the intended condi-
25	tions of use.

1	"(16) Safety Standard.—The term 'safety
2	standard' means a standard that ensures that no
3	unreasonable risk of harm to human health or the
4	environment will result from exposure to a chemical
5	substance.".
6	SEC. 4. CHEMICAL ASSESSMENT FRAMEWORK;
7	PRIORITIZATION SCREENING; TESTING.
8	(a) In General.—Section 4 (15 U.S.C. 2603) is
9	amended—
10	(1) in the heading, by striking "TESTING OF
11	CHEMICAL SUBSTANCES AND MIXTURES" and
12	inserting "CHEMICAL ASSESSMENT FRAME-
13	WORK; PRIORITIZATION SCREENING; TEST-
14	ING''.
15	(2) by redesignating subsection (e) as sub-
16	section (l);
17	(3) in subsection (l) (as so redesignated)—
18	(A) by striking "rule" each place it ap-
19	pears and inserting "rule, testing consent
20	agreement, or order";
21	(B) by striking "under subsection (a)"
22	each place it appears and inserting "under this
23	subsection"; and
24	(C) in paragraph (1)(B), by striking "rule-
25	making"; and

1	(4) by striking subsections (a) through (d), (f),
2	and (g) and inserting the following:
3	"(a) Chemical Assessment Framework.—
4	"(1) In General.—The Administrator shall
5	develop a framework in accordance with subsection
6	(e) and sections 5 and 6 for evaluating the safety of
7	chemical substances in commerce that shall employ
8	the best available science and risk assessment prin-
9	ciples in existence at the time the Administrator is
10	developing the framework.
11	"(2) Policies and procedures.—
12	"(A) IN GENERAL.—After the date of en-
13	actment of the Chemical Safety Improvement
14	Act, the Administrator shall promptly develop
15	appropriate policies and procedures for imple-
16	menting the framework, including procedures
17	on the collection, evaluation, and development
18	of data and information.
19	"(B) Contents.—The policies and proce-
20	dures shall require—
21	"(i) the collection of existing data and
22	information from manufacturers and proc-
23	essors of chemical substances and other
24	sources, including the use of voluntary

1	agreements to provide the data and infor-
2	mation;
3	"(ii) an evaluation of the quality of
4	existing data and information;
5	"(iii) an analysis of data and informa-
6	tion;
7	"(iv) a determination of the need for
8	additional data and information, including
9	information related to the exposures of dif-
10	ferent subpopulations; and
11	"(v) subject to section 14, trans-
12	parency of data and information consid-
13	ered by the Administrator, including both
14	positive and negative findings.
15	"(3) Transparency and validity.—The Ad-
16	ministrator shall ensure that the evaluation frame-
17	work described in subsection (a)(1)—
18	"(A) is transparent;
19	"(B) assures that data and information
20	are valid;
21	"(C) addresses the strengths and limita-
22	tions of—
23	"(i) the design of the framework,
24	"(ii) the reliability of the test meth-
25	ods; and

"(iii) the quality of the data and in-
formation; and
"(D) pursues the goal of maximizing the
quality, objectivity, utility, and integrity of the
data and information.
"(b) Data and Information Quality.—
"(1) In general.—The Administrator shall es-
tablish and publish scientifically sound criteria for
evaluating all of the data and information, including
the results of animal and nonanimal testing, regard-
less of affiliation or funding source, on which the
Administrator relies in making a decision under this
Act.
"(2) Disclosure of sources of funding.—
The Administrator shall require that the submitter
of any health and safety study disclose to the Ad-
ministrator and to the public the sources of any
funding used for the study or publication of the
study received by the researcher who conducted the
study, to the extent reasonably ascertainable.
"(3) Test data developed
under this Act, the Administrator shall encourage
the use of good laboratory practices, peer review, sci-
entifically reliable and relevant test methods, stand-
ardized protocols, and other methods to ensure sci-

1	entific quality for all data and information sub-
2	mitted under this Act.
3	"(4) Data and information that do not
4	MEET CRITERIA.—
5	"(A) In general.—Nothing in this sub-
6	section shall preclude the Administrator from
7	considering data and information which do not
8	meet the quality criteria established under
9	paragraph (1).
10	"(B) IDENTIFICATION.—The Adminis-
11	trator shall—
12	"(i) identify any data and information
13	described in subparagraph (A) on which
14	the Administrator relies;
15	"(ii) describe the quality of the data
16	and information described in subparagraph
17	(A) and the extent to which the data and
18	information depart from those criteria;
19	"(iii) indicate any limitations on the
20	usefulness of the data and information de-
21	scribed in subparagraph (A); and
22	"(iv) explain how the data and infor-
23	mation described in subparagraph (A) was
24	used and the basis for reliance on the data
25	and information.

1	"(5) Evaluative framework for decision-
2	MAKING.—
3	"(A) IN GENERAL.—The Administrator
4	shall develop and use a structured evaluative
5	framework consisting of science-based criteria,
6	consistent with the protection of human health
7	and the environment, for making any decision
8	under this Act, and for determining the rel-
9	evance, quality, and reliability of data and in-
10	formation.
11	"(B) Contents.—The framework de-
12	scribed in subparagraph (A) shall, at a min-
13	imum—
14	"(i) use sound and objective scientific
15	practices in assessing risks;
16	"(ii) consider the current best avail-
17	able science (including peer-reviewed stud-
18	ies);
19	"(iii) when consistent with the under-
20	lying data, consider, for both cancer and
21	noncancer endpoints, whether available
22	data support or do not support the identi-
23	fication of threshold doses of a chemical
24	substance below which no adverse effects
25	can be expected to occur; and

1	"(iv) include a description of the	
2	weight of the scientific evidence concerning	
3	risks, including mechanistic information	
4	(such as appropriate modes of action).	
5	"(c) Data and Information Sources.—In making	
6	any decision with respect to a chemical substance under	
7	subsection (e) and sections 5 and 6, the Administrator	
8	shall consider data and information relevant to the sub	
9	stance that are reasonably available to the Administrator	
10	at that time, including data and information that are—	
11	"(1) submitted to the Administrator by—	
12	"(A) manufacturers and processors of the	
13	substance;	
14	"(B) the public; or	
15	"(C) a Governor of a State or a State	
16	agency with responsibility for protecting health	
17	or the environment;	
18	"(2) submitted to a governmental body in an-	
19	other jurisdiction under a governmental requirement	
20	relating to the protection of human health and the	
21	environment, if the information is accessible to the	
22	Administrator;	
23	"(3) derived through the application of scientif-	
24	ically reliable and relevant structure-activity rela-	
25	tionship, or other methods or models to estimate the	

1 environmental and human health effects, environ-2 mental and biological fate and behavior, and expo-3 sure potential for the substance; "(4) inferred based on the degree of structural 4 5 similarity or properties of the substance, or cat-6 egories of substances, to those of 1 or more other 7 chemical substances for which reliable information 8 exists that is relevant to predicting the potential en-9 vironmental or human health effects, environmental 10 or biological fate and behavior, or exposure potential 11 for the chemical substance; and 12 "(5) identified through an active search by the 13 Administrator of information sources that are pub-14 licly available or otherwise accessible to the Adminis-15 trator. "(d) Transparency.— 16 17 "(1) IN GENERAL.—Subject to section 14, the 18 data and information considered by the Adminis-19 trator in taking action under this Act shall be avail-20 able to the public. 21 "(2) Types of information available to 22 THE PUBLIC.—The Administrator shall make avail-23 able to the public the guidance, procedures, and 24 tools used in evaluating data and information under

1	this section, including models, studies, and, as ap-
2	propriate, the data underlying any study.
3	"(3) Guidance of gen-
4	eral applicability prepared by the Administrator
5	under this Act shall be subject to public notice and
6	an opportunity for comment.
7	"(e) Prioritization Screening Process.—
8	"(1) In general.—
9	"(A) Process.—Not later than 1 year
10	after the date of enactment of the Chemical
11	Safety Improvement Act, the Administrator
12	shall establish a risk-based screening process
13	for identifying existing chemical substances that
14	are—
15	"(i) a high priority for a safety as-
16	sessment and determination under section
17	6, to be known as 'high-priority sub-
18	stances'; and
19	"(ii) a low priority for a safety assess-
20	ment and determination, to be known as
21	'low-priority substances'.
22	"(B) Consideration of active and in-
23	ACTIVE SUBSTANCES.—
24	"(i) Consideration of active sub-
25	STANCES.—In implementing the process

1	described in subparagraph (A), the Admin-
2	istrator shall only consider active sub-
3	stances, as determined under section
4	8(b)(6), as either high-priority substances
5	or low-priority substances.
6	"(ii) Consideration of inactive
7	SUBSTANCES.—In implementing the proc-
8	ess described in subparagraph (A), the Ad-
9	ministrator shall only consider inactive
10	substances, as determined under section
11	8(b)(7), that the Administrator deter-
12	mines, on the basis of credible scientific
13	evidence that—
14	"(I) have not been subject to a
15	regulatory or other enforceable action
16	by the Administrator to ban or phase
17	out the substances; and
18	"(II) demonstrate high hazard
19	and high exposure.
20	"(C) Timely completion of
21	PRIORITIZATION PROCESS.—
22	"(i) IN GENERAL.—The Administrator
23	shall make every effort to complete the
24	prioritization of all active substances in a
25	timely manner.

1	"(ii) Consideration.—The Adminis-
2	trator shall prioritize substances taking
3	into consideration the ability of the Admin-
4	istrator to schedule and complete safety as-
5	sessments and determinations under sec-
6	tion 6 in a timely manner.
7	"(D) Use of data.—In making a decision
8	under the prioritization screening process, the
9	Administrator shall use reasonably available
10	data and information concerning the hazard
11	exposure, and use characteristics of chemical
12	substances on the list developed by the Admin-
13	istrator under section 8(b)(1) at the time the
14	decision is made.
15	"(E) Screening of categories or
16	CLASSES OF SUBSTANCES.—The Administrator
17	may screen categories or classes of chemical
18	substances to ensure an efficient prioritization
19	screening process to allow for timely and ade-
20	quate safety assessments and determinations.
21	"(F) Publication of List of Chemical
22	SUBSTANCES.—From time to time the Adminis-
23	trator shall—

1	"(i) publish a list of chemical sub-
2	stances being considered in the
3	prioritization screening process; and
4	"(ii) request the submission of data
5	and information on the chemical sub-
6	stances.
7	"(2) Proposed process.—
8	"(A) In General.—The Administrator
9	shall—
10	"(i) publish for public comment a pro-
11	posed prioritization screening process; and
12	"(ii) establish criteria for determining
13	whether a substance is a high or low pri-
14	ority for a safety assessment and deter-
15	mination.
16	"(B) Initial list.—
17	"(i) In general.—The proposal shall
18	include an initial list of chemical sub-
19	stances that includes, at a minimum, those
20	substances prioritized by the Administrator
21	before the date of enactment of the Chem-
22	ical Safety Improvement Act and for which
23	assessments or safety determinations have
24	not been completed, and proposed

1	prioritization outcomes based on the pro-
2	posed criteria.
3	"(ii) Contents.—The initial list shall
4	contain as many chemical substances as
5	the Administrator determines appropriate.
6	"(iii) Modification.—The Adminis-
7	trator may modify the initial list on the
8	basis of comments received on the pro-
9	posed process and criteria.
10	"(C) Criteria.—The criteria described in
11	subparagraph (A) shall consider—
12	"(i) the recommendation of a Gov-
13	ernor of a State or a State agency with re-
14	sponsibility for protecting health or the en-
15	vironment from chemical substances appro-
16	priate for prioritization screening;
17	"(ii) the hazard and exposure poten-
18	tial of the chemical substance (or category
19	or class of substances), including specific
20	scientific classifications and designations
21	by authoritative governmental entities;
22	"(iii) the intended conditions of use or
23	significant changes in the conditions of use
24	of the chemical substance;

1	"(iv) evidence and indicators of expo-
2	sure potential to humans or the environ-
3	ment from the chemical substance;
4	"(v) the volume of a chemical sub-
5	stance manufactured or processed;
6	"(vi) whether the volume of a chem-
7	ical substance as reported under a regula-
8	tion issued under section 8(a) (as in effect
9	on the date on which the criteria are pro-
10	posed) has significantly increased or de-
11	creased since a previous report or since the
12	date on which a notice has been submitted
13	under section 5(a);
14	"(vii) the availability of information
15	about potential hazards and exposures
16	needed for conducting a safety assessment
17	or determination, with limited availability
18	of relevant data and information to be a
19	factor in designating a substance as a high
20	priority; and
21	"(viii) the extent of Federal or State
22	regulation of the chemical substance or the
23	extent of the impact of State regulation of
24	the chemical substance on the United
25	States, with existing Federal or State reg-

1	ulation of any uses evaluated in the
2	prioritization screening process as a factor
3	in designating a chemical substance to be
4	a low priority.
5	"(3) Prioritization screening decisions.—
6	"(A) In general.—For the chemical sub-
7	stances considered for prioritization screening,
8	the Administrator shall apply the criteria iden-
9	tified in paragraph (2), using the information
10	identified in subsection (c), to identify a chem-
11	ical substance as a high-priority substance or a
12	low-priority substance.
13	"(B) ADDITIONAL TEST DATA.—If the Ad-
14	ministrator determines that additional test data
15	and information are needed to establish the pri-
16	ority of a chemical substance, the Administrator
17	shall provide an opportunity for interested per-
18	sons to submit data and information to the ex-
19	tent that it is reasonably ascertainable.
20	"(C) Deferring a decision.—If the Ad-
21	ministrator determines that it is appropriate,
22	the Administrator may defer a prioritization
23	screening decision for a chemical substance
24	under subparagraph (A) for a reasonable period

1	to allow for the submission and evaluation of
2	additional data and information.
3	"(D) Integration of data and infor-
4	MATION.—During the prioritization screening of
5	a chemical substance, the Administrator shall
6	integrate any hazard and exposure data and in-
7	formation related to a chemical substance avail-
8	able to the Administrator.
9	"(E) Identification of high-priority
10	SUBSTANCES.—The Administrator—
11	"(i) shall identify as a high-priority
12	substance a chemical substance that, rel-
13	ative to other substances, has the potential
14	for high hazard and high exposure;
15	"(ii) may identify as a high-priority
16	substance a chemical substance that, rel-
17	ative to other substances, has the potential
18	for high hazard or high exposure; and
19	"(iii) may identify as a high-priority
20	substance an inactive substance, as deter-
21	mined under section 8(b)(7), that the Ad-
22	ministrator determines, on the basis of
23	credible scientific evidence that—
24	"(I) has not been subject to a
25	regulatory action by the Adminis-

1	trator to ban or phase out the sub-
2	stance; and
3	"(II) demonstrates high hazard
4	and high exposure.
5	"(F) Identification of Low-Priority
6	SUBSTANCES.—The Administrator shall identify
7	as a low-priority substance a chemical sub-
8	stance that the Administrator on the basis of
9	the available information determines is likely to
10	meet the safety standard under the intended
11	conditions of use.
12	"(G) Notice and comment.—The identi-
13	fications made under subparagraphs (E) and
14	(F) shall be subject to notice and an oppor-
15	tunity for comment.
16	"(H) Order of safety assessments.—
17	"(i) High-priority substances.—
18	The Administrator—
19	"(I) shall determine the order for
20	performing safety assessments on
21	high-priority substances under section
22	6; and
23	"(II) may revise the order as the
24	Administrator determines appropriate.

1	"(ii) Low-priority substance.—
2	The Administrator shall not perform safety
3	assessments on low-priority substances, un-
4	less a low-priority substance is redesig-
5	nated under subparagraph (I).
6	"(I) REVISION BASED ON NEW DATA.—
7	"(i) In general.—Subject to sub-
8	paragraph (D), at any time the Adminis-
9	trator may revise the identification of a
10	chemical substance as a high-priority sub-
11	stance or a low-priority substance based on
12	consideration of data or information made
13	available to the Administrator after the
14	date on which the Administrator makes the
15	identification under subparagraphs (E)
16	and (F).
17	"(ii) Reevaluation.—
18	"(I) In General.—The Admin-
19	istrator shall evaluate the data or in-
20	formation described in clause (i) on a
21	high-priority substance or a low-pri-
22	ority substance for possible reevalua-
23	tion of the priority of the substance.
24	"(II) LIMITED AVAILABILITY.—If
25	limited availability of relevant data

1	and information was a factor in the
2	original identification of a chemical
3	substance as a high-priority sub-
4	stance, the Administrator shall re-
5	evaluate the prioritization screening of
6	the substance on receiving the rel-
7	evant data and information.
8	"(J) Publication of a list of high-
9	PRIORITY AND LOW-PRIORITY SUBSTANCES.—
10	"(i) In General.—The Administrator
11	shall publish and keep current a list of
12	high-priority substances and a list of low-
13	priority substances.
14	"(ii) Justification.—Whenever the
15	Administrator places a chemical substance
16	on one of the lists described in clause (i)
17	or changes the priority of the chemical
18	substance, the Administrator shall include
19	a justification for the decision in accord-
20	ance with paragraph (2)(C).
21	"(K) Removal.—The Administrator shall
22	remove a chemical substance from the list of
23	high-priority substances on the date on which a
24	safety determination for the chemical substance
25	is published.

1	"(L) Effect.—Subject to section 18, a
2	decision by the Administrator under this para-
3	graph with respect to a chemical substance
4	shall not affect the manufacture, processing,
5	distribution, use, or disposal of the chemical
6	substance, or regulation of those activities.
7	"(4) Expedited prioritization screen-
8	ING.—
9	"(A) In General.—Not later than 180
10	days after the date on which the Administrator
11	receives a recommendation and relevant data
12	and information from a Governor of a State or
13	a State agency with responsibility for protecting
14	health and the environment that an active
15	chemical substance be identified as a high-pri-
16	ority or low-priority substance, the Adminis-
17	trator shall make a prioritization screening de-
18	cision for the substance.
19	"(B) Notice and comment.—The public
20	shall be provided notice and an opportunity to
21	comment on the recommendation described in
22	subparagraph (A).
23	"(C) EXPLANATION OF REASONS.—The
24	Administrator shall—

1	"(i) make available to the Governor or
2	the appropriate State agency, as applica-
3	ble, and to the public a brief explanation of
4	reasons for identifying a chemical sub-
5	stance recommended by the Governor or
6	the agency for prioritization screening as
7	either a high-priority substance or a low-
8	priority substance; and
9	"(ii) identify the information relied
10	upon in making that identification.
11	"(5) Final agency action.—Any action by
12	the Administrator under this subsection shall not
13	be—
14	"(A) considered to be a final agency ac-
15	tion; or
16	"(B) subject to judicial review.
17	"(f) DEVELOPMENT OF NEW TEST DATA AND IN-
18	FORMATION.—
19	"(1) In general.—The Administrator may re-
20	quire the development of new test data and informa-
21	tion related to a chemical substance or mixture in
22	accordance with this section if the Administration
23	determines that the data and information are need-
24	ed—
25	"(A) to perform a safety assessment;

1	"(B) to make a safety determination; or
2	"(C) to meet the testing needs of the im-
3	plementing authority under another Federal
4	statute.
5	"(2) FORM.—The Administrator may require
6	the development of test data and information de-
7	scribed in paragraph (1) by—
8	"(A) promulgating a rule;
9	"(B) entering into a testing consent agree-
10	ment; or
11	"(C) issuing an order.
12	"(3) Requirements.—
13	"(A) In General.—In promulgating a
14	rule, adopting a testing consent agreement, or
15	issuing an order described in paragraph (2), the
16	Administrator shall require the use of—
17	"(i) an evaluation framework that,
18	prior to requiring additional testing of
19	vertebrate animals, integrates relevant in-
20	formation from multiple sources, including,
21	to the extent reliable—
22	"(I) toxicity information;
23	"(II) computational toxicology;
24	"(III) bioinformatics;

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1	"(IV) high-throughput screening
2	methods; and
3	"(V) scientifically reliable and
4	relevant alternatives to vertebrate ani-
5	mal tests; and
6	"(ii) tiered testing in accordance with
7	subsection (h), wherein the results of a
8	screening level tier of tests relating to a
9	toxicity pathway or target organ or target
10	system inform the decision of the Adminis-
11	trator as to whether tests from a higher
12	tier related to that pathway or organ or
13	system are necessary.
14	"(B) STATEMENT TO THE PUBLIC.—The
15	Administrator shall explain the basis for a deci-
16	sion made in subparagraph (A)(ii) in a state-
17	ment made available to the public.
18	"(4) Contents.—
19	"(A) IN GENERAL.—A rule, testing con-
20	sent agreement, or order issued under para-
21	graph (2) shall include—
22	"(i) identification of the chemical sub-
23	stance or mixture for which testing is re-
24	quired;

1	"(ii) identification of the persons re-
2	quired to conduct the testing;
3	"(iii) procedures for the development
4	of test data and information for the chem-
5	ical substance or mixture, including spe-
6	cific reference to reliable nonanimal test
7	procedures; and
8	"(iv) specification of the period within
9	which persons required to conduct the test-
10	ing shall submit to the Administrator test
11	data and information developed in accord-
12	ance with the procedures described in
13	clause (iii).
14	"(B) DURATION.—The period described in
15	subparagraph (A)(iv) shall not be of an unrea-
16	sonable duration.
17	"(C) Considerations.—In determining
18	the procedures and period to be required under
19	subparagraph (A), the Administrator shall con-
20	sider—
21	"(i) the relative costs of the various
22	test protocols and methodologies that may
23	be required; and

1	"(ii) the reasonably foreseeable avail-
2	ability of facilities and personnel needed to
3	perform the testing.
4	"(g) Statement of Need.—
5	"(1) In general.—In promulgating a rule, en-
6	tering into a testing consent agreement, or issuing
7	an order for development of additional data and in-
8	formation (including information on exposure or ex-
9	posure potential) under subsection (f)(2), the Ad-
10	ministrator shall issue a statement—
11	"(A) identifying the need intended to be
12	met by the rule, agreement, or order;
13	"(B) explaining why existing data and in-
14	formation reasonably available to the Adminis-
15	trator at that time are inadequate to meet that
16	need; and
17	"(C) encouraging, to the extent possible,
18	the use of nonanimal test methods to develop
19	additional data and information.
20	"(2) Contents of statement in case of
21	ORDER.—
22	"(A) In General.—If the Administrator
23	issues an order, the statement described in
24	paragraph (1) shall explain why good cause ex-
25	ists for issuance of an order instead of promul-

1	gating a rule or entering into a testing consent
2	agreement.
3	"(B) Contents.—A statement described
4	in subparagraph (A) shall contain a discussion
5	of—
6	"(i) data and information that are
7	readily accessible to the Administrator, in-
8	cluding data and information submitted
9	under any other provision of law;
10	"(ii) the extent to which the Adminis-
11	trator has obtained or attempted to obtain
12	the data and information through vol-
13	untary submissions;
14	"(iii) the extent to which the Adminis-
15	trator may use available data and informa-
16	tion for structurally related substances
17	(grouping or read-across), or use valid
18	structure-activity relationship models or
19	nonanimal test alternatives; and
20	"(iv) safety assessments, and the data
21	and information relied on in the assess-
22	ments, on other chemical substances to the
23	extent relevant to the chemical substances
24	that would be the subject of the rule or
25	order.

"(h) TIERED TOXICITY TESTING AND EVALUA-
TION.—
"(1) In general.—The Administrator shall
develop an evidence-based review system for con-
ducting consistent evaluations of the relevance and
reliability of studies of chemical substances and their
exposure (including exposure pathways), and a
structured evaluative framework to provide a sys-
tematic and transparent approach for assessing the
overall weight of the evidence for observed biological
or other effects, mechanistic information, and expo-
sure.
"(2) Tiers.—Subject to subsections (b) and
(c), the framework shall have 2 tiers.
"(A) TIER 1.—
"(i) In general.—Tier 1 shall in-
clude both a screening level exposure as-
sessment, including modeling if appro-
priate, and screening tests for hazard.
"(ii) Uses of screening tests and
MODELING.—Screening tests for hazard
(which may include, as appropriate, sci-
entifically reliable and relevant in silico, in
vitro, and focused in vivo tests) and expo-

1	sure information and modeling shall be
2	used—
3	"(I) to screen chemical sub-
4	stances or mixtures for major toxic ef-
5	fects (including acute toxicity, sub-
6	chronic toxicity, chronic toxicity, car-
7	cinogenicity, genotoxicity, develop-
8	mental toxicity, and neurotoxicity);
9	and
10	"(II) to direct planning for more
11	complex and targeted testing in tier 2,
12	if necessary.
13	"(B) TIER 2.—If the Administrator deter-
14	mines that additional testing is necessary,
15	based on the results of tier 1 testing and mod-
16	eling and any other available relevant informa-
17	tion, tier 2 shall include—
18	"(i) an exposure assessment and tests
19	for specific endpoints triggered on the
20	basis of biologically based decisions; and
21	"(ii) an assessment of potential expo-
22	sure using scientifically valid approaches.
23	"(3) Guidance.—The Administrator shall pre-
24	pare guidance for implementing this subsection and

1	review that guidance not less than once every 5
2	years thereafter.
3	"(i) REDUCTION OF ANIMAL-BASED TESTING.—
4	"(1) In General.—The Administrator shall
5	minimize the use of animals in testing of chemical
6	substances or mixtures, including by—
7	"(A) encouraging and facilitating, to the
8	maximum extent practicable—
9	"(i) the use of integrated and tiered
10	testing and assessment strategies;
11	"(ii) the use of data and information
12	of sufficient scientific quality in existence
13	on the date on which the test is conducted;
14	"(iii) the use of test methods that
15	eliminate or reduce the use of animals
16	while providing test data and information
17	of high scientific quality;
18	"(iv) the grouping of 2 or more chem-
19	ical substances into scientifically appro-
20	priate categories in cases in which testing
21	of a chemical substance would provide reli-
22	able and useful test data and information
23	on others in the category;

1	"(v) the formation of industry con-
2	sortia to jointly conduct testing to avoid
3	unnecessary duplication of tests;
4	"(vi) the submission of test data and
5	information from animal-based studies and
6	from emerging methods and models; and
7	"(vii) the use of exposure potential as
8	a factor in decisions to require new testing;
9	and
10	"(B) funding research and validation stud-
11	ies to reduce, refine, and replace the use of ani-
12	mal tests in accordance with this subsection.
13	"(2) Implementation of alternative test-
14	ING METHODS.—To promote the development and
15	timely incorporation of new testing methods that are
16	not laboratory animal-based, the Administrator
17	shall—
18	"(A) after providing an opportunity for
19	public comment, develop a strategic plan to pro-
20	mote the development and implementation of al-
21	ternative test methods and testing strategies to
22	generate information used for any safety-stand-
23	ard determination made that reduce, refine, or
24	replace the use of laboratory animals, including
25	toxicity pathway-based risk assessment, in vitro

1	studies, systems biology, computational toxi-
2	cology, bioinformatics, and high-throughput
3	screening;
4	"(B) beginning on the date that is 5 years
5	after the date of enactment of the Chemical
6	Safety Improvement Act and every 5 years
7	thereafter, submit to Congress a report that de-
8	scribes the progress made in implementing this
9	section; and
10	"(C) fund and carry out research, develop-
11	ment, performance assessment, and
12	translational studies to accelerate the develop-
13	ment of test methods and testing strategies that
14	reduce, refine, or replace the use of laboratory
15	animals in any safety-standard determination
16	made under this section.
17	"(3) Criteria for adapting or waiving ani-
18	MAL TESTING REQUIREMENTS.—On request from a
19	manufacturer or processor that is required to con-
20	duct animal-based testing of a chemical substance or
21	mixture under this title, the Administrator may
22	adapt or waive the animal-testing requirement if the
23	Administrator determines that—
24	"(A) there is sufficient evidence from sev-
25	eral independent sources of information to sup-

1	port a conclusion that a chemical substance or
2	mixture has, or does not have, a particular
3	property if the information from each individual
4	source alone is insufficient to support the con-
5	clusion;
6	"(B) because of 1 or more physical or
7	chemical properties of the chemical substance
8	or mixture or other toxicokinetic consider-
9	ations—
10	"(i) the material cannot be absorbed
11	or
12	"(ii) testing for a specific endpoint is
13	technically not practicable to conduct; or
14	"(C) a chemical substance or mixture can-
15	not be tested in animals at concentrations that
16	do not result in significant pain or distress, be-
17	cause of physical or chemical properties of the
18	chemical substance or mixture, such as a poten-
19	tial to cause severe corrosion or severe irritation
20	to the tissues of the animal.
21	"(j) Testing Requirements.—
22	"(1) Persons required to develop test
23	DATA AND INFORMATION —

1	(A) IN GENERAL.—The Administrator
2	may require the following persons to develop
3	test data and information:
4	"(i) Manufacturers and processors of
5	the chemical substance or mixture identi-
6	fied in subsection (f)(4)(A)(i).
7	"(ii) Persons who begin to manufac-
8	ture or process such chemical substance or
9	mixture—
10	"(I) after the effective date of
11	the rule, testing consent agreement,
12	or order; but
13	"(II) subject to subparagraph
14	(C), before the period ending 180
15	days after the end of the period iden-
16	tified in subsection $(f)(4)(A)(iv)$ .
17	"(B) Designation.—The Administrator
18	may permit 2 or more of the persons identified
19	in subparagraph (A) to designate a person or a
20	qualified third party—
21	"(i) to develop the data and informa-
22	tion; and
23	"(ii) to submit the data and informa-
24	tion on behalf of the persons making the
25	designation.

1	"(C) Exemptions.—
2	"(i) In general.—A person other-
3	wise subject to a rule, testing consent
4	agreement, or order under subsection (f)
5	may submit to the Administrator an appli-
6	cation for an exemption on the basis that
7	the data and information are being devel-
8	oped by a person designated under sub-
9	paragraph (B).
10	"(ii) Fair and equitable reim-
11	BURSEMENT TO DESIGNEE.—
12	"(I) IN GENERAL.—If the Ad-
13	ministrator accepts an application
14	submitted under clause (i), the Ad-
15	ministrator shall direct the applicant
16	to provide to the person designated
17	under subparagraph (B) fair and eq-
18	uitable reimbursement, as agreed to
19	between the applicant and the person
20	designated.
21	"(II) Arbitration.—If the ap-
22	plicant and a person designated under
23	subparagraph (B) cannot reach agree-
24	ment on the amount of fair and equi-

1	table reimbursement, the amount shall
2	be determined by arbitration.
3	"(iii) Termination.—If, after grant-
4	ing an exemption under this subparagraph,
5	the Administrator determines that no per-
6	son has complied with the rule, testing
7	consent agreement, or order, the Adminis-
8	trator shall—
9	"(I) by order terminate the ex-
10	emption; and
11	"(II) notify in writing each per-
12	son who received an exemption of the
13	requirements with respect to which
14	the exemption was granted.
15	"(2) Types of health and environmental
16	DATA AND INFORMATION.—
17	"(A) In General.—The Administrator
18	may prescribe guidelines for the development of
19	test data and information under subsection (f)
20	for health and environmental information, in-
21	cluding—
22	"(i) test data pertaining to acute tox-
23	icity, subchronic toxicity, chronic toxicity,
24	carcinogenicity, genotoxicity, developmental

1	toxicity, and neurotoxicity that may be in-
2	dicative of an adverse effect;
3	"(ii) test data and information per-
4	taining to exposure to the chemical sub-
5	stance or mixture, including information
6	regarding bioaccumulation, persistence,
7	and the presence of the chemical substance
8	or mixture in human blood, fluids, or tis-
9	sue; and
10	"(iii) information pertaining to aggre-
11	gate exposure, or other effects that may be
12	considered in a safety assessment.
13	"(B) Methodologies.—
14	"(i) In General.—The Adminis-
15	trator—
16	"(I) may prescribe methodologies
17	in guidelines for the development of
18	data and information; and
19	"(II) shall encourage the use of
20	nonanimal methodologies.
21	"(ii) Development of Guide-
22	LINES.—The Administrator may develop
23	guidelines for evaluating data from bio-
24	monitoring studies.

1	"(III) REQUIREMENT.—Prior to pre-
2	scribing epidemiologic studies of employ-
3	ees, the Administrator shall coordinate
4	with the Director of the National Institute
5	for Occupational Safety and Health.
6	"(C) Review.—Periodically, but not less
7	frequently than once every 5 years, the Admin-
8	istrator shall—
9	"(i) review the adequacy of the guide-
10	lines for development of data and informa-
11	tion prescribed under subparagraph (B);
12	"(ii) if necessary, institute pro-
13	ceedings to make appropriate revisions of
14	the guidelines; and
15	"(iii) revise the guidelines as appro-
16	priate, particularly to—
17	"(I) reflect the availability of sci-
18	entifically reliable and relevant non-
19	animal test methods; and
20	"(II) eliminate obsolete meth-
21	odologies that do not produce reliable
22	and relevant results.
23	"(k) Transparency.—Subject to section 14, the Ad-
24	ministrator shall make available to the public all testing

1	consent agreements and orders and all data and informa-
2	tion submitted under this section.".
3	(b) Conforming Amendments.—Section
4	104(i)(5)(A) of the Comprehensive Environmental Re-
5	sponse, Compensation, and Liability Act of 1980 (42
6	U.S.C. 9604(i)(5)(A)) is amended by striking "section
7	4(e)" and inserting "section 4(l)".
8	SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.
9	Section 5 (15 U.S.C. 2604) is amended—
10	(1) by striking the section designation and
11	heading and inserting the following:
12	"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.";
13	(2) in subsection (a)(1), in the matter following
14	subparagraph (B)—
15	(A) by striking "subsection (d)" and in-
16	serting "subsection (b)"; and
17	(B) by striking "and such person complies
18	with any applicable requirement of subsection
19	(b)";
20	(3) by striking subsection (b);
21	(4) by redesignating subsection (d) as sub-
22	section (b) and moving the subsection so as to ap-
23	pear after subsection (a);
24	(5) in subsection (b) (as so redesignated)—

1	(A) by striking paragraph (1) and insert-
2	ing the following:
3	"(1) In general.—The notice required by sub-
4	section (a) shall include, with respect to a chemical
5	substance—
6	"(A) the information required by sections
7	720.45 and 720.50 of title 40, Code of Federal
8	Regulations (or successor regulations); and
9	"(B) information regarding intended condi-
10	tions of use and reasonably anticipated expo-
11	sure.";
12	(B) in paragraph (2)—
13	(i) in the matter preceding subpara-
14	graph (A), by striking "or of data under
15	subsection (b)";
16	(ii) in subparagraph (A), by adding
17	"and" after the semicolon at the end;
18	(iii) in subparagraph (B), by striking
19	"; and" and inserting a period; and
20	(iv) by striking subparagraph (C); and
21	(C) in paragraph (3), by striking ", (b),";
22	(6) by striking subsection (c) and inserting the
23	following:
24	"(c) Review of Notice.—
25	"(1) Initial review.—

1	"(A) IN GENERAL.—Subject to subpara-
2	graph (B), not later than 90 days after the date
3	of receipt of a notice submitted under sub-
4	section (a), the Administrator shall—
5	"(i) conduct an initial review of the
6	notice;
7	"(ii) as needed, develop a profile of
8	the relevant chemical substance and the
9	potential for exposure to humans and the
10	environment; and
11	"(iii) make any necessary determina-
12	tion under paragraph (4).
13	"(B) Extension.—Except as provided in
14	paragraph (6), the Administrator may extend
15	the period described in subparagraph (A) for
16	good cause for 1 or more periods, the total of
17	which shall be not more than 90 days.
18	"(2) Notice of commencement.—Unless the
19	Administrator determines under paragraph (4)(A)
20	that a chemical substance is not likely to meet the
21	safety standard, at the end of the applicable period
22	for review under paragraph (1), a chemical sub-
23	stance may be the subject of a notice of commence-
24	ment under subsection (d).

(3) INFORMATION SOURCES.—In evaluating a
notice under paragraph (1), the Administrator shall
take into consideration—
"(A) the information identified in section
4(c); and
"(B) any additional information provided
by the submitter.
"(4) Determinations.—Before the end of the
applicable period for review under paragraph (1),
based on the information described in paragraph (3),
the Administrator shall determine that—
"(A) the relevant chemical substance is not
likely to meet the safety standard under the in-
tended conditions of use, in which case the Ad-
ministrator shall take appropriate action under
paragraph (5);
"(B) the relevant chemical substance is
likely to meet the safety standard under the in-
tended conditions of use, in which case the Ad-
ministrator shall allow the review period to ex-
pire without additional restrictions; or
"(C) additional information is necessary in
order to make a determination under subpara-
graph (A) or (B), in which case the Adminis-

1	trator shall take appropriate action under para-
2	graph (6).
3	"(5) Prohibitions and Limitations.—
4	"(A) IN GENERAL.—If the Administrator
5	makes a determination under paragraph (4)(A)
6	with respect to a notice, before the end of the
7	applicable period for review under paragraph
8	(1), the Administrator shall, by consent agree-
9	ment or order, as appropriate—
10	"(i) prohibit manufacture of the
11	chemical substance, or prohibit such manu-
12	facture without compliance with restric-
13	tions specified in a relevant consent agree-
14	ment or order; or
15	"(ii) prohibit manufacture or proc-
16	essing of the chemical substance for a sig-
17	nificant new use, or prohibit such manu-
18	facture or processing without compliance
19	with restrictions specified in a relevant
20	consent agreement or order.
21	"(B) Inclusions.—A prohibition or limi-
22	tation under subparagraph (A) may include, as
23	appropriate—
24	"(i) a requirement that a chemical
25	substance be marked with, or accompanied

1	by, clear and adequate warnings and in-
2	structions with respect to use, distribution
3	in commerce, or disposal, or any combina-
4	tion of those activities, with the form and
5	content of the warnings and instructions to
6	be prescribed by the Administrator;
7	"(ii) a requirement that manufactur-
8	ers or processors, as applicable, of the
9	chemical substance make and retain
10	records of the processes used to manufac-
11	ture or process the chemical substance;
12	"(iii) a requirement that manufactur-
13	ers or processors, as applicable, monitor or
14	conduct such additional tests as are rea-
15	sonably necessary to ensure compliance
16	with this Act, subject to section 4(g);
17	"(iv) a limitation on the quantity of
18	the chemical substance that may be manu-
19	factured, processed, or distributed in com-
20	merce;
21	"(v) a limitation on the quantity of
22	the chemical substance that may be manu-
23	factured, processed, or distributed in com-
24	merce for a particular use;

1	"(vi) a prohibition or other regulation
2	of the manufacture, processing, or dis-
3	tribution in commerce of the chemical sub-
4	stance for a significant new use;
5	"(vii) a prohibition or other regulation
6	of any method of commercial use of the
7	chemical substance;
8	"(viii) a prohibition or other regula-
9	tion of any method of disposal of the
10	chemical substance;
11	"(ix) a prohibition on the manufac-
12	ture, processing, or distribution in com-
13	merce of the chemical substance;
14	"(x) a prohibition on the manufac-
15	ture, processing, or distribution in com-
16	merce of the chemical substance for a par-
17	ticular use; or
18	"(xi) such other requirements as the
19	Administrator determines to be necessary.
20	"(6) Additional data and information.—If
21	the Administrator determines under paragraph
22	(4)(C) that additional data and information (includ-
23	ing, for example, information on exposure or expo-
24	sure potential) are needed in order to conduct a re-
25	view under this subsection, the Administrator—

1	"(A) shall provide an opportunity for the
2	submitter of the notice to submit such addi-
3	tional information;
4	"(B) may, by agreement with the sub-
5	mitter, extend the review period for a reason-
6	able time to allow the development and submis-
7	sion of the additional information;
8	"(C) on receipt of the information, shall
9	promptly make a determination under para-
10	graph (4); and
11	"(D) may take action under paragraph (5)
12	pending receipt of the additional data and in-
13	formation, which may, as appropriate, permit
14	the submitter of the notice to file a notice of
15	commencement under subsection (d).";
16	(7) by striking subsections (e) through (g) and
17	inserting the following:
18	"(d) Notice of Commencement.—
19	"(1) In general.—Not later than 30 days
20	after the date on which a manufacturer or processor
21	that has submitted a notice under subsection (a)
22	commences nonexempt commercial manufacture of a
23	chemical substance or nonexempt commercial manu-
24	facture or processing of a chemical substance for a
25	significant new use, as applicable, the manufacturer

1	or processor shall submit to the Administrator a no-
2	tice of commencement that identifies—
3	"(A) the name of the manufacturer or
4	processor; and
5	"(B) the initial date of nonexempt com-
6	mercial manufacture or nonexempt commercial
7	manufacture or processing for a significant new
8	use.
9	"(2) WITHDRAWAL.—A manufacturer or proc-
10	essor that has submitted a notice under subsection
11	(a), but that has not commenced nonexempt com-
12	mercial manufacture or processing of the chemical
13	substance, may withdraw the notice.
14	"(e) Further Evaluation.—The Administrator
15	may review a chemical substance under section 4(e) at any
16	time after the Administrator receives—
17	"(1) a notice of commencement for a chemical
18	substance under subsection (d); or
19	"(2) significant new information regarding the
20	chemical substance.
21	"(f) Transparency.—Subject to section 14, the Ad-
22	ministrator shall make available to the public all notices,
23	rules and orders of the Administrator, and all data and
24	information submitted or issued under this section.";

1	(8) by redesignating subsections (h) and (i) as
2	subsections (g) and (h), respectively; and
3	(9) in subsection (g) (as so redesignated)—
4	(A) in paragraph (1), in the matter pre-
5	ceding subparagraph (A), by striking "or (b)";
6	(B) by striking paragraph (2);
7	(C) by redesignating paragraphs (3)
8	through (6) as paragraphs (2) through (5), re-
9	spectively;
10	(D) in paragraph (2) (as so redesignated),
11	by striking "subsections (a) and (b)" and in-
12	serting "subsection (a)";
13	(E) in paragraph (3) (as so redesignated),
14	in the first sentence, by striking "will not
15	present an unreasonable risk of injury to health
16	or the environment" and inserting "is expected
17	to meet the safety standard under the intended
18	conditions of use";
19	(F) in paragraph (4) (as so redesignated),
20	by striking "subsections (a) and (b)" and in-
21	serting "subsection (a)"; and
22	(G) in paragraph (5) (as so redesignated),
23	in the first sentence, by striking "paragraph (1)
24	or (5)" and inserting "paragraph (1) or (4),".

1	SEC. 6. SAFETY ASSESSMENTS AND DETERMINATIONS.
2	Section 6 (15 U.S.C. 2605) is amended—
3	(1) by striking the section designation and
4	heading and inserting the following:
5	"SEC. 6. SAFETY ASSESSMENTS AND DETERMINATIONS.";
6	(2) by striking subsections (a) through (d) and
7	inserting the following:
8	"(a) In General.—The Administrator shall—
9	"(1) conduct a safety assessment of each high-
10	priority substance in accordance with subsection (b);
11	"(2) make a safety determination for each high-
12	priority substance; and
13	"(3) as appropriate based on the results of a
14	safety determination, establish requirements for risk
15	management of a high-priority substance.
16	"(b) Safety Assessments.—
17	"(1) In General.—The Administrator shall
18	conduct a risk-based safety assessment of each high-
19	priority substance, in accordance with such schedule
20	as the Administrator establishes, to be based solely
21	on considerations of risk to human health and the
22	environment.
23	"(2) Procedural rules.—
24	"(A) In General.—The Administrator
25	shall establish procedural rules for safety as-
26	sessments and determinations under this sub-

1	section, including schedules for the submission
2	of relevant data and information and the initi-
3	ation and completion of safety assessments and
4	safety determinations.
5	"(B) Requirements.—
6	"(i) In general.—The rules under
7	subparagraph (A) shall—
8	"(I) identify the basis on which
9	the Administrator shall decide which
10	high-priority substances take prece-
11	dence in the safety assessment and
12	determination process;
13	"(II) require the Administrator
14	to inform the public regarding—
15	"(aa) the approximate order
16	in which safety assessments and
17	determinations will be performed;
18	"(bb) the informational
19	needs of the Administrator relat-
20	ing to the safety assessment and
21	determination process;
22	"(cc) the importance of ex-
23	peditiously completing safety as-
24	sessments and determinations

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

1	proposed safety assessments and
2	determinations; and
3	"(cc) to publish final safety
4	assessments and determinations.
5	"(ii) Deadlines.—
6	"(I) IN GENERAL.—The rules de-
7	scribed in subparagraph (A) shall also
8	include—
9	"(aa) a schedule by which
10	each safety assessment and de-
11	termination is expected to be con-
12	ducted; and
13	"(bb) a deadline for the
14	completion of each assessment
15	and determination.
16	"(II) FLEXIBILITY AND REASON-
17	ABLE EXTENSIONS.—The deadlines
18	described in subclause (I)(bb)—
19	"(aa) may vary among
20	chemical substances to grant the
21	Administrator flexibility; and
22	"(bb) shall allow for reason-
23	able extensions after an adequate
24	public justification.

1	"(C) Inclusions in final assess-
2	MENTS.—Each safety assessment under this
3	subsection shall include—
4	"(i) a weight-of-the evidence sum-
5	mary; and
6	"(ii) a nontechnical summary explain-
7	ing what the relevant information dem-
8	onstrates in the context of the intended
9	conditions of use and exposure patterns of
10	the chemical substance.
11	"(3) Data and information sources.—In
12	conducting a safety assessment under this sub-
13	section, the Administrator shall, at a minimum, take
14	into consideration—
15	"(A) the information described in section
16	4(c); and
17	"(B) any additional information submitted
18	under paragraph (5).
19	"(4) Methodology.—
20	"(A) In General.—The Administrator
21	shall—
22	"(i) develop an appropriate science-
23	based methodology for conducting safety
24	assessments under this subsection, which
25	shall include consideration of the weight of

1	the evidence for observed effects, mecha-
2	nistic information, and exposure evalua-
3	tions; and
4	"(ii) make the proposed methodology
5	available for public comment and scientific
6	peer review.
7	"(B) REVIEW AND REVISIONS.—Not later
8	than 5 years after the date of enactment of the
9	Chemical Safety Improvement Act, and not less
10	frequently than once every 5 years thereafter,
11	the Administrator—
12	"(i) shall review the methodology de-
13	veloped under subparagraph (A); and
14	"(ii) may revise the methodology to
15	reflect new scientific developments or un-
16	derstandings, in accordance with subpara-
17	graph (A).
18	"(C) REQUIREMENTS.—The methodology
19	shall apply scientifically recognized factors to
20	address the following topics:
21	"(i) Strengths and limitations of
22	study design.
23	"(ii) Reliability and relevance of test
24	methods to human health and the environ-
25	ment.

1	"(111) Quality of data.
2	"(iv) Use of good laboratory practices.
3	"(v) Peer review and peer review proc-
4	esses.
5	"(vi) Use of standardized protocols.
6	"(vii) Structured evaluative frame-
7	works to determine the overall weight of
8	the evidence, based on a review of positive
9	and negative findings.
10	"(D) HAZARD, USE, AND EXPOSURE IN-
11	FORMATION.—
12	"(i) In general.—A safety assess-
13	ment under this subsection shall evaluate
14	existing hazard, use, and exposure infor-
15	mation for the chemical substance under
16	the intended conditions of use of the chem-
17	ical substance, including information sub-
18	mitted by interested persons.
19	"(ii) Exposure.—For purposes of
20	evaluating exposure under clause (i), a
21	safety assessment shall take into consider-
22	ation—
23	"(I) exposures or significant sub-
24	sets of exposures;

1	$(\Pi)$ exposure duration, inten-
2	sity, frequency, and number; and
3	"(III) the vulnerability of ex-
4	posed subpopulations.
5	"(E) Best available science.—The Ad-
6	ministrator shall use the best available science
7	in conducting a safety assessment under this
8	subsection.
9	"(5) Additional test information.—If the
10	Administrator determines that additional test infor-
11	mation is needed in order to make a safety assess-
12	ment for a high-priority substance, the Adminis-
13	trator—
14	"(A) shall provide an opportunity for inter-
15	ested persons to submit the additional informa-
16	tion;
17	"(B) may promulgate a rule, enter into a
18	testing consent agreement, or issue an order
19	under section 4 to require the development of
20	the information; and
21	"(C) may defer, for a reasonable period, a
22	safety assessment until after receipt of the in-
23	formation.
24	"(6) Treatment.—A safety assessment under
25	this subsection—

1	"(A) shall not be considered to be a final
2	agency action; and
3	"(B) shall not be subject to judicial review.
4	"(c) Safety Determination.—
5	"(1) In general.—As soon as possible after
6	the date on which the safety assessment is com-
7	pleted for a high-priority substance under subsection
8	(b), the Administrator shall determine whether the
9	chemical substance meets the safety standard under
10	the intended conditions of use of the chemical sub-
11	stance.
12	"(2) Determinations.—Based on a review of
13	the information described in paragraph (3), the Ad-
14	ministrator shall determine, based solely on consid-
15	erations of risk to human health and the environ-
16	ment, that—
17	"(A) the relevant chemical substance meets
18	the safety standard under intended conditions
19	of use;
20	"(B) the relevant chemical substance does
21	not meet the safety standard under intended
22	conditions of use, in which case the Adminis-
23	trator shall impose additional restrictions, as
24	appropriate, under paragraph (9); or

1	"(C) additional information is necessary in
2	order to make a determination under subpara-
3	graph (A) or (B), in which case the Adminis-
4	trator shall take appropriate action under para-
5	graph (8).
6	"(3) Considerations.—In making a safety de-
7	termination under this subsection, the Administrator
8	shall take into consideration and publish a statement
9	that includes, at a minimum—
10	"(A) the safety assessment for the chem-
11	ical substance, including the uses considered in
12	the assessment and any uses that are consid-
13	ered critical or essential;
14	"(B) the range of exposure to the chemical
15	substance under the intended conditions of use
16	of the chemical substance and appropriate ref-
17	erence parameters;
18	"(C) the weight of the evidence of risk
19	posed by the chemical substance under the in-
20	tended conditions of use of the chemical sub-
21	stance; and
22	"(D) the magnitude of the risk posed by
23	the chemical substance under the intended con-
24	ditions of use of the chemical substance.

1	"(4) Information sources.—In making a
2	safety determination under this subsection, the Ad-
3	ministrator shall take into consideration, at a min-
4	imum—
5	"(A) the information described in section
6	4(c); and
7	"(B) the safety assessment conducted with
8	respect to the chemical substance under sub-
9	section (b).
10	"(5) Best available science.—The Adminis-
11	trator shall use the best available science in making
12	a safety determination under this subsection.
13	"(6) Notice and comment.—Subject to sec-
14	tion 14, the Administrator shall provide notice and
15	an opportunity for public comment on each proposed
16	safety determination under this subsection.
17	"(7) Transparency.—Subject to section 14,
18	the Administrator shall publish—
19	"(A) each safety determination under this
20	subsection, together with a summary of the in-
21	formation considered in the determination;
22	"(B) a summary of the evaluation by the
23	Administrator of the information; and
24	"(C) an explanation of the reasons for the
25	determination.

1	(8) ADDITIONAL TEST DATA AND INFORMA-
2	TION.—If the Administrator determines that addi-
3	tional test data and information is needed in order
4	to make a safety determination for a high-priority
5	substance, the Administrator—
6	"(A) shall provide an opportunity for inter-
7	ested persons to submit the additional data and
8	information;
9	"(B) may promulgate a rule, enter into a
10	testing consent agreement, or issue an order
11	under section 4 to require the development of
12	the data and information;
13	"(C) may defer, for a reasonable period, a
14	safety determination until after receipt of the
15	data and information; and
16	"(D) on receipt of the data and informa-
17	tion, shall make a determination under para-
18	graph (2).
19	"(9) Additional restrictions.—
20	"(A) In general.—
21	"(i) Determination.—If the Admin-
22	istrator makes a determination under
23	paragraph (2)(B) with respect to a chem-
24	ical substance, the Administrator shall pro-
25	mulgate a rule establishing necessary re-

1	strictions (based on the weight of the evi-
2	dence of risk and the magnitude of risk),
3	including if appropriate, a ban or phase
4	out of the manufacture, processing, or use
5	of the chemical substance in accordance
6	with subparagraph (C).
7	"(ii) Rules.—Rules promulgated
8	under this section may apply to mixtures
9	containing the chemical substance, as ap-
10	propriate.
11	"(B) Inclusions.—A restriction under
12	subparagraph (A) may include, as appro-
13	priate—
14	"(i) a requirement that a chemical
15	substance be marked with, or accompanied
16	by, clear and adequate warnings and in-
17	structions with respect to use, distribution
18	in commerce, or disposal, or any combina-
19	tion of those activities, with the form and
20	content of the warnings and instructions to
21	be prescribed by the Administrator;
22	"(ii) a requirement that manufactur-
23	ers and processors of the chemical sub-
24	stance—

1	"(I) make and retain records of
2	the processes used to manufacture or
3	process the chemical substance; and
4	"(II) subject to section 4(f), de-
5	velop test information that is reason-
6	ably necessary to ensure compliance
7	with this Act;
8	"(iii) a limitation on the quantity of
9	the chemical substance that may be manu-
10	factured, processed, or distributed in com-
11	merce;
12	"(iv) a requirement to ban or phase
13	out or other regulation on the manufac-
14	ture, processing, or distribution in com-
15	merce of the chemical substance—
16	"(I) for a particular use; or
17	"(II) for a particular use at a
18	concentration in excess of a level spec-
19	ified by the Administrator;
20	"(v) a limitation on the quantity of
21	the chemical substance that may be manu-
22	factured, processed, or distributed in com-
23	merce—
24	"(I) for a particular use; or

1	"(11) for a particular use at a
2	concentration in excess of a level spec-
3	ified by the Administrator;
4	"(vi) a requirement to ban or phase
5	out or other regulation of any method of
6	commercial use of the chemical substance;
7	"(vii) a requirement to ban or phase
8	out or other regulation of any method of
9	disposal of the chemical substance or any
10	article containing the chemical substance;
11	"(viii) a requirement directing manu-
12	facturers or processors of the chemical
13	substance to give notice of unreasonable
14	risks of harm to distributors in commerce
15	of the chemical substance and, to the ex-
16	tent reasonably ascertainable, to other per-
17	sons in the chain of commerce in posses-
18	sion of the chemical substance; and
19	"(ix) such other requirements as the
20	Administrator determines to be necessary.
21	"(C) BANS AND PHASE OUTS.—The Ad-
22	ministrator shall base a determination under
23	subparagraph (A) that a ban or phase out of
24	the manufacture, processing, or use of a chem-

I	ical substance is necessary on the consider-
2	ations described in subparagraph (D).
3	"(D) DETERMINATION THAT CHEMICAL
4	SUBSTANCE DOES NOT MEET SAFETY STAND-
5	ARD.—If the Administrator determines that the
6	chemical substance does not meet the safety
7	standard under the intended conditions of use,
8	the Administrator shall consider and publish a
9	statement on—
10	"(i) the availability of technically and
11	economically feasible alternatives for the
12	chemical substance under the intended
13	conditions of use;
14	"(ii) the risks posed by those alter-
15	natives as compared to those of the chem-
16	ical substance;
17	"(iii) the economic and social costs
18	and benefits of the proposed regulatory ac-
19	tion and options considered, and of poten-
20	tial alternatives; and
21	"(iv) the economic and social benefits
22	and costs of—
23	"(I) the chemical substance;
24	"(II) alternatives to the chemical
25	substance; and

1	"(III) any necessary restrictions
2	on the chemical substance or alter-
3	natives.
4	"(10) Exemptions.—The Administrator may
5	exempt the use of a chemical substance from any ad-
6	ditional restriction established under paragraph (9)
7	if the Administrator determines that—
8	"(A) the exemption is in the interest of na-
9	tional security;
10	"(B) the lack of availability of the chemical
11	substance would cause significant disruption in
12	the national economy;
13	"(C) the use for which the exemption is
14	sought is a critical or essential use for which—
15	"(i) no feasible alternative for the use
16	would materially reduce risk to health or
17	the environment; or
18	"(ii) no feasible alternative for the use
19	is economically, technically, or efficiently
20	available; or
21	"(D) the use, as compared to reasonably
22	available alternatives, provides a net benefit to
23	human health, the environment, or public safe-
24	ty.

1	"(11) Final agency action.—A safety deter-
2	mination under this subsection shall be—
3	"(A) considered to be a final agency ac-
4	tion; and
5	"(B) subject to judicial review, including
6	review of the associated safety assessment
7	under this subsection.";
8	(3) by redesignating subsections (e) and (f) as
9	subsections (d) and (e), respectively; and
10	(4) in subsection (d) (as so redesignated)—
11	(A) by striking paragraph (4); and
12	(B) by redesignating paragraph (5) as
13	paragraph (4).
13 14	paragraph (4).  SEC. 7. IMMINENT HAZARDS.
14	SEC. 7. IMMINENT HAZARDS.
14 15	SEC. 7. IMMINENT HAZARDS.  Section 7 (15 U.S.C. 2606) is amended—
<ul><li>14</li><li>15</li><li>16</li></ul>	SEC. 7. IMMINENT HAZARDS.  Section 7 (15 U.S.C. 2606) is amended—  (1) by striking subsection (a) and inserting the
<ul><li>14</li><li>15</li><li>16</li><li>17</li></ul>	SEC. 7. IMMINENT HAZARDS.  Section 7 (15 U.S.C. 2606) is amended—  (1) by striking subsection (a) and inserting the following:
14 15 16 17 18	SEC. 7. IMMINENT HAZARDS.  Section 7 (15 U.S.C. 2606) is amended—  (1) by striking subsection (a) and inserting the following:  "(a) CIVIL ACTIONS.—
<ul><li>14</li><li>15</li><li>16</li><li>17</li><li>18</li><li>19</li></ul>	SEC. 7. IMMINENT HAZARDS.  Section 7 (15 U.S.C. 2606) is amended—  (1) by striking subsection (a) and inserting the following:  "(a) Civil Actions.—  "(1) In General.—The Administrator may
14 15 16 17 18 19 20	SEC. 7. IMMINENT HAZARDS.  Section 7 (15 U.S.C. 2606) is amended—  (1) by striking subsection (a) and inserting the following:  "(a) Civil Actions.—  "(1) In General.—The Administrator may commence a civil action in an appropriate district
14 15 16 17 18 19 20 21	SEC. 7. IMMINENT HAZARDS.  Section 7 (15 U.S.C. 2606) is amended—  (1) by striking subsection (a) and inserting the following:  "(a) CIVIL ACTIONS.—  "(1) IN GENERAL.—The Administrator may commence a civil action in an appropriate district court of the United States for—

1	(B) relief (as authorized by subsection
2	(b)) against any person who manufactures,
3	processes, distributes in commerce, uses, or dis-
4	poses of, an imminently hazardous chemical
5	substance or mixture or any article containing
6	the substance or mixture; or
7	"(C) both seizure described in subpara-
8	graph (A) and relief described in subparagraph
9	(B).
10	"(2) Rule, order, or other proceeding.—
11	A civil action may be commenced under this para-
12	graph notwithstanding—
13	"(A) the existence of—
14	"(i) a decision by the Administrator
15	under section $4(e)(3)$ , $5(e)(4)$ , or $6(e)(2)$ ;
16	or
17	"(ii) a rule, testing consent agree-
18	ment, or order under section 4(f), 5(g),
19	6(b)(5), 6(c)(8), 6(c)(9), or 6(d); or
20	"(B) the pendency of any administrative or
21	judicial proceeding under any provision of this
22	Act.";
23	(2) in subsection (d), by striking "section 6(a)"
24	and inserting "section 6(c)"; and

1	(3) in subsection (f), in the first sentence, by
2	striking "and unreasonable".
3	SEC. 8. INFORMATION COLLECTION AND REPORTING.
4	Section 8 (15 U.S.C. 2607) is amended—
5	(1) in subsection (a), by adding at the end the
6	following:
7	"(4) Regulations.—
8	"(A) In General.—The Administrator
9	shall promulgate rules requiring the reporting
10	of information known by, or reasonably ascer-
11	tainable by, the person making the report, in-
12	cluding rules requiring processors to report in-
13	formation, so that the Administrator has the in-
14	formation necessary to carry out sections 4 and
15	6.
16	"(B) Contents.—The rules promulgated
17	under subparagraph (A)—
18	"(i) may impose different reporting
19	requirements on manufacturers and proc-
20	essors;
21	"(ii) shall be limited to active sub-
22	stances or mixtures containing active sub-
23	stances as designated under subsection (b);
24	and

1	"(iii) shall apply only to the extent the
2	Administrator determines the submission
3	of reports is necessary for the effective en-
4	forcement of this Act.
5	"(5) GUIDANCE.—The Administrator shall de-
6	velop guidance relating to the information required
7	to be reported under the rules promulgated under
8	this subsection that—
9	"(A) include the level of detail necessary to
10	be reported; and
11	"(B) describes the manner by which manu-
12	facturers and processors may report use and ex-
13	posure information on a voluntary basis.";
14	(2) in subsection (b), by adding at the end the
15	following:
16	"(3) Nomenclature.—
17	"(A) In General.—In carrying out para-
18	graph (1), the Administrator shall—
19	"(i) maintain the use of Class 2 no-
20	menclature in use on date of enactment of
21	the Chemical Safety Improvement Act;
22	"(ii) maintain the use of the Soap and
23	Detergent Association Nomenclature Sys-
24	tem, published in March 1978 by the Ad-
25	ministrator in section 1 of addendum III

1	of the document entitled 'Candidate List of
2	Chemical Substances', and further de-
3	scribed in the appendix A of volume I of
4	the 1985 edition of the Toxic Substances
5	Control Act Substances Inventory (EPA
6	Document No. EPA-560/7-85-002a); and
7	"(iii) treat all components of cat-
8	egories that are considered to be statutory
9	mixtures under this Act as being included
10	on the list published under paragraph (1)
11	under the Chemical Abstracts Service
12	numbers for the respective categories, in-
13	cluding, without limitation—
14	"(I) cement, Portland, chemicals,
15	CAS No. 65997–15–1;
16	"(II) cement, alumina, chemicals,
17	CAS No. 65997–16–2;
18	"(III) glass, oxide, chemicals,
19	CAS No. 65997–17–3;
20	"(IV) frits, chemicals, CAS No.
21	65997–18–4;
22	"(V) steel manufacture, chemi-
23	cals, CAS No. 65997–19–5; and

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1	"(VI) ceramic materials and
2	wares, chemicals, CAS No. 66402-
3	68–4.
4	"(B) Multiple nomenclature conven-
5	TIONS.—
6	"(i) IN GENERAL.—In the event that
7	existing guidance allows for multiple no-
8	menclature conventions, the Administrator
9	shall—
10	"(I) maintain the nomenclature
11	conventions for substances; and
12	"(II) develop new guidance
13	that—
14	"(aa) establishes equivalency
15	between the nomenclature con-
16	ventions for chemical substances
17	on the list published under para-
18	graph (1); and
19	"(bb) permits persons to
20	rely on that new guidance for
21	purposes of determining whether
22	a chemical substance is on the
23	list published under paragraph
24	(1).

1	"(ii) Multiple cas numbers.—For
2	any chemical substance appearing multiple
3	times on the list under different Chemical
4	Abstracts Service numbers, the Adminis-
5	trator shall develop guidance recognizing
6	the multiple listings as a single chemical
7	substance.
8	"(4) CANDIDATE LIST OF ACTIVE SUBSTANCES
9	IN COMMERCE.—
10	"(A) In general.—Subject to section 14,
11	the Administrator shall make publicly available
12	a candidate list of active chemical substances,
13	which shall include—
14	"(i) any chemical substance reported
15	under part 711 of title 40, Code of Federal
16	Regulations, as in effect on the date of en-
17	actment of the Chemical Safety Improve-
18	ment Act, during the period beginning on
19	the date that is 10 years before the date
20	of enactment of the Chemical Safety Im-
21	provement Act and ending on the date of
22	enactment of the Chemical Safety Improve-
23	ment Act;

1	"(ii) any chemical substance for which
2	a notice of commencement of manufacture
3	has been submitted;
4	"(iii) any chemical substance for
5	which a significant new use notice has
6	been submitted;
7	"(iv) any chemical substance for
8	which an export notification has been sub-
9	mitted during the period beginning on the
10	date that is 10 years before the date of en-
11	actment of the Chemical Safety Improve-
12	ment Act and ending on the date of enact-
13	ment of the Chemical Safety Improvement
14	Act; and
15	"(v) any other chemical substance
16	identified by the Administrator as likely to
17	qualify as active.
18	"(B) Rule.—The Administrator shall, by
19	rule, require manufacturers and processors to
20	notify the Administrator that the manufacturer
21	or processor, as applicable, has manufactured
22	or processed a chemical substance on the list
23	described in subparagraph (A), or the list pub-
24	lished under paragraph (1) for a nonexempt
25	commercial purpose during the 5-year period

1	prior to the date of enactment of the Chemical
2	Safety Improvement Act.
3	"(C) Guidance.—Before issuing a final
4	rule under subparagraph (A), the Administrator
5	shall make publicly available guidance relating
6	to the rule for chemical substances on the con-
7	fidential portion of the candidate list of active
8	substances and of the list published under para-
9	graph (1), including —
10	"(i) accession numbers;
11	"(ii) premanufacture notice case num-
12	bers, if applicable; and
13	"(iii) generic names.
14	"(D) Confidential Chemical Sub-
15	STANCES.—The rule under subparagraph (B)
16	shall require a manufacturer or processor that
17	is reporting information relating to a chemical
18	substance on the confidential portion of the list
19	published under paragraph (1) to indicate
20	whether the manufacturer or processor claims
21	the specific identity of the substance as con-
22	fidential pursuant to section 14.
23	"(E) CERTIFICATION.—The rule under
24	subparagraph (B) shall require a manufacturer
25	or processor—

1	"(i) to certify the accuracy of each re-
2	port of the manufacturer or processor car-
3	ried out under the rule; and
4	"(ii) to retain a record supporting
5	that certification for a period of 5 years
6	beginning on the last day of the submis-
7	sion period.
8	"(F) Applicability.—Nothing in this
9	paragraph requires the resubstantiation of a
10	claim for protection against disclosure for infor-
11	mation submitted to the Administrator prior to
12	the date of enactment of the Chemical Safety
13	Improvement Act.
14	"(5) List.—
15	"(A) In general.—Based on the notifica-
16	tions received in response to the rule under
17	paragraph (4), the Administrator shall des-
18	ignate each chemical substance that is on the
19	list published under paragraph (1) on the date
20	of enactment of the Chemical Safety Improve-
21	ment Act as active or inactive.
22	"(B) UPDATE.—The Administrator shall
23	update the list of chemicals designated as active
24	or inactive as soon as practicable following the
25	publication of the most recent data reported

1	under part 711 of title 40, Code of Federal
2	Regulations.
3	"(6) ACTIVE SUBSTANCES.—The Administrator
4	shall designate as an active substance—
5	"(A) a chemical substance that has been
6	manufactured or processed for a nonexempt
7	commercial purposes at any point during the 5-
8	year period prior to the date of enactment of
9	the Chemical Safety Improvement Act;
10	"(B) a chemical substance that is added to
11	the list published under paragraph (1) after the
12	date of enactment of the Chemical Safety Im-
13	provement Act;
14	"(C) a chemical substance for which a no-
15	tice is received under paragraph (7)(C); and
16	"(D) a chemical substance reported under
17	part 711 of title 40, Code of Federal Regula-
18	tions, after the date of enactment of the Chem-
19	ical Safety Improvement Act.
20	"(7) Inactive substances.—
21	"(A) In General.—The Administrator
22	shall designate as an inactive substance each
23	chemical substance on the list published under
24	paragraph (1) that has not been manufactured
25	or processed for a nonexempt commercial pur-

1	pose in the 5-year period ending on the date of
2	enactment of the Chemical Safety Improvement
3	Act.
4	"(B) Treatment.—Each inactive sub-
5	stance shall remain on the list published under
6	paragraph (1).
7	"(C) CHANGE TO ACTIVE STATUS.—
8	"(i) In General.—Any person who
9	intends to manufacture or process for a
10	nonexempt commercial purpose a chemical
11	substance that is designated as an inactive
12	substance shall notify the Administrator
13	before the date on which the substance is
14	manufactured or processed.
15	"(ii) Active status.—On receiving
16	notification under clause (i), the Adminis-
17	trator—
18	"(I) shall designate the chemical
19	substance as an active substance; and
20	"(II) shall, pursuant to section
21	4(e), review the priority of the chem-
22	ical substance as the Administrator
23	determines necessary.

1	"(D) CATEGORY STATUS.—The list of in-
2	active chemical substances shall not be consid-
3	ered a category for purposes of section 26(c).
4	"(8) Public Participation.—
5	"(A) In General.—Subject to subpara-
6	graph (B), the Administrator shall make avail-
7	able to the public—
8	"(i) the specific identity of each chem-
9	ical substance on the nonconfidential por-
10	tion of the list published under paragraph
11	(5) that the Administrator has designated
12	as an active substance;
13	"(ii) the specific identity of each
14	chemical substance on the nonconfidential
15	portion of the list published under para-
16	graph (1) that the Administrator has des-
17	ignated as an inactive substance;
18	"(iii) the accession number, generic
19	name, and, if applicable, premanufacture
20	notice case number for each chemical sub-
21	stance on the confidential portion of the
22	list published under paragraph (1) for
23	which a claim of confidentiality was re-
24	ceived; and

1	"(iv) the specific identity of any active
2	or inactive substance on the confidential
3	portion of the list published under para-
4	graph (1) for which no claim of confiden-
5	tiality was received, subject to the condi-
6	tion that, before revealing the specific iden-
7	tity of the substance, the Administrator
8	shall—
9	"(I) publish a notice in the Fed-
10	eral Register identifying the accession
11	number, generic name, and, if applica-
12	ble, premanufacture notice case num-
13	ber for that substance; and
14	"(II) provide an opportunity for
15	any person—
16	"(aa) to certify to the Ad-
17	ministrator that the person in-
18	tends to manufacture or process
19	the substance at any point in the
20	subsequent 4-year period; and
21	"(bb) to claim confiden-
22	tiality for the specific identity of
23	the substance.
24	"(B) Confidentiality.—Subject section
25	14, the Administrator shall not make available

1	to the public the specific chemical identity of
2	any substance for which the Administrator re-
3	ceives a notice under subparagraph (A)(iv).";
4	and
5	(3) in subsection (e)—
6	(A) by striking "Any person" and inserting
7	the following:
8	"(1) In general.—Any person"; and
9	(B) by adding at the end the following:
10	"(2) APPLICABILITY.—Any person may submit
11	to the Administrator data and information reason-
12	ably supporting the conclusion that a chemical sub-
13	stance or mixture does not present a substantial risk
14	of injury to health and the environment.".
15	SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.
16	Section 9 (15 U.S.C. 2608) is amended—
17	(1) in subsection (a)—
<ul><li>17</li><li>18</li></ul>	
	(1) in subsection (a)—
18	(1) in subsection (a)—  (A) in the first sentence of paragraph
18 19	<ul><li>(1) in subsection (a)—</li><li>(A) in the first sentence of paragraph</li><li>(1)—</li></ul>
18 19 20	<ul> <li>(1) in subsection (a)—</li> <li>(A) in the first sentence of paragraph</li> <li>(1)—</li> <li>(i) by striking "presents or will</li> </ul>
18 19 20 21	<ul> <li>(1) in subsection (a)—</li> <li>(A) in the first sentence of paragraph</li> <li>(1)—</li> <li>(i) by striking "presents or will present an unreasonable risk to health or</li> </ul>

1	(ii) by striking "such risk" the first
2	place it appears and inserting "the risk
3	posed by the substance or mixture";
4	(B) in paragraph (2), in the matter fol-
5	lowing subparagraph (B), by striking "section 6
6	or 7" and inserting "paragraph (8) or (9) of
7	subsection (c) of section 6 or section 7"; and
8	(C) in paragraph (3), by striking "section
9	6 or 7" and inserting "paragraph (8) or (9) of
10	subsection (c) of section 6 or section 7"; and
11	(2) in subsection (d), in the first sentence, by
12	striking "Health, Education, and Welfare" and in-
13	serting "Health and Human Services".
14	SEC. 10. RESEARCH, DEVELOPMENT, COLLECTION, DIS-
	SEC. 10. RESEARCH, DEVELOPMENT, COLLECTION, DIS- SEMINATION, AND UTILIZATION OF DATA.
14	
<ul><li>14</li><li>15</li><li>16</li></ul>	SEMINATION, AND UTILIZATION OF DATA.
<ul><li>14</li><li>15</li><li>16</li><li>17</li></ul>	Section 10 (15 U.S.C. 2609) is amended by striking
<ul><li>14</li><li>15</li><li>16</li><li>17</li></ul>	Section 10 (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears
<ul><li>14</li><li>15</li><li>16</li><li>17</li><li>18</li></ul>	Section 10 (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".
<ul><li>14</li><li>15</li><li>16</li><li>17</li><li>18</li><li>19</li></ul>	Section 10 (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".  SEC. 11. EXPORTS.
14 15 16 17 18 19 20	Section 10 (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".  SEC. 11. EXPORTS.  Section 12 (15 U.S.C. 2611) is amended—
14 15 16 17 18 19 20 21	Section 10 (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".  SEC. 11. EXPORTS.  Section 12 (15 U.S.C. 2611) is amended—  (1) in subsection (a), by striking paragraph (2)
14 15 16 17 18 19 20 21 22	Section 10 (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".  SEC. 11. EXPORTS.  Section 12 (15 U.S.C. 2611) is amended—  (1) in subsection (a), by striking paragraph (2) and inserting the following:

1	"(A) under section 5 is not likely to meet
2	the safety standard under the intended condi-
3	tions of use of the chemical substance; or
4	"(B) under section 6 does not meet the
5	safety standard under the intended conditions
6	of use of the chemical substance.
7	"(3) Waivers.—For a mixture or article con-
8	taining a chemical substance described in paragraph
9	(2), the Administrator may—
10	"(A) determine that paragraph (1) shall
11	not apply to that mixture or article; and
12	"(B) establish a threshold concentration in
13	a mixture or article at which paragraph (1)
14	shall not apply.";
15	(2) by striking subsection (b) and inserting the
16	following:
17	"(b) Notice.—
18	"(1) In general.—A person shall notify the
19	Administrator that the person is exporting or in-
20	tends to export to a foreign country—
21	"(A) a chemical substance or a mixture
22	containing a chemical substance that the Ad-
23	ministrator has determined under section 5 is
24	not likely to meet the safety standard under the

1	intended conditions of use of the chemical sub-
2	stance;
3	"(B) a chemical substance or a mixture
4	containing a chemical substance that the Ad-
5	ministrator has determined under section 6
6	does not meet the safety standard under the in-
7	tended conditions of use of the chemical sub-
8	stance; or
9	"(C) a chemical substance for which the
10	United States is obligated by treaty to provide
11	export notification.
12	"(2) Regulations.—
13	"(A) In General.—The Administrator
14	shall promulgate regulations to carry out para-
15	graph (1).
16	"(B) Contents.—The regulations pro-
17	mulgated under subparagraph (A) shall—
18	"(i) include any exemptions the Ad-
19	ministrator determines to be appropriate,
20	which may include exemptions identified
21	under section 5(g); and
22	"(ii) indicate whether or to what ex-
23	tent the regulations apply to articles con-
24	taining a chemical substance or mixture
25	described in paragraph (1).

1	"(3) Notification.—The Administrator shall
2	submit to the government of each country to which
3	a chemical substance or mixture is exported—
4	"(A) for a chemical substance or mixture
5	described in subparagraph (A) or (B) of para-
6	graph (1), a notice that information on the
7	chemical substance or mixture can be obtained
8	from the Administrator, unless the Adminis-
9	trator determines that good cause exists not to
10	provide the notice; and
11	"(B) for a chemical substance described in
12	paragraph (1)(C), a notice that satisfies the ob-
13	ligation of the United States under the applica-
14	ble treaty."; and
15	(3) in subsection (e)—
16	(A) by striking paragraph (3); and
17	(B) by redesignating paragraphs (4)
18	through (6) as paragraphs (3) through (5), re-
19	spectively.
20	SEC. 12. IMPORTS.
21	Section 13 (15 U.S.C. 2612) is amended to read as
22	follows:

"CTC	19	IMPORTS	

2	"(a) Definition of Chemical Substance or Mix-
3	TURE.—In this section, the term 'chemical substance or
4	mixture' includes—
5	"(1) a mixture containing a chemical substance
6	or mixture; and
7	"(2) an article containing a chemical substance
8	or mixture.
9	"(b) Refusal of Entry.—
10	"(1) IN GENERAL.—The Secretary of Homeland
11	Security shall refuse entry into the customs territory
12	of the United States (as defined in general note 2
13	to the Harmonized Tariff Schedule of the United
14	States) any chemical substance or mixture offered
15	for such entry if—
16	"(A) the Administrator has determined
17	under section 6(c) that the chemical substance
18	or mixture does not meet the safety standard
19	under the intended conditions of use of the
20	chemical substance; or
21	"(B) the chemical substance or mixture is
22	offered for entry in violation of a rule or order
23	in effect under this Act.
24	"(2) Procedure.—
25	"(A) In General.—Subject to subpara-
26	graph (B), if a chemical substance or mixture

1	is refused entry under paragraph (1), the Sec-
2	retary of Homeland Security—
3	"(i) shall notify the consignee of the
4	entry of the refusal;
5	"(ii) shall not release the chemical
6	substance or mixture to the consignee; and
7	"(iii) shall cause the disposal or stor-
8	age of the chemical substance or mixture
9	under such rules as the Secretary may pre-
10	scribe, if the chemical substance or mix-
11	ture has not been exported by the con-
12	signee in the 90-day period beginning on
13	the date of receipt of the notice of the re-
14	fused entry.
15	"(B) Exception.—
16	"(i) In General.—The Secretary of
17	Homeland Security may, pending a review
18	by the Administrator, release to the con-
19	signee the chemical substance or mixture if
20	the consignee—
21	"(I) executes a bond for the
22	amount of the full invoice of the
23	chemical substance or mixture (as set
24	forth in the customs entry); and

shall—

24

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

1	"(A) certify to the Secretary of Homeland
2	Security that, after reasonable inquiry and to
3	the best knowledge and belief of the person, the
4	chemical substance or mixture is—
5	"(i) in compliance with any applicable
6	rule, consent agreement, or order under
7	section 5 or 6; and
8	"(ii)(I) included on the list under sec-
9	tion 8(b); or
10	"(II) exempt from any requirement to
11	be included on that list; and
12	"(B) provide to the Secretary of Homeland
13	Security any notice required under paragraph
14	(2).
15	"(2) Notice.—A person offering a chemical
16	substance or mixture for entry into the customs ter-
17	ritory of the United States shall notify the Secretary
18	of Homeland Security if—
19	"(A) the chemical substance is a high-pri-
20	ority substance;
21	"(B) the chemical substance is a chemical
22	for which the United States is obligated to pro-
23	vide export notification by treaty; or

1	"(C) the chemical substance or mixture or
2	any article containing the substance or mix-
3	ture—
4	"(i) is the subject of a safety assess-
5	ment and safety determination conducted
6	pursuant to section 6 and has been found
7	not to meet the safety standard; and
8	"(ii) is identified in a rule promul-
9	gated by the Secretary of Homeland Secu-
10	rity pursuant to subsection (c) as meriting
11	notification due to the potential impact of
12	the chemical substance or mixture or any
13	article containing the substance or mixture
14	on human health or the environment.
15	"(d) Rules.—The Secretary of Homeland Security
16	after consultation with the Administrator, shall issue rules
17	for the administration of subsection (c), including wheth-
18	er, or to what extent, the provisions of subsections (b) and
19	(c) apply.".
20	SEC. 13. CONFIDENTIAL INFORMATION.
21	Section 14 (15 U.S.C. 2613) is amended to read as
22	follows:

4				
1	"CTC	11	CONFIDENTIAL	INFORMATION

2	"(a) In General.—Except as provided in sub-
3	sections (c) and (e), the Administrator shall not disclose
4	information described in subsection (b)—
5	"(1) that is reported to, or otherwise obtained
6	by, the Administrator under this Act; and
7	"(2) for which the requirements of subsection
8	(d) are met.
9	"(b) Information Generally Protected From
10	DISCLOSURE.—
11	"(1) In general.—Information referred to in
12	subsection (a) includes confidential information that
13	is exempt from disclosure pursuant to subsection (a)
14	of section 552 of title 5, United States Code, under
15	subsection (b)(4) of that section.
16	"(2) Presumption of Protection.—The fol-
17	lowing information submitted by a manufacturer,
18	processor, or distributor is presumed to be protected
19	from disclosure:
20	"(A) Specific information describing the
21	manufacture, processing, or distribution in com-
22	merce of a chemical substance, mixture, or arti-
23	cle.
24	"(B) Marketing and sales information.
25	"(C) Information identifying suppliers or
26	customers.

1	(D) The identity of constituents in a mix-
2	ture and the respective percentages of those
3	constituents.
4	"(E) Specific information about the use,
5	function, or application of a chemical substance
6	or mixture in a process, mixture, or product.
7	"(F) Specific production or import volumes
8	of a manufacturer and specific volumes aggre-
9	gated across manufacturers if the Adminis-
10	trator determines that disclosure of the aggre-
11	gated data could reveal confidential informa-
12	tion.
13	"(G) The specific identity of a chemical
14	substance, including the chemical name, molec-
15	ular formula, Chemical Abstracts Service num-
16	ber, and other information that would identify
17	a specific chemical substance, if—
18	"(i) the specific identity was claimed
19	as confidential information at the time it
20	was submitted; and
21	"(ii) the claim has not subsequently
22	been withdrawn or found by the Adminis-
23	trator not to warrant protection as con-
24	fidential information under subsection (g).

1	"(c) Information Not Protected From Disclo-
2	SURE.—
3	"(1) In General.—Notwithstanding sub-
4	sections (a) and (b), and except as provided in para-
5	graph (2), the following information shall not be
6	protected from disclosure:
7	"(A) For information submitted after the
8	date of enactment of the Chemical Safety Im-
9	provement Act, the identity of a chemical sub-
10	stance if the person submitting the information
11	does not meet the requirements of subsection
12	(d).
13	"(B) A safety assessment developed or a
14	safety determination made under section 6.
15	"(C) Health and safety data that are sub-
16	mitted under this Act with respect to a chem-
17	ical substance or mixture that has been offered
18	for commercial distribution as of the date on
19	which the study is to be disclosed or for which
20	testing is required under section 4.
21	"(D) Health and safety data in notices of
22	substantial risk submitted under section 8(e)
23	and in the underlying studies.

1	(E) General information describing the
2	manufacturing volumes, expressed in ranges
3	would not reveal confidential information.
4	"(F) General descriptions of industrial,
5	commercial, or consumer functions and uses of
6	a chemical substance or mixture.
7	"(2) Exception.—Information elements con-
8	tained in submissions described in paragraph (1)
9	that are otherwise eligible for protection under this
10	section shall be protected from disclosure if the sub-
11	mitter complies with subsection (d).
12	"(d) Requirements for Confidentiality
13	CLAIMS.—
14	"(1) Claims.—
15	"(A) In general.—For information to be
16	protected from disclosure under this section, a
17	person who submits information to the Admin-
18	istrator under this Act shall—
19	"(i) indicate the information that the
20	person believes is entitled to protection
21	from disclosure under this section in a sub-
22	mission to the Administrator in such man-
23	ner and at such time as the Administrator
24	shall prescribe; and

1	"(ii) except in the case of information
2	described in subparagraphs (A) through
3	(F) of subsection (b)(2), submit written
4	documentation justifying why the informa-
5	tion qualifies for protection from disclo-
6	sure.
7	"(B) CERTIFICATION.—An authorized offi-
8	cial of the person described in subparagraph
9	(A) shall certify that the information that has
10	been submitted is true and correct.
11	"(2) Additional requirements for con-
12	FIDENTIALITY CLAIMS FOR CHEMICAL IDENTI-
13	TIES.—A person submitting information under this
14	Act related to a chemical identity and who claims
15	protection from disclosure for that identity shall pro-
16	vide the Administrator with—
17	"(A) information establishing that—
18	"(i) the person takes reasonable meas-
19	ures to protect the confidentiality of the
20	chemical identity;
21	"(ii) the chemical identity is not re-
22	quired to be disclosed, or otherwise made
23	available, to the public under any other
24	Federal law in connection with 1 or more
25	uses subject to this Act;

"(iii) disclosure of the chemical iden-
tity is likely to cause substantial harm to
the competitive position of the person; and
"(iv) the chemical identity is not rea-
sonably believed to be readily discoverable
through reverse engineering;
"(B) the time period for which protection
of the chemical identity from disclosure is nec-
essary;
"(C) a generic name for the chemical sub-
stance that the Administrator may disclose to
the public, subject to the condition that the ge-
neric name discloses a maximum amount of in-
formation on the chemical structure of the sub-
stance while protecting those features of the
chemical structure that are considered confiden-
tial and the disclosure of which would poten-
tially harm the competitive position of the per-
son; and
"(D) in the event the Administrator makes
a request under subsection (f)—
"(i) redocumentation and recertifi-
cation of the information submitted under
subsection (a); or

1	"(ii) withdrawal of the claim for pro-
2	tection of the chemical identity from disclo-
3	sure.
4	"(3) Guidance.—The Administrator shall de-
5	velop guidance, after notice and opportunity to com-
6	ment, on the determination of generic names for
7	confidential chemical identities.
8	"(e) Exceptions to Protection From Disclo-
9	SURE.—Subsection (a) shall not apply if—
10	"(1) the information is to be disclosed to an of-
11	ficer or employee of the United States in connection
12	with the official duties of that person under any law
13	for the protection of human health or the environ-
14	ment or for specific law enforcement purposes;
15	"(2) the information is to be disclosed to a con-
16	tractor with the United States and employees of that
17	contractor if, in the opinion of the Administrator,
18	the disclosure is necessary for the satisfactory per-
19	formance by the contractor of a contract with the
20	United States for the performance of work in con-
21	nection with this Act and under such conditions as
22	the Administrator shall specify;
23	"(3) the Administrator determines that disclo-
24	sure is necessary to protect human health or the en-
25	vironment;

1	"(4) the information is to be disclosed to a
2	State or political subdivision of a State, on written
3	request, for the purpose of development, administra-
4	tion, or enforcement of a law, if—
5	"(A) 1 or more applicable agreements with
6	the Administrator ensure that the recipient gov-
7	ernment will take appropriate steps, and has
8	adequate authority, to maintain the confiden-
9	tiality of the information in accordance with
10	procedures as stringent as those which the Ad-
11	ministrator uses to safeguard the information;
12	and
13	"(B) the Administrator notifies the person
14	who submitted the information that the infor-
15	mation has been disclosed to a State or political
16	subdivision of a State;
17	"(5) a health professional employed by a Fed-
18	eral or State agency or a treating physician or nurse
19	in a nonemergency situation provides a written
20	statement of need and a written confidentiality
21	agreement, subject to the conditions that—
22	"(A) the written statement of need is a
23	statement that the person has a reasonable
24	basis to suspect that—

1	(1) the information is needed for pur-
2	poses of diagnosis or treatment of 1 or
3	more individuals;
4	"(ii) 1or more individuals being diag-
5	nosed or treated have been exposed to the
6	chemical substance concerned; and
7	"(iii) knowledge of the specific chem-
8	ical identity of the chemical substance will
9	assist in diagnosis or treatment; and
10	"(B) the confidentiality agreement pro-
11	vides that the person will not use the specific
12	chemical identity for any purpose other than
13	the health needs asserted in the statement of
14	need, except as may otherwise be authorized by
15	the terms of the agreement or by the person
16	submitting the specific chemical identity to the
17	Administrator;
18	"(6) a treating physician or nurse requests the
19	information, subject to the conditions that—
20	"(A) the treating physician or nurse deter-
21	mines that—
22	"(i) a medical emergency exists;
23	"(ii) the specific chemical identity of
24	the chemical substance concerned is nec-

1	essary for or will assist in emergency or
2	first-aid diagnosis or treatment; and
3	"(iii) the 1 or more individuals being
4	diagnosed or treated have likely been ex-
5	posed to the chemical substance concerned
6	"(B) if requested by the person submitting
7	the specific chemical identity to the Adminis-
8	trator, the treating physician or nurse provides
9	a written statement of need and a confiden-
10	tiality agreement as described in paragraph (5)
11	and
12	"(C) the written confidentiality agreement
13	or statement of need is submitted as soon as
14	practicable, but not necessarily before the infor-
15	mation is disclosed;
16	"(7) the Administrator determines that disclo-
17	sure is necessary in a proceeding under this Act
18	subject to the condition that the disclosure is made
19	in such a manner as to preserve confidentiality to
20	the maximum extent practicable without impairing
21	the proceeding; or
22	"(8) the information is to be disclosed, on writ-
23	ten request of any duly authorized committee of the
24	Congress, to that committee.

1	"(f) DURATION OF PROTECTION FROM DISCLO-
2	SURE.—
3	"(1) In general.—The Administrator shall
4	protect from disclosure information described in sub-
5	section (b) that meets the requirements of sub-
6	section (d)(2) for the period of time requested by the
7	person submitting the claim or for such period of
8	time as the Administrator, after reviewing the re-
9	quest for confidential treatment and the documenta-
10	tion, otherwise determines to be reasonable, unless—
11	"(A) prior to the expiration of the period
12	the person notifies the Administrator that the
13	person is withdrawing the confidentiality claim
14	in which case, the Administrator shall promptly
15	make the information available to the public; or
16	"(B) prior to the expiration of the period
17	the Administrator otherwise becomes aware
18	that the need for protection from disclosure can
19	no longer be substantiated, in which case the
20	Administrator shall take the actions described
21	in subsection $(g)(2)$ .
22	"(2) Redocumentation.—The Administrator
23	may request—
24	"(A) at any time, a person who has re-
25	quested protection from disclosure for the iden-

1	tity of a substance under subsection (d) to re-
2	document the confidentiality claim of the per-
3	son; and
4	"(B) any person who has requested that
5	confidential information be protected from dis-
6	closure under section 8(b) to reassert the con-
7	fidentiality claim of the person after the chem-
8	ical substance is identified as a high-priority
9	substance under section 4(e).
10	"(g) Duties of the Administrator.—
11	"(1) Determination.—
12	"(A) IN GENERAL.—Except as provided in
13	subsection (b)(2), the Administrator shall—
14	"(i) review a request received under
15	this section to maintain the confidentiality
16	of information submitted under this Act;
17	and
18	"(ii) determine whether to approve,
19	modify, or deny that request.
20	"(B) Denial or modification.—
21	"(i) In General.—The Administrator
22	shall deny a claim to protect a chemical
23	identity from disclosure only if the person
24	who has submitted the request fails to
25	meet the requirements of subsection (d).

1	"(ii) Reasons for denial or modi-
2	FICATION.—The Administrator shall pro-
3	vide to the person who has submitted the
4	request a written statement of the reasons
5	for the denial or modification of the claim.
6	"(C) Subsets.—If it is not feasible for the
7	Administrator to review each request under this
8	section, the Administrator shall review a rep-
9	resentative subset.
10	"(2) Notification.—
11	"(A) In general.—Except as provided in
12	subsections (c) and (e), if the Administrator de-
13	nies a request under paragraph (1), the Admin-
14	istrator shall notify, in writing and by certified
15	mail, the person who submitted the request of
16	the intent of the Administrator to release the
17	information.
18	"(B) Release of information.—
19	"(i) In general.—Except as pro-
20	vided in clause (ii), the Administrator may
21	not release information under this sub-
22	section until the date that is 30 days after
23	the date on which the person who sub-
24	mitted the request receives notification
25	under subparagraph (A).

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1	"(11) EXCEPTIONS.—
2	"(I) In general.—For informa-
3	tion under paragraph (3) or (8) of
4	subsection (e), the Administrator may
5	not release that information until the
6	date that is 15 days after the date on
7	which the person who submitted the
8	request receives a notification, unless
9	the Administrator determines that re-
10	lease of the information is necessary
11	to protect against an imminent and
12	substantial harm to human health or
13	the environment, in which case, no
14	prior notification is necessary.
15	"(II) NO NOTIFICATION.—For
16	information under paragraph (6) or
17	(7) of subsection (e), no prior notifica-
18	tion is necessary.
19	"(3) Appeals.—
20	"(A) In general.—A person who receives
21	notification under this subsection may, if the
22	person believes disclosure of the information is
23	prohibited under subsection (a), before the date
24	on which the information is to be released,

1	bring an action to restrain disclosure of the in-
2	formation in—
3	"(i) the district court of the United
4	States in the district in which—
5	"(I) the complainant resides or
6	has the principal place of business; or
7	"(II) the information is located
8	or
9	"(ii) the United States District Court
10	for the District of Columbia.
11	"(B) No disclosure.—The Adminis-
12	trator shall not disclose any information under
13	this section prior to the date on which the ap-
14	plicable court rules on an action under subpara-
15	graph (A).
16	"(4) Administration.—In carrying out this
17	subsection, the Administrator shall employ the pro-
18	cedures in part 2 of title 40, Code of Federal Regu-
19	lations (or successor regulations).
20	"(h) Criminal Penalty for Wrongful Disclo-
21	SURE.—
22	"(1) In general.—Subject to paragraph (2)
23	any officer or employee of the United States or
24	former officer or employee of the United States
25	who—

1	"(A) by virtue of that employment or offi-
2	cial position has obtained possession of, or has
3	access to, material the disclosure of which is
4	prohibited by subsection (a); and
5	"(B) knowing that disclosure of that mate-
6	rial is prohibited by subsection (a), willfully dis-
7	closes the material in any manner to any person
8	not entitled to receive that material, shall be—
9	"(i) guilty of a misdemeanor and
10	fined under title 18, United States Code
11	imprisoned for not more than 1 year, or
12	both; and
13	"(ii) removed from office or employ-
14	ment.
15	"(2) Other laws.—Section 1905 of title 18
16	United States Code, shall not apply with respect to
17	the publishing, divulging, disclosure, making known
18	of, or making available, information reported or oth-
19	erwise obtained under this Act.
20	"(3) Contractors.—For the purposes of this
21	subsection, any contractor of the United States who
22	is furnished information in accordance with sub-
23	section (e)(2), including any employee of that con-
24	tractor, shall be considered to be an employee of the
25	United States.

1	"(i) APPLICABILITY.—Except as otherwise provided
2	in this section, the Administrator shall have no author-
3	ity—
4	"(1) to require the documentation or redocu-
5	mentation of a claim for the protection from disclo-
6	sure of information submitted to the Administrator
7	under this Act prior to the date of enactment of the
8	Chemical Safety Improvement Act; or
9	"(2) to impose redocumentation requirements
10	under this Act that are more extensive than those
11	required under this section.".
12	SEC. 14. PROHIBITED ACTS.
13	Section 15 (15 U.S.C. 2614) is amended by striking
14	paragraph (1) and inserting the following:
15	"(1) fail or refuse to comply with—
16	"(A) any rule promulgated, consent agree-
17	ment entered into, or order issued under section
18	4;
19	"(B) any requirement prescribed by section
20	5 or 6;
21	"(C) any rule promulgated, consent agree-
22	ment entered into, or order issued under section
23	5 or 6;

1	"(D) any requirement of title II or any
2	rule promulgated or order issued under title II;
3	or
4	"(E) any requirement of title VII or any
5	rule promulgated or order issued under title
6	VII;".
7	SEC. 15. PREEMPTION.
8	Section 18 (15 U.S.C. 2617) is amended by striking
9	subsections (a) and (b) and inserting the following:
10	"(a) In General.—Except as provided in sub-
11	sections (c) and (d), no State or political subdivision of
12	a State may establish or continue to enforce—
13	"(1) a requirement for the development of test
14	data or information on a chemical substance or cat-
15	egory of substances that is reasonably likely to
16	produce the same data and information required
17	under section 4, 5, or 6 by—
18	"(A) a rule promulgated by the Adminis-
19	trator;
20	"(B) a consent agreement entered into by
21	the Administrator; or
22	"(C) an order issued by the Administrator;
23	"(2) a prohibition or restriction on the manu-
24	facture, processing, or distribution in commerce or
25	use of a chemical substance after issuance of a com-

pleted safety determination for a chemical substance
under section 6, consistent with the scope of the re-
view and decisions addressed by the Administrator;
or
"(3) a requirement for the notification of a use
of a chemical substance that the Administrator has
specified as a significant new use and for which the
Administrator has required notification pursuant to
a rule promulgated under section 5.
"(b) New Prohibitions or Restrictions.—Ex-
cept as provided in subsections (c) and (d), no State or
political subdivision of a State may establish (after the
date of enactment of the Chemical Safety Improvement
Act)—
"(1) a prohibition or restriction on the manu-
facture, processing, distribution in commerce or use
of a chemical substance that is a high-priority sub-
stance identified under section 4(e)(3) (as of the
date on which the Administrator publishes a sched-
ule under section 6(b)); or
"(2) a prohibition or restriction on the manu-
facture, processing, distribution in commerce or use
of a chemical substance that is a low-priority sub-
stance identified under section $4(e)(3)$ .

1	"(c) Exceptions.—Subsections (a) and (b) shall not
2	apply to a requirement, prohibition, or restriction of a
3	State or a political subdivision of a State that—
4	"(1) is adopted under the authority of any
5	other Federal law;
6	"(2) implements a reporting or information col-
7	lection requirement not otherwise required by the
8	Administrator under this Act or required under any
9	other Federal law; or
10	"(3) is adopted pursuant to authority under a
11	law of the State or political subdivision of the State
12	related to water quality, air quality, or waste treat-
13	ment or disposal that—
14	"(A) does not impose a restriction on the
15	manufacture, processing, distribution in com-
16	merce, or use of a chemical substance; and
17	"(B) is not otherwise required by or incon-
18	sistent with an action by the Administrator
19	under section 5 or 6.
20	"(d) State Waivers.—Upon application of a State
21	or political subdivision of a State, the Administrator may
22	provide a waiver from subsection (a) and subsection
23	(b)(1), regarding a requirement of that State or political
24	subdivision of the State that relates to the effects or expo-

1	sure to any chemical substance under the intended condi-
2	tions of use if—
3	"(1)(A) the State or political subdivision of the
4	State determines it cannot wait until the end of the
5	period specified in the established schedule and
6	deadline for the completion of a full safety assess-
7	ment and determination established under section
8	6(b)(2)(B)(ii); and
9	"(B) the Administrator determines that—
10	"(i) compelling State or local conditions
11	warrant granting the waiver to protect human
12	health or the environment;
13	"(ii) compliance with the proposed require-
14	ment of the State or political subdivision of the
15	State does not unduly burden interstate and
16	foreign commerce in the manufacture, proc-
17	essing, distribution in commerce, or use of a
18	chemical substance;
19	"(iii) compliance with the proposed re-
20	quirement of the State or political subdivision
21	of the State would not cause a violation of any
22	applicable Federal law, rule, or order; and
23	"(iv) the proposed requirement of the
24	State or political subdivision of the State is

1	based on the best available science and is sup-
2	ported by the weight of the evidence; or
3	"(2)(A) the Administrator finds a safety assess-
4	ment or determination has been unreasonably de-
5	layed; and
6	"(B) the State certifies that—
7	"(i) the State has a compelling local inter-
8	est to protect human health or the environment
9	"(ii) compliance with the proposed require-
10	ment of the State does not unduly burden inter-
11	state and foreign commerce in the manufacture
12	processing, distribution in commerce, or use of
13	a chemical substance;
14	"(iii) compliance with the proposed re-
15	quirement would not cause a violation of any
16	applicable Federal law, rule, or order; and
17	"(iv) the proposed requirement is grounded
18	in reasonable scientific concern.
19	"(3) Approval of a state waiver re-
20	QUEST.—The Administrator shall grant or deny a
21	waiver application—
22	"(A) not later than 180 days after the date
23	on which an application under paragraph (1) is
24	submitted; and

1	"(B) not later than 90 days after the date
2	on which an application under paragraph (2) is
3	submitted.
4	"(4) Notice and comment.—The application
5	of a State or political subdivision of the State shall
6	be subject to public notice and comment.
7	"(5) Final agency action.—The decision of
8	the Administrator on the application of a State or
9	political subdivision of the State shall be—
10	"(A) considered to be a final agency ac-
11	tion; and
12	"(B) subject to judicial review.
13	"(6) Duration of State Waivers.—A State
14	waiver—
15	"(A) granted under paragraph (1) shall re-
16	main in effect unless the waiver is found to be
17	in conflict with a completed safety assessment
18	and determination; and
19	"(B) granted under paragraph (2) shall re-
20	main in effect until such time as the safety as-
21	sessment and determination is completed.
22	"(7) Judicial review.—Not later than 60
23	days after the date on which the Administrator
24	makes a determination on an application of a State
25	or political subdivision of the State under paragraph

1	(1), any person may file a petition for judicial review
2	in the United States Court of Appeals for the Dis-
3	trict of Columbia Circuit, which shall have exclusive
4	jurisdiction over the determination.
5	"(e) Effect on Private Remedies.—
6	"(1) In general.—If the Administrator com-
7	pletes a safety determination for a high-priority sub-
8	stance under section 6, the determination shall be
9	admissible as evidence in any public or private ac-
10	tion in any court of the United States or State court
11	for recovery of damages or for equitable relief relat-
12	ing to injury to human health or the environment
13	from exposure to a chemical substance.
14	"(2) Safety Standard.—The safety deter-
15	mination shall be determinative of whether the sub-
16	stance meets the safety standard under the condi-
17	tions of use addressed in the safety determination.".
18	SEC. 16. JUDICIAL REVIEW.
19	Section 19 (15 U.S.C. 2618) is amended—
20	(1) in subsection (a)—
21	(A) by striking paragraph (1) and insert-
22	ing the following:
23	"(1) FILING OF PETITION.—
24	"(A) IN GENERAL.—Not later than 60
25	days after the date of the promulgation of a

1	rule under section $4(1)$ , $6(c)$ , $6(e)$ , or 8, any
2	person may file a petition for judicial review of
3	the rule in—
4	"(i) the United States Court of Ap-
5	peals for the District of Columbia Circuit;
6	"(ii) the circuit in which the person
7	resides; or
8	"(iii) the circuit in which the principal
9	place of business of the person is located.
10	"(B) EXCLUSIVE JURISDICTION OF
11	COURTS OF APPEALS.—The courts of appeals of
12	the United States shall have exclusive jurisdic-
13	tion of any action to obtain judicial review
14	(other than in an enforcement proceeding)
15	under subparagraph (A) if any district court of
16	the United States would have had jurisdiction
17	of the action but for this paragraph.";
18	(B) in paragraph (2), by striking "para-
19	graph (1)(A)" and inserting "paragraph (1)";
20	and
21	(C) by striking paragraph (3); and
22	(2) in subsection (c)(1), by striking subpara-
23	graph (B) and inserting the following:
24	"(B) Applicability of Section 706 of
25	TITLE 5, UNITED STATES CODE.—

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S.L.C.

(1) DEFINITION OF EVIDENCE.—In	1
this subparagraph, the term 'evidence	2
means any matter in the rulemaking	3
record.	4
"(ii) Applicability.—Section 706 of	5
title 5, United States Code, shall apply to	6
review of a rule under this section, except	7
that—	8
"(I) in the case of a rule under	9
section $4(f)$ , $6(e)$ , or $6(e)$ —	10
"(aa) the standard of review	11
prescribed in section $706(2)(E)$	12
of title 5, United States Code	13
shall not apply; and	14
"(bb) the court shall hold as	15
unlawful and set aside the rule is	16
the court finds that the rule is	17
not supported by substantial evi-	18
dence in the rulemaking record	19
and	20
"(II) the court shall not review	21
the contents and adequacy of the	22
statement of basis and purpose re-	23
quired by section 553(c) of title 5	24
United States Code, to be incor-	25

1	porated in the rule except as part of
2	a review of the rulemaking record
3	taken as a whole.".
4	SEC. 17. CITIZENS' PETITIONS.
5	Section 21 (15 U.S.C. 2620) is amended—
6	(1) in subsection (a), by striking "an order
7	under section $5(e)$ or $6(b)(2)$ " and inserting "an
8	order under section 4(f) or 5(c)"; and
9	(2) in subsection (b)—
10	(A) in paragraph (1), by striking "an
11	order under section $5(e)$ , $6(b)(1)(A)$ , or
12	6(b)(1)(B)" and inserting "an order under sec-
13	tion 4(f) or 5(c)"; and
14	(B) by striking subparagraph (B) of para-
15	graph (4) and inserting the following:
16	"(B) DE NOVO PROCEEDING.—
17	"(i) In General.—In an action
18	under subparagraph (A) to initiate a pro-
19	ceeding to issue a rule under section 4(f),
20	6(b), 6(c), 6(d), or 8 or an order issued
21	under section 4(f) or 5(c), the petitioner
22	shall be provided an opportunity to have
23	the petition considered by the court in a de
24	novo proceeding.
25	"(ii) Demonstration.—

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1	"(I) IN GENERAL.—The court
2	shall order the Administrator to ini-
3	tiate the action requested by the peti-
4	tioner if the petitioner demonstrates
5	to the satisfaction of the court by a
6	preponderance of the evidence that—
7	"(aa) in the case of a peti-
8	tion to initiate a proceeding for
9	the issuance of a rule or order
10	under section 4(f), the informa-
11	tion available to the Adminis-
12	trator is insufficient for the Ad-
13	ministrator to perform an action
14	described in section $4(f)$ , $6(b)(5)$ ,
15	or $6(e)(8)$ ;
16	"(bb) in the case of a peti-
17	tion to issue an order under sec-
18	tion 5(c), there is a reasonable
19	basis to conclude that the sub-
20	stance is not likely to meet the
21	safety standard under the in-
22	tended conditions of use;
23	"(ce) in the case of a peti-
24	tion to initiate a proceeding for
25	the issuance of a rule under sec-

1	10	5
		,,

1	tion $b(c)(9)$ , there is a reasonable
2	basis to conclude that the sub-
3	stance will not meet the safety
4	standard under the intended con-
5	ditions of use; or
6	"(dd) in the case of a peti-
7	tion to initiate a proceeding for
8	the issuance of a rule under sec-
9	tion $6(b)(2)$ , $6(d)$ or 8, there is a
10	reasonable basis to conclude that
11	the rule is necessary to protect
12	human health or the environment
13	from an unreasonable risk of
14	harm to human health or the en-
15	vironment.
16	"(II) Deferment.—The court
17	may permit the Administrator to defer
18	initiating the action requested by the
19	petitioner until such time as the court
20	prescribes if the court finds that—
21	"(aa) the extent of the risk
22	to human health or the environ-
23	ment alleged by the petitioner is
24	less than the extent of risks to
25	human health or the environment

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1	with respect to which the Admin-
2	istrator is taking action under
3	this Act; and
4	"(bb) there are insufficient
5	resources available to the Admin-
6	istrator to take the action re-
7	quested by the petitioner.".
8	SEC. 18. STUDIES.
9	Section 25 (15 U.S.C. 2624) is repealed.
10	SEC. 19. ADMINISTRATION.
11	Section 26(e) (15 U.S.C. 2625(e)) is amended by
12	striking "Health, Education, and Welfare" each place it
13	appears and inserting "Health and Human Services".
14	SEC. 20. DEVELOPMENT AND EVALUATION OF TEST METH-
15	ODS.
16	Section 27(a) (15 U.S.C. 2626(a)) is amended by
17	striking "Health, Education, and Welfare" and inserting
18	"Health and Human Services".
19	SEC. 21. STATE PROGRAMS.
20	Section 28 (15 U.S.C. 2627) is amended by striking
21	subsections (e) and (d).
22	SEC. 22. AUTHORIZATION OF APPROPRIATIONS.
23	Section 29 (15 U.S.C. 2628) is repealed.

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ı	SEC	93	$\Delta$ NNII $\Delta$ I.	REPORT

2	Section 30 (15 U.S.C. 2629) is amended by striking
3	paragraph (2) and inserting the following:
4	"(2)(A) the number of notices received during
5	each year under section 5; and
6	"(B) the number of the notices described in
7	subparagraph (A) for chemical substances subject to
8	a rule, testing consent agreement, or order under
9	section 4(f);".