113TH CONGRESS
1ST SESSION

S. _____

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS; REFERENCES.

(a) SHORT TITLE.—This Act may be cited as the ''Chemical Safety Improvement Act''.

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

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

SEC. 2. FINDINGS, POLICY, AND INTENT.

(a) PURPOSES.—The purposes of this Act are—

(1) to improve the safety of consumers in the United States; and

(2) to ensure that risks from chemical substances are adequately understood and managed by modernizing title I of the Toxic Substances Control Act (15 U.S.C. 2601 et seq.).

(b) FINDINGS, POLICY, AND INTENT.—Section 2 (15 U.S.C. 2601) is amended by striking subsections (a) through (c) and inserting the following:

''(a) FINDINGS.—Congress finds that—

''(1) chemicals should be safe for the intended use of the chemicals;

''(2) the unmanaged risks of chemical substances may pose a danger to human health and the environment;

''(3) public confidence in the Federal chemical regulatory program has diminished over time;

''(4) scientific understanding of chemicals and the possible risks of the chemicals has evolved greatly since 1976, requiring that Congress update the law to ensure that chemical regulation in the United States reflects modern science, technology and knowledge;

''(5) this Act should be modernized to create a robust Federal system for assessing and managing chemical risks;

''(6) chemicals are used in diverse manufacturing industries and other valuable commercial, institutional, and consumer applications that have benefitted society;

''(7) for the purposes of promoting uniform protections through regulation of chemical substances in commerce, to minimize undue burdens on commerce, and to minimize burdens on States, specified actions by the Administrator should preempt requirements by States and political subdivisions of States that relate to the effects of or exposure to a chemical substance under the intended conditions of use; and

''(8) innovation in the development of new chemical substances, especially safer chemical substances, should be encouraged to reduce risk, provide improved products, stimulate the economy, create jobs, and protect interstate commerce.

''(b) POLICY.—It is the policy of the United States that—

''(1) this Act—

''(A) should protect the health of people and the environment from the unmanaged risks of chemical substances; and

''(B) should be modernized to build public confidence in the ability of the Federal regulatory system to protect health and the environment, promote innovation, and sustain a glob-

ally competitive chemical industry in the United States;

''(2) the Administrator—

''(A) should have the appropriate hazard, use, and exposure information necessary to make safety determinations;

''(B) should minimize the use of animal testing through the use of scientifically reliable and relevant test methods, where appropriate;

''(C) should encourage the use of best laboratory practices to ensure high quality, relevant, and reliable results from test methods and studies;

''(D) should have the authority to share confidential business information with States and political subdivisions of the States, subject to appropriate safeguards against inappropriate disclosure;

''(E) should have the resources and tools necessary to implement this Act; and

''(F) should implement this Act in a manner that promotes transparency of information and decisionmaking, protects substantiated confidential business information, and promotes innovation, including innovation in chemical sub-

stances that have reduced hazard, exposure, and risk patterns;

''(3) adequate data and information should be available with respect to the effect of and exposure to chemical substances and mixtures on health and the environment, to the extent necessary for safety assessments and determinations, and that, where necessary, the development of such test data and information should be the primary responsibility of those who manufacture or process such chemical substances and mixtures; and

''(4) States have an important role in protecting health and the environment from the unmanaged risks of chemical substances in commerce, particularly in recommending priorities for Federal assessment and regulation, providing safety assessment information, and fostering programs to protect consumers.

''(c) INTENT OF CONGRESS.—It is the intent of Congress that the Administrator shall—

''(1) rely on robust scientific evidence to implement this Act in a way that balances the mutual goals of promoting the safety of American consumers and preventing harm to American innovation, manufacturing, and the economy; and

''(2) implement this Act to protect the health of the people of the United States and the environment in such a manner as not to unduly impede commerce or create unnecessary economic barriers to technological innovation, including safer chemistry.''.

SEC. 3. DEFINITIONS.

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

(1) by redesignating paragraphs (2) through (6), (7) through (11), and (12) through (14) as paragraphs (3) through (7), (9) through (13), and (17) through (19), respectively;

(2) by inserting after paragraph (1) the following:

''(2) BEST AVAILABLE SCIENCE.—The term 'best available science' means science that—

''(A) maximizes the quality, objectivity, and integrity of information, including statistical information;

''(B) uses peer-reviewed and publically available data; and

''(C) clearly documents and communicates risks and uncertainties in the scientific basis for decisions.'';

(3) by inserting after paragraph (7) (as so redesignated) the following:

''(8) INTENDED CONDITIONS OF USE.—The term 'intended conditions of use' means the circumstances under which a chemical substance is intended or reasonably anticipated to be manufactured, processed, distributed in commerce, used, and disposed of.''; and

(4) by inserting after paragraph (13) (as so redesignated) the following:

''(14) SAFETY ASSESSMENT.—The term 'safety assessment' means a risk-based assessment of the safety of a chemical substance that—

''(A) integrates hazard; use; and exposure information about a chemical substance; and

''(B) includes—

''(i) an assessment of exposure under the intended conditions of use; and

''(ii) reference parameters that may be appropriate with regard to a specific chemical substance (such as a margin of exposure).

''(15) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the intended conditions of use.

''(16) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures that no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance.''.

SEC. 4. CHEMICAL ASSESSMENT FRAMEWORK; PRIORITIZATION SCREENING; TESTING.

(a) IN GENERAL.—Section 4 (15 U.S.C. 2603) is amended—

(1) in the heading, by striking ''**TESTING OF CHEMICAL SUBSTANCES AND MIXTURES**'' and inserting ''**CHEMICAL ASSESSMENT FRAMEWORK; PRIORITIZATION SCREENING; TESTING**''.

(2) by redesignating subsection (e) as subsection (l);

(3) in subsection (l) (as so redesignated)—

(A) by striking ''rule'' each place it appears and inserting ''rule, testing consent agreement, or order'';

(B) by striking ''under subsection (a)'' each place it appears and inserting ''under this subsection''; and

(C) in paragraph (1)(B), by striking ''rulemaking''; and

(4) by striking subsections (a) through (d), (f), and (g) and inserting the following:

''(a) CHEMICAL ASSESSMENT FRAMEWORK.—

''(1) IN GENERAL.—The Administrator shall develop a framework in accordance with subsection (e) and sections 5 and 6 for evaluating the safety of chemical substances in commerce that shall employ the best available science and risk assessment principles in existence at the time the Administrator is developing the framework.

''(2) POLICIES AND PROCEDURES.—

''(A) IN GENERAL.—After the date of enactment of the Chemical Safety Improvement Act, the Administrator shall promptly develop appropriate policies and procedures for implementing the framework, including procedures on the collection, evaluation, and development of data and information.

''(B) CONTENTS.—The policies and procedures shall require—

''(i) the collection of existing data and information from manufacturers and processors of chemical substances and other sources, including the use of voluntary

agreements to provide the data and information;

''(ii) an evaluation of the quality of existing data and information;

''(iii) an analysis of data and information;

''(iv) a determination of the need for additional data and information, including information related to the exposures of different subpopulations; and

''(v) subject to section 14, transparency of data and information considered by the Administrator, including both positive and negative findings.

''(3) TRANSPARENCY AND VALIDITY.—The Administrator shall ensure that the evaluation framework described in subsection (a)(1)—

''(A) is transparent;

''(B) assures that data and information are valid;

''(C) addresses the strengths and limitations of—

''(i) the design of the framework,

''(ii) the reliability of the test methods; and

''(iii) the quality of the data and information; 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 establish and publish scientifically sound criteria for evaluating all of the data and information, including the results of animal and nonanimal testing, regardless 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 Administrator 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.—For test data developed under this Act, the Administrator shall encourage the use of good laboratory practices, peer review, scientifically reliable and relevant test methods, standardized protocols, and other methods to ensure sci-

entific quality for all data and information submitted under this Act.

''(4) DATA AND INFORMATION THAT DO NOT MEET CRITERIA.—

''(A) IN GENERAL.—Nothing in this subsection shall preclude the Administrator from considering data and information which do not meet the quality criteria established under paragraph (1).

''(B) IDENTIFICATION.—The Administrator shall—

''(i) identify any data and information described in subparagraph (A) on which the Administrator relies;

''(ii) describe the quality of the data and information described in subparagraph (A) and the extent to which the data and information depart from those criteria;

''(iii) indicate any limitations on the usefulness of the data and information described in subparagraph (A); and

''(iv) explain how the data and information described in subparagraph (A) was used and the basis for reliance on the data and information.

''(5) EVALUATIVE FRAMEWORK FOR DECISION-MAKING.—

''(A) IN GENERAL.—The Administrator shall develop and use a structured evaluative framework consisting of science-based criteria, consistent with the protection of human health and the environment, for making any decision under this Act, and for determining the relevance, quality, and reliability of data and information.

''(B) CONTENTS.—The framework described in subparagraph (A) shall, at a minimum—

''(i) use sound and objective scientific practices in assessing risks;

''(ii) consider the current best available science (including peer-reviewed studies);

''(iii) when consistent with the underlying data, consider, for both cancer and noncancer endpoints, whether available data support or do not support the identification of threshold doses of a chemical substance below which no adverse effects can be expected to occur; and

''(iv) include a description of the weight of the scientific evidence concerning risks, including mechanistic information (such as appropriate modes of action).

''(c) DATA AND INFORMATION SOURCES.—In making any decision with respect to a chemical substance under subsection (e) and sections 5 and 6, the Administrator shall consider data and information relevant to the substance that are reasonably available to the Administrator at that time, including data and information that are—

''(1) submitted to the Administrator by—

''(A) manufacturers and processors of the substance;

''(B) the public; or

''(C) a Governor of a State or a State agency with responsibility for protecting health or the environment;

''(2) submitted to a governmental body in another jurisdiction under a governmental requirement relating to the protection of human health and the environment, if the information is accessible to the Administrator;

''(3) derived through the application of scientifically reliable and relevant structure-activity relationship, or other methods or models to estimate the

environmental and human health effects, environmental and biological fate and behavior, and exposure potential for the substance;

''(4) inferred based on the degree of structural similarity or properties of the substance, or categories of substances, to those of 1 or more other chemical substances for which reliable information exists that is relevant to predicting the potential environmental or human health effects, environmental or biological fate and behavior, or exposure potential for the chemical substance; and

''(5) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible to the Administrator.

''(d) TRANSPARENCY.—

''(1) IN GENERAL.—Subject to section 14, the data and information considered by the Administrator in taking action under this Act shall be available to the public.

''(2) TYPES OF INFORMATION AVAILABLE TO THE PUBLIC.—The Administrator shall make available to the public the guidance, procedures, and tools used in evaluating data and information under

this section, including models, studies, and, as appropriate, the data underlying any study.

''(3) GUIDANCE.—Any written guidance of general applicability prepared by the Administrator under this Act shall be subject to public notice and an opportunity for comment.

''(e) PRIORITIZATION SCREENING PROCESS.—

''(1) IN GENERAL.—

''(A) PROCESS.—Not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall establish a risk-based screening process for identifying existing chemical substances that are—

''(i) a high priority for a safety assessment and determination under section 6, to be known as 'high-priority substances'; and

''(ii) a low priority for a safety assessment and determination, to be known as 'low-priority substances'.

''(B) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

''(i) CONSIDERATION OF ACTIVE SUBSTANCES.—In implementing the process

described in subparagraph (A), the Administrator shall only consider active substances, as determined under section 8(b)(6), as either high-priority substances or low-priority substances.

"(ii) CONSIDERATION OF INACTIVE SUBSTANCES.—In implementing the process described in subparagraph (A), the Administrator shall only consider inactive substances, as determined under section 8(b)(7), that the Administrator determines, on the basis of credible scientific evidence that—

"(I) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(II) demonstrate high hazard and high exposure.

"(C) TIMELY COMPLETION OF PRIORITIZATION PROCESS.—

"(i) IN GENERAL.—The Administrator shall make every effort to complete the prioritization of all active substances in a timely manner.

''(ii) CONSIDERATION.—The Administrator shall prioritize substances taking into consideration the ability of the Administrator to schedule and complete safety assessments and determinations under section 6 in a timely manner.

''(D) USE OF DATA.—In making a decision under the prioritization screening process, the Administrator shall use reasonably available data and information concerning the hazard, exposure, and use characteristics of chemical substances on the list developed by the Administrator under section 8(b)(1) at the time the decision is made.

''(E) SCREENING OF CATEGORIES OR CLASSES OF SUBSTANCES.—The Administrator may screen categories or classes of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate safety assessments and determinations.

''(F) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—From time to time the Administrator shall—

''(i) publish a list of chemical substances being considered in the prioritization screening process; and

''(ii) request the submission of data and information on the chemical substances.

''(2) PROPOSED PROCESS.—

''(A) IN GENERAL.—The Administrator shall—

''(i) publish for public comment a proposed prioritization screening process; and

''(ii) establish criteria for determining whether a substance is a high or low priority for a safety assessment and determination.

''(B) INITIAL LIST.—

''(i) IN GENERAL.—The proposal shall include an initial list of chemical substances that includes, at a minimum, those substances prioritized by the Administrator before the date of enactment of the Chemical Safety Improvement Act and for which assessments or safety determinations have not been completed, and proposed

prioritization outcomes based on the proposed criteria.

''(ii) CONTENTS.—The initial list shall contain as many chemical substances as the Administrator determines appropriate.

''(iii) MODIFICATION.—The Administrator may modify the initial list on the basis of comments received on the proposed process and criteria.

''(C) CRITERIA.—The criteria described in subparagraph (A) shall consider—

''(i) the recommendation of a Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances appropriate for prioritization screening;

''(ii) the hazard and exposure potential of the chemical substance (or category or class of substances), including specific scientific classifications and designations by authoritative governmental entities;

''(iii) the intended conditions of use or significant changes in the conditions of use of the chemical substance;

"(iv) evidence and indicators of exposure potential to humans or the environment from the chemical substance;

"(v) the volume of a chemical substance manufactured or processed;

"(vi) whether the volume of a chemical substance as reported under a regulation issued under section 8(a) (as in effect on the date on which the criteria are proposed) has significantly increased or decreased since a previous report or since the date on which a notice has been submitted under section 5(a);

"(vii) the availability of information about potential hazards and exposures needed for conducting a safety assessment or determination, with limited availability of relevant data and information to be a factor in designating a substance as a high priority; and

"(viii) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State reg-

ulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a low priority.

''(3) PRIORITIZATION SCREENING DECISIONS.—

''(A) IN GENERAL.—For the chemical substances considered for prioritization screening, the Administrator shall apply the criteria identified in paragraph (2), using the information identified in subsection (c), to identify a chemical substance as a high-priority substance or a low-priority substance.

''(B) ADDITIONAL TEST DATA.—If the Administrator determines that additional test data and information are needed to establish the priority of a chemical substance, the Administrator shall provide an opportunity for interested persons to submit data and information to the extent that it is reasonably ascertainable.

''(C) DEFERRING A DECISION.—If the Administrator determines that it is appropriate, the Administrator may defer a prioritization screening decision for a chemical substance under subparagraph (A) for a reasonable period

to allow for the submission and evaluation of additional data and information.

"(D) INTEGRATION OF DATA AND INFORMATION.—During the prioritization screening of a chemical substance, the Administrator shall integrate any hazard and exposure data and information related to a chemical substance available to the Administrator.

"(E) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(i) shall identify as a high-priority substance a chemical substance that, relative to other substances, has the potential for high hazard and high exposure;

"(ii) may identify as a high-priority substance a chemical substance that, relative to other substances, has the potential for high hazard or high exposure; and

"(iii) may identify as a high-priority substance an inactive substance, as determined under section 8(b)(7), that the Administrator determines, on the basis of credible scientific evidence that—

"(I) has not been subject to a regulatory action by the Adminis-

trator to ban or phase out the substance; and

"(II) demonstrates high hazard and high exposure.

"(F) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a low-priority substance a chemical substance that the Administrator on the basis of the available information determines is likely to meet the safety standard under the intended conditions of use.

"(G) NOTICE AND COMMENT.—The identifications made under subparagraphs (E) and (F) shall be subject to notice and an opportunity for comment.

"(H) ORDER OF SAFETY ASSESSMENTS.—

"(i) HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(I) shall determine the order for performing safety assessments on high-priority substances under section 6; and

"(II) may revise the order as the Administrator determines appropriate.

"(ii) LOW-PRIORITY SUBSTANCE.—The Administrator shall not perform safety assessments on low-priority substances, unless a low-priority substance is redesignated under subparagraph (I).

"(I) REVISION BASED ON NEW DATA.—

"(i) IN GENERAL.—Subject to subparagraph (D), at any time the Administrator may revise the identification of a chemical substance as a high-priority substance or a low-priority substance based on consideration of data or information made available to the Administrator after the date on which the Administrator makes the identification under subparagraphs (E) and (F).

"(ii) REEVALUATION.—

"(I) IN GENERAL.—The Administrator shall evaluate the data or information described in clause (i) on a high-priority substance or a low-priority substance for possible reevaluation of the priority of the substance.

"(II) LIMITED AVAILABILITY.—If limited availability of relevant data

and information was a factor in the original identification of a chemical substance as a high-priority substance, the Administrator shall re-evaluate the prioritization screening of the substance on receiving the relevant data and information.

''(J) PUBLICATION OF A LIST OF HIGH-PRIORITY AND LOW-PRIORITY SUBSTANCES.—

''(i) IN GENERAL.—The Administrator shall publish and keep current a list of high-priority substances and a list of low-priority substances.

''(ii) JUSTIFICATION.—Whenever the Administrator places a chemical substance on one of the lists described in clause (i) or changes the priority of the chemical substance, the Administrator shall include a justification for the decision in accordance with paragraph (2)(C).

''(K) REMOVAL.—The Administrator shall remove a chemical substance from the list of high-priority substances on the date on which a safety determination for the chemical substance is published.

''(L) EFFECT.—Subject to section 18, a decision by the Administrator under this paragraph with respect to a chemical substance shall not affect the manufacture, processing, distribution, use, or disposal of the chemical substance, or regulation of those activities.

''(4) EXPEDITED PRIORITIZATION SCREENING.—

''(A) IN GENERAL.—Not later than 180 days after the date on which the Administrator receives a recommendation and relevant data and information from a Governor of a State or a State agency with responsibility for protecting health and the environment that an active chemical substance be identified as a high-priority or low-priority substance, the Administrator shall make a prioritization screening decision for the substance.

''(B) NOTICE AND COMMENT.—The public shall be provided notice and an opportunity to comment on the recommendation described in subparagraph (A).

''(C) EXPLANATION OF REASONS.—The Administrator shall—

''(i) make available to the Governor or the appropriate State agency, as applicable, and to the public a brief explanation of reasons for identifying a chemical substance recommended by the Governor or the agency for prioritization screening as either a high-priority substance or a low-priority substance; and

''(ii) identify the information relied upon in making that identification.

''(5) FINAL AGENCY ACTION.—Any action by the Administrator under this subsection shall not be—

''(A) considered to be a final agency action; or

''(B) subject to judicial review.

''(f) DEVELOPMENT OF NEW TEST DATA AND INFORMATION.—

''(1) IN GENERAL.—The Administrator may require the development of new test data and information related to a chemical substance or mixture in accordance with this section if the Administration determines that the data and information are needed—

''(A) to perform a safety assessment;

''(B) to make a safety determination; or

''(C) to meet the testing needs of the implementing authority under another Federal statute.

''(2) FORM.—The Administrator may require the development of test data and information described in paragraph (1) by—

''(A) promulgating a rule;

''(B) entering into a testing consent agreement; or

''(C) issuing an order.

''(3) REQUIREMENTS.—

''(A) IN GENERAL.—In promulgating a rule, adopting a testing consent agreement, or issuing an order described in paragraph (2), the Administrator shall require the use of—

''(i) an evaluation framework that, prior to requiring additional testing of vertebrate animals, integrates relevant information from multiple sources, including, to the extent reliable—

''(I) toxicity information;

''(II) computational toxicology;

''(III) bioinformatics;

''(IV) high-throughput screening methods; and

''(V) scientifically reliable and relevant alternatives to vertebrate animal tests; and

''(ii) tiered testing in accordance with subsection (h), wherein the results of a screening level tier of tests relating to a toxicity pathway or target organ or target system inform the decision of the Administrator as to whether tests from a higher tier related to that pathway or organ or system are necessary.

''(B) STATEMENT TO THE PUBLIC.—The Administrator shall explain the basis for a decision made in subparagraph (A)(ii) in a statement made available to the public.

''(4) CONTENTS.—

''(A) IN GENERAL.—A rule, testing consent agreement, or order issued under paragraph (2) shall include—

''(i) identification of the chemical substance or mixture for which testing is required;

''(ii) identification of the persons required to conduct the testing;

''(iii) procedures for the development of test data and information for the chemical substance or mixture, including specific reference to reliable nonanimal test procedures; and

''(iv) specification of the period within which persons required to conduct the testing shall submit to the Administrator test data and information developed in accordance with the procedures described in clause (iii).

''(B) DURATION.—The period described in subparagraph (A)(iv) shall not be of an unreasonable duration.

''(C) CONSIDERATIONS.—In determining the procedures and period to be required under subparagraph (A), the Administrator shall consider—

''(i) the relative costs of the various test protocols and methodologies that may be required; and

''(ii) the reasonably foreseeable availability of facilities and personnel needed to perform the testing.

''(g) STATEMENT OF NEED.—

''(1) IN GENERAL.—In promulgating a rule, entering into a testing consent agreement, or issuing an order for development of additional data and information (including information on exposure or exposure potential) under subsection (f)(2), the Administrator shall issue a statement—

''(A) identifying the need intended to be met by the rule, agreement, or order;

''(B) explaining why existing data and information reasonably available to the Administrator at that time are inadequate to meet that need; and

''(C) encouraging, to the extent possible, the use of nonanimal test methods to develop additional data and information.

''(2) CONTENTS OF STATEMENT IN CASE OF ORDER.—

''(A) IN GENERAL.—If the Administrator issues an order, the statement described in paragraph (1) shall explain why good cause exists for issuance of an order instead of promul-

gating a rule or entering into a testing consent agreement.

''(B) CONTENTS.—A statement described in subparagraph (A) shall contain a discussion of—

''(i) data and information that are readily accessible to the Administrator, including data and information submitted under any other provision of law;

''(ii) the extent to which the Administrator has obtained or attempted to obtain the data and information through voluntary submissions;

''(iii) the extent to which the Administrator may use available data and information for structurally related substances (grouping or read-across), or use valid structure-activity relationship models or nonanimal test alternatives; and

''(iv) safety assessments, and the data and information relied on in the assessments, on other chemical substances to the extent relevant to the chemical substances that would be the subject of the rule or order.

''(h) TIERED TOXICITY TESTING AND EVALUATION.—

''(1) IN GENERAL.—The Administrator shall develop an evidence-based review system for conducting 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 systematic and transparent approach for assessing the overall weight of the evidence for observed biological or other effects, mechanistic information, and exposure.

''(2) TIERS.—Subject to subsections (b) and (c), the framework shall have 2 tiers.

''(A) TIER 1.—

''(i) IN GENERAL.—Tier 1 shall include both a screening level exposure assessment, including modeling if appropriate, and screening tests for hazard.

''(ii) USES OF SCREENING TESTS AND MODELING.—Screening tests for hazard (which may include, as appropriate, scientifically reliable and relevant in silico, in vitro, and focused in vivo tests) and expo-

sure information and modeling shall be used—

"(I) to screen chemical substances or mixtures for major toxic effects (including acute toxicity, subchronic toxicity, chronic toxicity, carcinogenicity, genotoxicity, developmental toxicity, and neurotoxicity); and

"(II) to direct planning for more complex and targeted testing in tier 2, if necessary.

"(B) TIER 2.—If the Administrator determines that additional testing is necessary, based on the results of tier 1 testing and modeling and any other available relevant information, tier 2 shall include—

"(i) an exposure assessment and tests for specific endpoints triggered on the basis of biologically based decisions; and

"(ii) an assessment of potential exposure using scientifically valid approaches.

"(3) GUIDANCE.—The Administrator shall prepare guidance for implementing this subsection and

review that guidance not less than once every 5 years thereafter.

''(i) REDUCTION OF ANIMAL-BASED TESTING.—

''(1) IN GENERAL.—The Administrator shall minimize the use of animals in testing of chemical substances or mixtures, including by—

''(A) encouraging and facilitating, to the maximum extent practicable—

''(i) the use of integrated and tiered testing and assessment strategies;

''(ii) the use of data and information of sufficient scientific quality in existence on the date on which the test is conducted;

''(iii) the use of test methods that eliminate or reduce the use of animals while providing test data and information of high scientific quality;

''(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful test data and information on others in the category;

''(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests;

''(vi) the submission of test data and information from animal-based studies and from emerging methods and models; and

''(vii) the use of exposure potential as a factor in decisions to require new testing; and

''(B) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

''(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not laboratory animal-based, the Administrator shall—

''(A) after providing an opportunity for public comment, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information used for any safety-standard determination made that reduce, refine, or replace the use of laboratory animals, including toxicity pathway-based risk assessment, in vitro

studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) beginning on the date that is 5 years after the date of enactment of the Chemical Safety Improvement Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this section; and

"(C) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of laboratory animals in any safety-standard determination made under this section.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct animal-based testing of a chemical substance or mixture under this title, the Administrator may adapt or waive the animal-testing requirement if the Administrator determines that—

"(A) there is sufficient evidence from several independent sources of information to sup-

port a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) because of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the material cannot be absorbed; or

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

"(C) a chemical substance or mixture cannot be tested in animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(j) TESTING REQUIREMENTS.—

"(1) PERSONS REQUIRED TO DEVELOP TEST DATA AND INFORMATION.—

''(A) IN GENERAL.—The Administrator may require the following persons to develop test data and information:

''(i) Manufacturers and processors of the chemical substance or mixture identified in subsection (f)(4)(A)(i).

''(ii) Persons who begin to manufacture or process such chemical substance or mixture—

''(I) after the effective date of the rule, testing consent agreement, or order; but

''(II) subject to subparagraph (C), before the period ending 180 days after the end of the period identified in subsection (f)(4)(A)(iv).

''(B) DESIGNATION.—The Administrator may permit 2 or more of the persons identified in subparagraph (A) to designate a person or a qualified third party—

''(i) to develop the data and information; and

''(ii) to submit the data and information on behalf of the persons making the designation.

''(C) EXEMPTIONS.—

''(i) IN GENERAL.—A person otherwise subject to a rule, testing consent agreement, or order under subsection (f) may submit to the Administrator an application for an exemption on the basis that the data and information are being developed by a person designated under subparagraph (B).

''(ii) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

''(I) IN GENERAL.—If the Administrator accepts an application submitted under clause (i), the Administrator shall direct the applicant to provide to the person designated under subparagraph (B) fair and equitable reimbursement, as agreed to between the applicant and the person designated.

''(II) ARBITRATION.—If the applicant and a person designated under subparagraph (B) cannot reach agreement on the amount of fair and equi-

table reimbursement, the amount shall be determined by arbitration.

''(iii) TERMINATION.—If, after granting an exemption under this subparagraph, the Administrator determines that no person has complied with the rule, testing consent agreement, or order, the Administrator shall—

''(I) by order terminate the exemption; and

''(II) notify in writing each person who received an exemption of the requirements with respect to which the exemption was granted.

''(2) TYPES OF HEALTH AND ENVIRONMENTAL DATA AND INFORMATION.—

''(A) IN GENERAL.—The Administrator may prescribe guidelines for the development of test data and information under subsection (f) for health and environmental information, including—

''(i) test data pertaining to acute toxicity, subchronic toxicity, chronic toxicity, carcinogenicity, genotoxicity, developmental

toxicity, and neurotoxicity that may be indicative of an adverse effect;

''(ii) test data and information pertaining to exposure to the chemical substance or mixture, including information regarding bioaccumulation, persistence, and the presence of the chemical substance or mixture in human blood, fluids, or tissue; and

''(iii) information pertaining to aggregate exposure, or other effects that may be considered in a safety assessment.

''(B) METHODOLOGIES.—

''(i) IN GENERAL.—The Administrator—

''(I) may prescribe methodologies in guidelines for the development of data and information; and

''(II) shall encourage the use of nonanimal methodologies.

''(ii) DEVELOPMENT OF GUIDELINES.—The Administrator may develop guidelines for evaluating data from biomonitoring studies.

''(iii) REQUIREMENT.—Prior to prescribing epidemiologic studies of employees, the Administrator shall coordinate with the Director of the National Institute for Occupational Safety and Health.

''(C) REVIEW.—Periodically, but not less frequently than once every 5 years, the Administrator shall—

''(i) review the adequacy of the guidelines for development of data and information prescribed under subparagraph (B);

''(ii) if necessary, institute proceedings to make appropriate revisions of the guidelines; and

''(iii) revise the guidelines as appropriate, particularly to—

''(I) reflect the availability of scientifically reliable and relevant non-animal test methods; and

''(II) eliminate obsolete methodologies that do not produce reliable and relevant results.

''(k) TRANSPARENCY.—Subject to section 14, the Administrator shall make available to the public all testing

consent agreements and orders and all data and information submitted under this section.''.

(b) CONFORMING AMENDMENTS.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended by striking ''section 4(e)'' and inserting ''section 4(l)''.

SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 (15 U.S.C. 2604) is amended—

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

''SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.'';

(2) in subsection (a)(1), in the matter following subparagraph (B)—

(A) by striking ''subsection (d)'' and inserting ''subsection (b)''; and

(B) by striking ''and such person complies with any applicable requirement of subsection (b)'';

(3) by striking subsection (b);

(4) by redesignating subsection (d) as subsection (b) and moving the subsection so as to appear after subsection (a);

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

(A) by striking paragraph (1) and inserting the following:

''(1) IN GENERAL.—The notice required by subsection (a) shall include, with respect to a chemical substance—

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

''(B) information regarding intended conditions of use and reasonably anticipated exposure.'';

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking ''or of data under subsection (b)'';

(ii) in subparagraph (A), by adding ''and'' after the semicolon at the end;

(iii) in subparagraph (B), by striking ''; and'' and inserting a period; and

(iv) by striking subparagraph (C); and

(C) in paragraph (3), by striking '', (b),'';

(6) by striking subsection (c) and inserting the following:

''(c) REVIEW OF NOTICE.—

''(1) INITIAL REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (a), the Administrator shall—

"(i) conduct an initial review of the notice;

"(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

"(iii) make any necessary determination under paragraph (4).

"(B) EXTENSION.—Except as provided in paragraph (6), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.

"(2) NOTICE OF COMMENCEMENT.—Unless the Administrator determines under paragraph (4)(A) that a chemical substance is not likely to meet the safety standard, at the end of the applicable period for review under paragraph (1), a chemical substance may be the subject of a notice of commencement 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 intended conditions of use, in which case the Administrator shall take appropriate action under paragraph (5);

''(B) the relevant chemical substance is likely to meet the safety standard under the intended conditions of use, in which case the Administrator shall allow the review period to expire without additional restrictions; or

''(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Adminis-

trator shall take appropriate action under paragraph (6).

''(5) PROHIBITIONS AND LIMITATIONS.—

''(A) IN GENERAL.—If the Administrator makes a determination under paragraph (4)(A) with respect to a notice, before the end of the applicable period for review under paragraph (1), the Administrator shall, by consent agreement or order, as appropriate—

''(i) prohibit manufacture of the chemical substance, or prohibit such manufacture without compliance with restrictions specified in a relevant consent agreement or order; or

''(ii) prohibit manufacture or processing of the chemical substance for a significant new use, or prohibit such manufacture or processing without compliance with restrictions specified in a relevant consent agreement or order.

''(B) INCLUSIONS.—A prohibition or limitation under subparagraph (A) may include, as appropriate—

''(i) a requirement that a chemical substance be marked with, or accompanied

by, clear and adequate warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the warnings and instructions to be prescribed by the Administrator;

''(ii) a requirement that manufacturers or processors, as applicable, of the chemical substance make and retain records of the processes used to manufacture or process the chemical substance;

''(iii) a requirement that manufacturers or processors, as applicable, monitor or conduct such additional tests as are reasonably necessary to ensure compliance with this Act, subject to section 4(g);

''(iv) a limitation on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

''(v) a limitation on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for a particular use;

"(vi) a prohibition or other regulation of the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

"(vii) a prohibition or other regulation of any method of commercial use of the chemical substance;

"(viii) a prohibition or other regulation of any method of disposal of the chemical substance;

"(ix) a prohibition on the manufacture, processing, or distribution in commerce of the chemical substance;

"(x) a prohibition on the manufacture, processing, or distribution in commerce of the chemical substance for a particular use; or

"(xi) such other requirements as the Administrator determines to be necessary.

"(6) ADDITIONAL DATA AND INFORMATION.—If the Administrator determines under paragraph (4)(C) that additional data and information (including, for example, information on exposure or exposure potential) are needed in order to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit such additional information;

"(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(C) on receipt of the information, shall promptly make a determination under paragraph (4); and

"(D) may take action under paragraph (5) pending receipt of the additional data and information, which may, as appropriate, permit the submitter of the notice to file a notice of commencement under subsection (d).";

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

"(d) NOTICE OF COMMENCEMENT.—

"(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer or processor that has submitted a notice under subsection (a) commences nonexempt commercial manufacture of a chemical substance or nonexempt commercial manufacture or processing of a chemical substance for a significant new use, as applicable, the manufacturer

or processor shall submit to the Administrator a notice of commencement that identifies—

''(A) the name of the manufacturer or processor; and

''(B) the initial date of nonexempt commercial manufacture or nonexempt commercial manufacture or processing for a significant new use.

''(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (a), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

''(e) FURTHER EVALUATION.—The Administrator may review a chemical substance under section 4(e) at any time after the Administrator receives—

''(1) a notice of commencement for a chemical substance under subsection (d); or

''(2) significant new information regarding the chemical substance.

''(f) TRANSPARENCY.—Subject to section 14, the Administrator shall make available to the public all notices, rules and orders of the Administrator, and all data and information submitted or issued under this section.'';

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

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

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking ''or (b)'';

(B) by striking paragraph (2);

(C) by redesignating paragraphs (3) through (6) as paragraphs (2) through (5), respectively;

(D) in paragraph (2) (as so redesignated), by striking ''subsections (a) and (b)'' and inserting ''subsection (a)'';

(E) in paragraph (3) (as so redesignated), in the first sentence, by striking ''will not present an unreasonable risk of injury to health or the environment'' and inserting ''is expected to meet the safety standard under the intended conditions of use'';

(F) in paragraph (4) (as so redesignated), by striking ''subsections (a) and (b)'' and inserting ''subsection (a)''; and

(G) in paragraph (5) (as so redesignated), in the first sentence, by striking ''paragraph (1) or (5)'' and inserting ''paragraph (1) or (4),''.

SEC. 6. SAFETY ASSESSMENTS AND DETERMINATIONS.

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

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

"SEC. 6. SAFETY ASSESSMENTS AND DETERMINATIONS.";

(2) by striking subsections (a) through (d) and inserting the following:

''(a) IN GENERAL.—The Administrator shall—

''(1) conduct a safety assessment of each high-priority substance in accordance with subsection (b);

''(2) make a safety determination for each high-priority substance; and

''(3) as appropriate based on the results of a safety determination, establish requirements for risk management of a high-priority substance.

''(b) SAFETY ASSESSMENTS.—

''(1) IN GENERAL.—The Administrator shall conduct a risk-based safety assessment of each high-priority substance, in accordance with such schedule as the Administrator establishes, to be based solely on considerations of risk to human health and the environment.

''(2) PROCEDURAL RULES.—

''(A) IN GENERAL.—The Administrator shall establish procedural rules for safety assessments and determinations under this sub-

section, including schedules for the submission of relevant data and information and the initiation and completion of safety assessments and safety determinations.

''(B) REQUIREMENTS.—

''(i) IN GENERAL.—The rules under subparagraph (A) shall—

''(I) identify the basis on which the Administrator shall decide which high-priority substances take precedence in the safety assessment and determination process;

''(II) require the Administrator to inform the public regarding—

''(aa) the approximate order in which safety assessments and determinations will be performed;

''(bb) the informational needs of the Administrator relating to the safety assessment and determination process;

''(cc) the importance of expeditiously completing safety assessments and determinations

and the need for rigorous evaluation of the data and information;

"(dd) the schedule by which each assessment and determination will be conducted; and

"(ee) subject to clause (ii), the deadline for the completion of each assessment and determination;

"(III) allow interested persons, including States, to submit information, including safety assessments, regarding high-priority substances that may facilitate the safety assessment and determination process; and

"(IV) subject to section 14, require the Administrator—

"(aa) to make available to the public the information taken into consideration in preparing each safety assessment and determination;

"(bb) to publish and provide an opportunity for comment on

proposed safety assessments and determinations; and

"(cc) to publish final safety assessments and determinations.

"(ii) DEADLINES.—

"(I) IN GENERAL.—The rules described in subparagraph (A) shall also include—

"(aa) a schedule by which each safety assessment and determination is expected to be conducted; and

"(bb) a deadline for the completion of each assessment and determination.

"(II) FLEXIBILITY AND REASONABLE EXTENSIONS.—The deadlines described in subclause (I)(bb)—

"(aa) may vary among chemical substances to grant the Administrator flexibility; and

"(bb) shall allow for reasonable extensions after an adequate public justification.

"(C) INCLUSIONS IN FINAL ASSESSMENTS.—Each safety assessment under this subsection shall include—

"(i) a weight-of-the evidence summary; and

"(ii) a nontechnical summary explaining what the relevant information demonstrates in the context of the intended conditions of use and exposure patterns of the chemical substance.

"(3) DATA AND INFORMATION SOURCES.—In conducting a safety assessment under this subsection, the Administrator shall, at a minimum, take into consideration—

"(A) the information described in section 4(c); and

"(B) any additional information submitted under paragraph (5).

"(4) METHODOLOGY.—

"(A) IN GENERAL.—The Administrator shall—

"(i) develop an appropriate science-based methodology for conducting safety assessments under this subsection, which shall include consideration of the weight of

the evidence for observed effects, mechanistic information, and exposure evaluations; and

''(ii) make the proposed methodology available for public comment and scientific peer review.

''(B) REVIEW AND REVISIONS.—Not later than 5 years after the date of enactment of the Chemical Safety Improvement Act, and not less frequently than once every 5 years thereafter, the Administrator—

''(i) shall review the methodology developed under subparagraph (A); and

''(ii) may revise the methodology to reflect new scientific developments or understandings, in accordance with subparagraph (A).

''(C) REQUIREMENTS.—The methodology shall apply scientifically recognized factors to address the following topics:

''(i) Strengths and limitations of study design.

''(ii) Reliability and relevance of test methods to human health and the environment.

''(iii) Quality of data.

''(iv) Use of good laboratory practices.

''(v) Peer review and peer review processes.

''(vi) Use of standardized protocols.

''(vii) Structured evaluative frameworks to determine the overall weight of the evidence, based on a review of positive and negative findings.

''(D) HAZARD, USE, AND EXPOSURE INFORMATION.—

''(i) IN GENERAL.—A safety assessment under this subsection shall evaluate existing hazard, use, and exposure information for the chemical substance under the intended conditions of use of the chemical substance, including information submitted by interested persons.

''(ii) EXPOSURE.—For purposes of evaluating exposure under clause (i), a safety assessment shall take into consideration—

''(I) exposures or significant subsets of exposures;

''(II) exposure duration, intensity, frequency, and number; and

''(III) the vulnerability of exposed subpopulations.

''(E) BEST AVAILABLE SCIENCE.—The Administrator shall use the best available science in conducting a safety assessment under this subsection.

''(5) ADDITIONAL TEST INFORMATION.—If the Administrator determines that additional test information is needed in order to make a safety assessment for a high-priority substance, the Administrator—

''(A) shall provide an opportunity for interested persons to submit the additional information;

''(B) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

''(C) may defer, for a reasonable period, a safety assessment until after receipt of the information.

''(6) TREATMENT.—A safety assessment under this subsection—

''(A) shall not be considered to be a final agency action; and

''(B) shall not be subject to judicial review.

''(c) SAFETY DETERMINATION.—

''(1) IN GENERAL.—As soon as possible after the date on which the safety assessment is completed for a high-priority substance under subsection (b), the Administrator shall determine whether the chemical substance meets the safety standard under the intended conditions of use of the chemical substance.

''(2) DETERMINATIONS.—Based on a review of the information described in paragraph (3), the Administrator shall determine, based solely on considerations of risk to human health and the environment, that—

''(A) the relevant chemical substance meets the safety standard under intended conditions of use;

''(B) the relevant chemical substance does not meet the safety standard under intended conditions of use, in which case the Administrator shall impose additional restrictions, as appropriate, under paragraph (9); or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (8).

"(3) CONSIDERATIONS.—In making a safety determination under this subsection, the Administrator shall take into consideration and publish a statement that includes, at a minimum—

"(A) the safety assessment for the chemical substance, including the uses considered in the assessment and any uses that are considered critical or essential;

"(B) the range of exposure to the chemical substance under the intended conditions of use of the chemical substance and appropriate reference parameters;

"(C) the weight of the evidence of risk posed by the chemical substance under the intended conditions of use of the chemical substance; and

"(D) the magnitude of the risk posed by the chemical substance under the intended conditions of use of the chemical substance.

''(4) INFORMATION SOURCES.—In making a safety determination under this subsection, the Administrator shall take into consideration, at a minimum—

''(A) the information described in section 4(c); and

''(B) the safety assessment conducted with respect to the chemical substance under subsection (b).

''(5) BEST AVAILABLE SCIENCE.—The Administrator shall use the best available science in making a safety determination under this subsection.

''(6) NOTICE AND COMMENT.—Subject to section 14, the Administrator shall provide notice and an opportunity for public comment on each proposed safety determination under this subsection.

''(7) TRANSPARENCY.—Subject to section 14, the Administrator shall publish—

''(A) each safety determination under this subsection, together with a summary of the information considered in the determination;

''(B) a summary of the evaluation by the Administrator of the information; and

''(C) an explanation of the reasons for the determination.

''(8) ADDITIONAL TEST DATA AND INFORMATION.—If the Administrator determines that additional test data and information is needed in order to make a safety determination for a high-priority substance, the Administrator—

''(A) shall provide an opportunity for interested persons to submit the additional data and information;

''(B) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the data and information;

''(C) may defer, for a reasonable period, a safety determination until after receipt of the data and information; and

''(D) on receipt of the data and information, shall make a determination under paragraph (2).

''(9) ADDITIONAL RESTRICTIONS.—

''(A) IN GENERAL.—

''(i) DETERMINATION.—If the Administrator makes a determination under paragraph (2)(B) with respect to a chemical substance, the Administrator shall promulgate a rule establishing necessary re-

strictions (based on the weight of the evidence of risk and the magnitude of risk), including if appropriate, a ban or phase out of the manufacture, processing, or use of the chemical substance in accordance with subparagraph (C).

''(ii) RULES.—Rules promulgated under this section may apply to mixtures containing the chemical substance, as appropriate.

''(B) INCLUSIONS.—A restriction under subparagraph (A) may include, as appropriate—

''(i) a requirement that a chemical substance be marked with, or accompanied by, clear and adequate warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the warnings and instructions to be prescribed by the Administrator;

''(ii) a requirement that manufacturers and processors of the chemical substance—

''(I) make and retain records of the processes used to manufacture or process the chemical substance; and

''(II) subject to section 4(f), develop test information that is reasonably necessary to ensure compliance with this Act;

''(iii) a limitation on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

''(iv) a requirement to ban or phase out or other regulation on the manufacture, processing, or distribution in commerce of the chemical substance—

''(I) for a particular use; or

''(II) for a particular use at a concentration in excess of a level specified by the Administrator;

''(v) a limitation on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

''(I) for a particular use; or

"(II) for a particular use at a concentration in excess of a level specified by the Administrator;

"(vi) a requirement to ban or phase out or other regulation of any method of commercial use of the chemical substance;

"(vii) a requirement to ban or phase out or other regulation of any method of disposal of the chemical substance or any article containing the chemical substance;

"(viii) a requirement directing manufacturers or processors of the chemical substance to give notice of unreasonable risks of harm to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance; and

"(ix) such other requirements as the Administrator determines to be necessary.

"(C) BANS AND PHASE OUTS.—The Administrator shall base a determination under subparagraph (A) that a ban or phase out of the manufacture, processing, or use of a chem-

ical substance is necessary on the considerations described in subparagraph (D).

''(D) DETERMINATION THAT CHEMICAL SUBSTANCE DOES NOT MEET SAFETY STANDARD.—If the Administrator determines that the chemical substance does not meet the safety standard under the intended conditions of use, the Administrator shall consider and publish a statement on—

''(i) the availability of technically and economically feasible alternatives for the chemical substance under the intended conditions of use;

''(ii) the risks posed by those alternatives as compared to those of the chemical substance;

''(iii) the economic and social costs and benefits of the proposed regulatory action and options considered, and of potential alternatives; and

''(iv) the economic and social benefits and costs of—

''(I) the chemical substance;

''(II) alternatives to the chemical substance; and

''(III) any necessary restrictions on the chemical substance or alternatives.

''(10) EXEMPTIONS.—The Administrator may exempt the use of a chemical substance from any additional restriction established under paragraph (9) if the Administrator determines that—

''(A) the exemption is in the interest of national security;

''(B) the lack of availability of the chemical substance would cause significant disruption in the national economy;

''(C) the use for which the exemption is sought is a critical or essential use for which—

''(i) no feasible alternative for the use would materially reduce risk to health or the environment; or

''(ii) no feasible alternative for the use is economically, technically, or efficiently available; or

''(D) the use, as compared to reasonably available alternatives, provides a net benefit to human health, the environment, or public safety.

''(11) FINAL AGENCY ACTION.—A safety determination under this subsection shall be—

''(A) considered to be a final agency action; and

''(B) subject to judicial review, including review of the associated safety assessment under this subsection.'';

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

(4) in subsection (d) (as so redesignated)—

(A) by striking paragraph (4); and

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

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—

''(A) seizure of an imminently hazardous chemical substance or mixture or any article containing the substance or mixture;

''(B) relief (as authorized by subsection (b)) against any person who manufactures, processes, distributes in commerce, uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing the substance or mixture; or

''(C) both seizure described in subparagraph (A) and relief described in subparagraph (B).

''(2) RULE, ORDER, OR OTHER PROCEEDING.—A civil action may be commenced under this paragraph notwithstanding—

''(A) the existence of—

''(i) a decision by the Administrator under section 4(c)(3), 5(c)(4), or 6(c)(2); or

''(ii) a rule, testing consent agreement, or order under section 4(f), 5(g), 6(b)(5), 6(c)(8), 6(c)(9), or 6(d); or

''(B) the pendency of any administrative or judicial proceeding under any provision of this Act.'';

(2) in subsection (d), by striking ''section 6(a)'' and inserting ''section 6(c)''; and

(3) in subsection (f), in the first sentence, by striking ''and unreasonable''.

SEC. 8. INFORMATION COLLECTION AND REPORTING.

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

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

''(4) REGULATIONS.—

''(A) IN GENERAL.—The Administrator shall promulgate rules requiring the reporting of information known by, or reasonably ascertainable by, the person making the report, including rules requiring processors to report information, so that the Administrator has the information necessary to carry out sections 4 and 6.

''(B) CONTENTS.—The rules promulgated under subparagraph (A)—

''(i) may impose different reporting requirements on manufacturers and processors;

''(ii) shall be limited to active substances or mixtures containing active substances as designated under subsection (b); and

''(iii) shall apply only to the extent the Administrator determines the submission of reports is necessary for the effective enforcement of this Act.

''(5) GUIDANCE.—The Administrator shall develop guidance relating to the information required to be reported under the rules promulgated under this subsection that—

''(A) include the level of detail necessary to be reported; and

''(B) describes the manner by which manufacturers and processors may report use and exposure information on a voluntary basis.'';

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

''(3) NOMENCLATURE.—

''(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

''(i) maintain the use of Class 2 nomenclature in use on date of enactment of the Chemical Safety Improvement Act;

''(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III

of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a); and

"(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

"(I) cement, Portland, chemicals, CAS No. 65997–15–1;

"(II) cement, alumina, chemicals, CAS No. 65997–16–2;

"(III) glass, oxide, chemicals, CAS No. 65997–17–3;

"(IV) frits, chemicals, CAS No. 65997–18–4;

"(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

"(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—In the event that existing guidance allows for multiple nomenclature conventions, the Administrator shall—

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on that new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

''(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

''(4) CANDIDATE LIST OF ACTIVE SUBSTANCES IN COMMERCE.—

''(A) IN GENERAL.—Subject to section 14, the Administrator shall make publicly available a candidate list of active chemical substances, which shall include—

''(i) any chemical substance reported under part 711 of title 40, Code of Federal Regulations, as in effect on the date of enactment of the Chemical Safety Improvement Act, during the period beginning on the date that is 10 years before the date of enactment of the Chemical Safety Improvement Act and ending on the date of enactment of the Chemical Safety Improvement Act;

"(ii) any chemical substance for which a notice of commencement of manufacture has been submitted;

"(iii) any chemical substance for which a significant new use notice has been submitted;

"(iv) any chemical substance for which an export notification has been submitted during the period beginning on the date that is 10 years before the date of enactment of the Chemical Safety Improvement Act and ending on the date of enactment of the Chemical Safety Improvement Act; and

"(v) any other chemical substance identified by the Administrator as likely to qualify as active.

"(B) RULE.—The Administrator shall, by rule, require manufacturers and processors to notify the Administrator that the manufacturer or processor, as applicable, has manufactured or processed a chemical substance on the list described in subparagraph (A), or the list published under paragraph (1) for a nonexempt commercial purpose during the 5-year period

prior to the date of enactment of the Chemical Safety Improvement Act.

''(C) GUIDANCE.—Before issuing a final rule under subparagraph (A), the Administrator shall make publicly available guidance relating to the rule for chemical substances on the confidential portion of the candidate list of active substances and of the list published under paragraph (1), including —

''(i) accession numbers;

''(ii) premanufacture notice case numbers, if applicable; and

''(iii) generic names.

''(D) CONFIDENTIAL CHEMICAL SUBSTANCES.—The rule under subparagraph (B) shall require a manufacturer or processor that is reporting information relating to a chemical substance on the confidential portion of the list published under paragraph (1) to indicate whether the manufacturer or processor claims the specific identity of the substance as confidential pursuant to section 14.

''(E) CERTIFICATION.—The rule under subparagraph (B) shall require a manufacturer or processor—

''(i) to certify the accuracy of each report of the manufacturer or processor carried out under the rule; and

''(ii) to retain a record supporting that certification for a period of 5 years beginning on the last day of the submission period.

''(F) APPLICABILITY.—Nothing in this paragraph requires the resubstantiation of a claim for protection against disclosure for information submitted to the Administrator prior to the date of enactment of the Chemical Safety Improvement Act.

''(5) LIST.—

''(A) IN GENERAL.—Based on the notifications received in response to the rule under paragraph (4), the Administrator shall designate each chemical substance that is on the list published under paragraph (1) on the date of enactment of the Chemical Safety Improvement Act as active or inactive.

''(B) UPDATE.—The Administrator shall update the list of chemicals designated as active or inactive as soon as practicable following the publication of the most recent data reported

under part 711 of title 40, Code of Federal Regulations.

''(6) ACTIVE SUBSTANCES.—The Administrator shall designate as an active substance—

''(A) a chemical substance that has been manufactured or processed for a nonexempt commercial purposes at any point during the 5-year period prior to the date of enactment of the Chemical Safety Improvement Act;

''(B) a chemical substance that is added to the list published under paragraph (1) after the date of enactment of the Chemical Safety Improvement Act;

''(C) a chemical substance for which a notice is received under paragraph (7)(C); and

''(D) a chemical substance reported under part 711 of title 40, Code of Federal Regulations, after the date of enactment of the Chemical Safety Improvement Act.

''(7) INACTIVE SUBSTANCES.—

''(A) IN GENERAL.—The Administrator shall designate as an inactive substance each chemical substance on the list published under paragraph (1) that has not been manufactured or processed for a nonexempt commercial pur-

pose in the 5-year period ending on the date of enactment of the Chemical Safety Improvement Act.

"(B) TREATMENT.—Each inactive substance shall remain on the list published under paragraph (1).

"(C) CHANGE TO ACTIVE STATUS.—

"(i) IN GENERAL.—Any person who intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the substance is manufactured or processed.

"(ii) ACTIVE STATUS.—On receiving notification under clause (i), the Administrator—

"(I) shall designate the chemical substance as an active substance; and

"(II) shall, pursuant to section 4(e), review the priority of the chemical substance as the Administrator determines necessary.

''(D) CATEGORY STATUS.—The list of inactive chemical substances shall not be considered a category for purposes of section 26(c).

''(8) PUBLIC PARTICIPATION.—

''(A) IN GENERAL.—Subject to subparagraph (B), the Administrator shall make available to the public—

''(i) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (5) that the Administrator has designated as an active substance;

''(ii) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as an inactive substance;

''(iii) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received; and

"(iv) the specific identity of any active or inactive substance on the confidential portion of the list published under paragraph (1) for which no claim of confidentiality was received, subject to the condition that, before revealing the specific identity of the substance, the Administrator shall—

"(I) publish a notice in the Federal Register identifying the accession number, generic name, and, if applicable, premanufacture notice case number for that substance; and

"(II) provide an opportunity for any person—

"(aa) to certify to the Administrator that the person intends to manufacture or process the substance at any point in the subsequent 4-year period; and

"(bb) to claim confidentiality for the specific identity of the substance.

"(B) CONFIDENTIALITY.—Subject section 14, the Administrator shall not make available

to the public the specific chemical identity of any substance for which the Administrator receives a notice under subparagraph (A)(iv).''; and

(3) in subsection (e)—

(A) by striking ''Any person'' and inserting the following:

''(1) IN GENERAL.—Any person''; and

(B) by adding at the end the following:

''(2) APPLICABILITY.—Any person may submit to the Administrator data and information reasonably supporting the conclusion that a chemical substance or mixture does not present a substantial risk of injury to health and the environment.''.

SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.

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

(1) in subsection (a)—

(A) in the first sentence of paragraph (1)—

(i) by striking ''presents or will present an unreasonable risk to health or the environment'' and inserting ''does not meet the safety standard under the intended conditions of use''; and

(ii) by striking ''such risk'' the first place it appears and inserting ''the risk posed by the substance or mixture'';

(B) in paragraph (2), in the matter following subparagraph (B), by striking ''section 6 or 7'' and inserting ''paragraph (8) or (9) of subsection (c) of section 6 or section 7''; and

(C) in paragraph (3), by striking ''section 6 or 7'' and inserting ''paragraph (8) or (9) of subsection (c) of section 6 or section 7''; and

(2) in subsection (d), in the first sentence, by striking ''Health, Education, and Welfare'' and inserting ''Health and Human Services''.

SEC. 10. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA.

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:

''(2) EXCEPTION.—Paragraph (1) shall not apply to any chemical substance that the Administrator determines—

''(A) under section 5 is not likely to meet the safety standard under the intended conditions of use of the chemical substance; or

''(B) under section 6 does not meet the safety standard under the intended conditions of use of the chemical substance.

''(3) WAIVERS.—For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—

''(A) determine that paragraph (1) shall not apply to that mixture or article; and

''(B) establish a threshold concentration in a mixture or article at which paragraph (1) shall not apply.'';

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

''(b) NOTICE.—

''(1) IN GENERAL.—A person shall notify the Administrator that the person is exporting or intends to export to a foreign country—

''(A) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 5 is not likely to meet the safety standard under the

intended conditions of use of the chemical substance;

''(B) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 6 does not meet the safety standard under the intended conditions of use of the chemical substance; or

''(C) a chemical substance for which the United States is obligated by treaty to provide export notification.

''(2) REGULATIONS.—

''(A) IN GENERAL.—The Administrator shall promulgate regulations to carry out paragraph (1).

''(B) CONTENTS.—The regulations promulgated under subparagraph (A) shall—

''(i) include any exemptions the Administrator determines to be appropriate, which may include exemptions identified under section 5(g); and

''(ii) indicate whether or to what extent the regulations apply to articles containing a chemical substance or mixture described in paragraph (1).

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

"(A) for a chemical substance or mixture described in subparagraph (A) or (B) of paragraph (1), a notice that information on the chemical substance or mixture can be obtained from the Administrator, unless the Administrator determines that good cause exists not to provide the notice; and

"(B) for a chemical substance described in paragraph (1)(C), a notice that satisfies the obligation of the United States under the applicable treaty."; and

(3) in subsection (c)—

(A) by striking paragraph (3); and

(B) by redesignating paragraphs (4) through (6) as paragraphs (3) through (5), respectively.

SEC. 12. IMPORTS.

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

"SEC. 13. IMPORTS.

''(a) DEFINITION OF CHEMICAL SUBSTANCE OR MIXTURE.—In this section, the term 'chemical substance or mixture' includes—

''(1) a mixture containing a chemical substance or mixture; and

''(2) an article containing a chemical substance or mixture.

''(b) REFUSAL OF ENTRY.—

''(1) IN GENERAL.—The Secretary of Homeland Security shall refuse entry into the customs territory of the United States (as defined in general note 2 to the Harmonized Tariff Schedule of the United States) any chemical substance or mixture offered for such entry if—

''(A) the Administrator has determined under section 6(c) that the chemical substance or mixture does not meet the safety standard under the intended conditions of use of the chemical substance; or

''(B) the chemical substance or mixture is offered for entry in violation of a rule or order in effect under this Act.

''(2) PROCEDURE.—

''(A) IN GENERAL.—Subject to subparagraph (B), if a chemical substance or mixture

is refused entry under paragraph (1), the Secretary of Homeland Security—

"(i) shall notify the consignee of the entry of the refusal;

"(ii) shall not release the chemical substance or mixture to the consignee; and

"(iii) shall cause the disposal or storage of the chemical substance or mixture under such rules as the Secretary may prescribe, if the chemical substance or mixture has not been exported by the consignee in the 90-day period beginning on the date of receipt of the notice of the refused entry.

"(B) EXCEPTION.—

"(i) IN GENERAL.—The Secretary of Homeland Security may, pending a review by the Administrator, release to the consignee the chemical substance or mixture if the consignee—

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

"(II) pays a duty on the chemical substance or mixture.

"(ii) ADMINISTRATION.—If a consignee fails to return a chemical substance or mixture released to that consignee under clause (i) for any cause to the custody of the Secretary of Homeland Security when demanded, the consignee shall be liable to the United States for liquidated damages equal to the full amount of the bond.

"(C) STORAGE.—All charges for storage, cartage, and labor on and for the disposal of a chemical substance or mixture that is refused entry or released under this subsection shall be paid by the owner or consignee, and a default on that payment shall constitute a lien against any future entry made by the owner or consignee.

"(c) NOTICE.—

"(1) IN GENERAL.—A person offering a chemical substance or mixture subject to this Act for entry into the customs territory of the United States shall—

''(A) certify to the Secretary of Homeland Security that, after reasonable inquiry and to the best knowledge and belief of the person, the chemical substance or mixture is—

''(i) in compliance with any applicable rule, consent agreement, or order under section 5 or 6; and

''(ii)(I) included on the list under section 8(b); or

''(II) exempt from any requirement to be included on that list; and

''(B) provide to the Secretary of Homeland Security any notice required under paragraph (2).

''(2) NOTICE.—A person offering a chemical substance or mixture for entry into the customs territory of the United States shall notify the Secretary of Homeland Security if—

''(A) the chemical substance is a high-priority substance;

''(B) the chemical substance is a chemical for which the United States is obligated to provide export notification by treaty; or

''(C) the chemical substance or mixture or any article containing the substance or mixture—

''(i) is the subject of a safety assessment and safety determination conducted pursuant to section 6 and has been found not to meet the safety standard; and

''(ii) is identified in a rule promulgated by the Secretary of Homeland Security pursuant to subsection (c) as meriting notification due to the potential impact of the chemical substance or mixture or any article containing the substance or mixture on human health or the environment.

''(d) RULES.—The Secretary of Homeland Security, after consultation with the Administrator, shall issue rules for the administration of subsection (c), including whether, or to what extent, the provisions of subsections (b) and (c) apply.''.

SEC. 13. CONFIDENTIAL INFORMATION.

Section 14 (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

''(a) IN GENERAL.—Except as provided in subsections (c) and (e), the Administrator shall not disclose information described in subsection (b)—

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

''(2) for which the requirements of subsection (d) are met.

''(b) INFORMATION GENERALLY PROTECTED FROM DISCLOSURE.—

''(1) IN GENERAL.—Information referred to in subsection (a) includes confidential information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section.

''(2) PRESUMPTION OF PROTECTION.—The following information submitted by a manufacturer, processor, or distributor is presumed to be protected from disclosure:

''(A) Specific information describing the manufacture, processing, or distribution in commerce of a chemical substance, mixture, or article.

''(B) Marketing and sales information.

''(C) Information identifying suppliers or customers.

''(D) The identity of constituents in a mixture and the respective percentages of those constituents.

''(E) Specific information about the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

''(F) Specific production or import volumes of a manufacturer and specific volumes aggregated across manufacturers if the Administrator determines that disclosure of the aggregated data could reveal confidential information.

''(G) The specific identity of a chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if—

''(i) the specific identity was claimed as confidential information at the time it was submitted; and

''(ii) the claim has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (g).

"(c) INFORMATION NOT PROTECTED FROM DISCLOSURE.—

"(1) IN GENERAL.—Notwithstanding subsections (a) and (b), and except as provided in paragraph (2), the following information shall not be protected from disclosure:

"(A) For information submitted after the date of enactment of the Chemical Safety Improvement Act, the identity of a chemical substance if the person submitting the information does not meet the requirements of subsection (d).

"(B) A safety assessment developed or a safety determination made under section 6.

"(C) Health and safety data that are submitted under this Act with respect to a chemical substance or mixture that has been offered for commercial distribution as of the date on which the study is to be disclosed or for which testing is required under section 4.

"(D) Health and safety data in notices of substantial risk submitted under section 8(e) and in the underlying studies.

"(E) General information describing the manufacturing volumes, expressed in ranges would not reveal confidential information.

"(F) General descriptions of industrial, commercial, or consumer functions and uses of a chemical substance or mixture.

"(2) EXCEPTION.—Information elements contained in submissions described in paragraph (1) that are otherwise eligible for protection under this section shall be protected from disclosure if the submitter complies with subsection (d).

"(d) REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—

"(1) CLAIMS.—

"(A) IN GENERAL.—For information to be protected from disclosure under this section, a person who submits information to the Administrator under this Act shall—

"(i) indicate the information that the person believes is entitled to protection from disclosure under this section in a submission to the Administrator in such manner and at such time as the Administrator shall prescribe; and

''(ii) except in the case of information described in subparagraphs (A) through (F) of subsection (b)(2), submit written documentation justifying why the information qualifies for protection from disclosure.

''(B) CERTIFICATION.—An authorized official of the person described in subparagraph (A) shall certify that the information that has been submitted is true and correct.

''(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS FOR CHEMICAL IDENTITIES.—A person submitting information under this Act related to a chemical identity and who claims protection from disclosure for that identity shall provide the Administrator with—

''(A) information establishing that—

''(i) the person takes reasonable measures to protect the confidentiality of the chemical identity;

''(ii) the chemical identity is not required to be disclosed, or otherwise made available, to the public under any other Federal law in connection with 1 or more uses subject to this Act;

"(iii) disclosure of the chemical identity is likely to cause substantial harm to the competitive position of the person; and

"(iv) the chemical identity is not reasonably believed to be readily discoverable through reverse engineering;

"(B) the time period for which protection of the chemical identity from disclosure is necessary;

"(C) a generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name discloses a maximum amount of information on the chemical structure of the substance while protecting those features of the chemical structure that are considered confidential and the disclosure of which would potentially harm the competitive position of the person; and

"(D) in the event the Administrator makes a request under subsection (f)—

"(i) redocumentation and recertification of the information submitted under subsection (a); or

''(ii) withdrawal of the claim for protection of the chemical identity from disclosure.

''(3) GUIDANCE.—The Administrator shall develop guidance, after notice and opportunity to comment, on the determination of generic names for confidential chemical identities.

''(e) EXCEPTIONS TO PROTECTION FROM DISCLOSURE.—Subsection (a) shall not apply if—

''(1) the information is to be disclosed to an officer or employee of the United States in connection with the official duties of that person under any law for the protection of human health or the environment or for specific law enforcement purposes;

''(2) the information is to be disclosed to a contractor with the United States and employees of that contractor if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act and under such conditions as the Administrator shall specify;

''(3) the Administrator determines that disclosure is necessary to protect human health or the environment;

''(4) the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, if—

''(A) 1 or more applicable agreements with the Administrator ensure that the recipient government will take appropriate steps, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures as stringent as those which the Administrator uses to safeguard the information; and

''(B) the Administrator notifies the person who submitted the information that the information has been disclosed to a State or political subdivision of a State;

''(5) a health professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and a written confidentiality agreement, subject to the conditions that—

''(A) the written statement of need is a statement that the person has a reasonable basis to suspect that—

"(i) the information is needed for purposes of diagnosis or treatment of 1 or more individuals;

"(ii) 1or more individuals being diagnosed or treated have been exposed to the chemical substance concerned; and

"(iii) knowledge of the specific chemical identity of the chemical substance will assist in diagnosis or treatment; and

"(B) the confidentiality agreement provides that the person will not use the specific chemical identity for any purpose other than the health needs asserted in the statement of need, except as may otherwise be authorized by the terms of the agreement or by the person submitting the specific chemical identity to the Administrator;

"(6) a treating physician or nurse requests the information, subject to the conditions that—

"(A) the treating physician or nurse determines that—

"(i) a medical emergency exists;

"(ii) the specific chemical identity of the chemical substance concerned is nec-

essary for or will assist in emergency or first-aid diagnosis or treatment; and

''(iii) the 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned;

''(B) if requested by the person submitting the specific chemical identity to the Administrator, the treating physician or nurse provides a written statement of need and a confidentiality agreement as described in paragraph (5); and

''(C) the written confidentiality agreement or statement of need is submitted as soon as practicable, but not necessarily before the information is disclosed;

''(7) the Administrator determines that disclosure is necessary in a proceeding under this Act, subject to the condition that the disclosure is made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding; or

''(8) the information is to be disclosed, on written request of any duly authorized committee of the Congress, to that committee.

''(f) DURATION OF PROTECTION FROM DISCLOSURE.—

''(1) IN GENERAL.—The Administrator shall protect from disclosure information described in subsection (b) that meets the requirements of subsection (d)(2) for the period of time requested by the person submitting the claim or for such period of time as the Administrator, after reviewing the request for confidential treatment and the documentation, otherwise determines to be reasonable, unless—

''(A) prior to the expiration of the period, the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case, the Administrator shall promptly make the information available to the public; or

''(B) prior to the expiration of the period, the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in subsection (g)(2).

''(2) REDOCUMENTATION.—The Administrator may request—

''(A) at any time, a person who has requested protection from disclosure for the iden-

tity of a substance under subsection (d) to redocument the confidentiality claim of the person; and

''(B) any person who has requested that confidential information be protected from disclosure under section 8(b) to reassert the confidentiality claim of the person after the chemical substance is identified as a high-priority substance under section 4(e).

''(g) DUTIES OF THE ADMINISTRATOR.—

''(1) DETERMINATION.—

''(A) IN GENERAL.—Except as provided in subsection (b)(2), the Administrator shall—

''(i) review a request received under this section to maintain the confidentiality of information submitted under this Act; and

''(ii) determine whether to approve, modify, or deny that request.

''(B) DENIAL OR MODIFICATION.—

''(i) IN GENERAL.—The Administrator shall deny a claim to protect a chemical identity from disclosure only if the person who has submitted the request fails to meet the requirements of subsection (d).

''(ii) REASONS FOR DENIAL OR MODIFICATION.—The Administrator shall provide to the person who has submitted the request a written statement of the reasons for the denial or modification of the claim.

''(C) SUBSETS.—If it is not feasible for the Administrator to review each request under this section, the Administrator shall review a representative subset.

''(2) NOTIFICATION.—

''(A) IN GENERAL.—Except as provided in subsections (c) and (e), if the Administrator denies a request under paragraph (1), the Administrator shall notify, in writing and by certified mail, the person who submitted the request of the intent of the Administrator to release the information.

''(B) RELEASE OF INFORMATION.—

''(i) IN GENERAL.—Except as provided in clause (ii), the Administrator may not release information under this subsection until the date that is 30 days after the date on which the person who submitted the request receives notification under subparagraph (A).

''(ii) EXCEPTIONS.—

''(I) IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator may not release that information until the date that is 15 days after the date on which the person who submitted the request receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to human health or the environment, in which case, no prior notification is necessary.

''(II) NO NOTIFICATION.—For information under paragraph (6) or (7) of subsection (e), no prior notification is necessary.

''(3) APPEALS.—

''(A) IN GENERAL.—A person who receives notification under this subsection may, if the person believes disclosure of the information is prohibited under subsection (a), before the date on which the information is to be released,

bring an action to restrain disclosure of the information in—

"(i) the district court of the United States in the district in which—

"(I) the complainant resides or has the principal place of business; or

"(II) the information is located; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information under this section prior to the date on which the applicable court rules on an action under subparagraph (A).

"(4) ADMINISTRATION.—In carrying out this subsection, the Administrator shall employ the procedures in part 2 of title 40, Code of Federal Regulations (or successor regulations).

"(h) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.—

"(1) IN GENERAL.—Subject to paragraph (2), any officer or employee of the United States or former officer or employee of the United States, who—

''(A) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

''(B) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material, shall be—

''(i) guilty of a misdemeanor and fined under title 18, United States Code, imprisoned for not more than 1 year, or both; and

''(ii) removed from office or employment.

''(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

''(3) CONTRACTORS.—For the purposes of this subsection, any contractor of the United States who is furnished information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

''(i) APPLICABILITY.—Except as otherwise provided in this section, the Administrator shall have no authority—

''(1) to require the documentation or redocumentation of a claim for the protection from disclosure of information submitted to the Administrator under this Act prior to the date of enactment of the Chemical Safety Improvement Act; or

''(2) to impose redocumentation requirements under this Act that are more extensive than those required under this section.''.

SEC. 14. PROHIBITED ACTS.

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

''(1) fail or refuse to comply with—

''(A) any rule promulgated, consent agreement entered into, or order issued under section 4;

''(B) any requirement prescribed by section 5 or 6;

''(C) any rule promulgated, consent agreement entered into, or order issued under section 5 or 6;

''(D) any requirement of title II or any rule promulgated or order issued under title II; or

''(E) any requirement of title VII or any rule promulgated or order issued under title VII;''.

SEC. 15. PREEMPTION.

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

''(a) IN GENERAL.—Except as provided in subsections (c) and (d), no State or political subdivision of a State may establish or continue to enforce—

''(1) a requirement for the development of test data or information on a chemical substance or category of substances that is reasonably likely to produce the same data and information required under section 4, 5, or 6 by—

''(A) a rule promulgated by the Administrator;

''(B) a consent agreement entered into by the Administrator; or

''(C) an order issued by the Administrator;

''(2) a prohibition or restriction on the manufacture, processing, or distribution in commerce or 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 review 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.—Except 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 manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance identified under section 4(e)(3) (as of the date on which the Administrator publishes a schedule under section 6(b)); or

''(2) a prohibition or restriction on the manufacture, processing, distribution in commerce or use of a chemical substance that is a low-priority substance identified under section 4(e)(3).

''(c) EXCEPTIONS.—Subsections (a) and (b) shall not apply to a requirement, prohibition, or restriction of a State or a political subdivision of a State that—

''(1) is adopted under the authority of any other Federal law;

''(2) implements a reporting or information collection requirement not otherwise required by the Administrator under this Act or required under any other Federal law; or

''(3) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal that—

''(A) does not impose a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

''(B) is not otherwise required by or inconsistent with an action by the Administrator under section 5 or 6.

''(d) STATE WAIVERS.—Upon application of a State or political subdivision of a State, the Administrator may provide a waiver from subsection (a) and subsection (b)(1), regarding a requirement of that State or political subdivision of the State that relates to the effects or expo-

sure to any chemical substance under the intended conditions of use if—

''(1)(A) the State or political subdivision of the State determines it cannot wait until the end of the period specified in the established schedule and deadline for the completion of a full safety assessment and determination established under section 6(b)(2)(B)(ii); and

''(B) the Administrator determines that—

''(i) compelling State or local conditions warrant granting the waiver to protect human health or the environment;

''(ii) compliance with the proposed requirement of the State or political subdivision of the State does not unduly burden interstate and foreign commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

''(iii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

''(iv) the proposed requirement of the State or political subdivision of the State is

based on the best available science and is supported by the weight of the evidence; or

''(2)(A) the Administrator finds a safety assessment or determination has been unreasonably delayed; and

''(B) the State certifies that—

''(i) the State has a compelling local interest to protect human health or the environment;

''(ii) compliance with the proposed requirement of the State does not unduly burden interstate and foreign commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

''(iii) compliance with the proposed requirement would not cause a violation of any applicable Federal law, rule, or order; and

''(iv) the proposed requirement is grounded in reasonable scientific concern.

''(3) APPROVAL OF A STATE WAIVER REQUEST.—The Administrator shall grant or deny a waiver application—

''(A) not later than 180 days after the date on which an application under paragraph (1) is submitted; and

"(B) not later than 90 days after the date on which an application under paragraph (2) is submitted.

"(4) NOTICE AND COMMENT.—The application of a State or political subdivision of the State shall be subject to public notice and comment.

"(5) FINAL AGENCY ACTION.—The decision of the Administrator on the application of a State or political subdivision of the State shall be—

"(A) considered to be a final agency action; and

"(B) subject to judicial review.

"(6) DURATION OF STATE WAIVERS.—A State waiver—

"(A) granted under paragraph (1) shall remain in effect unless the waiver is found to be in conflict with a completed safety assessment and determination; and

"(B) granted under paragraph (2) shall remain in effect until such time as the safety assessment and determination is completed.

"(7) JUDICIAL REVIEW.—Not later than 60 days after the date on which the Administrator makes a determination on an application of a State or political subdivision of the State under paragraph

(1), any person may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.

''(e) EFFECT ON PRIVATE REMEDIES.—

''(1) IN GENERAL.—If the Administrator completes a safety determination for a high-priority substance under section 6, the determination shall be admissible as evidence in any public or private action in any court of the United States or State court for recovery of damages or for equitable relief relating to injury to human health or the environment from exposure to a chemical substance.

''(2) SAFETY STANDARD.—The safety determination shall be determinative of whether the substance meets the safety standard under the conditions of use addressed in the safety determination.''.

SEC. 16. JUDICIAL REVIEW.

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

(1) in subsection (a)—

(A) by striking paragraph (1) and inserting the following:

''(1) FILING OF PETITION.—

''(A) IN GENERAL.—Not later than 60 days after the date of the promulgation of a

rule under section 4(f), 6(c), 6(e), or 8, any person may file a petition for judicial review of the rule in—

''(i) the United States Court of Appeals for the District of Columbia Circuit;

''(ii) the circuit in which the person resides; or

''(iii) the circuit in which the principal place of business of the person is located.

''(B) EXCLUSIVE JURISDICTION OF COURTS OF APPEALS.—The courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) under subparagraph (A) if any district court of the United States would have had jurisdiction of the action but for this paragraph.'';

(B) in paragraph (2), by striking ''paragraph (1)(A)'' and inserting ''paragraph (1)''; and

(C) by striking paragraph (3); and

(2) in subsection (c)(1), by striking subparagraph (B) and inserting the following:

''(B) APPLICABILITY OF SECTION 706 OF TITLE 5, UNITED STATES CODE.—

"(i) DEFINITION OF EVIDENCE.—In this subparagraph, the term 'evidence' means any matter in the rulemaking record.

"(ii) APPLICABILITY.—Section 706 of title 5, United States Code, shall apply to review of a rule under this section, except that—

"(I) in the case of a rule under section 4(f), 6(c), or 6(e)—

"(aa) the standard of review prescribed in section 706(2)(E) of title 5, United States Code, shall not apply; and

"(bb) the court shall hold as unlawful and set aside the rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record; and

"(II) the court shall not review the contents and adequacy of the statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incor-

porated in the rule except as part of a review of the rulemaking record taken as a whole.''.

SEC. 17. CITIZENS' PETITIONS.

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

(1) in subsection (a), by striking ''an order under section 5(e) or 6(b)(2)'' and inserting ''an order under section 4(f) or 5(c)''; and

(2) in subsection (b)—

(A) in paragraph (1), by striking ''an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)'' and inserting ''an order under section 4(f) or 5(c)''; and

(B) by striking subparagraph (B) of paragraph (4) and inserting the following:

''(B) DE NOVO PROCEEDING.—

''(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to issue a rule under section 4(f), 6(b), 6(c), 6(d), or 8 or an order issued under section 4(f) or 5(c), the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.

''(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a rule or order under section 4(f), the information available to the Administrator is insufficient for the Administrator to perform an action described in section 4(f), 6(b)(5), or 6(c)(8);

"(bb) in the case of a petition to issue an order under section 5(c), there is a reasonable basis to conclude that the substance is not likely to meet the safety standard under the intended conditions of use;

"(cc) in the case of a petition to initiate a proceeding for the issuance of a rule under sec-

tion 6(c)(9), there is a reasonable basis to conclude that the substance will not meet the safety standard under the intended conditions of use; or

"(dd) in the case of a petition to initiate a proceeding for the issuance of a rule under section 6(b)(2), 6(d) or 8, there is a reasonable basis to conclude that the rule is necessary to protect human health or the environment from an unreasonable risk of harm to human health or the environment.

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

"(aa) the extent of the risk to human health or the environment alleged by the petitioner is less than the extent of risks to human health or the environment

with respect to which the Administrator is taking action under this Act; and

''(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.''.

SEC. 18. STUDIES.

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

SEC. 19. ADMINISTRATION.

Section 26(e) (15 U.S.C. 2625(e)) is amended by striking ''Health, Education, and Welfare'' each place it appears and inserting ''Health and Human Services''.

SEC. 20. DEVELOPMENT AND EVALUATION OF TEST METHODS.

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

SEC. 21. STATE PROGRAMS.

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

SEC. 22. AUTHORIZATION OF APPROPRIATIONS.

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

SEC. 23. ANNUAL REPORT.

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

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

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