Udall-Vitter Draft Revisions to S.1009 (September 2014)

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.

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

(1) By striking "injury" in paragraph (2) and inserting "harm";

(2) In paragraph (2), striking "and" at the end thereof;

(3) Redesignating paragraph (3) as paragraph (6); and

(4) Inserting the following:

"(3) reform of this Act shall be administered to protect the health of children, pregnant women, the elderly, workers, consumers, the general public and the environment from the risks of harmful exposures to chemical substances and mixtures;
"(4) reform of this Act shall not displace or supplant common law rights of action or remedies for civil relief;
"(5) reform of this Act shall be administered to ensure that appropriate information on chemical substances and mixtures should be available to public health officials and first responders in the event of an emergency; and"

~~(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 globally 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 substances 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 (9~~11~~), (10) , (11) and (12) through (14) as paragraphs ~~(3) through (7),~~ (9) through (11~~3~~), (13), (15) and (18~~7~~) through (20~~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.";~~

(2~~3~~) by inserting after paragraph ~~(7) (as so redesignated)~~ the following:

"(7) INFORMATION.—The term 'information' means any qualitative, quantitative or descriptive facts, data, analysis or assessment related to chemical hazards, use, or exposure (including the nature and extent of exposure to a chemical substance), including from health and safety studies.

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

(3) by inserting after paragraph 11 (as so redesignated) the following:

"(12) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.— The term 'potentially exposed or susceptible population' means a group or groups of individuals within the general population who may be differentially exposed to chemical substances under the intended or reasonably anticipated conditions of use and/or who may be susceptible to greater adverse health consequences from chemical exposures than the general population, which when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; ~~and~~

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

"(14) PUBLICLY AVAILABLE INFORMATION.—The term 'publicly available information' means information that is generally accessible and available to the general public or in the public domain, including information that has been published in periodicals, books, print, electronic or other media available for general distribution to any member of the public.";

"(15~~4~~) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by ~~risk-based assessment of the safety of~~ a chemical substance under the intended or reasonably anticipated conditions of use, integrating ~~that —~~

~~"(A) integrates~~ hazard; use; and exposure information about ~~a~~the 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)~~.

"(16~~5~~) 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 or reasonably anticipated conditions of use.

"(17~~6~~) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other non-risk factors, that no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance under the intended or reasonably anticipated conditions of use, including no unreasonable risk of harm to the general population or to any potentially exposed or susceptible subpopulation that the Administrator has identified as relevant to the safety assessment and determination for a chemical substance.".

SEC. 3A. POLICIES, PROCEDURES AND GUIDANCE.

(a) DEADLINE.—Not later than 2 years after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall, after providing an opportunity for public notice and comment, develop any policies, procedures and guidance the Administrator determines are needed to carry out sections 4, 4A, 5 and 6, which shall include the policies, procedures and guidance required by this section. As used in this subsection the term "guidance" includes any significant written guidance of general applicability prepared by the Administrator.

"(b) USE OF SCIENCE .--The Administrator shall establish policies, ~~-~~procedures, and guidance, on the use of science in making decisions under sections 4, 4A, 5 and 6. A goal of the policies and procedures shall be to make the basis of decisions clear to the public. The policies, procedures and any guidance issued under this subsection shall describe how the Administrator will ensure that —

"(1~~A~~) decisions by the Administrator—

"(A~~i~~) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(B~~ii~~) take into account the extent to which—

"(i~~I~~) assumptions and methods are clearly and completely described and documented;

"(ii~~II~~) variability and uncertainty are evaluated and characterized;

"(iii~~III~~) the information has been subject to independent verification and peer review; and

"(C~~iii~~) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information; and

"(2~~C~~) to the extent practicable and where appropriate, the use of peer review,

standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(3~~D~~) what organizations or individuals funding the generation and assessment of information and the degree of control they had over the generation, assessment and dissemination of information (including control over the design of the work and the publication of information) will be made clear; and

"(4~~E~~) where appropriate, the recommendations in reports of the National Academy of Sciences that provide advice on assessing the hazards, exposures and risks of chemical substances are considered.

"(c) EXISTING EPA POLICIES, PROCEDURES AND GUIDANCE.—The policies, procedures and guidance described in subsection (a) shall incorporate, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies and other relevant guidelines and policies.

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

"(A) review the adequacy of any policies, procedures, and guidance developed under this section, including animal, non-animal and epidemiological test methods and procedures for assessing and determining risk under this Act; and

"(B) after providing an opportunity for public notice and comment, revise them if necessary to reflect new scientific developments or understandings.

"(e) SOURCES OF INFORMATION.—In making any decision with respect to a chemical substance under sections 4, 4A, 5 and 6, the Administrator shall consider information on the hazards and exposures of a chemical substance under the intended or reasonably anticipated conditions of use that is reasonably available to the Administrator, including information that is—

"(1) submitted to the Administrator pursuant to any rule, consent agreement, order or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act by—

"(A) manufacturers and processors of a substance;

"(B) the public;

"(C) other Federal agencies and departments; or

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

"(2) submitted to a governmental body in any jurisdiction under a governmental requirement relating to the protection of human health and the environment; or

"(3) identified through an active search by the Administrator of information sources that

are publicly available or otherwise accessible by the Administrator.

"(f) TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.—

"(1) IN GENERAL.—The Administrator shall establish policies and procedures for the testing of chemical substances or mixtures under section 4. A goal of the policies and procedures shall be to make the basis of decisions clear to the public.

"(2) CONTENTS.--The policies, procedures and guidance established under paragraph (1) shall—

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, provided that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential;

"(B) describe how the Administrator will determine that additional information is needed to carry out this Act, including information related to potentially exposed or susceptible populations;

"(C) require the Administrator to consult with the Director of the National Institute for Occupational Safety and Health prior to prescribing epidemiologic studies of employees; and

"(D) prior to adopting a requirement for testing using vertebrate animals, require the Administrator to consider, as appropriate and to the extent practicable, reasonably available —

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

"(iii) high-throughput screening methods and their prediction models; and

"(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.

"(3) TIERED TESTING.—Except as provided in subparagraph (C), the Administrator shall employ a tiered screening and testing process, wherein the results of screening level tests or assessments of available information inform the decision as to whether one or more additional tests are necessary.

"(A) SCREENING LEVEL.—The screening level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate. Screening level tests shall be used—

"(i) to screen chemical substances or mixtures for potential adverse effects; and

"(ii) to inform the decision of the Administrator whether more complex and targeted additional testing is necessary.

"(B) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (A) that additional testing is necessary to provide more definitive information for safety assessments and determinations, the Administrator may require more advanced

tests for potential human health or environmental effects or exposure potential.

"(C) ADVANCED TESTING WITHOUT SCREENING.--The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced test, pursuant to guidance developed by the Administrator under this section.

"(g) SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(1) SCHEDULE – The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and determination as soon as possible after designation as a high priority substance pursuant to section 4A. The time allotted may be different for different chemicals, provided that all schedules shall comply with the deadlines established under section 6.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—The Administrator shall, by rule, establish policies and procedures on how the Administrator shall carry out section 6. A goal of the policies and procedures shall be to make the basis of decisions clear to the public. At a minimum, the policies and procedures shall --

"(A) describe—

"(i) how the Administrator will identify informational needs and seek such information from the public;

"(ii) what information (including draft safety assessments) may be submitted by interested persons, including States; and

"(iii) the criteria by which that information will be evaluated.

"(B) require the Administrator to –

(i) identify the hazards, exposures, intended or reasonably anticipated conditions of use and potentially exposed and susceptible populations that the Administrator expects to consider in a safety assessment, explain the basis for their selection, and take comment on them; and

(ii) identify the items in clause (i) that the Administrator has considered in a safety statement in the final safety assessment and explain the basis for their consideration.

"(C) describe how aggregate exposures, or significant subsets of exposures, to a chemical substance under the intended or reasonably anticipated conditions of use will be considered, and explain the basis for their consideration in the final safety assessment;

"(E) require that each safety assessment and safety determination include —

"(i) a description of the weight of the scientific evidence of risk;

"(ii) a summary of the information on the human health and the environment impact of the chemical substance that was used to make the

assessment or determination, including, where available, mechanistic, animal toxicity, and epidemiology studies; and

"(F) establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the assessment or determination.

"(h) PUBLICLY AVAILABLE INFORMATION.—Subject to section 14, the Administrator shall —

"(1) make available to the public a nontechnical summary and the final version of each safety assessment and safety determination;

"(2) provide public notice and an opportunity for comment on proposed safety assessments and safety determinations; and

"(3) make public in a final safety assessment and safety determination the list of studies considered by the Administrator in carrying out the safety assessment and safety determination, as well as the list of policies, procedures and guidance that were followed in carrying out the safety assessment and safety determination.

''(i~~f~~) CONSULTATION WITH SCIENCE ADVISORY COMMITTEE ON CHEMICALS.—

"(1) The Administrator shall establish a Science Advisory Committee on Chemicals within one year of the date of enactment of the Chemical Safety Improvement Act. The purpose of the Committee shall be to provide independent advice and expert consultation, upon the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(2) The Committee shall be composed of representatives of such science, government, labor, public health, public interest, industry and other groups as the Administrator deems advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

"(3) The Administrator shall convene the Committee on a schedule the Administrator determines appropriate, but not less frequently than once every 2 years.

"(4) All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act, 5 U.S.C. App. 2 et seq."

SEC. 4. ~~CHEMICAL ASSESSMENT FRAMEWORK; PRIORITIZATION SCREENING;~~ TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

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

(1) by striking subsection (g) and redesignating subsection (e) as subsection (g);

(2) in subsection (g) (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";

(3) in subsection (f)—

(A) by striking "from cancer, gene mutations, or birth defects";

(B) by striking the last sentence; and

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

~~(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 (c) 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 scientific 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 DECISIONMAKING.—~~

~~"(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 regulation 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 Administrator 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 reevaluate 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.~~

"(a~~f~~) DEVELOPMENT OF NEW ~~TEST DATA AND~~ INFORMATION ON CHEMICAL SUBSTANCES AND MIXTURES.—

"(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~~is needed—

"(A) to perform a safety assessment or determination under section 6;

"(B) to implement a requirement imposed in a consent agreement or order issued under section 5(c)(4~~5~~);~~make a safety determination; or~~

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

"(D) at the request of ~~to meet the testing needs of~~ the implementing authority under another Federal statute, to meet the regulatory testing needs of such authority.

"(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—The Administrator may require the development of new information for the purposes of section 4A, provided, however, that any such testing is not required for the purpose of establishing or implementing minimum information requirements. Use of this authority shall be limited to cases where the Administrator determines additional information is needed to establish the priority of a chemical substance.

"(3~~2~~) FORM.—Subject to section 3A(c), t~~T~~he Administrator may require the development of test data and information described in paragraph (1) or (2) 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)~~this subsection 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) test protocols and methodologies ~~procedures~~ for the development of ~~test data and~~ information for the chemical substance or mixture, including specific reference to reliable non-animal test procedures; and

"(iv) specification of the period within which persons required to conduct the testing shall submit to the Administrator the ~~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.

"(b~~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)~~this section, the Administrator shall ~~issue a statement~~ —

"(A) identify~~ing~~ the need intended to be met by the rule, agreement, or order;

"(B) explain~~ing~~ why ~~existing data and~~ information reasonably available to the Administrator at that time are inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B) of this subsection; and

"(C) ~~encouraging, to the extent possible, the use of nonanimal test methods to develop additional data and information~~explain the basis for any decision that requires the use of vertebrate animals.

"(2) ~~CONTENTS OF STATEMENT~~EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification why

described in paragraph (1) shall explain why good cause exists for issuance of an order is warranted instead of promulgating a rule or entering into a testing consent agreement.

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

"(i) data and information that are is 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; and

"(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

"(iiiv) safety assessments, and the data andany information relied on in the safety assessments for , 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 exposure 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.~~

"(c~~i~~) REDUCTION OF ~~ANIMAL-BASED~~ TESTING ON VERTEBRATE ANIMALS.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate 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~~best available science 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~~where 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 on vertebrate laboratory animals, 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~~in safety ~~standard~~ assessments and determinations under section 6 ~~made~~ that can reduce, refine, or replace the use of vertebrate 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 subsection and goals for future alternative test methods implementation; 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 vertebrate laboratory animals in any safety ~~standard~~ assessment or determination made under ~~this~~ section 6.

"(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 on vertebrate animals under this ~~title~~section, 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 support 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 ~~one~~ 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the ~~material~~ substance 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 vertebrate laboratory 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.

"(d~~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:

"(1~~i~~) Manufacturers and processors of the chemical substance or mixture; ~~identified in subsection (f)(4)(A)(i).~~

"(2~~ii~~) Persons who begin to manufacture or process such chemical substance or mixture—

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

"(B~~II~~) subject to ~~sub~~paragraph (4~~C~~), before the period ending 180 days after the end of the period identified in this section~~subsection (f)(4)(A)(iv)~~.

"(3~~B~~) DESIGNATION.—The Administrator may permit 2 or more of the persons identified in ~~subparagraph (A)~~paragraphs (1) or (2) to designate a person or a qualified third party—

"(A~~i~~) to develop the ~~data and~~ information; and

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

"(4~~C~~) EXEMPTIONS.—

"(A~~i~~) IN GENERAL.—A person otherwise subject to a rule, testing consent agreement, or order under ~~subsection (f)~~this section may submit to the Administrator an application for an exemption on the basis that the ~~data and~~ information ~~are~~ is being developed by a person designated under ~~sub~~paragraph (3~~B~~).

"(B~~ii~~) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

"(i~~I~~) IN GENERAL.—If the Administrator accepts an application submitted under ~~clause (i)~~subparagraph (A), the Administrator shall direct the applicant to provide to the person designated under ~~sub~~paragraph (3~~B~~) fair and equitable reimbursement, as agreed to between the applicant and the person designated.

"(ii~~II~~) ARBITRATION.—If the applicant and a person designated under ~~sub~~paragraph (3~~B~~) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.

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

"(i~~I~~) by order terminate the exemption; and

"(ii~~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 nonanimal test methods; and~~

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

"(e~~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(f~~l~~)".

SEC. 4A. PRIORITIZATION SCREENING

"(a) Prioritization Screening.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall by rule establish a risk-based screening process and criteria for identifying existing chemical substances that are—

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

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

"(2) INITIAL LIST OF HIGH PRIORITY SUBSTANCES.— Prior to promulgation of the rule established under paragraph (1) and not later than 6 months after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall consider and publish an initial list of high priority substances, which shall contain at least 10 chemical substances, and pursuant to section 6(b)(2), initiate or continue assessments and determinations for such substances.

"(3) IMPLEMENTATION

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) CONSIDERATION OF ACTIVE SUBSTANCES.—In implementing the process described in paragraph (1), the Administrator shall consider active substances, as determined under section 8, which may include substances on the interim list of active substances established under that section.

"(ii) CONSIDERATION OF INACTIVE SUBSTANCES.—In implementing the process described in paragraph (1), the Administrator may consider inactive substances, as determined under section 8, that the Administrator determines—

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

"(II) have the potential for high hazard and widespread exposure; or

"(III) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substance and there is the potential for residual high hazards or widespread exposures not otherwise addressed by the regulatory or other action.

"(iii) REPOPULATION.—Upon the completion of a safety determination under section 6 for a chemical substance the Administrator shall remove the substance from the list of high-priority substances. The Administrator shall add at least one chemical substance to the list of high-priority substances for each chemical substance removed from the list, until a safety assessment and determination is completed for all high-priority substances.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—Not later than 6 months after the effective date of the final rule under subsection (a)(1), the Administrator shall begin the prioritization screening process. The Administrator shall make every effort to complete the prioritization screening of all active substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after receipt of the information complying with a rule, testing consent agreement or order issued under section 4(a)(2), the Administrator shall designate the substance as either a high or low priority.

"(iii) CONSIDERATION.—The Administrator shall screen substances taking into consideration the ability of the Administrator to schedule and complete safety assessments and determinations under section 6 in a timely manner. The Administrator shall publish an annual goal for the number of substances to be subject to the prioritization screening process.

"(C) SCREENING OF CATEGORIES OF SUBSTANCES.—The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate safety assessments and determinations.

"(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—Not less frequently than annually, the Administrator shall—

"(i) publish a list of chemical substances being considered in the prioritization screening process and their status in the prioritization process, including those substances for which a prioritization decision has been deferred; and

"(ii) publish a list of those substances designated as high-priority and low-priority substances and the basis for the designations;

"(4) CRITERIA.—The criteria described in paragraph (1) shall consider—

"(A) 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;

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

"(C) the intended or reasonably anticipated conditions of use or significant changes in the conditions of use of the chemical substance;

"(D) evidence and indicators of exposure potential to humans or the environment from the chemical substance including potentially exposed or susceptible populations;

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

"(F) whether the volume of a chemical substance as reported under a regulation issued under section 8(a) has significantly increased or decreased since a previous report or

since the date on which a notice has been submitted under section 5(a) for that chemical substance;

"(G) the availability of information about potential hazards and exposures needed for conducting a safety assessment or determination, with limited availability of relevant information to be a sufficient basis for designating a substance as a high priority, provided, however, that such limited availability shall not require designation as a high priority; and

"(H) 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 regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a low-priority substance.

"(b) PRIORITIZATION SCREENING PROCESS AND DECISIONS.—

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

"(A) identify the chemicals being considered for prioritization;

"(B) request interested persons to supply information on the substances being considered;

"(C) apply the criteria identified in subsection (a)(4); and

"(D) subject to paragraph (5), using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.

"(2) INTEGRATION OF INFORMATION.—The prioritization screening decision on a chemical substance shall integrate any hazard and exposure information related to a chemical substance available to the Administrator.

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

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

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

"(C) may identify as a high-priority substance an inactive substance, as determined under section 8(b), that the Administrator determines, warrants a safety assessment and determination under section 6.

"(4) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that it is likely to meet the safety standard.

"(5) DEFERRING A DECISION.—If the Administrator determines that additional information is needed to establish the priority of a chemical substance, the Administrator may defer the prioritization screening decision for a reasonable period to—

"(i) allow for the submission and evaluation of additional information by an interested person; or

"(ii) require the development of information pursuant to a rule, testing consent agreement, or order issued under section 4(a)(2).

"(6) DEADLINES FOR SUBMISSION OF INFORMATION.—If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of such information, which deadline shall be of reasonable duration.

"(7) NOTICE AND COMMENT.—The Administrator shall publish the proposed decisions made under paragraphs (3), (4) and (5) and the basis for the decisions, and provide an opportunity for public comment.

"(8) REVISION BASED ON NEW INFORMATION.—

"(A) IN GENERAL.—At any time, and at the Administrator's discretion, the Administrator may revise the designation of a chemical substance as a high-priority or a low-priority substance based on new information made available to the Administrator after the date of the determination under paragraphs (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the substance on receiving the relevant information.

"(9) REVIEW.—Not less frequently than every 5 years after the date on which the process under this subsection is established, the Administrator shall review the process on the basis of experience and consider the resources available to efficiently and effectively screen and prioritize substances, and if necessary modify the prioritization screening process

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

"(c) EXPEDITED PRIORITIZATION SCREENING.—

"(1) IN GENERAL.—Not later than 180 days after the date on which the Administrator receives from a Governor of a State or a State agency with responsibility for protecting health and the environment a recommendation and relevant information justifying 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.

"(2) LIMITATION.—A Governor of a State or a State agency with responsibility for protecting health and the environment may annually recommend up to 2 chemical substances for prioritization screening under paragraph (1).

"(3) RECOMMENDATION.—Notwithstanding subsection (b)(8), a recommendation by a Governor of a State or a State agency with responsibility for protecting health and the

environment with respect to a chemical substance that has been previously prioritized need not be based on new information.

"(4) NOTICE AND COMMENT.—The public shall be provided notice and an opportunity to comment on the recommendations submitted under this subsection.

"(5) EXPLANATION OF REASONS.—The Administrator shall—

"(A) 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, or for deferring a prioritization screening decision; and

"(B) identify the information relied upon in making that identification.

"(d) FINAL AGENCY ACTION.— Except as provided in section 18(e)(6)(B), 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.

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 or reasonably anticipated conditions of use and reasonably anticipated exposures.";

(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 (3~~4~~).

"(B) EXTENSION.—Except as provided in paragraph (5~~6~~), the Administrator may extend the period described in subparagraph (A) for good cause for ~~one~~ 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).~~

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

"(A) ~~the~~ any relevant information identified ~~in section 4(c)~~in subsection (b)(1); and

"(B) any other relevant ~~additional~~ information ~~provided by the submitter~~available to, or submitted to, the Administrator.

"(3~~4~~) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), and based on the information described in paragraph (2~~3~~), the Administrator shall determine that—

"(A) the relevant chemical substance or a significant new use 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 or significant new use 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 Administrator shall take appropriate action under paragraph (5~~6~~).

"(4~~5~~) ~~PROHIBITIONS AND LIMITATIONS~~RESTRICTIONS.—

"(A) IN GENERAL.—If the Administrator makes a determination under paragraph (3~~4~~)(A) or (C) with respect to a notice submitted under subsection (a), ~~before the end of the applicable period for review under paragraph (1),~~ the Administrator shall before the end of the applicable period for review under paragraph (1) and~~,~~ by consent agreement or order, as appropriate, prohibit or restrict the manufacture, processing, use, distribution in commerce or disposal (as applicable) of the chemical substance or of the substance for a significant new use~~—~~

~~"(i) prohibit manufacture of the chemical substance, or prohibit such manufacture~~ without compliance with the restrictions specified in the ~~a relevant~~ consent agreement or order that the Administrator determines are

sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard.~~; 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) Within 90 days of issuing a consent agreement or order under subparagraph (A), the Administrator shall—

"(i) consider whether to promulgate a rule under subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce or disposal of the chemical substance, or of the chemical substance for a new use, that is not in compliance with the restrictions imposed by the consent agreement or order; and

"(ii) either initiate such rulemaking or publish a statement of the Administrator's reasons for not initiating such action.

"(C~~B~~) INCLUSIONS.—A prohibition or ~~limitation~~ restriction under subparagraph (A) may include, as appropriate—

"(i) a requirement that a chemical substance be marked with, or accompanied by, clear and adequate minimum 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~~address potential risks from the manufacture, processing, distribution in commerce, use or disposal of the chemical substance, subject to section 4~~(g)~~;

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

"(v) a ~~limitation~~ restriction 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 or other appropriate restriction on the manufacture, processing, or distribution in commerce of the chemical substance; or

"(x) a prohibition or other appropriate restriction 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~~.

"(D) WORKPLACE EXPOSURES.—The Administrator shall consult with the Occupational Safety and Health Administration prior to adopting any prohibition or restriction adopted under this subsection to address workplace exposures.

"(5~~6~~) ADDITIONAL ~~DATA AND~~ INFORMATION.—If the Administrator determines under paragraph (3~~4~~)(C) that additional ~~data and~~ information ~~(including, for example, information on exposure or exposure potential) are~~is 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).";~~

"(C) 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

"(D) shall upon receipt of information the Administrator finds supports the determination under paragraph (3), promptly make the determination.

"(6) REGULATION PENDING DEVELOPMENT OF INFORMATION.--Subject to paragraph (4)(B), the Administrator may permit manufacture for commercial purposes to commence pending receipt of the additional information, subject to compliance with any restrictions under paragraph (4) determined by the Administrator to be sufficient to ensure that the chemical substance is likely to meet the safety standard.

"(7) COMMENCEMENT OF MANUFACTURE.—Subject to paragraphs (4), (5), and (6), at the end of the applicable period for review under subparagraph (A) the submitter of a notice under subsection (a) may commence manufacture for commercial purposes a chemical substance, or a chemical substance for a significant new use.

(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 4A~~(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, determinations, consent agreements, 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~~ will 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),".

(10) following subsection (h)(as so redesignated), insert the following:

"(i) PRIOR ACTIONS.—Nothing in this section shall be construed as requiring the Administrator to modify or withdraw any rule or order promulgated under section 5 of this title prior to the enactment of the Chemical Safety Improvement Act."

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) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

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

"(2~~3~~) shall as appropriate based on the results of a safety determination, establish ~~requirements for risk management of a high-priority substance~~restrictions pursuant to subsection (d);

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

"(4) shall promulgate a final rule pursuant to section 6(d) not later than 2 years after the date on which the safety determination is completed; and

"(5) may extend any deadline under this subsection for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under paragraphs (3) and (4) of this subsection and any deferrals under subsection (c)(2) does not exceed 2 years.

~~"~~

"(b) SAFETY ASSESSMENTS AND DETERMINATIONS.—

"(1) IN GENERAL.—The Administrator shall conduct a risk-based safety assessment and make a risk-based safety determination 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) ALREADY INITIATED ASSESSMENTS.—Nothing in this Act shall be construed to prevent the Administrator from initiating assessments and determinations of chemical substances, or from continuing or completing assessments and determinations initiated prior to the date of enactment of the Chemical Safety Improvement Act, prior to the date on which the policies and procedures the Administrator is directed to establish under section 3A or 4A are effective. As policies and procedures under section 3A and 4A are established, the Administrator shall integrate them into ongoing assessments and determinations to the maximum extent practicable.

"(3) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act shall be construed to require the Administrator to revise or withdraw a completed safety assessment, safety determination, or rule merely because such action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of such assessment, determination or rule shall not be determined based on the content of such policy or procedure.

~~"(2) PROCEDURAL RULES.—~~

~~"(A) IN GENERAL.—The Administrator shall establish procedural rules for safety assessments and determinations under this subsection, 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 DETERMINATIONS.—

"(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 before the Administrator, including draft safety assessments submitted by interested persons, ~~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 by rule under subsection (d) impose ~~additional~~ restrictions~~,~~ necessary to assure that the substance meets the safety standard under the intended or reasonably anticipated conditions of use, or, where the safety standard cannot be met with the application of restrictions, to ban or phase out the substance, 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 (2~~8~~).

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is needed in order to make a safety assessment and determination 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;

"(C) may defer, for a reasonable period consistent with the deadlines in subsection (a), a safety assessment and determination until after receipt of the information; and

"(D) consistent with the deadlines in subsection (a), shall, upon receipt of information the Administrator finds supports the assessment and determination, make a determination under paragraph (1).

"(3) When requesting the development or submission of information under this section the Administrator shall establish a deadline for the submission of such

information, which deadline shall be of reasonable duration.

~~"(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.—~~

"(d) RULE.—

"(1) IMPLEMENTATION.—

~~"(i) DETERMINATION.—~~If the Administrator makes a determination under ~~paragraph (2)(B)~~subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a rule establishing ~~necessary~~ restrictions necessary to ensure that the chemical substance meets the safety standard ~~(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)~~.

"(2~~ii~~) ~~RULES~~SCOPE.—Rules promulgated under this subsection—

"(A) may—

"(i) apply to mixtures containing the chemical substance, as appropriate, and~~.~~

"(ii) exempt replacement parts for articles manufactured prior to the applicable compliance deadline; and

"(B) shall include dates by which compliance is mandatory, which shall be as soon as feasible and may vary for different affected persons, as the Administrator determines to be appropriate.

"(C) WORKPLACE EXPOSURES.—The Administrator shall consult with the Occupational Safety and Health Administration prior to adopting any prohibition or restriction adopted under this subsection to address workplace exposures.

"(3B) INCLUSIONSRESTRICTIONS.—A restriction under subparagraph (1A) may include, as appropriate—

"(Ai) 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;

"(Bii) a requirement that manufacturers and processors of the chemical substance—

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

"(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance;

"(iii) monitor or conduct tests which are reasonably necessary to assure compliance with the requirements of any rule under this subsection;

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

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

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

"(iI) for a particular use; or

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

"(iii) for all uses;

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

"(i~~I~~) for a particular use; or

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

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

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

"(H~~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 chemical substance is necessary on the considerations described in subparagraph (D).~~

"(4~~D~~) ~~DETERMINATION THAT CHEMICAL SUBSTANCE DOES NOT MEET SAFETY STANDARD~~ANALYSIS FOR RULEMAKING.—

"(A) When deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall consider, to the extent practicable based on reasonably available information, the quantifiable and non-quantifiable costs and benefits of the proposed regulatory action and of the primary alternative regulatory action or actions considered by the Administrator. As part of the analysis, the Administrator shall review such technically and economically feasible alternative or alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking; ~~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—~~

~~"(A~~i) ~~the availability of the technically and economically feasible alternatives for the chemical substance under the intended conditions of use if relevant to the risk management measures under consideration;~~

"(B~~ii~~) when proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under subparagraph (A); and

"(C) when making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account. ~~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.~~

"(5~~10~~) EXEMPTIONS.—

"(A) The Administrator—

"(i) may exempt the use of a chemical substance from any ~~additional~~ restriction in a rule promulgated ~~established~~ under ~~paragraph (9)~~paragraph (1) if the Administrator determines that the rule cannot be complied with, without—

"(I~~A~~) harming ~~the exemption is in the interest of~~ national security;

"(II~~B~~) ~~the lack of availability of the chemical substance would~~ causing~~e~~ significant disruption in the national economy due to the lack of availability of a chemical substance;

"(III~~C~~) interfering with ~~the use for which the exemption is sought is~~ a critical or essential use for which to technically and economically feasible safer alternative is available, considering hazard and exposure; —

~~"(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

"(ii~~I~~) may exempt the use of a chemical substance from a restriction in a rule issued under paragraph (1) if such use, as compared to reasonably available alternatives, provides a ~~net~~ substantial benefit to human health, the environment, or public safety.

"(B) EXEMPTION ANALYSIS.—When proposing a rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall make publicly available any analysis conducted under this paragraph to assess the need for such exemption.

"(C) When making final a rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall include a statement describing how the analysis was taken into account.

"(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.— In determining whether an exemption should be granted under this paragraph for a chemical substance for which a ban or phase-out is proposed, the Administrator shall consider, to the extent practicable based on reasonably available information, the quantifiable and non-quantifiable costs and benefits of the technically and economically feasible alternative or alternatives to the substance most likely to be used in place of the chemical substance under the intended or reasonably anticipated conditions of use if the rule is promulgated.

"(E) CONDITIONS.—As part of a rule issued under paragraph (1), the Administrator shall include conditions in any exemption established under this paragraph, including reasonable recordkeeping, monitoring and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect human health and the environment while achieving the purposes of the exemption.

"(F) DURATION.—The Administrator shall, as part of a rule under paragraph (1) that contains an exemption under this paragraph, set a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis. The Administrator may, by rule, extend, modify or eliminate the exemption when the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or is no longer necessary. The Administrator shall issue exemptions and establish time periods by considering factors determined by the Administrator as relevant to the goals of fostering innovation and the development of alternatives that meet the safety standard, provided that any renewal of an exemption in the case of a rule requiring the ban or phase out of a chemical substance shall not exceed five years.

"(e~~f~~) Immediate Effect.--The Administrator may declare a proposed rule under subsection (d) of this section to be effective upon its publication in the Federal Register and until the effective date of final action taken respecting such rule if—

"(1) the Administrator determines that—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before such effective date; and

"(B) making such proposed rule so effective is necessary to protect the public interest; and

"(2) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under paragraph (1)(A), a court has in an action under section 7 of this title granted relief with respect to such risk associated with such substance or mixture.

"(f~~g11~~) FINAL AGENCY ACTION.—~~A safety determination u~~Under this ~~sub~~section ~~shall be—~~

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

"(2) a final rule promulgated under subsection (d), together with the associated safety assessment and safety determination that a substance does not meet the safety standard, shall be considered to be final agency action on the date of promulgation of the final rule."

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

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

(6~~3~~) by redesignating subsections (e) and (f) as subsections (h~~d~~) and (i~~e~~), respectively; and

(7~~4~~) in subsection (h~~d~~) (as so redesignated)—

(A) by striking paragraph (4); and

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

(8) after subsection (i)(as so redesignated) insert the following:

"(j) PRIOR ACTIONS.—Nothing in this section shall be construed as requiring the Administrator to modify or withdraw any rule or order promulgated under section 6 of this title promulgated prior to the enactment of the Chemical Safety Improvement Act."

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~~6~~), ~~or~~ 6(c)(2) or 6(h); or

"(ii) a rule, testing consent agreement, or order under section 4(d~~f~~), 5~~(c)(45)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) DEADLINE.—Not later than 2 years after the date of enactment of the Chemical Safety Improvement Act, the Administrator shall promulgate rules requiring the maintenance of records and 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. In carrying out this subparagraph, the Administrator may modify, as appropriate, the regulations promulgated prior to the date of enactment of the Chemical Safety Improvement Act.

~~"(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 include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported~~be limited to active substances or mixtures containing active substances as designated under subsection (b)~~; and

"(iii) shall apply only ~~to the extent~~where the Administrator determines the submission of reports would assist in ~~is necessary for~~ the effective ~~enforcement~~ implementation of this Act.

"(C) ADMINISTRATION.—In implementing this paragraph, the Administrator shall take measures to—

"(i) limit the potential for duplication in reporting requirements;

"(ii) minimize the impact of the rules on small manufacturers and processors; and

"(iii) apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.".

"(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.~~

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A~~B~~) RULE.—Not later than 1 year after the date of enactment of the Chemical Safety Improvement Act, ~~T~~the Administrator shall~~,~~ by rule~~,~~ require manufacturers and processors to notify the Administrator, within 6 months of the date of promulgation of the rule, of each chemical substance on the list published under paragraph (1) 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 10~~5~~-year period prior to the date of enactment of the Chemical Safety Improvement Act. The Administrator shall consider chemical substances for which such notices are received to be active substances and shall, pursuant to paragraph 5(C), designate them as such on the list published under paragraph (1).

~~"(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.~~

"(B~~D~~) CONFIDENTIAL CHEMICAL SUBSTANCES.—The rule promulgated by the Administrator under subparagraph (A) shall—

"(i) require the Administrator to maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

"(ii) ~~under subparagraph (B) shall~~ require a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) of this paragraph ~~reporting information relating to~~for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor ~~claims~~ seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

"(iii) require the substantiation of such claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C).

"(C) REVIEW PLAN.—Not later than 1 year after the date of the Administrator's compilation of the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are notified pursuant to subparagraph (A) of this paragraph or identified as active substances under subparagraph (5)(A). The plan shall—

"(i) require, at the time requested by the Administrator, all manufacturers or processors asserting such claims under subparagraph (B) to substantiate such claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator within 5 years of the date of the Administrator's request;

"(ii) require the Administrator, in accordance with the requirements of section 14, to—

"(I) review each substantiation—

"(aa) submitted pursuant to clause (i) to determine if the claim warrants protection from disclosure; and

"(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if such substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

"(II) approve, modify or deny each claim; and

"(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years unless—

"(aa) 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

"(bb) 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); and

"(iii) encourage manufacturers or processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subparagraph (5)(B) to review and either withdraw or substantiate such claims.

"(D) TIMELINE FOR COMPLETION OF REVIEWS.—

"(i) The Administrator shall implement the plan so as to complete reviews of all claims specified in subparagraph (C) within 5 years of the Administrator's compilation of the initial list of active substances pursuant to subparagraph (A).

"(ii) CONSIDERATIONS.—The Administrator may extend the deadline for completion of the reviews for up to a maximum of 2 additional years, after an adequate public justification, if the Administrator finds the extension is necessary based on the number of such claims needing review and the available resources. The Administrator shall publish an annual goal for the number of reviews to be completed over the course of implementation of the plan.

"(E) The specific identity of any chemical that is not on the confidential portion of the list published under paragraph (1) or subsequently added to the confidential portion of the list pursuant to section 14 shall not be eligible for protection from disclosure.

"(F~~E~~) CERTIFICATION.—The rule under ~~subparagraph (B)~~this subsection 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~~ACTIVE AND INACTIVE SUBSTANCES.—

~~"(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.~~

"(A~~6~~) ACTIVE SUBSTANCES.—For the purposes of this section, the term 'active substance' means a chemical substance ~~The Administrator shall designate as an active substance—~~

~~"(A) a chemical substance~~ that has been manufactured or processed for a nonexempt commercial purpose~~s~~ at any point during the 10~~5~~-year period prior to the date of enactment of the Chemical Safety Improvement Act;

"(ii~~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; or

"(iii~~C~~) ~~a chemical substance~~ for which a notice is received under paragraph (5~~7~~)(D~~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~~.

"(B~~7~~) INACTIVE SUBSTANCES.—For purposes of this section, the term 'inactive substance' means a

~~"(A) IN GENERAL.—The Administrator shall designate as an inactive substance each~~ chemical substance on the list published under paragraph (1) that does not meet any of the criteria in subparagraph (A)~~has not been manufactured or processed for a nonexempt commercial purpose 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) The Administrator shall maintain and keep current designations of active and inactive substances on the list published under paragraph (1).

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

"(E~~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) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—

"(I) If a person submitting a notice under clause (i) for an inactive chemical substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the substance as confidential, the person shall—

"(aa) in the notice submitted under clause (i), assert the claim; and

"(bb) within 30 days of providing the notice under clause (i), substantiate the claim.

"(II) The specific identity of any inactive chemical that is not on the confidential portion of the list published under paragraph (1) or subsequently added to the confidential portion of the list pursuant to section 14 shall not be eligible for protection from disclosure.

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

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

"(II) ~~shall,~~ pursuant to section 14~~(c)~~, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for

protection against disclosure of the specific identity of the substance and approve, modify, or deny the claim~~ review the priority of the chemical substance as the Administrator determines necessary;~~.

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

"(aa) 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

"(bb) 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); and

"(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines necessary.

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

"(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the rule required under this subsection, the Administrator shall designate those substances reported under Part 711 of title 40, Code of Federal Regulations, during the reporting period that most closely preceded the date of enactment of the Chemical Safety Improvement Act, as the initial list of active substances for the purposes of section 4A.

"(7~~8~~) PUBLIC PARTICIPATION.—

~~"(A) IN GENERAL.—~~Subject to this subsection~~subparagraph (B)~~, the Administrator shall make available to the public—

"(A~~i~~) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1~~5~~) that the Administrator has designated as an active substance;

"(B~~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;

"(C~~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 approved by the Administrator pursuant to section 14; and

"(D~~iv~~) subject to section 14(g), the specific identity of any active ~~or inactive~~ substance—

"(i) ~~on the confidential portion of the list published under paragraph (1)~~ for which no claim of protection against disclosure of the specific identity pursuant to this subsection ~~confidentiality~~ was received~~, subject to the condition that, before revealing the specific identity of the substance, the Administrator shall—~~

"(ii) for which a claim for protection against disclosure of the specific identity of the substance has been denied by the Administrator; or

"(iii) for which the time period for protection against disclosure of the specific identity of the substance has expired.

~~"(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 presents or will present, or 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 "subsections (c) or (d) ~~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~~the mixture or article; and

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

"(4) TESTING.—The Administrator may require testing under section 4 of any chemical substance or mixture exempted from this Act by paragraph (1) for the purpose of determining whether or not the substance or mixture presents an unreasonable risk of harm to human health within the United States or to the environment of the United States.

(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~~and for which a prohibition or restriction has been proposed or established under that section;

"(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~~and for which a prohibition or restriction has been proposed or established under that section; ~~or~~

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

"(D) a chemical substance or mixture subject to a prohibition or restriction pursuant to a rule, order or consent agreement in effect under this Act; or

"(E) a chemical substance or mixture for which the submission of information is required under section 4.

"(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)(E), a notice of availability of the ~~that~~ information on the chemical substance or mixture ~~can be obtained from~~ submitted to the Administrator~~, unless the Administrator determines that good cause exists not to provide the notice~~;

"(B) for a chemical substance or mixture described in subparagraph (A), (B) or (D) of paragraph (1), a notice of the determination, rule, order, consent agreement, requirement or designation; and

"(CB) 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.

"(ab) 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 or article containing a chemical substance or mixture offered for such entry if—

"(A) the Administrator—

"(i) 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; orand

"(iiB) has promulgated a rule under section 6(d) banning the chemical substance or mixture, as of the effective date of the rule;

"(B) the chemical substance—

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

"(ii) is not exempt from any requirement to be included on that list by this title or a rule issued by the Administrator under this title; or

"(C) the chemical substance, mixture or any article containing the chemical substance or mixture is offered for entry in violation of a rule, consent agreement or order in effect under this Act or an order issued in a civil action brought under section 7 or title IV.

"(2) PROCEDURE.—

"(A) IN GENERAL.—Subject to subparagraph (B), if a chemical substance, ~~or~~ mixture, or article containing 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.

"(be) CERTIFICATIONNOTICE.—

"(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) certifyshall 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 that the chemical substance—

"(iiA)(I) is included on the list under section 8(b)(1); or

"(BII) is exempt from any requirement to be included on that list by this title or a rule issued by the Administrator under this title. ; and

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

"(2) ARTICLES.—The Administrator may, by rule, require certification under subsection (b)(1) for an article containing a chemical substance or mixture that is subject to regulation under section 5 or 6. Such rule shall identify with reasonable specificity the types of articles, including parts or components thereof, that will be subject to the certification requirement. In determining the need for and content of a certification rule under this paragraph, the Administrator shall consider—

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

"(B) the contribution of imported articles to the potential risk presented by exposure to the chemical substance or mixture subject to regulation under section 5 or 6;

"(C) the impact to commerce and potential for such certification to impede or disrupt import of articles;

"(D) the frequency or duration of the certification requirement; and

"(E) specification of the concentration of a chemical substance in an article that would subject the article to the certification requirement.

"(3) REASONABLE INQUIRY.—

"(A) For purposes of a certification under subsection (b)(1), reasonable inquiry shall include good faith reliance by an importer on—

"(i) a safety data sheet or similar declaration provided by a supplier that documents the specific identity of the chemical substance or the specific identities of all chemical substances in a mixture; or

"(ii) for chemical substances or mixtures claimed by the supplier as confidential, or not otherwise disclosed by the supplier, a certification by the supplier that the imported chemical substance or mixture satisfies the applicable certification requirements under subsection (b)(1).

"(B) For purposes of a certification under subsection (b)(2), reasonable inquiry shall include good faith reliance by an importer on a certification by the supplier that the imported article satisfies the applicable certification requirements in a rule promulgated under subsection (b)(2).

For purposes of this section, EPA shall provide publicly accessible information on the identity of a chemical substance or mixture subject to regulation under this Act that would be readily understood in import transactions.

"(c~~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 or chemical substance in a mixture is a high-priority substance;

"(B) the chemical substance or chemical substance in a mixture is ~~a chemical~~ one for which the United States is obligated to provide export notification by treaty; or

"(C) the chemical substance or chemical substance in a 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(d) 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 this section. Such rules may tailor the application of any requirement in this section, as appropriate for the efficient and effective implementation of this Act. ~~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:

(1) By striking the heading "Disclosure of Data" and inserting "Confidential Information."

(2) By striking subsection (c) and redesignating subsection (b) as subsection (c);

(3) By striking subsection (a) and inserting the following:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) IN GENERAL.—Except as otherwise provided in this ~~sub~~section~~s (c) and (e)~~, the Administrator shall not disclose 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~~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 specific to and submitted by a manufacturer, processor, or distributor that meets the requirements of subsection (d) is presumed to be protected from disclosure, except that nothing in this Act shall operate to prohibit the disclosure of such information through discovery, subpoena, other court orders, or

any other judicial process otherwise allowed under applicable state or federal laws: ~~submitted by a manufacturer, processor, or distributor is presumed to be protected from disclosure:~~

"(1~~A~~) Specific information describing the processes used in manufacture or ~~,~~ processing~~, or distribution in commerce~~ of a chemical substance, mixture, or article.

"(2~~B~~) Marketing and sales information.

"(3~~C~~) Information identifying suppliers or customers.

"(4~~D~~) Details of the full composition of ~~The identity of constituents in~~ a mixture and the respective percentages of ~~those~~ constituents.

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

"(6~~F~~) Specific production or import volumes of the~~a~~ manufacturer, and specific aggregated volumes ~~aggregated~~ across manufacturers if the Administrator determines that disclosure of the specific aggregated ~~data~~volumes ~~c~~would reveal confidential information.

"(7~~G~~) Except as otherwise provided in this section, t~~T~~he specific identity of a chemical substance prior to the date on which it is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if—

"(A~~i~~) the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5; and

"(B~~ii~~) the claim has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under subsection (e), (f)(2), or (g).

(4) By striking the heading "DATA FROM HEALTH AND SAFETY STUDIES" in subsection (c) (as so redesignated) and inserting "INFORMATION NOT PROTECTED FROM DISCLOSURE.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:"

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

"(3~~c~~) OTHER 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 specific identity of a chemical substance as of the date on which it is first offered for commercial distribution, 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.~~

"(C~~E~~) General information describing the manufacturing volumes, expressed as specific aggregated volumes or, when the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges ~~would not reveal confidential information~~.

"(D~~F~~) General descriptions of the processes used in manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, ~~or~~ mixture or article containing a chemical substance or mixture, including information specific to an industry or industry sector that would be customarily shared with the general public or within an industry or industry sector.

"(4~~2~~) EXCEPTION.—Information elements ~~contained in submissions described in paragraph (1)~~ that are otherwise eligible for protection under this section that are contained in submissions of information described in paragraph (1) shall be protected from disclosure if the submitter complies with subsection (d), but information in such submissions described in paragraph (1) that is not eligible for protection against disclosure shall be disclosed.

"(5) Except as provided in the second sentence of paragraph (1), the specific identity of any chemical that is not on the confidential portion of the list published under section 8(b)(1) or subsequently added to the confidential portion of the list pursuant to this section shall not be eligible for protection from disclosure.

"(6) BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase out on the manufacture, processing, or distribution in commerce of a chemical substance, any protection from disclosure provided under section 14 applicable for information on the chemical substance shall no longer apply and the Administrator shall promptly make the information public.

"(d) REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert a claim for such protection ~~For information to be protected from disclosure under this section, a person who submits information~~ to the Administrator at the time of the submission of the information, pursuant to rules applicable to claim for protection from disclosure that the Administrator has promulgated under this title.~~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—~~

"(B~~A~~) An assertion of a claim under subparagraph (A) shall include a statement that the person has ~~information establishing that~~—

"(i) ~~the person takes~~taken reasonable measures to protect the confidentiality of the chemical identity;

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

"(iii) a reasonable basis to conclude that disclosure of the ~~chemical identity~~information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information ~~the chemical identity~~ is not ~~reasonably believed to be~~ readily discoverable through reverse engineering.~~;~~

"(C) In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the conditions that the generic name conforms with guidance prescribed by the Administrator under paragraph (3)(A) and describes the chemical structure of the substance as specifically as possible 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.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS ~~FOR CHEMICAL IDENTITIES~~.—Except for information described in subsection (b)(1) through (7), a person asserting a claim to protect information from disclosure ~~A person submitting information~~ under this Act shall, in accordance with the rules promulgated and guidance issued by the Administrator, substantiate the claim. ~~related to a chemical identity and who claims protection from disclosure for that identity shall provide the Administrator with—~~

~~"(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 on—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5) and (6) of subsection (e).

~~, after notice and opportunity to comment, on the determination of generic names for confidential chemical identities.~~

"(4~~B~~) CERTIFICATION.—An authorized official of the person described in ~~sub~~paragraph (1)(A) shall certify that the information that has been submitted is true and correct.

"(e) EXCEPTIONS TO PROTECTION FROM DISCLOSURE.—Information described in ~~S~~subsection (a) shall be disclosed ~~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) one or more applicable agreements with the Administrator that conform with the guidance issued under subsection (d)(3)(B) 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~~comparable to 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 or environmental 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 agrees to sign a written confidentiality agreement with the Administrator that conforms with the guidance issued under subsection (d)(3)(B), 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 necessary for or will assist ~~needed for purposes of diagnosis~~in diagnosis or treatment of one or more individuals or in responding to an environmental release or exposure; and

"(ii) one or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred.~~; 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~~information for any purpose other than the health or environmental 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~~information to the Administrator, except that nothing in this Act shall operate to prohibit the disclosure of such information through discovery, subpoena, and other court orders, or any other judicial process otherwise allowed under applicable state or federal laws;

"(6) in the event of an emergency, a treating physician, ~~or~~ nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder requests the information, subject to the conditions that—

"(A) the treating ~~physician or nurse~~physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder has a reasonable basis to suspect ~~determines~~ that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the informationspecific chemical identity of the chemical substance concerned is necessary for or will assist in emergency or first-aid diagnosis or treatment; and

"(iii) the one or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or exposure to the chemical substance concerned has occurred; and

"(B) if requested by the person submitting the specific chemical identityinformation to the Administrator, the treating physician, or nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder provides a written statement of need and agrees to sign 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;

"(D) For the purposes of this paragraph, the term 'first responder' means a person duly authorized by a State or political subdivision of a State or a Federal agency, trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician.

"(7) the Administrator determines that disclosure is necessary relevant 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;

"(9) the information is publicly available; or

"(10) the information is required to be disclosed or otherwise made public under any other Federal law.

"(f) DURATION OF PROTECTION FROM DISCLOSURE.—

"(1) IN GENERAL.—

"(A) INFORMATION PROTECTED FROM DISCLOSURE.—Subject to paragraph (2), Tthe Administrator shall protect from disclosure information described in subsection (b) that meets the requirements of subsection (d)(2) for the a period of 10 years, 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—

"(i~~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

"(ii~~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).

"(B) EXTENSIONS.—

"(i) At least 60 days prior to the expiration of the period described in subparagraph (A), the Administrator shall provide notice of the impending expiration of the period to the person who asserted the claim.

"(ii) At least 30 days prior to expiration of the period described in subparagraph (A), the person reasserting the claim shall submit a statement substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(iii) Within 30 days of receipt of the statement described in clause (ii), the Administrator shall review the request and make a determination as to whether the information for which the request is made continues to meet the relevant criteria established in this section, and shall either grant an extension not to exceed 10 years or deny the claim.

"(C) LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph (B) as long as the Administrator finds that the substantiation establishes the need to extend the period and meets the requirements established by the Administrator, and that the length of any extension does not exceed 10 years.

"(2) REVIEW AND RESUBSTANTIATION~~REDOCUMENTATION~~.— ~~The Administrator may request —~~

"(A) The Administrator may at any time review a claim for protection against disclosure under subsection (a) for information submitted to the Administrator on a chemical substance and may require any~~, a~~ person who has claimed~~requested~~ protection for that information, whether before or after the

date of enactment of the Chemical Safety Improvement Act, to withdraw or reassert and substantiate or resubstantiate the claim in conformance with the requirements of this section—

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified pursuant to section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and determinations under section 6(b) and (c) or promulgating rules under section 6(d), provided that such information shall not be disclosed unless the claimant withdraws the claim or the Administrator finds that the information does not or no longer meets the requirements of subsection (d).

~~from disclosure for the identity 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).~~The Administrator shall review a claim for protection from disclosure under subsection (a) for information submitted to the Administrator on a chemical substance, and shall require any person who has claimed protection for that information, whether before or after the date of enactment of the Chemical Safety Improvement Act, to withdraw or reassert and substantiate or resubstantiate the claim in conformance with the requirements of this section—

"(i) if necessary to comply with a request for information the Administrator receives pursuant to section 552 of title 5, United States Code;

"(ii) if information available to the Administrator provides a basis that the requirements of subsection (b)(4) of section 552 of title 5, United States Code, are no longer met; or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) If the Administrator makes a request under subparagraph (A) or (B), the person receiving the request shall—

"(i) resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) Protection from disclosure of the information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term, and apply such identifier consistently to all information relevant to such substance;

"(B) annually publish and update a list of substances for which claims to protect specific chemical identity from disclosure have been approved, referred to by unique identifier, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a substance during the period of protection from disclosure is made public and identifies the substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator, upon expiration of the period for appeal under subsection (g)(3), that has expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the substance.

"(g) DUTIES OF THE ADMINISTRATOR.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b)~~(2)~~, the Administrator shall, subject to subparagraph (C), not later than 90 days after

the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and —

~~"(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 the~~at~~ claim or request.

"(B) DENIAL OR MODIFICATION.—

"(i) IN GENERAL.—Except as provided in subsections (c) and (f), t~~T~~he Administrator shall deny a claim to protect a chemical identity from disclosure only if the person who has submitted the ~~request~~ claim fails to meet the requirements of subsections (a) and (d).

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

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection (b)(7), review all claims under this section for the protection against disclosure of the specific identity of a chemical substance; and

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

~~If it is not feasible for the Administrator to review each request under this section, the Administrator shall review a representative subset.~~

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

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), ~~and~~ (e) and (f), if the Administrator denies or modifies a ~~request~~ claim under paragraph (1), the Administrator shall notify, in writing

and by certified mail, the person who submitted the ~~request~~ claim 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~~ shall 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~~ shall not release that information until the date that is 15 days after the date on which the person who submitted the ~~request~~ claim 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 (1), (2), (6), ~~or~~ (7), (9) or (10) of subsection (e), no prior notification is necessary.

"(3) APPEALS.—

"(A) IN GENERAL.—A person who receives notification under ~~this subsection~~paragraph (2) 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 that is the subject of an appeal 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) Except as otherwise provided by this section, section 8, or any other Federal law, the Administrator shall have no authority—

"(A) to require the ~~documentation or redocumentation~~substantiation or resubstantiation 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

"(B~~2~~) to impose ~~redocumentation~~ substantiation or resubstantiation requirements under this Act that are more extensive than those required under this section."

"(2) PRIOR ACTIONS.—Nothing in this Act shall be construed to prevent the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information prior to the effective date of rules applicable to such claims that the Administrator may promulgate after the date of enactment of the Chemical Safety Improvement Act.".

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. PENALTIES

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

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in the first sentence—

(I) by inserting "this Act or a rule or order promulgated or issued pursuant to this Act, as described in" after "a provision of"; and

(II) by striking "$25,000" and inserting "$37,500"; and

(ii) in the second sentence, by striking" violation of section 15 or 409" and

inserting “violation of this Act”; and

(2) in subsection (b)—

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

“(1) IN GENERAL.—Any person”;

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

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

(D) by adding at the end the following:

“(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—Any person who knowingly or willfully violates any provision of this Act, and who knows at the time of the violation that the violation places another person in imminent danger of death or serious bodily injury shall be subject, upon conviction, to a fine of not more than $250,000, imprisonment for not more than 15 years, or both. Any person committing such violation which is an organization shall, upon conviction under this paragraph, be subject to a fine of not more than $1,000,000 for each violation.”

“(3) KNOWLEDGE OF IMMINENT DANGER OR INJURY.—In determining whether a defendant knew that the violation placed another person in imminent danger of death or serious bodily injury, the defendant is responsible only for actual awareness or actual belief possessed, and knowledge possessed by another person is not the defendant may not be attributed to the defendant.”

SEC. 16. PREEMPTION.

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

“(a) IN GENERAL.—

“(1) ESTABLISHMENT OR ENFORCEMENT.--Except as provided in subsections (c) and (d), no State or political subdivision of a State may establish or continue to enforce—

“(A~~1~~) TESTING AND INFORMATION COLLECTION.--a statute or administrative action to require~~ment 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 in~~by~~—

“(A) a rule promulgated by the Administrator;

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

“(C) an order issued by the Administrator;

"(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—a statute or administrative action to prohibit or restrict "(2) a prohibition or restriction on the manufacture, processing, or distribution in commerce or use of a chemical substance—

"(i) for a substance found to meet the safety standard and consistent with the scope of the determination made by the after issuance of a completed safety determination for a chemical substance under section 6, consistent with the scope of the review and decisions addressed by the Administrator; or

"(ii) for a substance found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator; or

"(C3) SIGNIFICANT NEW USE.—a statute or administrative action requiring 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.

"(2) EFFECTIVE DATE FOR CERTAIN PREEMPTION.—Under this subsection, Federal preemption of State statutes and administrative actions applicable to specific substances shall be consistent with the scope of the determination made by the Administrator and shall not occur until the date of the Administrator's determination that the substance meets the safety standard or until the date on which compliance with the rule issued under section 6(d) is required.

"(b) NEW STATUTES OR ADMINISTRATIVE ACTIONS CREATING 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) HIGH PRIORITY.—a statute or administrative action prohibiting or restricting 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 4A, (e)(3) (as of the date on which the Administrator publishes a schedule under section 6(b)) commences a safety assessment under section 6; or

"(2) LOW PRIORITY.—a statute or administrative action prohibiting or restricting 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 4A, (e)(3)as of the date on which the Administrator designates the substance as a low priority.

"(c) EXCEPTIONS.—

"(1) Subsections (a) and (b) shall not apply to a requirement, prohibition, or restriction of a State or a political subdivision of a State that—

"(A1) is adopted under the authority of any other Federal law;

"(B2) implements a reporting, monitoring, or information collection requirement not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C3) 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.

"(2) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—Nothing in this Act, nor any amendment made by this Act, nor any regulation, requirement, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any regulation, requirement, standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

"(A) is adopted or authorized to comply with any other Federal law;

"(B) implements reporting, monitoring, or information collection requirement not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C) 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 does not impose a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance and is not otherwise required by or inconsistent with an action by the Administrator under section 5 or 6.

"(3) Nothing in this section shall be construed as requiring the Administrator to modify or withdraw, any rule or order under section 5 or 6 of this Act, or as modifying the effect of this section as enacted prior to the effective date of the Chemical Safety Improvement Act on any rule or order promulgated or issued under this Act prior to the effective date of the Chemical Safety Improvement Act.

"(d) PRESERVATION OF CERTAIN STATE LAW.—Nothing in this section shall be construed to preempt or otherwise affect any warning requirement relating to consumer products or substances that is established pursuant to State law that was in effect on August 31, 2003 unless a rule, consent agreement, or order is promulgated under section 6 imposing a warning requirement, which shall preempt a chemical specific State warning requirement consistent with the scope of the Administrator's determination under section 6.

"(e~~d~~) STATE WAIVERS.—

"(1) IN GENERAL.—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~~ statute or administrative action of that State or political subdivision of the State that relates to the effects or exposure to any chemical substance under the intended or reasonably anticipated conditions of use if—

"(A~~1~~)(i~~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)~~3A; and

"(ii~~B~~) the Administrator determines that—

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

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

"(III~~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~~iv~~) based on the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is consistent with sound objective scientific practices, the weight of the evidence, and ~~based on~~ the best available science ~~and is supported by the weight of the evidence~~; or

"(B~~2~~)(i~~A~~) the Administrator finds a safety assessment or determination has been unreasonably delayed; and

"(ii~~B~~) the State certifies that—

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

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

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

"(IViv) the proposed requirement is grounded in reasonable scientific concern; or

"(C)(i) the State has contracted with the National Academy of Sciences to assess the hazard, use and exposure, and risk of a chemical substance;

"(ii) the report complies with the requirements of the Federal Advisory Committee Act Amendments of 1997;and

(iii) based on the best available evidence described in the report of the National Academy of Sciences, the State establishes a requirement relating to the effects of or exposure to a chemical substance.

"(23) 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)(A) is submitted; and

"(B) not later than 90 days after the date on which an application under paragraph (12)(B) is submitted.

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

"(45) 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.

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

"(A) granted under paragraph (1)(A) 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)(B) or (C) shall remain in effect until such time as the safety assessment and determination is completed.

"(6~~7~~) JUDICIAL REVIEW.—

"(A) IN GENERAL.—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.

"(B) JUDICIAL REVIEW OF PRIORITIZATION SCREENING DECISION.—Not later than 60 days after the date on which the Administrator makes a decision on a recommendation made under section 4A(c) to designate a chemical substance as a low priority, the Governor of a State or a State agency with responsibility for protecting health and the environment that submitted the recommendation, as applicable, 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.

"(7) SAVINGS—

"(A) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF OR CRIMINAL CONDUCT.—Nothing in this Act, nor any amendment made by this Act, nor any regulation, requirement, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall be construed to preempt, displace, or supplant any state or federal common law rights or any state or federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.

"(B) CLARIFICATION OF NO PREEMPTION.—Notwithstanding any other provision in this Act, nothing in this Act, nor any amendments made by this Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any state, maritime, or federal common law or statutory theory.

"(C) NO EFFECT ON PRIVATE REMEDIES.—

"(i) Nothing in this Act, nor any amendments made by this Act, nor any rules, regulations, requirements, safety assessments, safety determinations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action; and;

"(ii) this Act does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, safety assessments, scientific assessments, or orders issued pursuant to this Act.

~~"(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. 1~~7~~6. JUDICIAL REVIEW.

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

(1) In subsection (a)--
- (i) Subparagraph (1)(A), striking "section 2603 (a), 2604 (a)(2), 2604 (b)(4), 2605 (a), 2605 (e), or 2607 of this title, or under subchapter II or IV of this chapter" and inserting "section 4(a), 5(c)(~~4~~5), 6(d), or 8 of this title" in lieu thereof;
- (ii) Subparagraph (1)(B), striking the reference to "paragraph (1)(A)" and inserting "paragraph (1)" in lieu thereof; and
- (iii) By striking paragraph (3).

(2) In subsection (c)—
- (i) Subparagraph (B)(1)(i), by striking "section 2603 (a), 2604 (b)(4), 2605 (a), or 2605 (e)" and inserting "section 4(a), 5(c)(~~4~~5), or 6(d)" in lieu thereof;
- (ii) By striking subparagraph (B)(1)(ii);
- (iii) By redesignating subparagraph (B)(1)(iii) as subparagraph (B)(1)(ii); and
- (iv) In subparagraph (B)(1)(ii) as so redesignated, striking "(I) any statement required to be made pursuant to section 2605(c)(1) of this title, or (II)"

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 incorporated in the rule except as part of a review of the rulemaking record taken as a whole.".~~

SEC. 1~~8~~87. 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)~~, 5(c), ~~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(d~~e~~)~~(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 section 6(d~~e~~)~~(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. 1~~8~~9. STUDIES.

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

SEC. 20~~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. 210. 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. 221. STATE PROGRAMS.

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

SEC. 232. AUTHORIZATION OF APPROPRIATIONS.

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

SEC. 243. 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);".