114TH CONGRESS
1ST SESSION

S. 725

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

IN THE SENATE OF THE UNITED STATES

MARCH 12, 2015

Mrs. BOXER (for herself, Mr. MARKEY, and Mr. SANDERS) introduced the following bill; which was read twice and referred to the Committee on Environment and Public Works

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A BILL

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

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act''.

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

SEC. 2. 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.).

TITLE I—AMENDMENTS TO THE TOXIC SUBSTANCES CONTROL ACT

SEC. 101. FINDINGS, POLICY, AND INTENT.

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

(1) In paragraph (2)—

(A) by striking ''injury'' and inserting ''harm''; and

(B) by striking ''and'' at the end;

(2) by redesignating paragraph (3) as paragraph (6); and

(3) by inserting after paragraph (2) 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''.

SEC. 102. DEFINITIONS.

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

(1) by redesignating paragraphs (7), (8), (9), (10), (11), (12), (13), and (14) as paragraphs (9), (10), (11), (13), (14), (19), (20), and (21), respectively;

(2) by inserting after paragraph (6) the following:

''(7) INFORMATION.—Except in section 14, 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 FORESEEABLE CONDITIONS OF USE.—The term 'intended or reasonably foreseeable conditions of use' means the circumstances under which a chemical substance is intended, reasonably known, or reasonably anticipated to be manufactured, processed, distributed in commerce, used, disposed of, and released into the envi-

ronment, including reasonably foreseeable but unintended exposure conditions from unplanned releases into the environment.'';

(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—

''(A) differentially exposed to chemical substances under the intended or reasonably foreseeable conditions of use; or

''(B) more susceptible to 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 (14) (as so redesignated) the following:

''(15) 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, includ-

ing information that has been published in periodicals, books, print, or electronic or other media available for general distribution to any member of the public.

''(16) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the intended or reasonably foreseeable conditions of use, integrating hazard, use, and exposure information about the chemical substance.

''(17) 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 foreseeable conditions of use.

''(18) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures with reasonable certainty, without taking into consideration cost or other non-risk factors, that no harm to human health or the environment will result from exposure to a chemical substance under the intended or reasonably foreseeable conditions of use, including no 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. 103. POLICIES, PROCEDURES AND GUIDANCE.

The Toxic Substances Control Act (15 U.S.C. 2601 et seq.) is amended by adding after section 3 the following:

''SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

''(a) DEADLINE.—Not later than 2 years after the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act, the Administrator shall, after providing an opportunity for public notice and comment, develop the policies, procedures and guidance required by this section. As used in this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.

''(b) USE OF SCIENCE.—In establishing any policies, procedures, and guidance, on the use of science in making decisions under this section and sections 4, 4A, 5, and 6, the Administrator shall have the goal of making 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) decisions by the Administrator—

''(A) are based on the best available science; and

''(B) take into account the extent to which—

''(i) assumptions and methods used to develop information considered by the Administrator are clearly and completely described and documented;

''(ii) variability and uncertainty in such information are evaluated and characterized; and

''(iii) the information has been subject to independent peer review;

''(2) to the extent practicable and where appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and appropriate laboratory practices will be encouraged;

''(3) the names of the 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) decisions by the Administrator follow the applicable recommendations in relevant National

Academy of Sciences reports, including the reports titled: Science and Decisions: Advancing Risk Assessment, Phthalates and Cumulative Risk Assessment: The Task Ahead, Review of EPA's Integrated Risk Information System (IRIS) Process, Review of the Formaldehyde Assessment in the National Toxicology Program 12th Report on Carcinogens, and Review of the Styrene Assessment in the National Toxicology Program 12th Report on Carcinogens.

''(c) EXISTING EPA POLICIES, PROCEDURES AND GUIDANCE.—The policies, procedures, and guidance described in subsections (a) and (b) 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 previously issued by the Administrator.

''(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—

''(1) review the adequacy of any policies, procedures, and guidance developed under this section, including procedures for assessing and determining risk under this Act; and

''(2) after providing an opportunity for public notice and comment, revise the policies, procedures, and guidance 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 foreseeable 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 and procedures 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 and that lack of information on exposure or ex-

posure potential shall not, by itself, be a reason not to require testing;

"(B) describe how the Administrator will determine that additional testing is needed to carry out this Act, including testing related to potentially exposed or susceptible populations and testing related to the accumulation of chemical substances in the human body;

"(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 mammals, 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 mammals that would provide equivalent information.

''(3) TIERED TESTING.—Except as provided in subparagraph (C), the Administrator shall employ a tiered screening and testing process, in which the results of screening level tests or assessments of available information inform the decision as to whether 1 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, 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 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 prioritization or safety assessments and safety determinations, the Administrator may require more advanced

tests for potential human health or environmental effects or exposure.

''(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 policies or procedures developed by the Administrator under this subsection.

''(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 safety 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 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, in each safety assessment and safety determination, to—

"(i) identify the substance's intended or reasonably foreseeable conditions of use based on information provided by its manufacturers and processors or otherwise available to the Administrator;

"(ii) identify all potentially exposed or susceptible populations that the Administrator determines are pertinent to the substance;

''(iii) identify the hazards of the substance and its metabolites and breakdown products and any differences in the magnitude or nature of these hazards for potentially exposed or susceptible populations, including the potential for chemical substances to accumulate in the human body;

''(iv) determine the nature and extent of exposures to the chemical substance by the general population and each potentially exposed or susceptible population, including aggregate exposures resulting from multiple pathways or routes of exposure;

''(v) to the extent practicable, review and incorporate any available scientific information on the cumulative effects of exposure to the chemical substance and other chemical substances posing similar hazards to human health and the environment; and

''(vi) characterize the nature and extent of the risk presented by the chemical substance, taking into account aggregate exposures resulting from multiple pathways or routes of exposure and the cumulative

effects of exposure to the chemical substance and other chemicals posing similar hazards; and

''(C) 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) RELEASE OF SAFETY ASSESSMENTS.—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 each proposed safety assessment and safety determination; 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 and procedures that were followed in carrying out the safety assessment and safety determination.

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

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act, the Administrator shall establish a Science Advisory Committee on Chemicals (referred to in this subsection as the 'Committee') 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) COMPOSITION OF COMMITTEE.—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) MEETINGS.—The Administrator shall convene the Committee on a schedule the Administrator determines appropriate, but not less frequently than once every 2 years.

''(4) FEDERAL ADVISORY COMMITTEE ACT.—All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).

''(5) CONFLICT OF INTEREST POLICIES.—The Administrator shall establish and make public conflict of interest policies that shall apply to the Committee members, who shall be appointed as Special Government Employees.

''(j) NATIONAL ACADEMY OF SCIENCES REPORTS.—Not later than 120 days after the issuance of any report by the National Academy of Sciences concerning hazards, exposures, or risks of chemical substances, the Administrator shall issue a public response to the principal recommendations of the report.''.

SEC. 104. 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 subsections (e) and subsection (f) as subsections (f) and (g), respectively;

(2) in subsection (f) (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 (g) (as so redesignated)—

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

(B) by striking ''unreasonable'' each place it appears and inserting ''significant''; and

(C) by striking the last sentence; and

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

''(a) DEVELOPMENT OF NEW INFORMATION ON CHEMICAL SUBSTANCES AND MIXTURES.—

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

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

''(B) to implement a requirement imposed in a consent agreement or order issued under section 5(c)(4);

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

''(D) at the request of the implementing authority under any other Federal law.

''(2) TESTING FOR PRIORITIZATION PURPOSES.—The Administrator may require the development of new information for the purposes of section 4A, provided that any such testing shall not be based on a set of uniform minimum information requirements for all or large groups of chemical substances. 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) FORM.—Subject to section 3A(f), the 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.

''(4) CONTENTS.—

''(A) IN GENERAL.—A rule, testing consent agreement, or order issued under 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) to the extent practicable, test protocols and methodologies for the development of information for the chemical substance or mixture, including specific reference to reliable nonmammal test procedures; and

''(iv) specification of the period within which persons required to conduct the testing shall submit to the Administrator the 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) STATEMENT OF NEED.—

"(1) IN GENERAL.—In promulgating a rule, entering into a testing consent agreement, or issuing an order for development of additional information (including information on exposure or exposure potential) under this section, the Administrator shall—

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

"(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of mammals.

"(2) 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 for issuance of an order instead of promulgating a rule or entering into a testing consent agreement.

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

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

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

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) REDUCTION OF TESTING ON MAMMALS.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of mam-

mals in testing of chemical substances or mixtures, by—

"(A) encouraging and facilitating—

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

"(ii) the use of 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 mammals while providing information of high scientific quality;

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

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

"(vi) the submission of information from animal-based studies and emerging methods and models; 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 based on mammals, 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 in safety assessments and determinations under section 6 that can reduce, refine, or replace the use of mammals, 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 Alan Reinstein and Trevor Schaefer Toxic Chemical Protection 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) to the extent practicable, 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 mammals in any safety assessment or determination made under section 6.

''(d) TESTING REQUIREMENTS.—

''(1) IN GENERAL.—The Administrator may require the following persons to develop information:

''(A) Manufacturers and processors of the chemical substance or mixture.

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

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

''(ii) subject to paragraph (3), not later than 180 days after the completion of the period for submitting information specified under subsection (a)(4)(A)(iv).

''(2) DESIGNATION.—The Administrator may permit 2 or more of the persons identified in sub-

paragraphs (A) and (B) of paragraph (1) to designate a person or a qualified third party—

"(A) to develop the information; and

"(B) to submit the information on behalf of the persons making the designation.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—A person otherwise subject to a rule, testing consent agreement, or order under this section may submit to the Administrator an application for an exemption on the basis that the information is being developed by a person designated under paragraph (2).

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

"(i) IN GENERAL.—If the Administrator accepts an application submitted under subparagraph (A), the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as agreed to between the applicant and the person designated.

"(ii) ARBITRATION.—If the applicant and a person designated under paragraph

(2) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.

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

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

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

''(e) TRANSPARENCY.—Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders 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)''.

SEC. 105. PRIORITIZATION SCREENING.

The Toxic Substances Control Act (15 U.S.C. 2601 et seq.) is amended by adding after section 4 the following:

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) PRIORITIZATION SCREENING.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act, the Administrator shall by rule establish a screening process and criteria for identifying existing chemical substances that are—

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

"(B) a low priority for a safety assessment and safety 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 Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act, the Administrator shall consider and publish an initial list of high priority substances, which shall contain not less than 15 chemical substances, and pursuant to sections 6(a) and 6(b)(2), initiate or continue safety assessments and safety determinations for such substances.

''(3) ADDITIONS TO PRIORITY LIST.—Starting 1 year after publication of the initial priority list under paragraph (2) and at 1 year intervals thereafter for the following 4 years, the Administrator shall add at least 15 high-priority substances to the list and, pursuant to sections 6(a) and 6(b)(2), initiate or continue safety assessments and safety determinations for those substances.

''(4) WORKPLAN AND ACTION PLAN CHEMICALS.—The Administration may list as high-priority substances under paragraphs (2) and (3) those chemical substances or categories of chemical substances that are included in the Administrator's March 2012 Workplan (as updated in October 2014 and by subsequent updates) or are the subject of Existing Chemical Action Plans published by the Administrator before the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act without providing further justification for listing or meeting the requirements of this section.

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

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

"(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substance; and

"(bb) 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 not less than 1 chemical substance to the list of high-priority substances for each chemical substance removed from the list, until a safety assessment and safety determination is completed for all active substances, except that not less than 3 chemical substances shall be added for each chemical substance removed from the list, subject to section 21, when fees are in place.

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

"(i) IN GENERAL.—In addition to the decisions required by paragraphs (1) and (2), not later than 6 months after the effective date of the final rule under para-

graph (1), the Administrator shall begin the prioritization screening process.

''(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 120 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 requirement to meet the deadlines under section 6 of this Act.

''(iv) ANNUAL GOAL.—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.

''(6) CRITERIA.—The criteria described in paragraph (1) shall include—

''(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, and the recommendations of the public;

''(B) the hazard of the chemical substance (or category of substances), including specific

scientific classifications and designations by authoritative governmental entities;

''(C) the intended or reasonably foreseeable conditions of use of a chemical substance or significant changes in the intended or reasonably foreseeable conditions of use of the chemical substance;

''(D) evidence and indicators of exposure and potential exposure 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, and past and anticipated future changes in volume;

''(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, provided that limited availability of relevant in-

formation shall not be a sufficient basis for failing to designate a substance as a high priority;

''(H) the potential threat the chemical substance poses to drinking water supplies, based on hazard, exposure, or exposure potential (including whether the chemical substance is stored near sources of drinking water);

''(I) the extent to which a chemical substance accumulates in the human body; and

''(J) other relevant criteria identified by the Administrator.

''(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)(5); and

''(D) subject to paragraph (4) and 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) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(A) shall identify as a high-priority substance a chemical substance that the Administrator determines has, or has the potential for, significant hazard and significant or substantial exposure;

"(B) may identify as a high-priority substance a chemical substance that the Administrator determines has, or has the potential for, significant hazard or significant or substantial exposure;

"(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; and

"(D) may identify as a high-priority substance a chemical substance that accumulates in the body.

"(3) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a

low-priority substance a chemical substance if the Administrator—

"(A) concludes that sufficient hazard and exposure information is available for an informed evaluation of the substance's risks to human health and the environment;

"(B) determines, based on a review of the information available, that the substance is likely to meet the safety standard under the intended or reasonably foreseeable conditions of use; and

"(C) identifies the information on which the determination is based and describes the Administrator's analysis of this information.

"(4) 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—

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

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

''(5) 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.

''(6) NOTICE AND COMMENT.—Except as provided in subsection (a)(4), the Administrator shall publish the proposed decisions made under paragraphs (2), (3) and (4) and the basis for the decisions, and provide an opportunity for public comment.

''(7) REVISION BASED ON NEW INFORMATION.—The Administrator may, at any time, 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 paragraph (2) or (3), following the procedures in this section.

''(8) REVIEW.—Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Adminis-

trator 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 in a manner that complies with this Act.

''(9) EFFECT.—Subject to section 18, a decision by the Administrator under this subsection 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) FINAL AGENCY ACTION.—Except for the designation of a substance as low priority under subsection (b)(3), any action by the Administrator under this section shall not be—

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

''(2) subject to judicial review.''.

SEC. 106. 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 under 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 foreseeable conditions of use and reasonably foreseeable 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).

''(B) EXTENSION.—Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for

good cause for 1 or more periods, the total of which shall be not more than 90 days.

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

''(A) any relevant information identified in subsection (b)(1); and

''(B) any other relevant information available to, or submitted to, the Administrator.

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

''(A) the relevant chemical substance or a significant new use is not likely to meet the safety standard, 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, 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 subpara-

graph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (5).

''(4) RESTRICTIONS.—

''(A) IN GENERAL.—If the Administrator makes a determination under paragraph (3)(A) or (C) with respect to a notice submitted under subsection (a), 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 without compliance with the restrictions specified in the 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.

''(B) RULEMAKING.—Not later than 90 days after 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)(I) initiate such rulemaking; or

"(II) publish a statement of the Administrator's reasons for not initiating such action.

"(C) INCLUSIONS.—A prohibition, restriction, or requirement under subparagraph (A) shall include, as appropriate, 1 or more of the following requirements:

"(i) A requirement that a chemical substance or mixture or article containing the 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 in-

structions to be prescribed by the Administrator.

''(ii) A requirement that manufacturers or processors, as applicable, of the chemical substance or mixture 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 address potential risks from the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, subject to section 4.

''(iv) A restriction on the quantity of the chemical substance or a mixture or article containing the substance that may be manufactured, processed, or distributed in commerce.

''(v) A restriction on the quantity of the chemical substance or a mixture or article containing the substance that may be

manufactured, processed, or distributed in commerce—

"(I) for a particular use; or

"(II) for a particular use in a concentration in excess of a level specified by the Administrator in the consent agreement or order imposing the requirement.

"(vi) A prohibition or other regulation of the manufacture, processing, or distribution in commerce of the chemical substance or a mixture or article containing the substance for a significant new use.

"(vii) A prohibition or other regulation of any manner or method of commercial use of the chemical substance or a mixture or article containing the substance.

"(viii) A prohibition or other regulation of any manner or method of disposal of or environmental release of the chemical substance or a mixture or article containing the substance, by its manufacturer or processor or by any other person who

uses, or disposes of it, for commercial purposes.

''(ix) A prohibition or other appropriate restriction or requirement on the manufacture, processing, or distribution in commerce of the chemical substance or a mixture or article containing the substance.

''(x) A prohibition or other appropriate restriction or requirement on the manufacture, processing, or distribution in commerce of the chemical substance or a mixture or article containing the substance for a particular use.

''(D) RULE OF CONSTRUCTION.—The requirement, warning, or instruction required under subparagraph (C) does not establish a uniform national standard for the purpose of supplanting, displacing, or preempting State law.

''(E) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or re-

striction adopted under this subsection to address workplace exposures.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information 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) 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, after receiving 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 ad-

ditional 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 paragraph (1)(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, the manufacturer or processor shall submit to the Administrator a notice of commencement that identifies—

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

''(B) the initial date of nonexempt commercial manufacture; and

''(C) additional information specified in section 720.102(c)(1) of title 40, Code of Federal Regulations (or successor regulations).

''(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 screen a chemical substance under section 4A or require testing under section 4 at any time after the Administrator receives—

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

''(2) 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 issued under this section.'';

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

(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 ''will meet the safety standard'';

(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),''; and

(10) by inserting after subsection (h) (as so redesignated) the following:

''(i) PRIOR ACTIONS.—Nothing in this section requires the Administrator to modify or withdraw any rule

or order promulgated under section 5 of this title prior to the enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act.''.

SEC. 107. 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 redesignating subsection (b) as subsection (m) and moving the subsection so as to appear after subsection (l) (as added by paragraph (6));

(3) in subsection (m) (as so redesignated), by striking ''unreasonable'' each place it appears and inserting ''significant'';

(4) by striking subsections (a), (c) and (d) and inserting in lieu thereof the following, and by redesignating subsection (b) as subsection (i):

''(a) IN GENERAL.—The Administrator—

''(1) shall conduct a safety assessment and make a safety determination of each high-priority substance designated under section 4A in accordance with subsections (b) and (c);

''(2) shall, when a safety determination concludes that a substance does not meet the safety

standard, establish restrictions pursuant to subsection (d);

"(3) shall complete a safety assessment and safety determination not later than 2 years after the date on which a substance is designated as a high priority;

"(4) shall promulgate a final rule pursuant to subsection (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.

"(2) ALREADY INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating safe-

ty assessments and safety determinations of chemical substances, or from continuing or completing safety assessments and safety determinations initiated prior to the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act, prior to the date on which the policies and procedures the Administrator is directed to establish under section 3A and 4A are effective.

''(B) INTEGRATION.—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 requires 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.

''(c) SAFETY DETERMINATIONS.—

''(1) IN GENERAL.—Based on a review of the information before the Administrator, including draft safety assessments, if any, submitted by interested persons, the Administrator shall determine that—

''(A) the relevant chemical substance meets the safety standard;

''(B) the relevant chemical substance does not meet the safety standard, in which case the Administrator shall by rule under subsection (d) impose restrictions necessary to assure that the substance meets the safety standard under the intended or reasonably foreseeable 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; or

''(C) additional information is necessary in order to make a safety determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).

''(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is needed in order to carry out a safety assessment and

safety 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 that complies with the deadlines in subsection (a), a safety assessment and determination until after receipt of the information; and

"(D) in compliance 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) DEADLINE FOR SUBMISSION OF INFORMATION.—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 and shall comply with the deadlines under subsection (a).

''(d) RULE.—

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

''(2) SCOPE.—A rule promulgated under this subsection—

''(A) may—

''(i) apply to a mixture or article containing the chemical substance, as appropriate; and

''(ii) exempt a replacement part 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, but which shall be no later than 2 years after the date on which the rule is promulgated.

''(3) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of

Labor for Occupational Safety and Health prior to adopting any prohibition or restriction adopted under this subsection to address workplace exposures.

''(4) RESTRICTIONS.—A restriction under paragraph (1) shall include, as appropriate, 1 or more of the following requirements:

''(A) A requirement that a chemical substance or a mixture or article containing the 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.

''(B) A requirement that manufacturers and processors of the chemical substance or a mixture or article containing the substance—

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

''(ii) describe and apply the relevant quality control procedures followed in the

manufacturing or processing of the substance; and

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

''(C) A restriction on the quantity of the chemical substance or a mixture or article containing the substance that may be manufactured, processed, or distributed in commerce.

''(D) A requirement to ban or phase out or other regulation on the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or a mixture or article containing the substance—

''(i) for a particular use;

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

''(iii) for all uses.

''(E) A restriction on the quantity of the chemical substance or mixture or article containing the substance that may be manufactured, processed, or distributed in commerce—

''(i) for a particular use; or

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

"(F) A requirement to restrict, ban, or phase out or other regulation of any manner or method of commercial use or environmental release of the chemical substance or mixture or article containing the substance.

"(G) A requirement to restrict, ban, or phase out or other regulation of any manner or method of disposal of the chemical substance or any mixture or article containing the chemical substance, by its manufacturer or processor or by any person who uses, or disposes of it, for commercial purposes, provided that such a requirement may not require any person to take any action that would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and that such a requirement shall require each person subject to the requirement to notify each State and political subdivision in which a required disposal may occur of such disposal.

"(H) A requirement directing manufacturers or processors of the chemical substance or

mixture or article containing the substance to give notice of significant risks of harm (without taking into consideration cost or other non-risk factors) 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 or mixture, and to give public notice of such significant risks of harm.

''(5) RULE OF CONSTRUCTION.—The requirement, warning, or instruction, under paragraph (4) does not establish a uniform national standard for the purpose of supplanting, displacing, or preempting State law.

''(6) ANALYSIS FOR RULEMAKING.—

''(A) IN GENERAL.—Where the Administrator determines that a rule under paragraph (1) is likely to have an annual effect on the economy of more than $100,000,000, then when deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1) to ensure that a chemical substance meets the safety standard, the Administrator shall consider, to the extent practicable based on reasonably available infor-

mation, the quantifiable and non-quantifiable costs and benefits of the proposed regulatory action and of the primary alternative regulatory action or actions that the Administrator determines will ensure that the substance meets the safety standard. 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.

''(B) PUBLIC DISCLOSURE OF ANALYSIS.—When proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under subparagraph (A).

''(C) CONSIDERATION OF ANALYSIS.—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.

''(7) EXEMPTIONS.—

''(A) IN GENERAL.—The Administrator, as part of a rulemaking under this subsection—

''(i) may exempt a use of a chemical substance from any restriction in a rule promulgated under paragraph (1) if the Administrator determines, based on reasonably available information, that the rule cannot be complied with without—

''(I) harming national security;

''(II) causing significant disruption in the national economy due to the lack of availability of a chemical substance for the exempted use; or

''(III) interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, considering hazard and exposure; and

''(ii) may exempt a particular use of a chemical substance from a restriction in a rule issued under paragraph (1) if available information demonstrates that the risks to health or the environment from continued use of the substance are substantially lower than the risks to health or the environment of replacing that use of

the substance with reasonably available alternatives.

"(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) CONSIDERATION OF ANALYSIS.—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) 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.

"(E) DURATION.—

''(i) IN GENERAL.—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 not to exceed 5 years.

''(ii) EXTENSION.—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.

''(iii) CONSIDERATION FOR EXTENSION.—The Administrator shall issue exemptions and establish time periods under this subparagraph 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.

''(iv) EXCEPTION FOR RULE REQUIRING BAN OR PHASE OUT.—Any renewal of an exemption in the case of a rule requiring the ban or phase out of a chemical substance shall not exceed 5 years.

''(e) IMMEDIATE EFFECT.—The Administrator may declare a proposed rule under subsection (d) of this section to be effective upon publication of the proposed rule in the Federal Register and until the effective date of a 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 a significant risk of serious or widespread injury (without taking into consideration cost or other non-risk factors) to health or the environment before such effective date; and

''(B) making the proposed rule 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 the risk associated with the substance or mixture.

''(f) EXPEDITED ACTION ON PBTS.—

''(1) LIST OF PBTS.—In addition to carrying out section 4A, not later than 180 days after the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act, the Administrator shall publish a list of chemical substances that the Administrator determines are persistent, bio-accumulative, and toxic and have the potential for high or widespread exposure (referred to in this subsection as 'PBTs').

''(2) USE AND EXPOSURE ASSESSMENT.—

''(A) IN GENERAL.—Not later than 60 days after publishing the PBT list required under paragraph (1), the Administrator shall require by order the submission by manufacturers or processors of chemical substances included in the list of any additional information the Administrator determines to be necessary to conduct an expedited assessment of the intended, known, or reasonably foreseeable uses of, and exposures to, such chemical substances.

''(B) PUBLICATION.—Not later than 1 year after receiving the information which manufacturers and processors are required to submit under subparagraph (A), the Administrator shall complete and publish an identification and

assessment of the intended or reasonably foreseeable conditions of use of, and exposures to, substances on the PBT list.

''(3) EXPOSURE REDUCTION.—

''(A) RULE.—As soon as practicable, but not later than 2 years after the date on which the Administrator completes the use and exposure assessment required under paragraph (2), the Administrator shall impose, by rule, restrictions that the Administrator determines to be necessary to achieve the maximum practicable reduction in human or environmental exposure to chemical substances included in the PBT list.

''(B) CONTENTS OF RULES.—A rule promulgated under subparagraph (A) may include any of the restrictions on manufacturing, processing, use, distribution in commerce, and disposal described in subsection (d)(4) which the Administrator determines are necessary to achieve maximum practicable reduction in exposure to the listed PBT substance.

''(C) EFFECTIVE DATE.—A rule promulgated under subparagraph (A) shall include an effective date in accordance with subsection

(d)(2)(B) and may be made effective upon publication of a proposed rule in accordance with subsection (f).

''(4) EXEMPTIONS.—

''(A) SCOPE AND BASIS.—A rule imposing a restriction on a listed PBT substance in accordance with subparagraph (3) may exempt a use of the substance from such restriction upon a showing satisfactory to the Administrator that the use meets the exemption criteria in subsection (d)(7).

''(B) CONDITIONS.—The Administrator shall include conditions in any exemption established under this paragraph, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent necessary to protect health or the environment while achieving the purposes of the exemption.

''(C) DURATION.—An exemption established under this paragraph shall be in effect for a period determined by the Administrator but not to exceed 5 years and, after public notice and an opportunity for comment, may be renewed by the Administrator for 1 or more periods not exceeding a total of 5 years by order

following submission of an application justifying the continuing need for the exemption and containing such information as the Administrator may require.

''(g) REPORT ON PUBLIC BUILDINGS.—Not later than 6 months after the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act, the Administrator shall submit to Congress a report on how data on exposure in public buildings will be gathered to carry out subsection (f) and on what testing is necessary to protect the public from exposures to chemical substances identified under subsection (f) in public buildings.

''(h) FINAL AGENCY ACTION.—Under this section—

''(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.'';

(5) by redesignating subsections (e) and (f) as subsections (i) and (j), respectively; and

(6) in subsection (i) (as so redesignated)—

(A) by striking paragraph (4); and

(B) by redesignating paragraph (5) as paragraph (4); and

(7) by inserting after subsection (j) (as so redesignated) the following:

''(k) 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 Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act.''.

''(l) ASBESTOS.—

''(1) LISTING.—The Administrator shall include all forms of asbestos as 1 high-priority chemical substance under section 4A(a)(2) in accordance with section 4A(a)(4).

''(2) SCHEDULE.—Notwithstanding paragraphs (3), (4) and (5) of subsection (a), the Administrator shall—

''(A) complete a safety assessment and safety determination of all forms of asbestos not later than 2 years after the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act; and

''(B) promulgate a final rule not later than 3 years after the date of enactment of that Act.''.

SEC. 108. 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 subsection notwithstanding—

''(A) the existence of—

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

''(ii) a rule, testing consent agreement, or order under section 4(d), 5(c)(4), 6(d), or title IV; or

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

(2) in subsection (b)(1), by striking ''unreasonable'';

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

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

SEC. 109. 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.—

''(i) IN GENERAL.—Not later than 2 years after the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection 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.

''(ii) PRIOR REGULATIONS.—In carrying out this subparagraph, the Administrator may modify, as appropriate, the regulations promulgated prior to the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act.

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

''(i) may impose different reporting and record retention 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; and

''(iii) shall require reporting of information or maintenance of records where the Administrator determines the submission of reports would assist in the effective 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 requirements 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 a rule promulgated under this subsection.'';

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

''(3) CHEMICAL SUBSTANCES IN COMMERCE.—

''(A) RULE.—

''(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act, the Administrator shall by rule require manufacturers and processors to notify the Administrator, not later than 180 days after 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 for a nonexempt commercial purpose during the 10-year period prior to the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act.

"(ii) CONSIDERATION AS ACTIVE SUBSTANCE.—The Administrator shall consider chemical substances for which notices are received under clause (i) to be active substances and shall, pursuant to paragraph (4)(C), designate the chemical substance as an active substance on the list published under paragraph (1).

"(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—

"(i) IN GENERAL.—The Administrator shall maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14.

"(ii) EXISTING CLAIM OF CONFIDENTIALITY.—The rule promulgated under subparagraph (A) shall require a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) 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 seeks to maintain any existing claim for protection

against disclosure of the specific identity of the substance as confidential pursuant to section 14.

''(iii) SUBSTANTIATION.—The rule promulgated under subparagraph (A) shall require the substantiation of a claim described in clause (ii) pursuant to section 14 and in accordance with the review plan described in subparagraph (C).

''(C) REVIEW PLAN AND REQUIREMENTS.—

''(i) IN GENERAL.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall develop a plan to review all claims to protect the specific identity of a chemical substance on the confidential portion of the list published under paragraph (1) that is identified as an active substance in a report submitted pursuant to subparagraph (A) or identified as active substances under paragraph (4)(A).

''(ii) CONTENTS.—The plan shall describe how the Administrator will carry out the requirements of this subparagraph.

''(iii) REQUIREMENTS.—The Administrator shall—

''(I) require, at a time determined by the Administrator, all manufacturers or processors asserting a claim under subparagraph (B) to substantiate each 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) in accordance with the requirements of section 14—

''(aa) review each substantiation—

''(AA) submitted pursuant to subclause (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 subclause (I), if such substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

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

"(cc) 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 and processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to paragraph (4)(B) to review and either withdraw or substantiate such claims.

"(D) TIMELINE FOR COMPLETION OF REVIEWS.—

"(i) IN GENERAL.—The Administrator shall complete reviews of all claims speci-

fied in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

''(ii) EXTENSION.—The Administrator may extend the deadline for completion of the reviews described in subparagraph (C) 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.

''(iii) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of reviews to be completed over the course of implementation of the plan.

''(E) NO CONFIDENTIALITY FOR UNLISTED CHEMICALS.—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) CERTIFICATION.—The Administrator shall require a manufacturer or processor—

''(i) to certify the accuracy of each report submitted or record maintained under this section; and

''(ii) to retain documentation supporting certification under clause (i) for a period of 5 years beginning on the last day of the submission period.

''(4) ACTIVE AND INACTIVE SUBSTANCES.—

''(A) ACTIVE SUBSTANCES.—For the purposes of this section, the term 'active substance' means a chemical substance that—

''(i) has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period prior to the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act; or

''(ii) that is added to the list published under paragraph (1) after the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act.

"(B) INACTIVE SUBSTANCES.—For purposes of this section, the term 'inactive substance' means a chemical substance on the list published under paragraph (1) that does not meet any of the criteria in subparagraph (A).

"(C) LIST OF DESIGNATIONS.—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) 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 not less than 90 days before the date on which the substance is manufactured or processed.

"(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—

"(I) IN GENERAL.—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) substantiate the claim.

"(II) NO CONFIDENTIALITY FOR UNLISTED CHEMICALS.—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.—After receiving notification under clause (i), the Administrator shall—

''(I) designate the chemical substance as an active substance;

''(II) pursuant to section 14, 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;

''(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 10-year 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 10-year 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) CATEGORY STATUS.—The list of inactive chemical substances shall not be considered a category for purposes of section 26(c).

''(5) 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 Alan Reinstein and Trevor Schaefer

Toxic Chemical Protection Act, as the initial list of active substances for the purposes of section 4A.

''(6) PUBLIC PARTICIPATION.—The Administrator shall make available to the public—

''(A) 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 active substance;

''(B) 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) 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;

''(D) subject to section 14, the specific identity of any active substance—

''(i) for which no claim of protection against disclosure of the specific identity pursuant to this subsection was received;

''(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; and

''(E) any substance previously classified as an inactive substance that has been reclassified as an active substance.''; 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 information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of injury to health and the environment.''.

SEC. 110. 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''; 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 (b) or (c) of section 6, or section 7''; and

(C) in paragraph (3), by striking ''section 6 or 7'' and inserting ''section 6(d) 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. 111. 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. 112. 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, mixture, or article that the Administrator determines—

''(A) under section 5 is not likely to meet the safety standard; or

''(B) under section 6 does not meet the safety standard.

''(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 the mixture or article if the Administrator finds that the chemical substance as contained in the mixture or article will meet the safety standard; and

''(B) establish a threshold concentration of the chemical substance in a mixture or article

at which paragraph (1) shall not apply if the Administrator finds that at or below this concentration the substance as contained in the article or mixture will meet the safety standard.

''(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 meets the safety standard within 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 and for which a notification, prohibition, or restriction has been proposed or established under that section;

''(B) a chemical substance or a mixture containing a chemical substance that the Ad-

ministrator has determined under section 6 does not meet the safety standard and for which a notification, prohibition, or restriction has been proposed or established under that section;

''(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;

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

''(F) a chemical substance or mixture containing a chemical substance with respect to which an action is pending, or relief has been granted under section 7.

''(2) REGULATIONS.—

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

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

any exemptions the Administrator determines to be appropriate, which may include exemptions identified under section 5(g).

''(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 paragraph (1)(E), a notice of availability of the information on the chemical substance or mixture submitted to the Administrator;

''(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, designation, action, or relief; and

''(C) 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. 113. IMPORTS.

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

"SEC. 13. IMPORTS.

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

"(A) the Administrator—

"(i) has determined under section 6(c) that the chemical substance, mixture or article does not meet the safety standard; and

"(ii) has promulgated a rule under section 6(d) banning the chemical substance, mixture, or article, 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 the list under sec-

tion 8(b)(1) 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 fails to comply with any requirement in effect under this Act or 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, 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 con-

signee 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.

''(b) CERTIFICATION.—

''(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 certify to the Secretary of Homeland Security that the chemical substance or mixture is in compliance with any applicable rule, consent agreement, or order under section 5 or 6, and that the chemical substance—

''(A) is included on the list under section 8(b)(1); or

''(B) is exempt from any requirement to be included on the list under section 8(b)(1) by this title or a rule issued by the Administrator under this title.

''(2) ARTICLES.—The Administrator may, by rule, require certification under paragraph (1) for an

article containing a chemical substance or mixture that is subject to regulation under section 5 or 6.

''(3) CONTENT OF CERTIFICATION RULE.—In determining the need for and content of a certification rule under this subsection, the Administrator may 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 frequency of the certification requirement; and

''(C) if applicable, specification of the concentration of a chemical substance in an article that would subject the article to the certification requirement.

''(4) PUBLIC INFORMATION.—For purposes of this section, the Administrator 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) NOTICE.—A person offering a chemical substance for entry into the customs territory of the United States shall notify the Secretary of Homeland Security if—

''(1) the chemical substance or chemical substance in a mixture is a high-priority substance;

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

''(3) the chemical substance or chemical substance in a mixture 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.

''(d) RULES.—

''(1) IN GENERAL.—The Secretary of Homeland Security, after consultation with the Administrator, shall issue rules for the administration of this section.

''(2) CONTENT.—A rule issued under paragraph (1) may tailor the application of any requirement in this section, as appropriate for the efficient and effective implementation of this Act.''.

SEC. 114. CONFIDENTIAL INFORMATION.

Section 14 (15 U.S.C. 2613) is amended—

(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 section, the Administrator shall not disclose information that is exempt from disclosure pursuant to section 552 of title 5, United States Code, under subsection (b)(4) of that section—

''(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.—The information described in paragraph (2) specific to and submitted by a manufacturer, processor, or distributor that meets the requirements of subsection (d) shall be protected from disclosure, except that—

''(A) such information may be disclosed in accordance with subsection (e);

''(B) such information is subject to the review and substantiation requirements in subsection (f)(2); and

''(C) 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.

''(2) PROTECTED INFORMATION.—Information subject to paragraph (1) shall include—

''(A) specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article;

''(B) marketing and sales plans and strategies;

''(C) information identifying suppliers or customers;

''(D) the percentages of the components of a mixture;

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

''(F) specific production or import volumes of the manufacturer, and specific aggregated volumes across manufacturers if the Adminis-

trator determines that disclosure of the specific aggregated volumes would reveal confidential information; and

"(G) except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which it was included on the list under section 8(b)(1), including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if—

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

"(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); and

"(iii) the substance is not an active substance under section 8(b)(4) of this Act.";

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

''(3) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—Information shall not be protected from disclosure under this section if it is—

''(A) for information submitted after the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act, the specific identity of a chemical substance as of the date on which it is included on the list under section 8(b)(1), 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) 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; or

''(D) general descriptions of the processes used in manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, 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) EXCEPTION.—Information elements 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) NO CONFIDENTIALITY FOR UNLISTED CHEMICALS.—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 to the Administrator at the time of the submission of the information, pursuant to rules applicable to a claim for protection from disclosure that the Administrator has promulgated under this title.

''(B) CONTENTS OF CLAIM.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

''(i) taken reasonable measures to protect the confidentiality of the information;

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

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

''(iv) a reasonable basis to believe that the information is not readily otherwise publicly available or discoverable through reverse engineering.

''(C) SPECIFIC CHEMICAL IDENTITY.—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—

"(i) the generic name conforms with guidance prescribed by the Administrator under paragraph (3)(A); and

"(ii) 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.—Except for information described in subsection (b)(2), a person asserting a claim to protect information from disclosure under this Act shall, in accordance with the rules promulgated and guidance issued by the Administrator, substantiate that the information meets the requirements for protection pursuant to section 552 of title 5, United States Code, under subsection (b)(4) of that section.

"(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).

''(4) CERTIFICATION.—An authorized official of the person described in paragraph (1)(A) shall certify that the statements and information included in assertions and substantiations of claims for protection submitted under this subsection are true and correct.

''(e) EXCEPTIONS TO PROTECTION FROM DISCLOSURE.—Information described in subsection (a) (including information subject to subsection (b)) shall be disclosed if—

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

''(2) the information is to be disclosed to a contractor with the United States and employees of that contractor if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the

United States for the performance of work in connection with this Act and under such conditions as the Administrator shall specify;

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

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

''(A) 1 or more applicable agreements with the Administrator 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 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 in diagnosis or treatment of 1 or more individuals or in responding to an environmental release or exposure; and

''(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

''(B) the confidentiality agreement provides that the person will not use the 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 information to the Adminis-

trator, 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, 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, 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 that—

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

''(ii) the information is necessary for or will assist in emergency or first-aid diagnosis or treatment; and

''(iii) 1 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 information to the Administrator, the treating physician, 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;

''(7) the Administrator determines that disclosure is 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;

''(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) and except as allowed under subsection (e), the Administrator shall protect from disclosure information that meets the requirements of subsection (d) for a period of 10 years, unless—

''(i) prior to the expiration of the 10-year 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;

''(ii) prior to the expiration of the 10-year 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); or

"(iii) the Administrator denies the claim under subsection (g)(1).

"(B) EXTENSIONS.—

"(i) IN GENERAL.—Not less than 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) SUBMISSION TO REASSERT A CLAIM.—Not less than 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) REVIEW.—Not later than 30 days of receipt of the statement described in clause (ii), the Administrator shall—

"(I) 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

''(II)(aa) grant an extension not to exceed 10 years; or

''(bb) 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.—

''(A) IN GENERAL.—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 (including information described in subsection (b)(2)), and may require any person who has claimed protection for that information, whether before or after the date of enactment of the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection 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) (B) or (C);

"(iii) for any inactive chemical substance identified pursuant to section 8(b)(4);

"(iv) 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);

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

"(vi) 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

"(vii) for information contained in a notice of substantial risk submitted under section 8(e).

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

"(i) resubstantiate the claim; or

"(ii) withdraw the claim.

"(C) EXTENSION.—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), 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 approve, modify, or deny the claim or request.

''(B) DENIAL OR MODIFICATION.—

''(i) IN GENERAL.—Except as provided in subsections (c) and (f), the Administrator shall deny a claim to protect a chemical identity from disclosure only if the person who has submitted the 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 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.

"(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), (e), and (f), if the Administrator denies or modifies a claim under paragraph (1), the Administrator shall notify, in writing and by certified mail, the person who submitted the 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 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 shall not release that information until the date that is 15 days after the date on which the person who submitted the 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), (7), (9) or (10) of subsection (e), no prior notification is necessary.

"(3) APPEALS.—

"(A) IN GENERAL.—A person who receives a notification under 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 the complainant resides or has the principal place of business; 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 guilty of a misdemeanor and fined under title 18, United States Code, imprisoned for not more than 1 year, or both.

''(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.—

''(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 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 Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act; or

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

''(2) PRIOR ACTIONS.—Nothing in this Act prevents 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 Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act.

''(j) DEFINITION OF FIRST RESPONDER.—For the purposes of this section, 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.''.

SEC. 115. 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 VI or any rule promulgated or order issued under title VI;''.

SEC. 116. 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 organiza-

tion 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 that is not the defendant may not be attributed to the defendant.''.

SEC. 117. PREEMPTION.

Section 18 (15 U.S.C. 2617) is amended—

(1) in subsection (a)(1), by striking ''(1) Except as provided in paragraph (2), nothing'' and inserting ''Nothing'';

(2) by striking subsection (a)(2); and

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

''(b) SAVINGS.—

''(1) 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.

''(2) 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.

''(3) NO EFFECT ON PRIVATE REMEDIES.—

''(A) IN GENERAL.—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.

"(B) NO EFFECT ON AUTHORITY OF COURT.—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.

"(4) NO PREEMPTION OF STATE LAWS.—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 is different from, or in addition to, any regulation, requirement, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act.".

SEC. 118. JUDICIAL REVIEW.

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

(1) in subsection (a)—

(A) in subparagraph (1)(A), by striking ''section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV'' and inserting ''section 4(a), 5(c)(4), 6(d), or 8'';

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

(C) by striking paragraph (3); and

(2) in subsection (c)—

(A) in subparagraph (1)(B), by striking clauses (i) and (ii) and the last sentence of the subparagraph;

(B) by redesignating paragraph (1)(B)(iii) as paragraph (1)(B)(i); and

(C) in paragraph (1)(B)(i) as so redesignated), by striking ''(I) any statement required to be made pursuant to section 6(c)(1) of this title, or (II)''.

SEC. 119. CITIZENS' PETITIONS.

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

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

(2) in subsection (b)—

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

(B) in paragraph (4), by striking subparagraph (B) 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, 5(c), 6(d), or 8 or an order issued under section 4 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, the information

available to the Administrator is insufficient for the Administrator to perform an action described in section 4, 4A, or 6(b);

''(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;

''(cc) in the case of a petition to initiate a proceeding for the issuance of a rule under section 6(d), there is a reasonable basis to conclude that the substance will not meet the safety standard; or

''(dd) in the case of a petition to initiate a proceeding for the issuance of a rule under section 8, there is a reasonable basis to conclude that the rule is necessary to require reporting or recordkeeping to obtain information relevant to determining

whether a substance or mixture may fail to meet the safety standard.

''(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. 120. STUDIES.

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

SEC. 121. ADMINISTRATION.

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

(1) by striking ''Health, Education, and Welfare'' each place it appears and inserting ''Health and Human Services''; and

(2) by striking subsection (b) and inserting—

''(b) FEES.—

''(1) IN GENERAL.—The Administrator shall, by rule, require manufacturers of chemical substances to pay reasonable fees to defray the costs of administering this title, including but not limited to costs resulting from—

''(A) issuing rules and orders to conduct testing under section 4 and reviewing data submitted under these requirements;

''(B) developing the priority list and designating substances as high-priority under section 4A;

''(C) reviewing notices submitted under section 5;

''(D) conducting safety assessments and making safety determinations under section 6;

''(E) promulgating rules and issuing orders to restrict chemical substances under section 6;

''(F) promulgating rules and issuing orders to report information and data and maintain records under section 8; and

''(G) reviewing confidentiality claims under section 14.

''(2) APPORTIONMENT.—

''(A) IN GENERAL.—The Administrator shall apportion fees among individual manufacturers in relation to the costs of administering this title which are attributable to each manufacturer's production or importation of chemical substances subject to action under sections 4, 4A, 5, 6 and 8.

''(B) MULTIPLE MANUFACTURERS.—If there is more than 1 manufacturer of such substance, the Administrator shall provide for the sharing of fees in proportion to each manufacturer's contribution to total production of such substance, unless there is some other basis for apportionment that better reflects considerations of hazard and exposure.

''(3) SMALL BUSINESS CONCERNS.—The rule promulgated under paragraph (1) may set separate fees for manufacturers of chemical substances that are small business concerns based on their ability to pay.

''(4) LIMITATION.—Fees collected under this subsection shall only be used to defray the costs of

administering this title and not for any other purpose.''.

''(5) LEVEL OF FEES.—The Administrator shall ensure that fees are set at a level sufficient to enable the Administrator to perform all of the responsibilities described in paragraph (1) and add not less than 3 chemical substances to the list of high-priority substances for each chemical substance removed from the list under section 4A(a)(5)(iii) and to complete safety assessments and determinations and any necessary rulemaking for these high-priority substances in accordance with section 6(a).''.

SEC. 122. 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. 123. STATE PROGRAMS.

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

SEC. 124. AUTHORIZATION OF APPROPRIATIONS.

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

SEC. 125. 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;''.

TITLE II—STRENGTHENING PROTECTIONS FOR CHILDREN AND COMMUNITIES FROM DISEASE CLUSTERS

SEC. 201. PURPOSES.

The purposes of this title are—

(1) to provide to the Administrator the authority to help conduct investigations into the potential for environmental pollutants or toxic substances to cause disease clusters;

(2) to ensure that the Administrator has the authority to undertake actions to help address existing and potential environmental pollution and toxic substances that may contribute to the creation of disease clusters; and

(3) to enable the Administrator to integrate and work in conjunction with other Federal, State, and local agencies, institutions of higher education, and

the public in investigating and helping to address the possible causes of disease clusters.

SEC. 202. DEFINITIONS.

In this title:

(1) ADMINISTRATOR.—The term ''Administrator'' means the Administrator of the Environmental Protection Agency.

(2) AGENCY.—The term ''Agency'' means the Environmental Protection Agency.

(3) DIRECTOR.—The term ''Director'' means the Director of the National Institute of Environmental Health Sciences.

(4) DISEASE CLUSTER.—The term ''disease cluster'' means—

(A) the occurrence of a greater-than-expected number of cases of a particular disease within a group of individuals, a geographical area, or a period of time; or

(B) the occurrence of a particular disease in such number of cases, or meeting such other criteria, as the Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, may determine.

(5) ENVIRONMENTAL POLLUTANTS OR TOXIC SUBSTANCES.—The term ''environmental pollutants or toxic substances'' includes the substances described in paragraph (7).

(6) FEDERAL AGENCY.—The term ''Federal agency'' means—

(A) any department, agency, or other instrumentality of the Federal Government;

(B) any independent agency or establishment of the Federal Government (including any Government corporation); and

(C) the Government Publishing Office.

(7) POTENTIAL CAUSES OF A DISEASE CLUSTER.—The term ''potential causes of a disease cluster'' includes environmental and public health factors that could increase the possibility of disease clusters, including environmental pollutants or toxic substances and sources of those pollutants and substances, including—

(A) emissions of air pollutants that are regulated under the Clean Air Act (42 U.S.C. 7401 et seq.);

(B) water pollutants that are regulated under the Federal Water Pollution Control Act (33 U.S.C. 1251 et seq.);

(C) a contaminant, as that term is defined in section 1401 of the Safe Drinking Water Act (42 U.S.C. 300f);

(D) a hazardous substance, as that term is defined in section 101 of the Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9601);

(E) solid waste and hazardous waste, as those terms are defined in section 1004 of the Solid Waste Disposal Act (42 U.S.C. 6903);

(F) a chemical substance, as that term is defined in section 3 of the Toxic Substances Control Act (15 U.S.C. 2602);

(G) a substance that is regulated under the Emergency Planning and Community Right-To-Know Act of 1986 (42 U.S.C. 11001 et seq.); and

(H) any other form of environmental pollution or toxic substance that is a known or potential cause of an adverse health effect, including a developmental, reproductive, neurotoxic, or carcinogenic effect.

(8) REGIONAL RESPONSE CENTER.—The term ''Regional Response Center'' means a Regional Dis-

ease Cluster Information and Response Center established under section 204.

(9) RESPONSE TEAM.—The term ''Response Team'' means a Regional Disease Cluster Information and Response Team established under section 204.

(10) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 203. GUIDELINES FOR ENVIRONMENTAL INVESTIGATIONS OF DISEASE CLUSTERS.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry, the Secretary, and the Director, shall develop, publish, and periodically update guidelines that describe a systematic, integrated approach that uses the best available science to investigate—

(A) 1 or more suspected or potential disease clusters;

(B) environmental pollutants or toxic substances associated with 1 or more suspected or potential disease clusters; or

(C) potential causes of 1 or more disease clusters.

(2) COORDINATION.—The Administrator shall ensure that the Office of Children's Health Protection, in consultation with appropriate advisory committees, such as the Children's Health Protection Advisory Committee, has a prominent role on behalf of the Agency in developing and updating guidelines under paragraph (1).

(b) REQUIREMENTS.—Guidelines developed under this section shall include—

(1) definitions of key concepts and actions;

(2) disease cluster identification and reporting protocols;

(3) standardized methods of reviewing and categorizing data, including from health surveillance systems and disease cluster reports;

(4) guidance for using, in a health-protective way, an appropriate epidemiological, statistical, or other approach for the circumstances of an investigation;

(5) procedures for peer review of key documents by individuals who have no direct or indirect conflict of interest; and

(6) a description of roles and responsibilities of the Administrator and the Administrator of the Agency for Toxic Substances and Disease Registry

in conducting investigations described in those guidelines, in accordance with this title.

(c) TIMING.—

(1) IN GENERAL.—Draft guidelines developed under this section shall be available for public review and comment for a period of not less than 60 days.

(2) FINAL GUIDELINES.—Not later than 1 year after the date of enactment of this Act, the Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry, the Secretary, and the Director, shall publish in the Federal Register final guidelines under this section.

SEC. 204. ENHANCED SUPPORT FOR ENVIRONMENTAL INVESTIGATIONS OF DISEASE CLUSTERS.

(a) ESTABLISHMENT OF REGIONAL DISEASE CLUSTER INFORMATION AND RESPONSE CENTERS AND TEAMS.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry, the Secretary, and the Director, and other appropriate Federal agencies, shall establish and operate Regional Disease Cluster Informa-

tion and Response Centers and Regional Disease Cluster Information and Response Teams.

(B) PRINCIPAL RESPONSIBILITY.—The Administrator shall be principally responsible for directing, coordinating, and approving Federal efforts and assistance authorized under this section.

(2) COORDINATION.—

(A) IN GENERAL.—The Administrator shall ensure that the Office of Children's Health Protection, in consultation with appropriate advisory committees, such as the Children's Health Protection Advisory Committee, has a prominent role on behalf of the Agency in establishing and operating the Regional Response Centers and the Response Teams.

(B) GRANTS AND COOPERATIVE AGREEMENTS.—

(i) IN GENERAL.—The Administrator shall provide support (including research, program implementation, and operational support activities) to individuals on Response Teams described in subsection (b) and Community Disease Cluster Advisory Committees described in subsection (c)

through grants and cooperative agreements with institutions of higher education that have programs or individuals with demonstrated expertise in research, training, studies, and technical assistance.

(ii) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subparagraph such sums as are necessary.

(3) TIMING.—Not later than 1 year after the date of enactment of this Act, the Administrator shall establish at least—

(A) 2 Regional Response Centers; and

(B) 2 Response Teams.

(b) RESPONSE TEAMS.—

(1) MEMBERSHIP.—Each Response Team shall include individuals who—

(A) have expertise in epidemiology, toxicogenomics, molecular biology, toxicology, pollution control requirements, data analysis, environmental health and disease surveillance, exposure assessment, pediatric health, community outreach and involvement, and other relevant fields; and

(B) have no direct or indirect conflict of interest.

(2) LEADERSHIP.—Each Response Team shall have—

(A) an individual who is the leader of the Response Team and who reports to the Administrator, the Administrator of the Agency for Toxic Substances and Disease Registry, and the Director; and

(B) an individual who has the skills or experience necessary to carry out community outreach and involvement activities, including—

(i) the establishment of Community Disease Cluster Advisory Committees under subsection (c); and

(ii) the facilitation of activities of those Committees.

(3) ACTIVITIES.—

(A) IN GENERAL.—The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, shall establish the scope of activities for Response Teams to ensure that the activities are consistent with achieving the purposes of this title.

(B) REQUIREMENTS.—The activities of the Response Teams shall include—

(i) making guidelines, protocols, data, and other relevant information and expertise available to State and local officials and the public to assist in efforts—

(I) to investigate suspected or potential disease clusters, environmental pollutants or toxic substances associated with those disease clusters, and potential causes of disease clusters; and

(II) to address potential causes of disease clusters;

(ii) responding rapidly to a petition described in subparagraph (C) from any person, including a State or local official, regarding the need—

(I) to investigate suspected or potential disease clusters, environmental pollutants or toxic substances associated with those disease clusters, and potential causes of disease clusters; and

(II) to address the potential causes of disease clusters;

(iii) providing the best available environmental sampling and laboratory equipment to collect, analyze, and interpret monitoring, health surveillance, and other relevant information at scales and timelines appropriate to an action;

(iv) involving community members, in accordance with established scientific methods and norms (including the preservation of the confidentiality of individuals), in—

(I) investigations of suspected or potential disease clusters, environmental pollutants or toxic substances associated with those disease clusters, or potential causes of disease clusters, including through—

(aa) environmental exposure assessments;

(bb) biomonitoring activities; and

(cc) community-based participatory research initiatives; and

(II) other efforts to address the potential causes of disease clusters;

(v) working with State and local agencies—

(I) to help make the use and management of integrated environmental health data consistent and timely; and

(II) to fill data gaps; and

(vi) investigating suspected or potential disease clusters, environmental pollutants or toxic substances associated with those disease clusters, and potential causes of disease clusters, and addressing the potential causes of disease clusters that the Administrator determines State and local officials need assistance in investigating or addressing, or that the Administrator determines should be investigated or addressed.

(C) PETITION.—

(i) IN GENERAL.—Any person, including a State or local official, may submit a petition referred to in subparagraph (B)(ii) to the Administrator, the Administrator of the Agency for Toxic Substances and Disease Registry, and the Director that requests that a Response Team conduct an investigation or take other action to address the potential causes of disease clusters in accordance with this title.

(ii) REQUIREMENTS.—Each petition submitted under clause (i) shall clearly describe the basis for the requested investigation or action, including any data supporting the request.

(iii) CONSIDERATION.—The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, shall establish criteria for the consideration of petitions submitted under this section using health-protective factors, including—

(I) evidence of the release of environmental pollutants or toxic substances;

(II) the locations in which there appear to be potentially significant health threats from the potential causes of disease clusters;

(III) cases in which existing data appear to be inadequate to fully assess the potential risks to public health; and

(IV) such other factors as the Administrator determines are necessary.

(iv) RESPONSE.—Not later than 60 days after the date of receipt of a petition under clause (iii), the Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, shall provide a written response that describes—

(I) the investigation or actions that will be undertaken in response to the petition, including the timeline and basis for the investigation or actions; and

(II) the reasons for any denial or deferral in providing such a response.

(v) TIMING OF ISSUANCE OF CRITERIA.—

(I) IN GENERAL.—The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, shall provide for public notice of draft criteria established under this subparagraph for a period of not less than 60 days.

(II) FINAL CRITERIA.—Not later than 1 year after the date of enactment of this Act, the Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, shall publish in the Federal Register final criteria required under this subparagraph.

(4) USE OF PUBLICLY AVAILABLE REPORTS.—Response Team investigations and actions shall—

(A) include publicly available reports prepared by the Response Team that contain statements of facts, findings, and recommendations for actions, to the extent appropriate; and

(B) be prepared in a manner that preserves the confidentiality of individuals.

(5) TRANSPARENCY AND ACCOUNTABILITY.—Response Team activities shall include measures to ensure—

(A) transparency and accountability to potentially affected individuals, State and local officials, the public, and other persons and agencies, while preserving the confidentiality of individuals;

(B) that consistent, accurate, and meaningful information is provided to potentially affected individuals, State and local officials, the public, and other persons and agencies through the use of comprehensive, community-based communications plans; and

(C) accountability to meeting goals and timetables.

(6) DATABASE.—

(A) IN GENERAL.—The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry, the Secretary, and the Director, shall compile and regularly update information in a comprehensive electronic database that—

(i) is publicly accessible through the Internet;

(ii) provides a centralized location for information relating to—

(I) disease cluster reports and investigations;

(II) environmental pollutants or toxic substances that are associated with suspected or potential disease clusters;

(III) illnesses associated with suspected or potential disease clusters, including locally generated information;

(IV) systematic tracking of environmental pollutants or toxic substances and illnesses associated with suspected or potential disease clusters;

(V) actions to help address the potential causes of disease clusters; and

(VI) any other information that the Administrator determines to be necessary; and

(iii) facilitates the rapid reporting and analysis of information described in clause (ii).

(B) CONFIDENTIALITY.—A database described in subparagraph (A) shall be maintained in a manner that preserves the confidentiality of individuals.

(c) COMMUNITY DISEASE CLUSTER ADVISORY COMMITTEES.—

(1) IN GENERAL.—The Administrator shall establish Community Disease Cluster Advisory Committees to provide oversight, guidance, and advice relating to—

(A) the investigation of suspected and potential disease clusters;

(B) the investigation of environmental pollutants or toxic substances associated with suspected or potential disease clusters;

(C) the investigation of potential causes of disease clusters;

(D) efforts to address the potential causes of disease clusters; and

(E) the most effective means of ensuring outreach to and involvement of community members.

(2) MEMBERSHIP.—Membership on Community Disease Cluster Advisory Committees shall be comprised of representatives that include—

(A) individuals who are or may be impacted by a suspected or potential disease cluster, and the designee of such an individual who may participate with or in the place of such an individual;

(B) State or local government health or environmental agencies;

(C) at least 2 individuals, appointed by the Administrator in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, with demonstrated knowledge of the activities described in paragraph (1); and

(D) other appropriate individuals, as determined by the Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director.

(3) PROHIBITION.—No member of a Committee may have any direct or indirect conflict of interest.

(4) TECHNICAL ASSISTANCE.—

(A) IN GENERAL.—The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry and the Director, may make grants available to any group of individuals that may be affected by a suspected or potential disease cluster.

(B) USE OF FUNDS.—Grants made available under subparagraph (A) may be used to facilitate active involvement in all aspects of Committee activities and to assist Committee members in obtaining technical assistance in interpreting information with regard to—

(i) the investigation of—

(I) suspected or potential disease clusters;

(II) environmental pollutants or toxic substances that are associated with suspected or potential disease clusters; and

(III) the potential causes of disease clusters;

(ii) addressing the potential causes of disease clusters;

(iii) understanding the health concerns associated with suspected or potential disease clusters; and

(iv) understanding other scientific and technical issues relating to the activities of a Regional Response Team and Community Disease Cluster Advisory Committee, including the potential need for and interpretation of any biomonitoring of individuals in the area.

(d) ENVIRONMENTAL RESEARCH AND ANALYSIS.—The Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry, the Secretary, and the Director, shall use available authorities and programs to compile, research, and analyze information generated by actions authorized under this section, including by—

(1) using those authorities to test environmental pollutants or toxic substances identified under subsection (b)(6); and

(2) incorporating environmental pollutants or toxic substances identified under subsection (b)(6) in appropriate national biomonitoring initiatives.

SEC. 205. FEDERAL REPORTS TO CONGRESS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act and annually thereafter, the Administrator, in consultation with the Administrator of the Agency for Toxic Substances and Disease Registry, the Secretary, and the Director, shall prepare a report that describes—

(1) the status of activities under this title to investigate and address the suspected and potential causes of disease clusters;

(2) environmental pollutants or toxic substances that are associated with suspected or potential disease clusters;

(3) the potential causes of disease clusters; and

(4) ways to address the potential causes of those disease clusters.

(b) REQUIREMENTS.—The report shall include a description of—

(1) outreach activities to State and local officials and communities;

(2) actions that the Administrator has taken to prioritize the testing of environmental pollutants or toxic substances;

(3) actions that the Administrator has taken to include environmental pollutants or toxic substances

identified under section 204(b)(7) in appropriate national biomonitoring initiatives;

(4) actions that the Administrator is taking or plans to take to address problems in implementing this title;

(5) actions that the Secretary is taking or plans to take to address problems in implementing this title;

(6) actions that the Administrator of the Agency for Toxic Substances and Disease Registry has undertaken or is considering taking with respect to any disease clusters under subparagraphs (D) and (E) of section 104(i)(1) of Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9604(i)(1)) and other provisions of that section;

(7) actions that the Director is taking or plans to take to address problems in implementing this title; and

(8) other relevant information.

(c) SUBMISSION AND AVAILABILITY.—The Administrator shall—

(1) submit the report under this subsection to—

(A) the Committees on Environment and Public Works and Health, Education, Labor, and Pensions of the Senate; and

(B) the Committee on Energy and Commerce of the House of Representatives; and

(2) make the report available to the public.

SEC. 206. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as are necessary to carry out this title.

SEC. 207. EFFECT ON OTHER LAW.

Nothing in this title modifies, limits, or otherwise affects the application of, or obligation to comply with, any law, including any environmental or public health law.

TITLE III—COMMUNITY DISEASE CLUSTER TECHNICAL ASSISTANCE GRANTS

SEC. 301. COMMUNITY DISEASE CLUSTER TECHNICAL ASSISTANCE GRANTS.

(a) IN GENERAL.—The Administrator of the Environmental Protection Agency (referred to in this title as the ''Administrator''), in coordination with the Secretary of Health and Human Services (referred to in this title as the ''Secretary'') may award grants in accordance with this title to any individual or group of individuals that may

be affected by a reported community-based disease cluster—

(1) to pay the Federal share of the technical assistance described in subsection (d);

(2) to protect public health and the environment;

(3) to promote healthy and safe environments; and

(4) to prevent and address harmful exposures to hazardous substances.

(b) APPLICATION.—

(1) IN GENERAL.—To be eligible for a grant under this title, an individual or group of individuals shall submit to the Administrator and the Secretary an application that contains a description of the—

(A) need for technical assistance, including the need to procure independent technical advisors to help grant recipients interpret the information described in subsection (d);

(B) expected outputs, including results, effects, or consequences that will occur from the technical assistance; and

(C) expected outcomes, including activity, effort, or associated work products that will be

produced or provided over a period of time or by a specific date.

(2) RESPONSE.—Not later than 120 days after the date on which an application is submitted under paragraph (1), the Administrator and the Secretary shall respond to each applicant in writing and describe whether the application is approved, denied, or will be considered after the applicant modifies the application.

(3) CRITERIA.—The Administrator, in coordination with the Secretary, shall develop criteria that, if satisfied, would result in the Administrator and the Secretary accepting an application submitted under paragraph (1).

(c) AMOUNT.—

(1) IN GENERAL.—Except as provided in paragraph (2), each grant awarded under this title shall not exceed $50,000.

(2) WAIVER.—The Administrator, in coordination with the Secretary, may waive the limitation described in paragraph (1) if the waiver is necessary to provide the technical assistance described in subsection (d).

(d) USE OF FUNDS.—Grants awarded under this title shall be used to obtain technical assistance in interpreting information regarding—

(1) investigating reported community-based disease clusters associated with 1 or more hazardous chemicals;

(2) the potential hazardous chemicals associated with a reported community-based disease cluster;

(3) providing individuals or groups of individuals with community-based tools to educate the individuals on the mitigation of hazardous chemicals associated with reported community-based disease clusters; or

(4) other scientific and technical issues related to reported community-based disease clusters.

(e) NUMBER OF GRANTS.—No individual or group of individuals shall be awarded more than 1 grant under this title.

(f) NON-FEDERAL SHARE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the non-Federal share for each grant awarded under this title is 20 percent.

(2) WAIVER.—The Administrator, in coordination with the Secretary, may waive the non-Federal share described in paragraph (1) if—

(A) the recipient of the grant demonstrates financial need; and

(B) the waiver is necessary to provide the technical assistance described in subsection (d).

(g) RENEWAL OF GRANT.—

(1) IN GENERAL.—Any grant awarded under this title may be renewed to facilitate technical assistance to any group of individuals that may be affected by a reported community-based disease cluster.

(2) CONDITIONS.—Each renewal of a grant awarded under this title is subject to the same conditions that apply to an initial grant.

(h) REPORTS.—Any recipient of a grant awarded under this title shall submit to the Administrator and the Secretary a report that describes the progress in addressing the needs and achieving the outputs and outcomes described in subsection (b).

SEC. 302. AUTHORIZATION OF APPROPRIATIONS.

For each of fiscal years 2016 through 2021, there are authorized to be appropriated to the Administrator and the Secretary from any funds made available to the Administrator and the Secretary for the purpose of providing community members with technical assistance and engagement on environmental health issues from the Haz-

ardous Substance Superfund established under section 9507 of the Internal Revenue Code of 1986 such sums as are necessary to carry out section 301.

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