[DISCUSSION DRAFT]

FEBRUARY 27, 2014

113TH CONGRESS
2D SESSION

H. R. _____

To provide for the safe and efficient flow of chemicals in interstate and foreign commerce.

IN THE HOUSE OF REPRESENTATIVES

M__. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

To provide for the safe and efficient flow of chemicals in interstate and foreign commerce.

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

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

(a) SHORT TITLE.—This Act may be cited as the ''Chemicals in Commerce Act''.

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

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

SEC. 2. FINDINGS AND PURPOSE.

(a) AMENDMENT.—Section 2 (15 U.S.C. 2601) is amended to read as follows:

"SEC. 2. FINDINGS AND PURPOSE.

''(a) FINDINGS.—Congress finds that—

''(1) chemicals in commerce should be safe for their intended use;

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

''(3) public confidence in the Federal chemical regulatory program is important;

''(4) chemical regulation should reflect modern science, technology, and knowledge; and

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

''(b) PURPOSE.—The purpose of this Act is to promote uniform protections to human health and the environment through regulating chemical substances in commerce while minimizing undue burdens on commerce.''.

(b) TABLE OF CONTENTS AMENDMENT.—The item relating to section 2 in the table of contents is amended to read as follows:

''Sec. 2. Findings and purpose.''.

SEC. 3. DEFINITIONS.

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

(1) by redesignating paragraphs (2) through (6), (7) through (9), (10), (11), and (12) through

(14) as paragraphs (3) through (7), (9) through (11), (13), (14), and (17) through (19), respectively;

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

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

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

''(B) uses studies conducted in accordance with sound and objective scientific practices;

''(C) applies scientifically valid, relevant, publicly available information;

''(D) enables assessment of the risks and uncertainties in the scientific basis for decisions; and

''(E) applies information that meets the information quality criteria established by the Administrator under section 26(i).'';

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

''(8) INTENDED CONDITIONS OF USE.—The term 'intended conditions of use' means the circumstances under which a chemical substance is intended or reasonably anticipated to be manufac-

tured, processed, distributed in commerce, and used.'';

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

''(12) POTENTIALLY EXPOSED SUBPOPULATION.—The term 'potentially exposed subpopulation' means a group or groups of individuals within the general population who may be differentially exposed to a chemical substance under the intended conditions of use or who may be susceptible to more serious health consequences from chemical substance exposures than the general population, which where appropriate may include infants, children, pregnant women, workers, and the elderly.''; and

(5) by inserting after paragraph (14) (as so redesignated) the following:

''(15) PUBLICLY AVAILABLE INFORMATION.—The term 'publicly available information' includes information that has been published in periodicals, books, or print, electronic, or other media readily accessible to any member of the public.

''(16) SAFETY DETERMINATION.—The term 'safety determination' means a safety determination made under section 6(b).''.

SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

(a) IN GENERAL.—Section 4 (15 U.S.C. 2603) is amended to read as follows:

"SEC. 4. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.

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

''(1) IN GENERAL.—Except as otherwise provided in this section, the Administrator may require manufacturers and processors to develop new hazard and exposure information related to a chemical substance or mixture in accordance with this section if the Administrator determines that the information is needed—

''(A) to perform a safety determination;

''(B) to ensure compliance with—

''(i) a rule, consent agreement, or order issued under section 5(c)(5); or

''(ii) a rule under section 6(f);

''(C) pursuant to section 12(a)(2); or

''(D) for the implementation of another Federal statute, as determined by the Federal agency implementing such statute, if such information is necessary to meet the regulatory testing needs of that agency.

''(2) FORM.—The Administrator may carry out paragraph (1) by—

''(A) promulgating a rule;

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

''(C) issuing an order.

''(3) AVAILABLE INFORMATION.—Before promulgating a rule, entering into a consent agreement, or issuing an order under this subsection, the Administrator shall consider available information, including exposure potential and screening level hazard and exposure information.

''(4) CONTENTS.—

''(A) IN GENERAL.—A rule promulgated, consent agreement entered into, or order issued under paragraph (2)—

''(i) shall identify the chemical substance or mixture for which information is required and those persons required to develop that information;

''(ii) may include protocols and methodologies for the development of information for the chemical substance or mixture, including, if available, specific reference to reliable nonanimal test procedures; and

''(iii) shall provide a reasonable period within which persons required to develop the information shall submit the information to the Administrator.

''(B) 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.

''(5) SCREENING LEVEL HAZARD AND EXPOSURE INFORMATION.—If the available information under paragraph (3) is not sufficient to make a determination under subsection (a)(1), to assist the Administrator in planning requirements for additional testing under this subsection, the Administrator may, by rule, consent agreement, or order, require the development of screening level information on a chemical substance or mixture (which may include scientifically reliable and relevant in silico, in vitro, and in vivo tests).

''(6) ADDITIONAL TESTING DEVELOPMENT.—If, after reviewing screening level information obtained under paragraph (5), the Administrator determines that additional information development is necessary, the Administrator shall require under paragraph (1) the development of such information for specific endpoints using scientifically valid approaches.

''(b) STATEMENT OF NEED.—

''(1) IN GENERAL.—In promulgating a rule, entering into a consent agreement, or issuing an order for development of additional information under this section, the Administrator shall issue a statement—

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

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

''(C) explaining the basis for a decision that requires the use of vertebrate animals.

''(2) EXPLANATION OF AN ORDER.—

''(A) IN GENERAL.—If the Administrator issues an order under this section, the Adminis-

trator shall explain why good cause exists for issuing an order instead of promulgating a rule or entering into a consent agreement.

''(B) CONTENTS.—The explanation described in subparagraph (A) shall detail—

''(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 required to be developed under the order through voluntary submissions;

''(iii) the extent to which the Administrator anticipates using—

''(I) available information for structurally related chemical substances;

''(II) valid structure-activity relationship models; or

''(III) nonanimal test alternatives; and

''(iv) safety determinations on other chemical substances or mixtures, and the

information relied on in such determinations, to the extent relevant to the chemical substances or mixtures that would be the subject of the order.

''(c) REDUCTION OF TESTING ON VERTEBRATE ANIMALS.—

''(1) IN GENERAL.—In carrying out this title, the Administrator shall minimize the use of vertebrate animals in testing of chemical substances or mixtures by—

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

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

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

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

''(C) before adopting a requirement for testing using vertebrate animals, considering the sufficiency of—

''(i) available toxicity information;

''(ii) computational toxicology and bioinformatics;

''(iii) high through-put screening methods and their prediction models;

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

''(v) available vertebrate animal-based studies.

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

''(A) after providing public notice and an opportunity for public comment, develop a plan to promote the development and implementation of alternative test methods and testing strategies to generate information used in safety determinations that can reduce, refine, or replace the use of vertebrate animals, including toxicity

pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high throughput screening; and

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

''(3) CRITERIA FOR MODIFYING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing on vertebrate animals of a chemical substance or mixture under this section, the Administrator may modify or waive the requirement if the Administrator determines that—

''(A) there is sufficient information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property;

''(B) because of one or more physical or chemical properties of the chemical substance

or mixture or other toxicokinetic considerations—

''(i) the chemical substance or mixture cannot be absorbed; or

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

''(C) the chemical substance or mixture, when tested on vertebrate animals at certain concentrations, causes severe tissue corrosion, severe irritation, or significant pain or distress.

''(4) REPORTS.—Not later than 5 years after the date of enactment of the Chemicals in Commerce Act, and every 5 years thereafter, the Administrator shall submit to Congress a report that describes the progress made in implementing this subsection.

''(d) REQUIREMENT TO DEVELOP INFORMATION.—

''(1) LIMITATION.—The Administrator may not require persons who begin to manufacture or process a chemical substance or mixture more than 180 days after the end of the period provided for that chemical substance or mixture under subsection (a)(4)(A)(iii) to develop information related to the chemical substance or mixture under subsection (a).

''(2) DESIGNATION.—If 2 or more manufacturers or processors designate one of themselves or a

third party to develop information required by the Administrator under subsection (a), the Administrator shall require any other manufacturer or processor seeking to use the information so developed in order to meet the requirements of subsection (a) to provide fair and equitable reimbursement for such information development.

''(3) ARBITRATION.—In the case of a dispute among the parties described in paragraph (2) regarding the amount that constitutes fair and equitable reimbursement under such paragraph, such dispute shall be resolved by arbitration according to—

''(A) the terms of any applicable contract among the parties; or

''(B) if no such contract exists, regulations developed by the Administrator.

''(e) INFORMATION AVAILABILITY.—Subject to section 14, the Administrator shall make available to the public consent agreements entered into, orders issued, and information submitted under this section.

''(f) CONSULTATION.—Prior to requiring the development of information from epidemiologic studies of workers, or applying such information, the Administrator shall

consult with the Director of the National Institute for Occupational Safety and Health.

''(g) EXPEDITED CONSIDERATION.—

''(1) IN GENERAL.—Upon the receipt of any information submitted under this title that provides a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human health, the Administrator shall, within the 180-day period beginning on the date of the receipt of such information—

''(A) initiate appropriate action under section 5, 6, or 7 to prevent or reduce such risk; or

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

''(2) EXTENSION.—For good cause shown the Administrator may extend such period for an additional period of not more than 90 days. The Administrator shall publish in the Federal Register notice of any such extension and the reasons therefor.''.

(b) CONFORMING AMENDMENT.—Section 104(i)(5)(A) of the Comprehensive Environmental Re-

sponse, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended by striking ''Before assuring the initiation of such program, the Administrator of ATSDR shall consider recommendations of the Interagency Testing Committee established under section 4(e) of the Toxic Substances Control Act on the types of research that should be done.''.

SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.

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

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

''(a) NOTICE REQUIREMENT.—

''(1) IN GENERAL.—Unless a person submits, not later than 90 days before manufacturing or processing begins, a notice to the Administrator of that person's intent to manufacture a new chemical substance or manufacture or process a chemical substance for a new use that the Administrator has determined, in accordance with paragraph (2), is a significant new use, such person may not—

''(A) manufacture a new chemical substance; or

''(B) manufacture or process a chemical substance for a use which the Admin-

istrator has determined, in accordance with paragraph (2), is a significant new use.

''(2) DETERMINATION OF SIGNIFICANT NEW USE.—A determination by the Administrator that a use of a chemical substance is a significant new use, with respect to which notification is required under paragraph (1), shall be made by a rule promulgated after a consideration of all relevant factors, including information on—

''(A) the projected volume of manufacturing and processing of the chemical substance for that use;

''(B) the extent to which a use changes the type or form of exposure of human beings or the environment to the chemical substance;

''(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to the chemical substance; and

''(D) the intended conditions of use.

''(3) ARTICLES.—The Administrator may determine that the use of a chemical substance as part of an article is a significant new use under this section, but only where the Administrator—

''(A) identifies specific types of articles that are, or likely will be, in United States commerce; and

''(B) determines that—

''(i) an unreasonable risk of harm to human health or the environment may result from exposure to a chemical substance in the article; and

''(ii) placing requirements on the articles is required because such risk cannot be addressed adequately through requirements placed on the chemical substance.

''(b) CONTENT OF NOTICE; PUBLICATION IN THE FEDERAL REGISTER.—

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

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

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

''(2) FEDERAL REGISTER PUBLICATION.—Subject to section 14, not later than 5 business days

after the date of the receipt of a notice under subsection (a)(1), the Administrator shall publish in the Federal Register—

"(A) the identity of the chemical substance for which such notice has been received by the Administrator; and

"(B) the intended conditions of use of such chemical substance as identified by the manufacturer or processor.

"(3) PUBLICLY ACCESSIBLE LISTS.—The Administrator shall maintain publicly accessible lists of—

"(A) each chemical substance for which notice has been received under subsection (a)(1) and for which the review period prescribed by subsection (c) has not expired; and

"(B) each chemical substance for which such review period has expired since the last publication of such list.

"(c) REVIEW AND DETERMINATION.—

"(1) REVIEW.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (a)(1), the Administrator shall—

''(i) conduct a review of the notice;

''(ii) to the extent the Administrator considers necessary, develop a profile of the chemical substance and the potential for exposure to humans and the environment;

''(iii) if the Administrator considers it necessary to conduct a review under clause (i) or to make a determination under paragraph (3), request additional information pursuant to paragraph (2)(B); and

''(iv) make a determination under paragraph (3).

''(B) EXTENSION OF REVIEW.—The Administrator may extend the period described in subparagraph (A) for good cause for one or more periods. Except as provided in paragraph (2)(B), the cumulative total of any such extensions shall not exceed 90 days.

''(2) INFORMATION.—

''(A) PREVIOUSLY SUBMITTED INFORMATION.—In conducting a review under paragraph (1)(A), the Administrator shall take into consideration any relevant information submitted

under subsection (a) or otherwise available to the Administrator.

''(B) ADDITIONAL INFORMATION.—If the Administrator determines that additional information (including information on exposure or exposure potential) is needed in order to conduct a review and make a determination under this subsection, the Administrator—

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

''(ii) may, by agreement with the submitter, extend the review period no longer than necessary to allow for the development and submission of the additional information;

''(iii) shall promptly make a determination under paragraph (3) upon receipt of the information; and

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

''(3) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1) or (2)(B), and based on the information described in paragraph (2), the Administrator shall determine that exposure to the chemical substance under the intended conditions of use—

''(A) is likely to result in an unreasonable risk of harm to human health or the environment, in which case the Administrator shall take appropriate action under paragraph (5); or

''(B) is not likely to result in an unreasonable risk of harm to human health or the environment, in which case the Administrator shall allow the review period to expire without imposing restrictions on the chemical substance.

''(4) COMMERCIAL PRODUCTION.—At the end of the applicable review period specified under paragraph (1) or (2)(B), the submitter of a notice under subsection (a)(1) may submit a notice of commencement under subsection (d), unless the Administrator—

''(A) determines under paragraph (3)(A) that exposure to the chemical substance under the intended conditions of use is likely to result

in an unreasonable risk of harm to human health or the environment; and

''(B) imposes a requirement or restriction under paragraph (5) that prohibits the manufacture of the chemical substance.

''(5) REQUIREMENTS AND RESTRICTIONS.—If, before the end of the applicable review period under paragraph (1) or (2)(B), the Administrator makes a determination under paragraph (3)(A), the Administrator shall, by rule, consent agreement, or order, impose one or more of the following requirements or restrictions on the manufacturer or processor:

''(A) A requirement or restriction that the chemical substance be marked with, or accompanied by, clear and adequate warnings and instructions with respect to distribution in commerce or use, 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 or restriction that manufacturers or processors of the chemical substance—

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

''(ii) monitor specific uses of or exposures to the chemical substance; or

''(iii) subject to section 4, develop additional information that is reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, or use of the chemical substance.

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

''(D) A requirement to restrict or ban the manufacture, processing, or distribution in commerce of the chemical 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 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 or ban a method of commercial use of the chemical substance.

''(G) A requirement directing manufacturers or processors of the chemical substance to give notice of unreasonable risks of harm to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

''(d) NOTICE OF COMMENCEMENT.—

''(1) IN GENERAL.—A person who has submitted a notice under subsection (a)(1) and commences manufacture of a new chemical substance shall, for a purpose not exempt under subsection (f), submit a notice of commencement to the Administrator—

''(A) not later than 30 days after the date on which the person commenced manufacture; and

''(B) which identifies the name of the manufacturer and the initial date of such manufacture.

''(2) WITHDRAWAL.—A person who has submitted a notice under subsection (a)(1), but has not commenced manufacture, may withdraw the notice.

''(e) ADDITIONAL EVALUATION.—The Administrator may initiate action under section 6 with respect to a chemical substance for which a notice has been submitted under subsection (a)(1) at any time after the Administrator, after publication of the chemical substance on the list required by section 8(b), becomes aware of new information regarding the chemical substance that provides a reasonable basis to conclude that a determination made with respect to the chemical substance under subsection (c)(3) should be reconsidered.

''(f) EXEMPTIONS.—

''(1) EXPERIMENTATION, RESEARCH, AND ANALYSIS.—

''(A) GENERAL RULE.—Except as provided in subparagraph (B), the requirements of subsection (a)(1) shall not apply with respect to the manufacturing or processing of any chemical substance that is manufactured or processed, or proposed to be manufactured or proc-

essed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

''(i) scientific experimentation or analysis; or

''(ii) chemical research on, or analysis of, such chemical substance or another chemical substance, including such research or analysis for the development of a product.

''(B) NOTICE REQUIREMENT.—A manufacturer or processor exempted under subparagraph (A) shall notify all persons engaged in such experimentation, research, or analysis, in such form and manner as the Administrator may prescribe, of any risk to health which the manufacturer, the processor, or the Administrator has reason to believe may be associated with such chemical substance.

''(2) TEST MARKETING.—

''(A) IN GENERAL.—The Administrator may, upon request, exempt any person from any requirement of subsection (a) in order to permit the person to manufacture or process a

chemical substance for test marketing purposes—

''(i) upon a showing by the person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, and use of the chemical substance, and that any combination of such activities, for such test marketing purposes is not likely to result in an unreasonable risk of harm to human health or the environment; and

''(ii) under such restrictions as the Administrator considers appropriate.

''(B) PUBLICATION OF RECEIPT.—Immediately upon receipt of a request under subparagraph (A), the Administrator shall publish in the Federal Register notice of the receipt of such request. The Administrator shall give interested persons an opportunity to comment upon any such request and shall, within 45 days of its receipt, either approve or deny the request. The Administrator shall publish in the Federal Register notice of the approval or denial of such a request.

''(3) LIKELIHOOD OF RISK.—The Administrator may, upon request and by rule or order, exempt a person who commences manufacture of a new chemical substance or manufacture or processing of a chemical substance for a significant new use from all or part of the requirements of this section if under prescribed conditions the Administrator determines that the manufacture, processing, distribution in commerce, and use of such chemical substance, and any combination of such activities under such prescribed conditions, is not likely to result in an unreasonable risk of harm to human health or the environment. A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule)—

''(A) shall be promulgated in accordance with section 553 of title 5, United States Code (without regard to any reference in such section to sections 556 and 557 of such title); and

''(B) shall be subject to public notice and an opportunity for public comment.

''(4) TEMPORARY EXISTENCE.—The Administrator may, by rule, make the requirements of subsection (a) inapplicable with respect to the manufacturing or processing of any chemical substance—

''(A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance; and

''(B) to which there is no, and will not be, human or environmental exposure.

''(5) BYPRODUCTS.—The Administrator shall, by rule, make the requirements of subsection (a) inapplicable to the manufacture or processing of any byproduct chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture if—

''(A) such byproduct chemical substance is not used for commercial purposes; or

''(B) the only intended commercial purpose of the byproduct chemical substance is for—

''(i) burning as a fuel;

''(ii) disposing as a waste, including in a landfill or for enriching soil; or

''(iii) extracting, by reaction or otherwise, a chemical substance to recycle or reclaim.

''(g) MIXTURES.—A combination of chemical substances physically combined without a chemical reaction

shall not be considered a new chemical substance for purposes of this section.''.

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

''Sec. 5. New chemicals and significant new uses.''.

SEC. 6. EXISTING CHEMICALS.

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

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

''SEC. 6. EXISTING CHEMICALS.'';

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

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

''(a) ASSIGNING PRIORITIES FOR SAFETY DETERMINATIONS.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Chemicals in Commerce Act, the Administrator shall, after providing public notice and an opportunity for public comment, establish a risk-based process for designating, based on the weight of the best available science, chemical substances as either high priority or low priority. In making such designations, the Administrator—

''(A) shall identify as high priority a chemical substance that has the potential for high hazard and high exposure;

''(B) may identify as high priority a chemical substance that has the potential for high hazard or high exposure; and

''(C) shall identify as low priority a chemical substance that is not likely to result in an unreasonable risk of harm to human health or the environment under the intended conditions of use.

''(2) TIMELY COMPLETION.—The Administrator shall designate a priority for all chemical substances identified as active under section 8 as soon as feasible, taking into account the ability of the Administrator to schedule and complete safety determinations under this section. The Administrator may defer designation of a priority in order to provide interested persons an opportunity to submit additional information not previously made available to the Administrator.

''(3) PUBLICATION OF LIST.—The Administrator shall publish, and update from time to time, a list of chemical substances—

''(A) identifying those under consideration for designation as high or low priority;

''(B) identifying those that have been designated as a high or low priority at the time a designation has been made under paragraph (1); and

''(C) indicating those for which a safety determination has been completed.

''(4) FACTORS FOR ASSIGNING PRIORITIES.—The factors used by the Administrator to assign priorities shall include—

''(A) the hazard and exposure potential of a chemical substance, including specific scientific classifications and designations by authoritative governmental entities;

''(B) the specific uses and exposures that are significant to the risk of harm to human health and the environment and the intended conditions of use, or changes in the conditions of use, of chemical substances;

''(C) evidence and indicators of exposure to humans or the environment from a chemical substance;

''(D) the volume of a chemical substance manufactured or processed;

''(E) 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;

''(F) the availability of information about potential hazards and exposures needed for conducting a safety determination, with limited availability of relevant information to be a factor in designating a chemical substance as a high priority; and

''(G) the extent of Federal or State regulation of a chemical substance or the extent of the impact of State regulation of that chemical substance on the United States, with existing Federal or State regulation as a factor in designating a chemical substance as a low priority.

''(5) EFFECT OF LOW-PRIORITY DESIGNATION.—Chemical substances designated by the Administrator as a low priority shall not be subject to a safety determination, and unless redesignated as a high priority, shall be considered not likely to result in an unreasonable risk of harm to human health or

the environment under the intended conditions of use.

''(6) NOTICE AND COMMENT.—The Administrator's proposed priority designations under this subsection shall be subject to public notice and an opportunity for public comment.

''(7) REVISION BASED ON NEW INFORMATION.—The Administrator may revise the priority designation of a chemical substance based on consideration of new information.

''(8) PROCESS REVIEW.—The Administrator shall periodically review and if necessary modify the process of assigning priorities to chemical substances under this subsection based upon experience and resources available to efficiently and effectively prioritize chemical substances.

''(9) LIMITATION.—Except as provided in section 18, a designation by the Administrator under this subsection of a chemical substance as a high priority shall not affect the manufacture, processing, distribution, use, or disposal of the chemical substance, or regulation of those activities.

''(10) FINAL AGENCY ACTION.—A designation by the Administrator under this subsection of a chemical substance as a high priority shall not be

considered to be a final agency action subject to judicial review.

''(b) MAKING SAFETY DETERMINATIONS.—The Administrator shall make a safety determination, based on the best available science related to health and environmental considerations, and in accordance with the weight of the scientific evidence, regarding whether—

''(1) a chemical substance designated as a high priority will not result in an unreasonable risk of harm to human health or the environment under the intended conditions of use;

''(2) a chemical substance designated as a high priority will result in an unreasonable risk of harm to human health or the environment under the intended conditions of use, in which case, the Administrator shall impose one or more of the restrictions identified in subsection (f)(3); or

''(3) additional information is necessary in order to make a determination under paragraph (1) or (2).

''(c) REQUIREMENTS FOR DETERMINATION.—In making a safety determination the Administrator shall—

''(1) afford greater weight to scientific evidence that meets the criteria established by the Administrator under section 26(i);

''(2) use the best available science, and integrate and assess information on hazards, exposures, and risks;

''(3) analyze exposure to the chemical substance for the specific uses that are significant to the risk of harm and subsets of exposure (including information on potentially exposed subpopulations), and the duration, intensity, frequency, and number of exposures under the intended conditions of use of the chemical substance;

''(4) describe the weight of the scientific evidence for observed biological effects and risks, including the appropriate modes of action;

''(5) incorporate reference parameters that may be appropriate with regard to a specific chemical substance (such as a margin of exposure); and

''(6) consider whether the weight of the evidence of the best available science supports the identification of threshold doses of a chemical substance below which no adverse effects can be expected to occur.

''(d) ADDITIONAL INFORMATION.—If the Administrator determines pursuant to subsection (b)(3) that additional information is needed in order to make a safety determination, the Administrator—

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

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

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

''(4) shall, upon receipt of the information, make a safety determination under subsection (b)(1) or (2).

''(e) PUBLICATION.—In making a safety determination, the Administrator shall publish a statement that includes—

''(1) such safety determination; and

''(2) a summary of the analysis performed pursuant to subsection (c) in support of that determination.

''(f) RULE.—

''(1) IMPLEMENTATION.—If the Administrator determines under subsection (b)(2) that a chemical substance will result in an unreasonable risk of harm to human health or the environment under the intended conditions of use, the Administrator shall

promulgate a rule, in accordance with this subsection.

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

''(A) may—

''(i) as appropriate, apply to mixtures containing the chemical substance; or

''(ii) apply to articles, but only where the Administrator—

''(I) identifies specific types of articles that are, or likely will be, in United States commerce; and

''(II) determines that ensuring that no unreasonable risk of harm to human health or the environment will result from exposure to the chemical substance requires placing requirements on such articles that cannot be addressed adequately through requirements placed on chemical substances or mixtures; and

''(B) shall—

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

''(ii) include dates by which compliance is mandatory, which may vary for different affected persons, as the Administrator determines to be appropriate.

''(3) RESTRICTION.—A rule promulgated under this subsection shall include, as appropriate, one or more of the following:

''(A) A requirement that a chemical substance be marked with, or accompanied by, clear and adequate warnings and instructions with respect to distribution in commerce, or use, 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—

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

''(ii) monitor specific uses of or exposures to the chemical substance; or

''(iii) subject to section 4, develop additional information that is reasonably nec-

essary to ensure compliance with this section.

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

''(D) A requirement to restrict, ban, or phase out the manufacture, processing, or distribution in commerce of the chemical 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 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 a method of commercial use of the chemical substance;

''(G) A requirement directing manufacturers or processors of the chemical substance to give notice of unreasonable risks of harm to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

''(4) LIMITATIONS.—When imposing requirements or restrictions on a chemical substance under this subsection, the Administrator shall—

''(A) determine that—

''(i) such requirements or restrictions are proportional to the risks of the chemical substance that are addressed in the safety determination;

''(ii) such requirements or restrictions will result in net benefits; and

''(iii) requirements or restrictions imposed on uses of the chemical substance are cost-effective in ensuring that the chemical substance will not result in an unreasonable risk of harm to human health or the environment under the intended conditions of use, compared to alternative

requirements or restrictions that the Administrator may reasonably adopt;

''(B) impose requirements or restrictions that prohibit or substantially prevent specific uses of the chemical substance only when technically and economically feasible alternatives that materially reduce risk to human health or the environment compared to the use proposed to be prohibited or substantially prevented are available and likely to be used as a substitute for the use proposed to be prohibited or substantially prevented; and

''(C) provide for a reasonable transition period for implementation.

''(g) FINAL AGENCY ACTION.—

''(1) DETERMINATION OF NO UNREASONABLE RISK.—A determination under subsection (b)(1) that a chemical substance will not result in an unreasonable risk of harm to human health or the environment under the intended conditions of use shall be considered a final agency action.

''(2) DETERMINATION OF UNREASONABLE RISK.—A determination under subsection (b)(2) that a chemical substance will result in an unreasonable risk of harm to human health or the environment

under the intended conditions of use shall be considered a final agency action on the date of publication of the final rule promulgated under subsection (f).''; and

(4) in subsection (i) (as so redesignated by paragraph (2) of this subsection)—

(A) by striking paragraph (4); and

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

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

''Sec. 6. Existing chemicals.''.

SEC. 7. IMMINENT HAZARDS.

Section 7 (15 U.S.C. 2606) is amended—

(1) by striking subsection (a) and inserting the following:

''(a) CIVIL ACTIONS.—

''(1) IN GENERAL.—The Administrator may commence a civil action in an appropriate district court of the United States for—

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

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

''(2) RULE, ORDER, OR OTHER PROCEEDING.—The Administrator may commence a civil action under this subsection notwithstanding—

''(A) the existence of—

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

''(ii) a rule, consent agreement, or order, as applicable, under section 4(a)(2), 5(c)(5), or 6(f); or

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

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

(3) in subsection (f)—

(A) in the first sentence, by striking ''and unreasonable risk of serious or widespread injury to health or the environment'' and insert-

ing ''risk of serious or widespread harm to human health or the environment''; and

(B) by striking ''such injury'' and inserting ''such harm''.

SEC. 8. INFORMATION COLLECTION AND REPORTING.

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

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

''(4) REQUIREMENTS.—Not later than 2 years after the date of enactment of the Chemicals in Commerce Act, the Administrator shall promulgate rules establishing reporting requirements for manufacturers and processors as necessary to carry out section 6.

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

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

''(B) describes the manner by which manufacturers and processors may voluntarily report use and exposure information.

''(6) NONAPPLICABILITY.—This subsection shall not apply to—

''(A) a chemical substance extracted, by reaction or otherwise, from another chemical substance

for the purpose of recycling or reclaiming such extracted chemical substance; or

''(B) a combination of chemical substances physically combined without a chemical reaction.'';

(2) in subsection (b)—

(A) in paragraph (1), by adding at the end the following: ''The Administrator shall establish and maintain a confidential portion and a nonconfidential portion of the list published under this paragraph, consistent with section 14. Chemical substances on each such portion of the list shall be identified as either active or inactive, as designated under paragraph (5).''; and

(B) by adding at the end the following new paragraphs:

''(3) NOMENCLATURE.—The Administrator shall develop guidance that—

''(A) permits the continued use of Class 2 nomenclature in use on date of enactment of the Chemical in Commerce Act;

''(B) permits the continued use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled

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

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

''(i) cement, Portland, chemicals, CAS No. 65997–15–1;

''(ii) cement, alumina, chemicals, CAS No. 65997–16–2;

''(iii) glass, oxide, chemicals, CAS No. 65997–17–3;

''(iv) frits, chemicals, CAS No. 65997–18–4;

''(v) steel manufacture, chemicals, CAS No. 65997–19–5; and

''(vi) ceramic materials and wares, chemicals, CAS No. 66402–68–4;

''(D) if guidance in effect before the guidance developed under this paragraph allowed for multiple nomenclature conventions—

''(i) permits the continued use of the nomenclature conventions for chemical substances; and

''(ii) includes new guidance that establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

''(E) for any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, includes guidance recognizing the multiple listings as a single chemical substance.

''(4) CHEMICAL SUBSTANCES IN COMMERCE.—

''(A) RULE.—

''(i) IN GENERAL.—The Administrator, by rule, shall require manufacturers and may require processors to notify the Administrator when the manufacturer or processor, as applicable, has manufactured or processed a chemical substance that has been placed on the list under paragraph (1) during the 5-year period prior to the date of enactment of the Chemicals in Commerce Act.

''(ii) PROCEDURE FOR NOTICE OF ACTIVE AND INACTIVE CHEMICAL SUBSTANCES.—A rule

under this subparagraph shall establish a procedure for any person to notify the Administrator of a chemical substance that the Administrator should identify as active or inactive under paragraph (5).

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

''(i) accession numbers;

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

''(iii) generic names.

''(C) CONFIDENTIAL CHEMICAL SUBSTANCES.—The rule issued under subparagraph (A) shall require a manufacturer or processor submitting a notice including information relating to a chemical substance to indicate whether the manufacturer or processor claims the information as confidential pursuant to section 14.

''(D) PRESERVATION OF RECORDS.—The rule issued under subparagraph (A) shall require a manufacturer or processor to retain a record supporting

the accuracy of the information submitted to the Administrator by the manufacturer or processor for a period of 5 years beginning on the last day of the submission period.

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

''(5) ACTIVE AND INACTIVE SUBSTANCES.—

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

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

''(I) in the case of a chemical substance manufactured or processed before the date of enactment of the Chemicals in Commerce Act, the 5-year period ending on such date of enactment; and

''(II) in the case of a chemical substance first manufactured or processed on or after the date of enactment of the Chemicals in Commerce Act, the 4-year period ending on the date on which the most recent data was reported under part 711 of title 40, Code of Federal Regulations (or successor regulations);

''(ii) that is added to the list published under paragraph (1) after the date of enactment of the Chemicals in Commerce Act;

''(iii) for which a person has notified the Administrator pursuant to subparagraph (C) that such person intends to manufacture or process a chemical substance that is designated as an inactive substance; or

''(iv) that has been reported under part 711 of title 40, Code of Federal Regulations (or successor regulations) after the date of enactment of the Chemicals in Commerce Act.

''(B) INACTIVE SUBSTANCES.—For purposes of this paragraph, the term 'inactive substance' means a chemical substance on the list published under paragraph (1) that has not been manufactured or processed at any point during—

''(i) in the case of a chemical substance manufactured or processed before the date of enactment of the Chemicals in Commerce Act, the 5-year period ending on such date of enactment; and

''(ii) in the case of a chemical substance first manufactured or processed on or after the date of enactment of the Chemicals in Commerce Act, the 4-year period ending on the date on which the most recent data were reported under part 711 of title 40, Code of Federal Regulations (or successor regulations).

''(C) CHANGE TO ACTIVE STATUS.—

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

''(ii) UPDATE OF STATUS.—On receiving notification under clause (i), the Administrator shall designate the chemical substance as an active substance and amend the list under paragraph (1) accordingly.

''(6) INFORMATION ON LIST.—The Administrator shall include on the list published under paragraph (1)—

''(A) the accession number, generic name, and, if applicable, premanufacture notice case number for each active or inactive substance, in the case of a chemical substance on the confidential portion of the list published under paragraph (1); and

''(B) the specific identity of any active or inactive substance for which no such claim of confidentiality was received under paragraph (4)(C), subject to the condition that, before revealing the specific identity of the chemical substance, the Administrator shall—

''(i) publish, if applicable, the accession number, generic name, and premanufacture notice case number for that chemical substance; and

''(ii) provide an opportunity for any person—

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

''(II) to claim confidentiality for the specific identity of the chemical substance.''; and

(3) in subsection (e), by striking ''injury to health or the environment'' and inserting ''harm to human health or the environment''.

SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.

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

(1) in subsection (a)—

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

(i) by striking ''the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment'' and inserting ''a chemical substance or mixture is likely to result in an unreasonable risk of harm to human health or the environment under the intended conditions of use''; and

(ii) by striking ''such risk'' the first place it appears and inserting ''the risk posed by the manufacture, processing, dis-

tribution in commerce, or use of the chemical substance or mixture'';

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

(C) in paragraph (3), by striking ''section 6 or 7'' and inserting ''section 6(f) or 7'';

(2) in subsection (b)—

(A) by inserting ''(1)'' before ''The'' in the first sentence; and

(B) by adding at the end the following:

''(2) In determining whether to initiate action under section 6(f), the Administrator shall compare—

''(A) the estimated costs of complying with actions taken under this title with the estimated costs of proceeding instead under other law or laws administered by the Administrator; and

''(B) the efficiency of actions under this title and under such other law or laws to protect against the risk being addressed.''; and

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

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

Section 10 (15 U.S.C. 2609) is amended by striking ''Health, Education, and Welfare'' each place it appears and inserting ''Health and Human Services''.

SEC. 11. INSPECTIONS AND SUBPOENAS.

Section 11(b)(2)(B) (15 U.S.C. 2610(b)(2)(B)) is amended by inserting ''or marketing'' after ''sales''.

SEC. 12. EXPORTS.

Section 12 (15 U.S.C. 2611) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking ''chemical substance, mixture, or to an article containing a chemical substance or mixture,'' and inserting ''chemical substance or mixture''; and

(ii) by striking ''substance, mixture or article'' each place it appears and inserting ''substance or mixture''; and

(B) in paragraph (2)—

(i) by striking ''substance, mixture or article'' both places it appears and inserting ''substance or mixture'' and

(ii) by striking ''unreasonable risk of injury to health'' both places it appears

and inserting ''unreasonable risk of harm to human health'';

(2) by amending subsection (b) to read as follows:

''(b) NOTICE.—

''(1) REGULATED SUBSTANCES.—

''(A) IN GENERAL.—The Administrator may require a person to notify the Administrator that the person is exporting or intends to export to a foreign country a chemical substance or mixture for which for which the Administrator has—

''(i) imposed a requirement or restriction under section 5(c)(5); or

''(ii) promulgated a rule under section 6(f).

''(B) FREQUENCY.—The Administrator shall require notice from a person under subparagraph (A) no more frequently than annually after the first notice submitted by that person for the chemical substance or mixture.

''(C) NOTICE TO GOVERNMENT OF RECEIVING COUNTRY.—Upon receipt of a notification under this paragraph, the Administrator may notify the government of the country to which

the chemical substance or mixture is being exported.

''(2) TREATY OBLIGATIONS.—

''(A) IN GENERAL.—The Administrator shall require a person to notify the Administrator that the person is exporting or intends to export to a foreign country a chemical substance or mixture, or an article containing such chemical substance or mixture, for which the United States is obligated by treaty to provide export notification.

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

''(C) FREQUENCY.—The Administrator shall require notice from a person under subparagraph (A) no more frequently than annually after the first notice submitted by that person for the chemical substance or mixture.''; 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. 13. IMPORTS.

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

"SEC. 13. IMPORTS.

"(a) NOTICE.—

"(1) IN GENERAL.—A person offering a chemical substance or mixture described in paragraph (2) for entry into the customs territory of the United States shall certify to the Secretary of Homeland Security that, after reasonable inquiry and to the best knowledge and belief of the person, the chemical substance or mixture is—

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

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

"(2) COVERED CHEMICAL SUBSTANCES AND MIXTURES.—The chemical substances or mixtures referred to in paragraph (1) are those that are or contain a chemical substance that is either—

''(A) designated as a high priority under section 6(a);

''(B) subject to prohibitions or restrictions under section 5(c)(5); or

''(C) subject to requirements or restrictions under a rule promulgated under section 6(f).

''(b) REFUSAL OF ENTRY.—

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

''(2) PROCEDURE.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), if a chemical substance or mixture is refused entry under paragraph (1), the Secretary of Homeland Security—

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

''(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 Administrator may prescribe, consistent with other applicable Federal law, if the chemical substance or mixture has not been removed from the United States in the 90-day period beginning on the date of receipt of the notice of the refusal of entry provided under clause (i).

''(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 any applicable duty on the chemical substance or mixture.

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

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

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

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

''Sec. 13. Imports.''.

SEC. 14. CONFIDENTIAL INFORMATION.

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

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) IN GENERAL.—Except as provided in subsection (d), the Administrator shall not disclose information obtained by the Administrator under this title that is—

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

"(2) specific information describing the manufacture, processing, or distribution in commerce of a chemical substance, mixture, or article;

"(3) marketing and sales information;

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

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

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

"(7) the specific identity of a chemical substance, including the chemical name, molecular for-

mula, Chemical Abstracts Service number, or other information that would identify a specific chemical substance, if the specific identity is claimed under subsection (b) as confidential information and the claim has not subsequently been withdrawn or found by the Administrator not to warrant protection as confidential information under this section.

''(b) REQUIREMENTS FOR CERTAIN CONFIDENTIALITY CLAIMS.—A person seeking protection from disclosure of information under this section shall—

''(1) claim such information as confidential by identifying such information to the Administrator; and

''(2) in the case of information described in paragraph (8) of subsection (a), submit—

''(A) written documentation justifying why the information qualifies for such protection, including documentation establishing that—

''(i) the submitting person takes reasonable measures to protect the confidentiality of the information;

''(ii) the information is not required to be disclosed, or otherwise made available, to the public under any other Federal

law in connection with one or more uses subject to this title;

''(iii) disclosure of the information is likely to cause meaningful harm to the competitive position of the person; and

''(iv) the information is not reasonably believed to be readily discoverable through reverse engineering;

''(B) the time period for which the person claims protection from disclosure of the information, which may be renewed upon request not later than 30 days before the expiration of the period; and

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

''(c) GUIDANCE.—The Administrator shall develop guidance on the determination of generic names for confidential chemical identities.

''(d) EXCEPTIONS TO PROTECTION FROM DISCLOSURE.—

''(1) IN GENERAL.—In accordance with subsection (l), subsection (a) shall not apply to—

''(A) health and safety information—

''(i) relating to a chemical substance or mixture that has been offered for commercial distribution as of the date on which the information is to be disclosed; or

''(ii) that is developed pursuant to a requirement under section 4, 5, or 6;

''(B) health and safety information submitted to the Administrator in connection with a notice of substantial risk required under section 8(e);

''(C) general information describing the manufacturing volumes, expressed in ranges, that would not reveal information protected as confidential under this section; and

''(D) general descriptions of industrial, commercial, or consumer functions and uses of a chemical substance or mixture that are customarily shared with the general public or within the industry to which the person submitting the information belongs, and would not reveal

information protected as confidential under this section.

''(2) LIMITED INFORMATION SHARING.—The Administrator may share information otherwise protected from disclosure by this section only as follows:

''(A) To an officer or employee of the United States—

''(i) to carry out that person's official duties; or

''(ii) for specific law enforcement purposes under this or any other Act.

''(B) 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 title and under such conditions as the Administrator shall specify.

''(C) To a State, upon written request, for the purpose of development, administration, or enforcement of a law, if—

''(i) the recipient agrees in writing to take appropriate steps, and has adequate authority, to maintain the confidentiality

of the information in accordance with procedures as stringent as those the Administrator uses to safeguard the information; and

''(ii) the Administrator notifies a person claiming protection of the information that the information will be disclosed to a State.

''(D) To a person who is a health professional employed by a Federal or State agency, or a treating physician or nurse, in a nonemergency situation if such person—

''(i) states in writing to the Administrator that the person has a reasonable basis to believe that disclosure of the information will assist in diagnosis or treatment of any person exposed to the chemical substance; and

''(ii) agrees in writing not to use the information for any purpose other than the diagnosis and treatment referred to in clause (i).

''(E) To a treating physician, nurse, or agent of a poison control center, or any other person such a physician, nurse, or agent deter-

mines is necessary to aid in diagnosis or treatment described in clause (i), if—

''(i) such physician, nurse, or agent states that the requested information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment and a person being diagnosed or treated has likely been exposed to the chemical substance; and

''(ii) each person receiving the protected information agrees in writing as soon as practicable, but not necessarily prior to receiving the information, not to use the information concerned for any purpose other than the diagnosis or treatment referred to in clause (i).

''(3) PROHIBITION.—No person who receives information under paragraph (2) may use such information for any purpose not specified in such paragraph, nor disclose such information to any person not authorized to receive such information.

''(4) USE OF INFORMATION BY THE ADMINISTRATOR.—Subsection (a) shall not apply to the extent that the Administrator determines that information disclosure is necessary—

''(A) to protect health or the environment from an imminent and substantial risk of harm; or

''(B) in a proceeding under this title, subject to the condition that the disclosure is made in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding.

''(e) DURATION OF PROTECTION FROM DISCLOSURE.—The Administrator shall protect from disclosure information as required under this section unless—

''(1) the person claiming confidentiality of such information under subsection (b) 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

''(2) the Administrator finds that—

''(A) the time period described in subsection (b)(2)(B) has expired;

''(B) the information has been publicly disclosed through some other means; or

''(C) the information no longer meets the criteria for protection under this section.

''(f) REESTABLISHMENT OF CONFIDENTIALITY.—

''(1) IN GENERAL.—Except as provided in paragraph (2), the Administrator may require a person who has claimed information as confidential under subsection (b) to reestablish such claim.

''(2) LIMITATION.—The Administrator may not under paragraph (1) require reestablishment of a claim for protection from disclosure of information if such claim was submitted to the Administrator under this title prior to the date of enactment of the Chemicals in Commerce Act, unless the Administrator has a reasonable basis to conclude that the claim does not meet the requirements of this section for protection from disclosure.

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

''(1) approve a claim of confidentiality received under subsection (b); or

''(2) if the person who has submitted the claim fails to meet the requirements of this section, approve the claim with conditions or deny the claim.

''(h) NOTICE AND EXPLANATION.—If the Administrator takes action under subsection (g)(2), makes a finding under subsection (e)(2), shares information under subsection (d)(2)(C) or (D), or discloses information pursuant to a determination under subsection (d)(4)(A), the Admin-

istrator shall provide to the person who has claimed confidentiality of information under subsection (b) a written statement of the release, or the Administrator's intent to release or otherwise condition the protection, of the information and the reasons for taking such action.

''(i) TIMING OF RELEASE OF INFORMATION.—

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

''(2) EXCEPTIONS.—

''(A) IN GENERAL.—The Administrator may not share information identified in subsection (d)(2)(A)(i) until 15 days after the date on which the person who submitted the claim of confidentiality receives a notification under subsection (h), 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.

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

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

''(k) JUDICIAL REVIEW.—

''(1) IN GENERAL.—A decision by the Administrator under subsection (g)(2) is subject to review and injunctive relief in a district court of the United States located in the district in which the person seeking protection of the information from disclosure resides, or the United States District Court for the District of Columbia.

''(2) STAY.—Except as provided in subsection (d), the Administrator shall disclose no information included in claim of confidentiality made under subsection (b) during the pendency of judicial review under this subsection.

''(l) SEPARABILITY OF INFORMATION.—In carrying out this title, the Administrator shall separate information as necessary to ensure that—

''(1) no information that is eligible for protection under this section is disclosed with information not protected under this section; and

''(2) all information required to be disclosed under this title is disclosed.

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

(b) TABLE OF CONTENTS AMENDMENT.—The item relating to section 14 in the table of contents is amended to read as follows:

''Sec. 14. Confidential information.''.

SEC. 15. PROHIBITED ACTS.

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

SEC. 16. PENALTIES.

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

(1) in subsection (a)(1)—

(A) in the first sentence—

(i) by striking ''section 15 or 409'' and inserting ''this title, or who otherwise

violates this Act, except as provided in section 207(b),''; and

(ii) by striking ''$25,000'' and inserting ''$37,500''; and

(B) in the second sentence, by striking ''violation of section 15 or 409'' and inserting ''violation of this Act'';

(2) in subsection (a)(2)(A), by striking ''of section 15 or 409'' and inserting ''described in paragraph (1)''; and

(3) 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 convic-

tion, to a fine of not more than $250,000, imprisonment for not more than 5 years, or both.''.

SEC. 17. PREEMPTION.

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

''(a) IN GENERAL.—Except as otherwise provided in this section, no State or local government may establish or continue in force a law or regulation that, for the purpose of regulating chemical substances, mixtures, or articles for intended conditions of use—

''(1) requires the development or submission of information—

''(A) that the Administrator has required under section 4, 5, or 6; or

''(B) relating to a chemical substance, mixture, or article and its intended conditions of use with respect to which the Administrator has completed a safety determination;

''(2) prohibits or restricts the manufacture, processing, distribution in commerce, or use of a chemical substance, mixture, or article for its intended conditions of use if—

''(A) the Administrator has—

''(i) determined under section 5(c)(3)(B) that the chemical substance,

mixture, or article for its intended conditions of use is not likely to result in an unreasonable risk of harm to human health or the environment;

''(ii) determined under section 6(b)(1) that the chemical substance, mixture, or article will not result in an unreasonable risk of harm to human health or the environment under the intended conditions of use;

''(iii) promulgated a rule, entered into a consent order, or issued an order under section 5(c)(5) or 6(f) with respect to the chemical substance, mixture, or article for its intended conditions of use; or

''(iv) designated the chemical substance as a low priority substance under section 6(a); or

''(B) the review period under section 5(c)(1) with respect to the chemical substance, mixture, or article for its intended conditions of use has expired;

''(3) requires the notification of a use of a chemical substance, mixture, or article with respect

to which the Administrator has required notification pursuant to section 5;

''(4) includes any requirement with respect to a chemical substance, mixture, or article, or its intended conditions of use, with respect to which the Administrator, before the date of enactment of the Chemicals in Commerce Act, has promulgated a rule, entered into a consent agreement, issued an order, or allowed the expiration of a significant new use review period under section 5 or 6; or

''(5) in the case of a law or regulation that was not in effect on the date of enactment of the Chemicals in Commerce Act and regulates a chemical substance, takes effect on or after the date the Administrator identifies that chemical substance as a low priority under section 6(a).

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

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

SEC. 18. JUDICIAL REVIEW.

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

(1) in subsection (a)—

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

''(1) FILING OF PETITION.—

''(A) IN GENERAL.—Not later than 60 days after the date of the promulgation of a rule under section 4, 5(c)(5), 6(f), or 8 or title II or IV or an order under section4 or 5(c)(5), any person may file a petition for judicial review of the rule or order in the United States Court of Appeals for—

''(i) the District of Columbia Circuit;

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

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

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

(B) in paragraph (2)—

(i) by inserting ''ADMINISTRATIVE RULES.—'' before ''Copies of any petition''; and

(ii) by striking ''paragraph (1)(A)'' and inserting ''paragraph (1)''; and

(C) in paragraph (3)—

(i) by inserting ''DEFINITION.—'' before ''For purposes of'';

(ii) by amending subparagraph (B) to read as follows:

''(B) in the case of a rule or order under section 4, the statement issued under section 4(b), in the case of a rule or order under section 5(c)(5), the determination required under section 5(c)(3), in the case of rule under section 6(f), the statement published under section 6(e), and in the case of a rule under title IV, the finding required for the issuance of such a rule;''.

(iii) by striking subparagraph (C); and

(iv) by redesignating subparagraphs (D) and (E) as subparagraphs (C) and (D), respectively; and

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

''(B) APPLICABILITY OF SECTION 706 OF TITLE 5, UNITED STATES CODE.—Section 706 of title 5, United States Code, shall apply to review of a rule, order, or final agency action under this section, except that—

''(i) in the case of a rule under section 4, 5(c)(5), or 6(f) or an order under section 4 or 5(c)(5)—

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

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

''(ii) the court shall not review the contents and adequacy of the statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule except as part of

a review of the rulemaking record taken as a whole.''.

SEC. 19. CITIZENS' PETITIONS.

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

(1) in subsection (a), by striking ''section 4, 6, or 8 or an order under section 5(e) or 6(b)(2)'' and inserting ''section 4, 6(f) or 8 or an order under section 4 or 5(e)''; and

(2) in subsection (b)—

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

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

''(B) DE NOVO PROCEEDING.—

''(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to issue a rule under section 4, 6(f), or 8 or an order issued under section 4 or 5(e), 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(a)(1);

"(bb) in the case of a petition to issue an order under section 5(c), there is a reasonable basis to conclude that the chemical substance is likely to result in an unreasonable risk of harm to human health or the environment under the intended conditions of use;

"(cc) in the case of a petition to initiate a proceeding for

the issuance of a rule under section 6(f), there is a reasonable basis to conclude that the chemical substance or mixture will result in an unreasonable risk of harm to human health or the environment under the intended conditions of use; or

''(dd) in the case of a 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 protect human health or the environment from an unreasonable risk of harm.

''(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 those risks to human health or the environment with respect to which the Administrator is otherwise taking action under this title; and

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

SEC. 20. NATIONAL SECURITY.

(a) AMENDMENT.—Section 22 (15 U.S.C. 2621) is amended to read as follows:

''SEC. 22. NATIONAL SECURITY.

''(a) WAIVER.—The Administrator shall waive compliance with any provision of this Act upon a determination by the President that the waiver is necessary in the interest of national security. Upon the issuance of such a waiver, the Administrator shall publish in the Federal Register a notice that the waiver was granted for national security purposes, unless the President directs the Administrator to omit such publication because the publication itself would be contrary to the interests of national security.

''(b) CONSULTATION.—The Administrator shall consult periodically with the President or the President's des-

ignee to discuss how implementation of this Act could affect national security.''.

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

''Sec. 22. National security.''.

SEC. 21. STUDIES.

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

SEC. 22. POLICIES, PROCEDURES, AND GUIDANCE.

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

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

(2) by adding at the end the following:

''(h) POLICIES, PROCEDURES, AND GUIDANCE.—Not later than 1 year after the date of enactment of the Chemicals in Commerce Act, the Administrator shall, after providing public notice and an opportunity for public comment, establish all policies, procedures, and guidance necessary to implement the amendments made to this title by the Chemicals in Commerce Act. Such policies, procedures, and guidance shall employ and rely upon the best available science and the best available risk assessment principles and methodologies.

''(i) INFORMATION QUALITY.—

''(1) IN GENERAL.—The Administrator shall establish scientifically sound criteria for evaluating the quality and reliability of all information, regardless of the affiliation or funding source of the person or organization generating or providing the information, that the Administrator considers under section 4, 5, or 6.

''(2) VALIDITY.—The policies, procedures, and guidance developed under subsection (h) shall establish criteria to—

''(A) ensure that information considered by the Administrator under this title is of high quality, reliable, and, where available, produced according to validated methods or processes;

''(B) address the strengths and limitations of test design and the reliability of test methods and protocols; and

''(C) maximize the quality, objectivity, utility, and integrity of the information.

''(3) STANDARD PRACTICES TO ENSURE QUALITY.—The Administrator shall—

''(A) require, to the extent practicable, the use of good laboratory practices, scientifically reliable test methods, standardized protocols, consistent data evaluation procedures, and

other methods to ensure that information developed or submitted pursuant to this title is of high scientific quality; and

''(B) in using information for decisions under sections 4, 5, and 6, describe the quality of, limitations on, and basis for reliance on such information.

''(j) BEST AVAILABLE SCIENCE.—In making a decision with respect to a chemical substance or mixture under section 4, 5, or 6, the Administrator shall use the best available science.

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

SEC. 23. TECHNICAL AMENDMENT.

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

SEC. 24. STATE PROGRAMS.

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

SEC. 25. AUTHORIZATION OF APPROPRIATIONS.

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

SEC. 26. 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 under section 5; and

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

SEC. 27. PRESERVATION OF AUTHORITY.

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

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

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