

# TSCA MODERNIZATION ACT OF 2015

JUNE 23, 2015.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce,  
submitted the following

## R E P O R T

[To accompany H.R. 2576]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2576) to modernize the Toxic Substances Control Act, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:  
Strike all after the enacting clause and insert the following:

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

(a) **SHORT TITLE.**—This Act may be cited as the “TSCA Modernization Act of 2015”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Definitions.
- Sec. 3. Testing of chemical substances and mixtures.
- Sec. 4. Regulation of hazardous chemical substances and mixtures.
- Sec. 5. Relationship to other Federal laws.
- Sec. 6. Disclosure of data.
- Sec. 7. Effect on State law.
- Sec. 8. Administration of the Act.
- Sec. 9. Conforming amendments.

**SEC. 2. DEFINITIONS.**

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) by redesignating paragraphs (7) through (14) as paragraphs (8) through (15) and (12) through (16), respectively;

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

“(7) The term ‘intended conditions of use’ means the circumstances under which a chemical substance is intended, known, or reasonably foreseeable to be manufactured, processed, distributed in commerce, used, and disposed of.”; and

(3) by inserting after paragraph (10), as so redesignated, the following:

“(11) The term ‘potentially exposed subpopulation’ means a group of individuals within the general population who, due to either greater susceptibility or greater potential exposure, are likely to be at greater risk than the general population of adverse health effects from exposure to a chemical substance.”.

**SEC. 3. TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.**

Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (A)(iii), by striking “; or” and inserting a semicolon;

(B) in subparagraph (B)(iii), by striking “; and” and inserting “; or”; and

(C) by adding at the end the following:

“(C) testing of a chemical substance is necessary to conduct a risk evaluation under section 6(b); and”;

(2) in the matter following subsection (a)(2), by inserting “, order, or consent agreement” after “by rule”; and

(3) in subsection (b)(5), by striking “paragraph (1)(A) or (1)(B)” and inserting “paragraph (1)(A), (1)(B), or (1)(C)”.

**SEC. 4. REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES.**

(a) **SCOPE OF REGULATION.**—Section 6(a) of the Toxic Substances Control Act (15 U.S.C. 2605(a)) is amended—

(1) by striking “finds that there is a reasonable basis to conclude” and inserting “determines under subsection (b)”;

(2) by inserting “or designates a chemical substance under subsection (i)(2),” before “the Administrator shall by rule”; and

(3) by striking “to protect adequately against such risk using the least burdensome requirements” and inserting “so that the chemical substance or mixture no longer presents or will present an unreasonable risk, including an identified unreasonable risk to a potentially exposed subpopulation”.

(b) **RISK EVALUATIONS.**—Section 6(b) of the Toxic Substances Control Act (15 U.S.C. 2605(b)) is amended to read as follows:

“(b) **RISK EVALUATIONS.**—

“(1) **IN GENERAL.**—The Administrator shall conduct risk evaluations pursuant to this subsection to determine whether or not a chemical substance presents or will present, in the absence of requirements under subsection (a), an unreasonable risk of injury to health or the environment.

“(2) **APPLYING REQUIREMENTS.**—The Administrator shall apply requirements with respect to a chemical substance through a rule under subsection (a) only if the Administrator determines through a risk evaluation under this subsection that the chemical substance presents or will present, in the absence of such requirements, an unreasonable risk of injury to health or the environment.

“(3) **CONDUCTING RISK EVALUATION.**—

“(A) **REQUIRED RISK EVALUATIONS.**—The Administrator shall conduct and publish the results of a risk evaluation under this subsection for a chemical substance if—

“(i) the Administrator determines that the chemical substance may present an unreasonable risk of injury to health or the environment because of potential hazard and a potential route of exposure under the intended conditions of use; or

“(ii) a manufacturer of the chemical substance requests such a risk evaluation.

“(B) TSCA WORK PLAN CHEMICALS.—The Administrator may, without making a determination under subparagraph (A)(i), conduct and publish the results of a risk evaluation under this subsection for a chemical substance that, on the date of enactment of the TSCA Modernization Act of 2015, is listed in the TSCA Work Plan for Chemical Assessments published by the Administrator.

“(4) REQUIREMENTS.—In conducting a risk evaluation under this subsection, the Administrator shall—

“(A) integrate and assess information on hazards and exposures for all of the intended conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed subpopulations;

“(B) not consider information on cost and other factors not directly related to health or the environment;

“(C) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the intended conditions of use of the chemical substance;

“(D) describe the weight of the scientific evidence for identified hazard and exposure;

“(E) consider whether the weight of the scientific evidence supports the identification of doses of the chemical substance below which no adverse effects can be expected to occur; and

“(F) in the case of a risk evaluation requested by a manufacturer under paragraph (3)(A)(ii), ensure that the costs to the Environmental Protection Agency, including contractor costs, of conducting the risk evaluation are paid for by the manufacturer.

“(5) DEADLINES.—

“(A) RISK EVALUATIONS.—The Administrator shall conduct and publish a risk evaluation under this subsection for a chemical substance as soon as reasonably possible, subject to the availability of resources, but not later than 3 years after the date on which—

“(i) the Administrator—

“(I) makes a determination under paragraph (3)(A)(i); or

“(II) begins the risk evaluation under paragraph (3)(B); or

“(ii) a manufacturer requests the risk evaluation under paragraph (3)(A)(ii).

“(B) SUBSECTION (a) RULES.—If, based on a risk evaluation conducted under this subsection, the Administrator determines that a chemical substance presents or will present, in the absence of a rule under subsection (a), an unreasonable risk of injury to health or the environment, the Administrator shall—

“(i) propose a rule under subsection (a) for the chemical substance not later than 90 days after the date on which the risk evaluation regarding such chemical substance is published under subparagraph (A); and

“(ii) publish in the Federal Register a final rule not later than 180 days after the date on which the risk evaluation regarding such chemical substance is published under subparagraph (A).

“(C) EXTENSION.—If the Administrator determines that additional information is necessary to make a risk evaluation determination under this subsection, the Administrator may extend the deadline under subparagraph (A) accordingly, except that the deadline may not be extended to a date that is later than—

“(i) 90 days after receipt of such additional information; or

“(ii) 2 years after the original deadline.

“(6) DETERMINATIONS OF NO UNREASONABLE RISK.—

“(A) NOTICE AND COMMENT.—Not later than 30 days before publishing a final determination under this subsection that a chemical substance does not and will not present an unreasonable risk of injury to health or the environment, the Administrator shall make a preliminary determination to such effect and provide public notice of, and an opportunity for comment regarding, such preliminary determination.

“(B) POTENTIALLY EXPOSED SUBPOPULATIONS.—The Administrator shall not make a determination under this subsection that a chemical substance will not present an unreasonable risk of injury to health or the environment if the Administrator determines that the chemical substance, under the intended conditions of use, presents or will present an unreasonable risk of injury to 1 or more potentially exposed subpopulations.

- “(C) FINAL ACTION.—A final determination under this subsection that a chemical substance will not present an unreasonable risk of injury to health or the environment shall be considered a final agency action.
- “(7) MINIMUM NUMBER.—Subject to the availability of appropriations, the Administrator shall initiate 10 or more risk evaluations under paragraphs (3)(A)(i) or (3)(B) in each fiscal year beginning in the fiscal year of the date of enactment of the TSCA Modernization Act of 2015.”
- (c) PROMULGATION OF SUBSECTION (a) RULES.—Section 6(c) of the Toxic Substances Control Act (15 U.S.C. 2605(c)) is amended—
- (1) by amending paragraph (1) to read as follows:
- “(1) REQUIREMENTS FOR RULE.—In promulgating any rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall—
- “(A) consider and publish a statement with respect to—
- “(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;
- “(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to the chemical substance or mixture;
- “(iii) the benefits of the chemical substance or mixture for various uses; and
- “(iv) the reasonably ascertainable economic consequences of the rule, including consideration of the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;
- “(B) impose requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to protect against the identified risk;
- “(C) based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific use of a chemical substance or mixture and in setting an appropriate transition period for such action, determine whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect;
- “(D) exempt replacement parts designed prior to the date of publication in the Federal Register of the rule unless the Administrator finds such replacement parts contribute significantly to the identified risk, including identified risk to identified potentially exposed subpopulations; and
- “(E) in selecting among prohibitions and other restrictions to address an identified risk, apply prohibitions or other restrictions to articles on the basis of a chemical substance or mixture contained in the article only to the extent necessary to protect against the identified risk.”;
- (2) in paragraph (2)—
- (A) by inserting “PROCEDURES.—” before “When prescribing a rule”;
- (B) by striking “provide an opportunity for an informal hearing in accordance with paragraph (3); (D)”;
- (C) by striking “, and (E)” and inserting “; and (D)”;
- (D) by moving such paragraph 2 ems to the right;
- (3) by striking paragraphs (3) and (4) and redesignating paragraph (5) as paragraph (3); and
- (4) in paragraph (3) (as so redesignated)—
- (A) by striking “Paragraphs (1), (2), (3), and (4)” and inserting “APPLICATION.—Paragraphs (1) and (2)”;
- (B) by moving such paragraph 2 ems to the right.
- (d) EFFECTIVE DATE.—Section 6(d)(2)(B) of the Toxic Substances Control Act (15 U.S.C. 2605(d)(2)(B)) is amended by adding at the end the following: “Any rule promulgated under subsection (a) shall provide for a reasonable transition period.”
- (e) NON-RISK FACTORS; CRITICAL USE EXEMPTIONS; PBT CHEMICALS.—Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended by adding at the end the following:
- “(g) NON-RISK FACTORS.—The Administrator shall not consider costs or other non-risk factors when deciding whether to initiate a rulemaking under subsection (a).
- “(h) CRITICAL USE EXEMPTIONS.—

“(1) **CRITERIA FOR EXEMPTION.**—The Administrator may grant an exemption from a requirement of a subsection (a) rule for a specific use of a chemical substance or mixture, if—

“(A) the requirement is not cost-effective with respect to the specific use, as determined by the Administrator pursuant to subsection (c)(1)(B); and

“(B) the Administrator finds that—

“(i) the specific use is a critical or essential use; or

“(ii) the requirement, as applied with respect to the specific use, would significantly disrupt the national economy, national security, or critical infrastructure.

“(2) **PROCEDURE.**—An exemption granted under paragraph (1) shall be—

“(A) supported by clear and convincing evidence;

“(B) preceded by public notice of the proposed exemption and an opportunity for comment; and

“(C) followed by notice of the granted exemption—

“(i) to the public, by the Administrator; and

“(ii) to known commercial purchasers of the chemical substance or mixture with respect to which the exemption applies, by the manufacturers and processors of such chemical substance or mixture.

“(3) **PERIOD OF EXEMPTION.**—An exemption granted under paragraph (1) shall expire after a period not to exceed 5 years, but may be renewed for one or more additional 5-year periods if the Administrator finds that the requirements of paragraph (1) continue to be met.

“(4) **CONDITIONS.**—The Administrator shall impose conditions on any use for which an exemption is granted under paragraph (1) to reduce risk from the chemical substance or mixture to the greatest extent feasible.

“(i) **CHEMICALS THAT ARE PERSISTENT, BIOACCUMULATIVE, AND TOXIC.**—

“(1) **IDENTIFICATION.**—Not later than 9 months after the date of enactment of the TSCA Modernization Act of 2015, the Administrator shall publish a list of those chemical substances that the Administrator has a reasonable basis to conclude are persistent, bioaccumulative, and toxic, not including any chemical substance that is a metal, a metal compound, or subject to subsection (e).

“(2) **CONFIRMATION OF CONCERN.**—Not later than 2 years after the date of enactment of the TSCA Modernization Act of 2015, the Administrator shall designate as a PBT chemical of concern each chemical substance on the list published under paragraph (1)—

“(A) that, with respect to persistence and bioaccumulation, scores high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012; and

“(B) exposure to which is likely to the general population or to a potentially exposed subpopulation identified by the Administrator.

“(3) **EXPEDITED ACTION.**—Notwithstanding subsection (b)(2), subject to the availability of appropriations, not later than 2 years after designating a chemical substance under paragraph (2), the Administrator shall promulgate a rule under subsection (a) with respect to the chemical substance to reduce likely exposure to the extent practicable.

“(4) **RELATIONSHIP TO SUBSECTION (b).**—If, at any time prior to the date that is 90 days after the date on which the Administrator publishes the list under paragraph (1), the Administrator makes a finding under subsection (b)(3)(A)(i), or a manufacturer requests a risk evaluation under subsection (b)(3)(A)(ii), with respect to a chemical substance, such chemical substance shall not be subject to this subsection.”.

#### **SEC. 5. RELATIONSHIP TO OTHER FEDERAL LAWS.**

Section 9(b) of the Toxic Substances Control Act (15 U.S.C. 2608(b)) is amended—

(1) by striking “The Administrator shall coordinate” and inserting “(1) The Administrator shall coordinate”; and

(2) by adding at the end the following:

“(2) In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this title with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider the relevant risks, and compare the estimated costs and efficiencies, of the action to be taken under this title and an action to be taken under such other law to protect against such risk.”.

#### **SEC. 6. DISCLOSURE OF DATA.**

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended—

(1) in subsection (a)—

- (A) by striking “or” at the end of paragraph (3);
  - (B) by striking the period at the end of paragraph (4) and inserting a semicolon; and
  - (C) by adding after paragraph (4) the following new paragraphs:
    - “(5) may be disclosed to a State, local, or tribal government official upon request of the official for the purpose of administration or enforcement of a law; and
    - “(6) shall be disclosed upon request—
      - “(A) to a health or environmental professional employed by a Federal or State agency in response to an environmental release; or
      - “(B) to a treating physician or other health care professional to assist in the diagnosis or treatment of 1 or more individuals.”;
  - (2) in subsection (b)(1), in the matter following subparagraph (B)—
    - (A) by striking “data which discloses” and inserting “data that disclose formulas (including molecular structures) of a chemical substance or mixture.”;
    - (B) by striking “mixture or,” and inserting “mixture, or,”; and
    - (C) by striking “the release of data disclosing”;
  - (3) in subsection (c)—
    - (A) by striking the subsection heading and inserting “DESIGNATING AND SUBSTANTIATING CONFIDENTIALITY.—”;
    - (B) by amending paragraph (1) to read as follows: “(1)(A) In submitting information under this Act after date of enactment of the TSCA Modernization Act of 2015, a manufacturer, processor, or distributor in commerce shall designate the information which such person believes is entitled to protection under this section, and submit such designated information separately from other information submitted under this Act. A designation under this subparagraph shall be made in writing and in such manner as the Administrator may prescribe, and shall include—
      - “(i) justification for each designation of confidentiality;
      - “(ii) a certification that the information is not otherwise publicly available; and
      - “(iii) separate copies of all submitted information, with 1 copy containing and 1 copy excluding the information to which the request applies.
    - (B) Designations made under subparagraph (A) after the date of enactment of the TSCA Modernization Act of 2015 shall expire after 10 years, at which time the information shall be made public unless the manufacturer, processor, or distributor in commerce has reasserted the claim for protection, in writing and in such manner as the Administrator may prescribe, including all of the elements required for the initial submission.
    - (C) Not later than 60 days prior to making information public under subparagraph (B), the Administrator shall notify, as appropriate and practicable, the manufacturer, processor, or distributor in commerce who designated the information under subparagraph (A) of the date on which such information will be made public unless a request for renewal is granted under subparagraph (B).”; and
    - (C) in paragraph (2)—
      - (i) in subparagraph (A), by inserting “, for a reason other than the expiration of such designation pursuant to paragraph (1)(B),” before “proposes to release”; and
      - (ii) in subparagraph (B)(i), by striking “or (4)” and inserting “(4), or (6)”; and
    - (4) by adding at the end the following new subsections:
      - “(f) PROHIBITION.—No person who receives information as permitted under subsection (a) may use such information for any purpose not specified in such subsection, nor disclose such information to any person not authorized to receive such information.
      - “(g) SAVINGS.—Nothing in this section shall be construed to affect the applicability of State or Federal rules of evidence or procedure in any judicial proceeding.”.
- SEC. 7. EFFECT ON STATE LAW.**
- (a) IN GENERAL.—Section 18(a) of the Toxic Substances Control Act (15 U.S.C. 2617(a)) is amended—
    - (1) in paragraph (2)(A), by striking “; and” and inserting a semicolon;
    - (2) by striking paragraph (2)(B) and inserting the following:
      - “(B) if the Administrator makes a final determination under section 6(b) that a chemical substance will not present an unreasonable risk of injury to health or the environment under the intended condition of use, no State or political subdivision may, after the date of publication of such determination, establish

or continue in effect any requirement that applies to such chemical substance under the intended conditions of use considered by the Administrator in the risk evaluation under section 6(b), and is designed to protect against exposure to such chemical substance under the intended conditions of use, unless the requirement of the State or political subdivision—

“(i) is adopted under the authority of a Federal law; or

“(ii) is adopted to protect air or water quality or is related to waste treatment or waste disposal, except that this clause does not apply to such a requirement if a provision of this title, or an action or determination made by the Administrator under this title, actually conflicts with the requirement; and

“(C) if the Administrator imposes a requirement, through a rule or order under section 5 or 6, that applies to a chemical substance or mixture (other than a requirement described in section 6(a)(6)) and is designed to protect against a risk of injury to health or the environment associated with such chemical substance or mixture, no State or political subdivision may, after the effective date of such requirement, establish or continue in effect any requirement that applies to such chemical substance or mixture (including a requirement that applies to an article because the article contains the chemical substance or mixture) and is designed to protect against exposure to the chemical substance or mixture either under the intended conditions of use considered by the Administrator in the risk evaluation under section 6(b) or from a use identified in a notice received by the Administrator under section 5(a), or, in the case of a requirement imposed pursuant to section 6(i), is designed to protect against a risk of injury considered by the Administrator in imposing such requirement, unless the requirement of the State or political subdivision—

“(i) is identical to the requirement imposed by the Administrator;

“(ii) is adopted under the authority of a Federal law; or

“(iii) is adopted to protect air or water quality or is related to waste treatment or waste disposal, except that this clause does not apply to such a requirement if a provision of this title, or an action or determination made by the Administrator under this title, actually conflicts with the requirement.”; and

(3) by adding at the end the following:

“(3) In the case of an identical requirement described in paragraph (2)(C)(i)—

“(A) a State may not assess a penalty for a specific violation for which the Administrator has assessed a penalty under section 16; and

“(B) if a State has assessed a penalty for a specific violation, the Administrator may not assess a penalty for that violation in an amount that would cause the total of the penalties assessed for the violation by the State and the Administrator combined to exceed the maximum amount that may be assessed for that violation by the Administrator under section 16.”.

(b) SAVINGS.—Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amended by adding at the end the following:

“(c) SAVINGS.—

“(1) PRIOR STATE ACTIONS.—Nothing in this title, nor any risk evaluation, rule, order, standard, or requirement completed or implemented under this title, shall be construed to preempt or otherwise affect the authority of a State or political subdivision of a State to continue to enforce any action taken before August 1, 2015, under the authority of a State law that prohibits or otherwise restricts the manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance, or any action taken pursuant to a State law that was in effect on August 31, 2003, unless an action or determination made by the Administrator under this title actually conflicts with the action taken pursuant to such a State law.

“(2) TORT AND CONTRACT LAW.—Nothing in this title, nor any risk evaluation, rule, order, standard, or requirement completed or implemented under this title, shall be construed to preempt or otherwise affect either Federal or State tort law or the law governing the interpretation of contracts of any State, including any remedy for civil relief, whether under statutory or common law, including a remedy for civil damages, and 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 relating to tort law.

“(3) INTENT OF CONGRESS.—It is not the intent of Congress that this title, or rules, regulations, or orders issued pursuant to this title, be interpreted as influencing, in either a plaintiff's or defendant's favor, the disposition of any civil action for damages in a State court, or the authority of any court to make a determination in an adjudicatory proceeding under applicable State law with re-

spect to the admissibility of evidence, unless a provision of this title actually conflicts with the State court action.

“(4) APPLICATION.—For purposes of this title, the term ‘requirements’ does not include civil tort actions for damages under State law.”.

(c) EFFECT OF ACTIONS BY ADMINISTRATOR.—Nothing in this Act, or the amendments made by this Act, shall be construed as changing the preemptive effect of an action taken by the Administrator prior to the date of enactment of this Act or under section 6(e).

#### SEC. 8. ADMINISTRATION OF THE ACT.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) in subsection (b)(1)—

(A) by striking “of a reasonable fee”;

(B) by inserting “of a fee that is sufficient and not more than reasonably necessary” after “section 4 or 5”;

(C) by inserting “, or who requests a risk evaluation under section 6(b)(3)(A)(ii),” before “to defray the cost”;

(D) by striking “this Act” and inserting “the provision of this title for which such fee is collected”; and

(E) by striking “Such rules shall not provide for any fee in excess of \$2,500 or, in the case of a small business concern, any fee in excess of \$100.” and inserting “Such rules shall provide for lower fees for small business concerns.”;

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

“(3) FUND.—

“(A) ESTABLISHMENT.—There is established in the Treasury of the United States a revolving fund, to be known as the TSCA Service Fee Fund (in this paragraph referred to as the ‘Fund’), consisting of such amounts as are deposited in the Fund under this paragraph.

“(B) COLLECTION AND DEPOSIT OF FEES.—The Administrator shall collect the fees described in paragraph (1) and deposit those fees in the Fund.

“(C) CREDITING AND AVAILABILITY OF FEES.—On request by the Administrator, the Secretary of the Treasury shall transfer from the Fund to the Administrator amounts appropriated to pay or recover the full costs incurred by the Environmental Protection Agency, including contractor costs, in carrying out the provisions of this title for which the fees are collected under paragraph (1).

“(D) USE OF FUNDS BY ADMINISTRATOR.—Amounts equivalent to fees collected by the Administrator and deposited in the Fund under this section shall be available without fiscal year limitation to the Administrator, subject to the availability of appropriations, for use only in administering the provisions of this title for which the fees are collected.

“(E) ACCOUNTING AND AUDITING.—

“(i) ACCOUNTING.—The Administrator shall biennially prepare and submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes an accounting of the fees paid to the Administrator under this paragraph and amounts disbursed from the Fund for the period covered by the report, as reflected by financial statements provided in accordance with sections 3515 and 3521 of title 31, United States Code.

“(ii) AUDITING.—

“(I) IN GENERAL.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of a covered executive agency.

“(II) COMPONENTS OF AUDIT.—The annual audit required in accordance with sections 3515 and 3521 of title 31, United States Code, of the financial statements of activities carried out using amounts from the Fund shall include an analysis of—

“(aa) the fees collected and amounts disbursed under this subsection;

“(bb) the reasonableness of the fees in place as of the date of the audit to meet current and projected costs of administering the provisions of the title for which the fees are collected; and

“(cc) the number of requests for a risk evaluation made by manufacturers under section 6(b)(3)(A)(ii).

“(III) FEDERAL RESPONSIBILITY.—The Inspector General of the Environmental Protection Agency shall conduct the annual audit described in subclause (II) and submit to the Administrator a report that describes the findings and any recommendations of the Inspector General resulting from the audit.”; and



(3) by adding at the end the following:

“(h) **SCIENTIFIC STANDARDS.**—In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall consider, as applicable—

“(1) the extent to which the scientific and technical procedures, measures, methods, or models employed to generate the information are reasonable for and consistent with the use of the information;

“(2) the extent to which the information is relevant for the Administrator’s use in making a decision about a chemical substance or mixture;

“(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

“(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, or models, are evaluated and characterized; and

“(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, or models.

“(i) **WEIGHT OF SCIENTIFIC EVIDENCE.**—The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence.

“(j) **AVAILABILITY OF INFORMATION.**—Subject to section 14, the Administrator shall make available to the public all notices, determinations, findings, rules, and orders of the Administrator under this title.

“(k) **POLICIES, PROCEDURES, AND GUIDANCE.**—

“(1) **DEVELOPMENT.**—Not later than 2 years after the date of enactment of the TSCA Modernization Act of 2015, the Administrator shall develop any policies, procedures, and guidance the Administrator determines are necessary to carry out the amendments to this Act made by the TSCA Modernization Act of 2015.

“(2) **REVIEW.**—Not later than 5 years after the date of enactment of the TSCA Modernization Act of 2015, and not less frequently than once every 5 years thereafter, the Administrator shall—

“(A) review the adequacy of the policies, procedures, and guidance developed under paragraph (1), including with respect to animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this title; and

“(B) revise such policies, procedures, and guidance as the Administrator determines necessary to reflect new scientific developments or understandings.

“(l) **REPORT TO CONGRESS.**—

“(1) **INITIAL REPORT.**—Not later than 6 months after the date of enactment of the TSCA Modernization Act of 2015, the Administrator shall submit to the Committees on Energy and Commerce and Appropriations of the House of Representatives and the Committees on Environment and Public Works and Appropriations of the Senate a report containing an estimation of—

“(A) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under subparagraphs (A)(i) and (B) of section 6(b)(3), and the resources necessary to initiate the minimum number of risk evaluations required under section 6(b)(7);

“(B) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under section 6(b)(3)(A)(ii), the likely demand for such risk evaluations, and the anticipated schedule for accommodating that demand;

“(C) the capacity of the Environmental Protection Agency to promulgate rules under section 6(a) as required based on risk evaluations conducted and published under section 6(b); and

“(D) the actual and anticipated efforts of the Environmental Protection Agency to increase the Agency’s capacity to conduct and publish risk evaluations under section 6(b).

“(2) **SUBSEQUENT REPORTS.**—The Administrator shall update and resubmit the report described in paragraph (1) not less frequently than once every 5 years.”.

#### **SEC. 9. CONFORMING AMENDMENTS.**

(a) **SECTION 4.**—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) in subsection (b)—

(A) in paragraph (1), by striking “rule” each place it appears and inserting “rule, order, or consent agreement”;

(B) in paragraph (2)(B), by striking “rules” and inserting “rules, orders, and consent agreements”;

- (C) in paragraph (3), by striking “rule” each place it appears and inserting “rule, order, or consent agreement”; and
  - (D) in paragraph (4)—
    - (i) by striking “rule under subsection (a)” each place it appears and inserting “rule, order, or consent agreement under subsection (a)”;
    - (ii) by striking “repeals the rule” each place it appears and inserting “repeals the rule or order or modifies the consent agreement to terminate the requirement”; and
    - (iii) by striking “repeals the application of the rule” and inserting “repeals or modifies the application of the rule, order, or consent agreement”;
  - (2) in subsection (c)—
    - (A) in paragraph (1), by striking “rule” and inserting “rule or order”;
    - (B) in paragraph (2)—
      - (i) in subparagraph (A), by striking “a rule under subsection (a) or for which data is being developed pursuant to such a rule” and inserting “a rule, order, or consent agreement under subsection (a) or for which data is being developed pursuant to such a rule, order, or consent agreement”;
      - (ii) in subparagraph (B), by striking “such rule or which is being developed pursuant to such rule” and inserting “such rule, order, or consent agreement or which is being developed pursuant to such rule, order, or consent agreement”; and
      - (iii) in the matter following subparagraph (B), by striking “the rule” and inserting “the rule or order”;
    - (C) in paragraph (3)(B)(i), by striking “rule promulgated” and inserting “rule, order, or consent agreement”; and
    - (D) in paragraph (4)—
      - (i) by striking “rule promulgated” each place it appears and inserting “rule, order, or consent agreement”;
      - (ii) by striking “such rule” each place it appears and inserting “such rule, order, or consent agreement”; and
      - (iii) in subparagraph (B), by striking “the rule” and inserting “the rule, order, or consent agreement”;
  - (3) in subsection (d), by striking “rule” and inserting “rule, order, or consent agreement”; and
  - (4) in subsection (g), by striking “rule” and inserting “rule, order, or consent agreement”.
- (b) SECTION 5.—Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—
- (1) in subsection (b)—
    - (A) in paragraph (1)(A)—
      - (i) by striking “rule promulgated” and inserting “rule, order, or consent agreement”; and
      - (ii) by striking “such rule” and inserting “such rule, order, or consent agreement”;
    - (B) in paragraph (1)(B)—
      - (i) by striking “rule promulgated” and inserting “rule or order”; and
      - (ii) by striking “the date of the submission in accordance with such rule” and inserting “the required date of submission”; and
    - (C) in paragraph (2)(A)(ii), by striking “rule promulgated” and inserting “rule, order, or consent agreement”;
  - (2) in subsection (d)(2)(C), by striking “rule” and inserting “rule, order, or consent agreement”; and
  - (3) in subsection (h)(4), by striking “paragraphs (2) and (3) of section 6(c)” and inserting “paragraph (2) of section 6(c)”.
- (c) SECTION 6.—Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—
- (1) in subsection (d)(2)(B)—
    - (A) by striking “, provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), for a hearing on such rule,” and inserting “in accordance with paragraph (2) of subsection (c),”; and
    - (B) by striking “, and if such a hearing is requested” and all that follows through “or revoke it.” and inserting a period; and
  - (2) in subsection (e)(4), by striking “paragraphs (2), (3), and (4) of subsection (c)” and inserting “paragraph (2) of subsection (c)”.
- (d) SECTION 7.—Section 7(a)(1) of the Toxic Substances Control Act (15 U.S.C. 2606(a)(1)) is amended, in the matter following subparagraph (C), by striking “a rule under section 4, 5, 6, or title IV or an order under section 5 or title IV” and insert-

ing “a rule under section 4, 5, or 6 or title IV, an order under section 4 or 5 or title IV, or a consent agreement under section 4”.

(e) SECTION 8.—Section 8(a)(3)(A)(ii)(I) of the Toxic Substances Control Act (15 U.S.C. 2607(a)(3)(A)(ii)(I)) is amended by striking “or an order in effect under section 5(e)” and inserting “, an order in effect under section 4 or 5(e), or a consent agreement under section 4”.

(f) SECTION 9.—Section 9(a) of the Toxic Substances Control Act (15 U.S.C. 2608(a)) is amended by striking “section 6” each place it appears and inserting “section 6(a)”.

(g) SECTION 11.—Section 11(b)(2)(E) of the Toxic Substances Control Act (15 U.S.C. 2610(b)(2)(E)) is amended by striking “rule promulgated” and inserting “rule promulgated, order issued, or consent agreement entered into”.

(h) SECTION 15.—Section 15(1) of the Toxic Substances Control Act (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 promulgated, order issued, or consent agreement entered into under this title, or”.

(i) SECTION 18.—Section 18(a)(2)(A) of the Toxic Substances Control Act (15 U.S.C. 2617(a)(2)(A)) is amended—

(1) by striking “rule promulgated” and inserting “rule, order, or consent agreement”; and

(2) by striking “such rule” each place it appears and inserting “such rule, order, or consent agreement”.

(j) SECTION 19.—Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)(A)—

(i) by striking “(A) Not later than 60 days after the date of the promulgation of a rule” and inserting “Not later than 60 days after the date on which a rule is promulgated”;

(ii) by inserting “or the date on which an order is issued under section 4,” before “any person”;

(iii) by striking “such rule” and inserting “such rule or order”; and

(iv) by striking “such a rule” and inserting “such a rule or order”;

(B) by striking paragraph (1)(B);

(C) in paragraph (2), by striking “the rule” and inserting “the rule or order”; and

(D) in paragraph (3)—

(i) in subparagraph (A), by striking “the rule” and inserting “the rule or order”;

(ii) in subparagraph (B), by striking “a rule under section 4(a)” and inserting “a rule or order under section 4(a)”;

(iii) in subparagraph (C), by striking “such rule” and inserting “such rule or order”;

(iv) in subparagraph (D), by striking “such rule” and inserting “such rule or order”; and

(v) in subparagraph (E)—

(I) by striking “to such rule” and inserting “to such rule or order”; and

(II) by striking “the date of the promulgation of such rule” and inserting “the date on which such rule is promulgated or such order is issued”;

(2) in subsection (b)—

(A) by striking “review a rule” and inserting “review a rule, or an order under section 4,”;

(B) by striking “such rule” and inserting “such rule or order”;

(C) by striking “the rule” and inserting “the rule or order”;

(D) by striking “new rule” each place it appears and inserting “new rule or order”; and

(E) by striking “modified rule” and inserting “modified rule or order”; and

(3) in subsection (c)—

(A) in paragraph (1)—

(i) in subparagraph (A)—

(I) by striking “a rule” and inserting “a rule, or an order under section 4”; and

(II) by striking “such rule” and inserting “such rule or order”; and

(ii) in subparagraph (B)—

(I) in the matter preceding clause (i), by striking “a rule” and inserting “a rule or order”;

- (II) in clause (i)—
  - (aa) by inserting “or an order under section 4,” before “the standard for review”;
  - (bb) by striking “such rule” and inserting “such rule or order”;
  - (cc) by striking “the rule” and inserting “the rule or order”; and
  - (dd) by striking the semicolon and inserting “; and”; and
- (III) by striking clause (ii) and redesignating clause (iii) as clause (ii); and
- (B) in paragraph (2), by striking “any rule” and inserting “any rule or order”.
- (k) SECTION 20.—Section 20(a)(1) of the Toxic Substances Control Act (15 U.S.C. 2619(a)(1)) is amended by striking “order issued under section 5” and inserting “order issued under section 4 or 5”.
- (l) SECTION 21.—Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—
  - (1) in subsection (a), by striking “order under section 5(e) or 6(b)(2)” and inserting “order under section 4 or 5(e)”; and
  - (2) in subsection (b)—
    - (A) in paragraph (1), by striking “order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)” and inserting “order under section 4 or 5(e)”; and
    - (B) in paragraph (4)(B)—
      - (i) in the matter preceding clause (i), by striking “order under section 5(e) or 6(b)(2)” and inserting “order under section 4 or 5(e)”; and
      - (ii) in clause (i), by striking “order under section 5(e)” and inserting “order under section 4 or 5(e)”; and
      - (iii) in clause (ii), by striking “or an order under section 6(b)(2)”.
- (m) SECTION 24.—Section 24(b)(2)(B) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)) is amended—
  - (1) by inserting “and” at the end of clause (i);
  - (2) by striking clause (ii); and
  - (3) by redesignating clause (iii) as clause (ii).
- (n) SECTION 27.—Section 27(a) of the Toxic Substances Control Act (15 U.S.C. 2626(a)) is amended by striking “rules promulgated” and inserting “rules, orders, or consent agreements”.
- (o) SECTION 30.—Section 30(2) of the Toxic Substances Control Act (15 U.S.C. 2629(2)) is amended by striking “rule” and inserting “rule, order, or consent agreement”.

## PURPOSE AND SUMMARY

To modernize the Toxic Substances Control Act of 1976, to identify and control unreasonable risks of injury to health or the environment from the manufacture, processing, distribution in commerce, use, and disposal of chemical substances, facilitate interstate commerce, and for other purposes.

## BACKGROUND AND NEED FOR LEGISLATION

In 1971, the President’s Council on Environmental Quality proposed comprehensive Federal legislation to identify and control potentially dangerous chemicals in U.S. commerce that were not adequately regulated under other Federal environmental statutes. President Ford signed the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*) into law on October 11, 1976.

Under TSCA, the Environmental Protection Agency (EPA) is responsible for identifying, testing, and regulating chemical substances in U.S. commerce whose manufacture, processing, distribution in commerce, use, and disposal present or will present an unreasonable risk of injury to health or the environment.

In the nearly four decades since its enactment and particularly during the last decade, there have been persistent concerns about the pace of EPA’s work under TSCA, the ability of the Agency to

use its existing authority, and whether the statute prevents certain regulatory efforts.

A variety of factors, including EPA's slow pace in regulating chemicals already on the market, has led to several new State chemical control statutes—ranging from specific chemical restrictions to general chemical control programs—and retailer-based systems to identify and promote products that were considered safer for consumers. Ultimately, public confusion about chemical-specific claims, a perceived lack of expeditious action by EPA, and a domestic and foreign marketplace that has become increasingly uneven, unpredictable, and incompatible with economic and regulatory realities led Congress to examine TSCA and how it can operate more effectively in the 21st century.

Oversight by the Committee yielded two conclusions about TSCA modernization. First, not every part of TSCA needs to be rewritten—and those that do are places where there is widespread agreement. Second, not every problem with TSCA is a statutory problem. EPA may, if it chooses, use existing authority to remedy these concerns.

In light of these conclusions, the Committee on Energy and Commerce focused on giving the Agency more direct tools to obtain testing information on chemical substances, restructuring the way existing chemicals are evaluated and regulated, clarifying the treatment and availability of trade secrets submitted to EPA, updating the collection of fees needed to support EPA's implementation of TSCA, assuring high quality science is used by the Agency, and organizing the Federal-State regulatory relationship in a way that makes sense for promoting interstate and global commerce, but also recognizes non-conflicting efforts taken by several States.

#### HEARINGS

The Subcommittee on Environment and the Economy held a hearing entitled “H.R. \_\_\_\_, the TSCA Modernization Act” on April 14, 2015. The Subcommittee received testimony from:

- Jim Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency;
- Michael P. Walls, Vice President of Regulatory and Technical Affairs, American Chemistry Council;
- Beth Bosley, President, Boron Specialties, LLC, on behalf of the Society of Chemical Manufacturers and Affiliates;
- Jennifer Thomas, Senior Director, Federal Government Affairs, Alliance of Automobile Manufacturers; and
- Andy Igrejas, Director, Safer Chemicals, Healthy Families.

#### COMMITTEE CONSIDERATION

On May 14, 2015, the Subcommittee on Environment and the Economy met in open markup session and forwarded a Committee Print entitled the “TSCA Modernization Act” to the full Committee, as amended, by a record vote of 21 yeas and 0 nays. On June 2 and June 3, 2015, the Committee on Energy and Commerce met in open markup session and ordered H.R. 2576, the “TSCA Modernization Act,” reported to the House, as amended, by a recorded vote of 47 yeas and 0 nays, and 1 present.

## COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. A motion by Mr. Upton to order H.R. 2576 reported to the House, with amendment, was agreed to by a record vote of 47 ayes and 0 nays, and 1 present. The following reflects the record votes taken during the Committee consideration:

**COMMITTEE ON ENERGY AND COMMERCE -- 114TH CONGRESS  
ROLL CALL VOTE # 17**

**BILL: H.R. 2576**, the "TSCA Modernization Act of 2015"

**AMENDMENT:** A motion by Mr. Upton to order H.R. 2576 favorably reported to the House, as amended.  
(Final Passage)

**DISPOSITION: AGREED TO**, by a roll call vote of 47 yeas, 0 nays, 1 present

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton	X			Mr. Pallone	X		
Mr. Barton				Mr. Rush			
Mr. Whitfield	X			Ms. Eshoo			X
Mr. Shimkus	X			Mr. Engel	X		
Mr. Pitts	X			Mr. Green	X		
Mr. Walden	X			Ms. DeGette	X		
Mr. Murphy	X			Ms. Capps	X		
Mr. Burgess	X			Mr. Doyle	X		
Mrs. Blackburn				Ms. Schakowsky	X		
Mr. Scalise				Mr. Butterfield	X		
Mr. Latta	X			Ms. Matsui	X		
Mrs. McMorris Rodgers				Ms. Castor	X		
Mr. Harper	X			Mr. Sarbanes	X		
Mr. Lance	X			Mr. McNerney	X		
Mr. Guthrie	X			Mr. Welch	X		
Mr. Olson	X			Mr. Lujan	X		
Mr. McKinley	X			Mr. Tonko	X		
Mr. Pompeo				Mr. Yarmuth	X		
Mr. Kinzinger	X			Ms. Clarke	X		
Mr. Griffith	X			Mr. Loeb sack	X		
Mr. Bilirakis	X			Mr. Schrader	X		
Mr. Johnson	X			Mr. Kennedy	X		
Mr. Long	X			Mr. Cardenas	X		
Mrs. Ellmers	X						
Mr. Bucshon	X						
Mr. Flores	X						
Mrs. Brooks	X						
Mr. Mullin	X						
Mr. Hudson	X						
Mr. Collins	X						
Mr. Cramer	X						

6/03/2015

## COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a hearing and made findings that are reflected in this report.

## STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

To better permit the Administrator of the Environmental Protection Agency to identify and control unreasonable risks of injury to health or the environment from the manufacture, processing, distribution in commerce, use, and disposal of chemical substances, mixture, and articles containing a chemical substance; to facilitate interstate commerce; to increase access to information about chemicals for necessary responses while protecting legitimate trade secrets; to increase consumer confidence; and for other purposes.

## NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 2576, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

## EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 2576 contains no earmarks, limited tax benefits, or limited tariff benefits.

## COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

## CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,  
CONGRESSIONAL BUDGET OFFICE,  
*Washington, DC, June 23, 2015.*

Hon. FRED UPTON,  
*Chairman, Committee on Energy and Commerce,  
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2576, the TSCA Modernization Act of 2015.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Susanne S. Mehlman.

Sincerely,

KEITH HALL.



Enclosure.

*H.R. 2576—TSCA Modernization Act of 2015*

Summary: H.R. 2576 would modify the Toxic Substances Control Act (TSCA), the law that regulates the manufacture, importation, and processing of chemicals, with the aim of strengthening the Environmental Protection Agency's (EPA's) ability to evaluate and regulate potentially hazardous chemicals.

CBO estimates that EPA would incur additional costs to conduct safety evaluations of chemical substances over the 2016–2020 period in order to meet the new requirements imposed by H.R. 2576; we estimate that implementing this legislation would cost \$64 million over the next five years and \$143 million over the 2016–2025 period, assuming appropriation actions consistent with the bill.

Under the legislation, EPA would be authorized to charge two types of fees for some of its work under the legislation. Those fees would have different budgetary treatments. One fee would be classified as a mandatory offsetting receipt and the other would be classified as a revenue. Based on information provided by the agency, CBO estimates that enacting the legislation would increase offsetting receipts, which are treated as reductions in direct spending, by \$115 million over the 2016–2025 period; revenues would increase by \$121 million over the same period, net of income and payroll tax offsets. Pay-as-you-go procedures apply because the bill would affect direct spending and revenues.

H.R. 2576 would impose intergovernmental and private-sector mandates, as defined in the Unfunded Mandates Reform Act (UMRA), on manufacturers, processors, importers, and users of chemical substances. CBO estimates that the aggregate cost of those mandates would fall below the annual thresholds established in UMRA for intergovernmental and private-sector mandates (\$77 million and \$154 million in 2015, respectively, adjusted annually for inflation).

Major provisions: The bill's major provisions would:

- Require EPA to develop policies, procedures, guidance, and rules to implement the bill;
- Authorize EPA to obtain new information from manufacturers and processors necessary to conduct risk evaluations on chemical substances;
- Require EPA to initiate at least 10 risk evaluations annually on chemical substances the agency determines may present an unreasonable risk of injury to human health or the environment;
- Require EPA to publish a list of chemicals that are considered to be persistent, bioaccumulative and toxic (PBTs) and to designate any such PBTs as a "chemical of concern" for which EPA can take regulatory action;
- Require EPA to review any renewed requests from manufacturers and processors to keep certain information confidential beginning 10 years after the original designations concerning confidentiality are made;
- Address when federal actions under TSCA preempt requirements of state and local governments related to restricting and banning chemical substances; and
- Require EPA to establish a new schedule for charging fees to chemical manufacturers who are required to submit data to the

agency or who request that EPA assess certain chemicals that are not yet prioritized for review by EPA.

**Estimated cost to the Federal Government:** The estimated budgetary impact of H.R. 2576 is shown in the following table. The costs of this legislation fall within budget function 300 (natural resources and environment).

	By fiscal year, in millions of dollars—											
	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2016– 2020	2016– 2025
CHANGES IN SPENDING SUBJECT TO APPROPRIATION												
Administrative Expenses under TSCA:												
Estimated Authoriza- tion Level .....	15	15	15	15	15	15	16	16	17	17	75	156
Estimated Outlays ....	6	13	15	15	15	15	15	16	16	17	64	143
CHANGES IN DIRECT SPENDING												
PMN Fee Collections:												
Estimated Budget Authority .....	0	–7	–10	–14	–14	–14	–14	–14	–14	–14	–45	–115
Estimated Outlays ....	0	–7	–10	–14	–14	–14	–14	–14	–14	–14	–45	–115
CHANGES IN REVENUES												
Estimated Revenues .....	2	7	7	15	15	15	15	15	15	15	46	121
NET INCREASE OR DECREASE (–) IN THE DEFICIT FROM CHANGES IN DIRECT SPENDING AND REVENUES												
Net Change in the Deficit	–2	–14	–17	–29	–29	–29	–29	–29	–29	–29	–91	–236

Notes: TSCA = Toxic Substances Control Act; PMN = Premanufacturing Notice.  
For direct spending, a negative number indicates a decrease in outlays; for revenue, a positive number indicates an increase in revenues.

**Basis of estimate:** For this estimate, CBO assumes that H.R. 2576 will be enacted near the end of 2015 and that the necessary amounts will be appropriated each year.

#### *Spending subject to appropriation*

CBO estimates that implementing H.R. 2576 would cost \$64 million over the 2016–2020 period, subject to appropriation of the necessary amounts. While some of the requirements in H.R. 2576 are similar to activities currently performed by EPA under TSCA, CBO estimates that implementing this legislation would increase EPA's administrative workload for regulating chemical safety by about 25 percent each year. That estimate is based on historical information about how other large regulatory programs have been implemented by EPA and on estimates that were provided by the agency of the additional workload under the bill. According to EPA, the agency currently requires, on average, an appropriation of about \$58 million annually to implement and enforce EPA's Chemical Risk Review and Reduction program under TSCA. That funding supports roughly 245 employees. Subject to appropriation of the necessary amounts, CBO estimates that EPA would require about \$15 million annually over the next five years to cover the costs of additional personnel, contractors, and other administrative activities associated with meeting the new requirements of H.R. 2576.

H.R. 2576 also specifies that all additional fees collected by EPA under the bill would be available for spending on the safety analysis of individual chemicals, subject to appropriation of those amounts. (A more detailed discussion of the fees is provided below.)

*Direct spending and revenues*

Enacting this legislation would affect one existing fee and would authorize EPA to collect a new fee. Those fees would be recorded differently in the budget, as discussed below. CBO estimates that the gross collections would total \$108 million over the 2016–2020 period, and would be available for spending on chemical safety evaluations, subject to appropriation of those amounts.

**Premanufacturing Notice (PMN) Fees.** Under the legislation the statutory cap in TSCA on the amount EPA can charge manufacturers and processors for premanufacturing notices would be eliminated. (Manufacturers or processors who plan to use a new chemical substance for a non-exempt commercial purpose are required to provide EPA with notice before initiating the activity. EPA then performs a risk assessment on the new chemical substance.) PMN fees are currently classified in the budget as offsetting receipts (a reduction in direct spending). CBO estimates that by eliminating the cap, EPA would begin collecting additional fees in 2017 and that such collections would total \$7 million in that year. By 2019, we estimate that as more chemicals are reviewed by EPA, collections would reach \$14 million annually. In total CBO estimates that direct spending would be reduced by \$45 million over the next five years and by \$115 million over the next 10 years.

**Manufacturing/Processor Requested Assessment Fees.** In addition, under H.R. 2576 EPA could charge fees to manufacturers and processors who request that EPA initiate risk evaluations for chemicals that have not been designated a priority for further assessment. Those new fees would be classified as revenues because their payment would be compulsory, enforced by the federal government's sovereign authority. CBO estimates that EPA would begin collecting additional fees in 2016 and that by 2019 such revenue would total \$20 million annually. We estimate that gross revenues would total \$63 million over the next five years and \$163 million over the next ten years. Such amounts would be available for spending on risk evaluations, subject to future appropriation action. However, the amount of revenue attributable to this bill would be approximately 25 percent less to account for income and payroll tax offsets. Net of those offsets, CBO estimates that enacting H.R. 2576 would increase revenues by \$121 million over the 2016–2025 period.

Enacting H.R. 2576 also could affect direct spending and revenues because this bill would establish new authority for EPA to assess civil and criminal penalties against persons who receive confidential business information and then improperly use or disclose such information. Criminal penalties are recorded as revenues, then deposited in the Crime Victims Fund, and later spent; civil penalties are recorded as revenues. CBO estimates that any increase in criminal or civil penalties under the bill would not be significant.

**Pay-as-You-Go considerations:** The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. CBO estimates that any fee collections over the 2016–2025 period would result in a decrease in direct spending and an increase in revenues as shown in the following table.

CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS FOR H.R. 2576, AS ORDERED REPORTED BY THE  
HOUSE COMMITTEE ON ENERGY AND COMMERCE ON JUNE 3, 2015

	By fiscal year, in millions of dollars—												
	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2015– 2020	2015– 2025
	NET INCREASE OR DECREASE (–) IN THE DEFICIT												
Statutory Pay-As-You-Go Impact ...	0	–2	–14	–17	–29	–29	–29	–29	–29	–29	–29	–91	–236
Memorandum:													
Changes in Outlays .....	0	0	–7	–10	–14	–14	–14	–14	–14	–14	–14	–45	–115
Changes in Revenues ...	0	2	7	7	15	15	15	15	15	15	15	46	121

Intergovernmental and private-sector impact: H.R. 2576 would impose intergovernmental and private-sector mandates, as defined in UMRA, on manufacturers, processors, importers, and users of chemical substances. CBO estimates that the aggregate cost of those mandates would fall below the annual thresholds established in UMRA for intergovernmental and private-sector mandates (\$77 million and \$154 million in 2015, respectively, adjusted annually for inflation).

*Mandates that apply to both public and private entities*

H.R. 2576 would modify the standard used to determine whether a chemical substance presents an unreasonable risk to human health or the environment and would allow EPA to regulate the manufacture, processing, distribution, use, and disposal of chemical substances to ensure the standard is met. If EPA determines that some chemical substances do not meet the standard and issues regulations for those substances, the bill would impose an intergovernmental and private-sector mandate. The bill also would impose an intergovernmental and private-sector mandate if EPA uses its authority under the bill to expedite the regulation of any chemical substance determined to be persistent, bioaccumulative, and toxic. EPA would have the authority to adopt a range of regulatory options to address risks from chemical substances. For example, EPA could limit the amount manufactured or require manufacturers to put warning labels on selected chemicals. EPA also could require users of chemicals, such as public and private universities conducting research, to handle or dispose of selected chemicals in a certain way. Based on information from industry experts, CBO expects that the annual cost of any restriction would not be substantial. Also, because of the amount of time involved in evaluating the risk of each chemical, any restrictions imposed would apply to few chemicals in the first five years the mandate is in effect. Therefore, CBO estimates that the cost of the mandate would be small for both public and private entities during that time.

*Mandates that apply to public entities only*

The bill would impose an intergovernmental mandate by preempting state regulations that conflict with the federal regulation of chemicals, but that preemption would impose no duty on states that would result in additional spending or a loss of revenues.

*Mandates that apply to private entities only*

The bill would impose additional private-sector mandates on manufacturers, importers, and processors of chemical substances. By removing the cap on fees assessed by EPA when manufacturers and importers submit premanufacture notices, the bill would increase the cost of an existing mandate to pay those fees. CBO estimates that the increase in fees would start in 2017 and would reach \$14 million annually beginning in 2019. The bill also would require manufacturers and processors of chemical substances to submit data to EPA for use in carrying out risk evaluations. Manufacturers and processors also would have to include additional information along with any data to substantiate a request that EPA protect their data as confidential business information. Based on information from industry experts, CBO expects that the cost to submit those data would not be substantial.

Previous CBO estimate: On June 5, 2015, CBO transmitted a cost estimate for S. 697, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as ordered reported by the Senate Committee on Environment and Public Works on April 28, 2015. Both S. 697 and H.R. 2576 would increase EPA's administrative workload by roughly equivalent amounts to meet new requirements under TSCA and both bills would enable EPA to charge fees to chemical manufacturers and processors for certain activities, though the types of fees charged and the amounts collected would vary between the two bills. Furthermore, because the classification of fees under the two bills differs, collections under the bills would have different budgetary implications. Under S. 697 the fees collected would be classified as offsetting collections and would more than offset the additional discretionary spending estimated under S. 697. In contrast, the fees collected under H.R. 2576 would result in a reduction in direct spending and an increase in revenues. The cost estimates for the two bills reflect the different budgetary treatment.

Estimate prepared by: Federal spending: Susanne Mehlman; impact on state, local, and tribal governments: Jon Sperl; impact on the private sector: Amy Petz.

Estimate approved by: Theresa Gullo, Assistant Director for Budget Analysis.

## FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

## DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 2576 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111-139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

## DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 2576 specifically directs to be completed at least 4 rule makings within the meaning of 5 U.S.C. 551.

## ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

## APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

## SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

*Section 1. Short title; table of contents*

Section 1 provides the short title of “TSCA Modernization Act of 2015.”

*Section 2. Definitions*

The legislation amends TSCA section 3 to add two new definitions to the law. First, the legislation defines the use of the term “intended conditions of use” to mean the circumstances under which a chemical substance is intended, known, or reasonably foreseeable to be manufactured, processed, distributed in commerce, used, and disposed. The Committee expects that the Agency will generally interpret this to mean intended by the manufacturer, known by the manufacturer or the public, or reasonably foreseeable by the manufacturer or the Administrator.

The section also defines “potentially exposed subpopulations” to mean a group or a number of individuals within the general population who, due to greater susceptibility or greater potential exposure, are likely to be at greater risk than the general populations of adverse health effects from exposure to the chemical substance. As this term does not specify any particular group, the Administrator may focus attention on persons whose settings or physical attributes predispose them to adverse health consequences based upon exposure to the chemical substance. This term may include, among others, workers, infants, children, pregnant women, and the elderly. It is the Committee’s intention that the Administrator be clear about who is being identified and the basis for such a decision when invoking provisions involving subpopulations.

*Section 3. Testing of chemical substances and mixtures*

Section 3 amends TSCA section 4 to improve EPA’s ability to develop hazard and exposure data about chemicals in commerce to inform decisions required by the updated law.

First, in addition to rulemaking authority, this section authorizes EPA to enter into a consent agreement or use order authority to require the development of health and environmental effects data on a chemical substance or mixture.

Second, this section allows EPA to require testing of a chemical substance when necessary to complete a risk evaluation of that chemical under section 6(b). The Committee intends “necessary” to mean that this grant of authority only be employed to fill a gap in the Agency’s existing data on the chemical substance that otherwise precludes a determination on a chemical substance.

The increased testing authority in H.R. 2576 reflects the Committee consensus that EPA should have the information necessary to fill knowledge gaps before making regulatory decisions. Curiosity alone is insufficient to compel new testing. The Committee believes that the broader and simpler manner of requiring new test information by order or consent agreement, the new authority given to EPA to compel the creation of new data under section 4(a)(1)(C), and the Agency’s existing authority under section 8 will enable EPA to close knowledge gaps.

#### *Section 4. Regulation of hazardous chemical substances and mixtures*

To help the Agency function more effectively in dealing with existing chemicals, the Committee reorganized TSCA section 6 to specify what is expected of the Administrator in making discrete decisions.

Section 4 makes substantive, clarifying, and structural changes to TSCA section 6. For example, where existing TSCA section 6(a) combines three undertakings—the finding of unreasonable risk, the standard for regulation, and the control measures available under any regulation, H.R. 2576 splits these actions into two separate subsections with distinct functions: section 6(a) establishes the standard for issuing regulations and the universe of available control measures for existing chemical substances and mixtures, and section 6(b) establishes a separate risk evaluation process for determining whether a chemical substance presents or will present an unreasonable risk of injury. If the Administrator makes such a determination, then a regulation to address that risk is warranted under section 6(a), and the Administrator must proceed to section 6(a) rulemaking.

Section 4(a) repeals the requirements in TSCA section 6(a) that a rule restricting a chemical substance or mixture apply the least burdensome requirements, be predicated upon the Administrator finding a “reasonable basis to conclude” an unreasonable risk is present or will be present, and “protect adequately” against the unreasonable risk. Instead, section 6(a) obliges the Administrator to apply requirements on a chemical substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents or will present an unreasonable risk, including an identified unreasonable risk, to a potentially exposed subpopulation.

The restrictions that the Administrator is authorized to impose are not changed by the TSCA Modernization Act. Because a chemical substance’s intended conditions of use are important in defining the risk it presents, the Committee expects that the Administrator, in applying any requirements, will address identified circumstances of manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance or mixture that presents or will present an unreasonable risk of injury to health or the environment that require control.

Section 4(b) replaces TSCA section (6)(b) (Quality Control) with a new section 6(b) to determine whether, based upon a scientific risk evaluation of a chemical substance, the substance presents or will present, in the absence of new requirements under TSCA section 6(a), an unreasonable risk of injury to human health or the environment. New section 6(b) generally prohibits EPA from restricting a chemical substance before making this determination based on the findings of the risk evaluation.

A risk evaluation under section 6(b) is initiated in one of two ways. Under subsection (b)(3)(A)(i), the Administrator is required to conduct and publish the results of a risk evaluation of a chemical substances already in commerce when the Administrator determines that it may present an unreasonable risk of injury to human health or the environment because of a combination of potential hazard from and a potential route of exposure to the chemical under its intended conditions of use. The standard for making this determination is broad and flexible because its application precedes the detailed scientific risk evaluation that it triggers.

Subsection (b)(3)(B) also allows the Administrator, without making the determination in (b)(3)(A)(i), to conduct and publish the results of a risk evaluation for a chemical listed on the TSCA Work Plan for Chemical Assessments as of the date of enactment of the TSCA Modernization Act.

The Committee understands that the TSCA Work Plan represents the Agency's current priorities for risk review and potential risk management under TSCA. Nothing in this bill is intended to require the Agency to change or revise those priorities. The Committee expects that many, if not all, of the Agency's selections for Agency initiated risk evaluations in the first years after enactment will come from the Work Plan and that risk evaluations for Work Plan chemicals will be completed in the first years.

Subsection (b)(3)(A)(ii) provides that the Administrator must also perform a risk evaluation if a manufacturer requests it.

Section 4(b) establishes new section 6(b)(4) and imposes six requirements on the Administrator for conducting a risk evaluation. First, the Administrator must integrate and assess information on hazards and exposures for all of the intended conditions of use of the chemical substance, including information relevant to specific risks of injury to health or the environment and information on potentially exposed subpopulations.

The Committee expects that the Administrator will consider existing Federal or State risk reduction measures (e.g., existing State labeling requirements) as part of its exposure calculation.

Second, the Administrator is barred from considering information on costs and other factors not related to health or the environment when performing section 6(b) risk evaluations. Thus, EPA's determination whether the chemical presents an unreasonable risk of injury and requires regulation should be strictly risk-based.

Third, the Administrator must take into account, where relevant, the likely duration, intensity frequency, and number of exposures under the intended conditions of use of the chemical substance.

Fourth, the Administrator must describe the weight of the scientific evidence for identified exposure and hazard.

Fifth, the Administrator must consider whether the weight of the scientific evidence supports the identification of doses of the chem-



ical substance below which no adverse effects can be expected to occur. The Committee does not intend to suggest when such doses can be expected to occur.

And sixth, when a risk evaluation is requested by a manufacturer pursuant to paragraph 3(A)(ii), the Administrator is required to ensure that the costs to the Environmental Protection Agency of conducting the risk evaluation are paid by the manufacturer, including contractor costs.

New section 6(b)(5) imposes deadlines on the Administrator when conducting risk evaluations under section 6(b) and promulgating rules pursuant to subsection (a). Under new paragraph (5)(A), the Administrator must conduct and publish the results of a risk evaluation as soon as reasonably possible, subject to the availability of resources, but no later than three years after making a determination under paragraph (3)(A)(i), beginning the risk evaluation under paragraph (3)(B), or after a manufacturer requests a risk evaluation under (3)(a)(ii). New paragraph (5)(C) provides that if the Administrator determines that additional information is needed to complete a risk evaluation, the Administrator may extend the deadline to no later than ninety days after receipt of such additional information, or two years after the original deadline.

New paragraph (5)(B) provides deadlines for rules issued under section 6(a). If, based on a risk evaluation conducted under section 6(b), the Administrator determines that in the absence of a new rule a chemical presents or will present an unreasonable risk of injury to health or the environment, the Administrator must propose a rule under subsection (a) for the chemical substance within ninety days of publishing the risk evaluation regarding such chemical substance. Additionally, new paragraph (5)(B) requires the Administrator to publish a final rule in the Federal Register no later than 180 days after publishing the risk evaluation regarding such chemical substance.

New paragraph 6 of TSCA section 6(b) requires the Administrator, no later than thirty days before publishing a final determination that a chemical substance does not and will not present an unreasonable risk of injury to health or the environment, to make a preliminary determination to such effect and to provide public notice of and an opportunity for comment regarding such preliminary determination.

New section 6(b)(6)(B) prevents the Administrator from making a determination that a chemical substance will not present an unreasonable risk of injury to health or the environment if, under the intended conditions of use, the chemical substance presents or will present an unreasonable risk of injury to one or more potentially exposed subpopulations. A final determination under subsection (b) that a chemical substance will not present an unreasonable risk of injury to health or the environment is designated a final agency action.

Finally, new section 6(b)(7) of section 4 of H.R. 2576 requires the Administrator, beginning in the fiscal year of the date of enactment, to initiate at least ten risk evaluations under paragraphs (3)(A)(i) or (3)(B), subject to the availability of appropriations.

Section 4(c) makes changes to TSCA section 6(c), which contains requirements for promulgating a section 6(a) rule. The existing section 6(c)(1) requirements for the Administrator to consider and

publish a statement about the impacts of the chemical substance or mixture are largely retained in new section 6(c)(1)(A), with the consideration of substitutes moved to section 6(c)(1)(C) and the requirements for addressing chemical risks under other statutes administered by the Agency now in section 9(b). Under new TSCA subsection (c)(1)(B), the Administrator must impose requirements under the rule that, consistent with information published under subparagraph (A), are cost-effective, unless the Administrator determines that additional or different requirements described in subsection (a) are necessary to protect against the identified risk.

The Committee chose this process to ensure that the universe of data from which the Administrator would be making a cost-effectiveness decision would be limited to only that information provided and considered as part of the rulemaking record. The Committee does not expect EPA to analyze the cost-effectiveness of an open-ended group of possible requirements, but to focus on those that meet the subsection (a) purpose of controlling an unreasonable risk of injury. The Administrator need not test each control measure in a rulemaking for its cost-effectiveness. While the Committee's preference is that selected requirements be cost-effective, if no restriction is available that the Administrator determines cost-effective in managing the risk, the identified unreasonable risk must still be addressed.

New subsection (c)(1)(C) requires the Administrator, in deciding whether to prohibit or substantially restrict a specific use of a chemical substance or mixture and in setting an appropriate transition period for such action, to determine whether a technically and economically feasible alternative to a chemical that benefits health or the environment, compared to the use proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or restriction takes effect.

New subsection (c)(1)(D) exempts replacement parts if they are designed prior to publication of the section 6(a) risk management rule in the Federal Register, unless the Administrator finds that they contribute significantly to the identified risk, including identified risks to identified potentially exposed subpopulations. Subsection (c)(1)(E) instructs the Administrator, when applying prohibitions or other restrictions to address an unreasonable risk of injury, to apply such prohibitions or restrictions to an article, on the basis of a chemical substance or mixture contained in that article, only to the extent necessary to protect against the unreasonable risk of injury from that article.

Section 4(c) repeals the requirement for informal hearings, including cross examination of witnesses, found in TSCA section 6(c)(3) and repeals the availability of compensation of attorney's fees, expert witness fees, and other costs of participating in a proceeding for the promulgation of a subsection (a) rule found in TSCA paragraph 6(c)(4).

Further, Section 4(d) adds a requirement at the end of section 6(d)(2)(B) providing for a reasonable transition period for any rule promulgated under section 6(a).

Section 4(e) of the TSCA Modernization Act adds three new subsections to the end of TSCA section 6 to address three distinct areas.

First, under section 4(e), new section 6(g) bars the Administrator from considering costs and other non-health factors when deciding whether to initiate a rulemaking under subsection (a). The intention of the Committee is to ensure that the decision whether a regulation under 6(a) is required be limited to whether a chemical substance presents or will present an unreasonable risk as determined in section 6(b). The Committee intends that decisions applying the standard of regulation in section 6(a) and selecting any control measures to achieve that standard are made in the context of the economic, practical, and other considerations set out in section 6(c)(1).

Second, section 4(e) adds a new TSCA section 6(h) for cases in which the Administrator might find that any requirements to prevent a chemical substance or mixture from presenting an unreasonable risk are not cost-effective, but that a specific use of the chemical substance is critical or essential to prevent disruption to the national economy, national security, or critical infrastructure.

Section 6(h) allows the Administrator to grant a renewable exemption from such a requirement for a specific use for up to five years. To obtain an exemption, the Administrator must determine, pursuant to section 6(c)(1)(B), that the requirement is not cost-effective with respect to a specific use and must find that either the specific use is critical or essential, or the requirement as applied with respect to the specific use would significantly disrupt the national economy, national security, or critical infrastructure. An exemption must be preceded by a notice and comment period and supported by clear and convincing evidence. If the exemption is granted, EPA must then provide notice of the exemption, and the manufacturer or processor must notify known commercial purchasers. The Administrator is required to impose conditions on any use for which an exemption is granted in order to reduce risk from the chemical substance or mixture to the greatest extent feasible.

Finally, section 4(e) adds a new TSCA section 6(i) regarding Persistent, Bioaccumulative, and Toxic Chemicals (PBTs). First, new section 6(i) instructs the Administrator to publish a list, not later than nine months after the date of enactment, of chemicals the Administrator has a reasonable basis to conclude are persistent, bioaccumulative, and toxic. Subsection (i) excludes the placement on this list of metals, metal compounds, or chemical substances already regulated under TSCA section 6(e). The Committee hopes the Administrator will rely on its TSCA Work Plan Chemicals Methods Document published in February 2012 in identifying PBT candidate substances for listing. Upon its publication, either the Administrator or a chemical substance's manufacturer has ninety days to decide whether to initiate a risk evaluation under TSCA section 6(b) rather than further evaluation under section 6(i).

Second, no later than two years after the date of enactment, the Administrator is to designate as a PBT chemical of concern any chemical substance on the list: (1) that scores "high" for persistence or bioaccumulation and "high" or "moderate" in regard to the other, using the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012, and (2) where exposure is likely to the general population or a potentially exposed subpopulation identified by the Administrator. Last, the Administrator, subject to availability of appropriations, within two years of

designating a chemical substance a PBT chemical of concern, must promulgate a rule under section 6(a), and in keeping with the rest of the factors in sections 6 and 9, to reduce, to the extent practicable, likely exposure to that PBT chemical.

These reforms to section 6 are intended to permit the Agency to identify unreasonable risks and address them effectively. To many members of the Committee, an important measure of TSCA reform proposals has been whether the proposal would enable EPA to take broader regulatory action to protect against unreasonable risks from asbestos. The Committee expects this legislation to enable that regulatory action.

Finally, while the phrase “unreasonable risk of injury” is not amended, it must be read in the context of the changes to section 6, including the functions and purposes delineated in subsections (a), (b), and (c).

#### *Section 5. Relationship to other Federal laws*

H.R. 2576 reinforces TSCA’s original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals. The Joint Explanatory Statement of the Committee of Conference for the legislation, which is now Title I of TSCA, clearly states that “[t]he conferees have drawn from both the Senate bill and the House amendment to assure that overlapping or duplicative regulation is avoided” and:

If the Administrator determines that a risk to health or the environment associated with a substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under authorities contained in other Federal laws, then the Administrator shall use such other authorities, unless the Administrator determines . . . it is in the public interest to use this Act.

This section adds a new paragraph to TSCA section 9(b) to help the Administrator decide whether using TSCA Title I or another Federal authority provided to the Administrator is “in the public interest.” Specifically, the new paragraph requires the Administrator to consider the relevant aspects of the risks posed by the chemical substance and compare the estimated costs of actions taken under Title I of TSCA or another Federal law with the relative efficiencies of protecting against the risk presented through actions taken under such laws. This new paragraph reflects language in section 6 current law that is removed by section 4 of the bill.

The Committee believes the added language will help to focus the Administrator’s exercise of discretion regarding which statute to apply and to encourage decisions that avoid confusion, complication, and duplication. For example, if the Administrator determines that a risk to health or the environment associated with disposal of a chemical substance could be eliminated or reduced to a sufficient extent under the Solid Waste Disposal Act, the Administrator should use those authorities to protect against the risk. Likewise, while section 5 makes no amendment to TSCA section 9(a), the Committee believes that the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupa-

tional safety. Specifically, the Committee does not intend for the implementation of TSCA to conflict with or disregard Occupational Safety and Health Administration's hierarchy of controls.

#### *Section 6. Disclosure of data*

Section 6 makes a number of changes to the way TSCA section 14 operates.

First, it authorizes three new classes of persons to receive information submitted to EPA and protected as confidential business information (CBI). These are State and local governments and tribal officials who request it for the purpose of administering or enforcing a law; Federal or State environmental professionals when responding to a release of a contaminant to the environment; and a treating physician or other health care professional for the purpose of diagnosing and treating an ailing person.

Second, the legislation requires persons receiving protected CBI to use the information only for the purpose for which it was obtained. Additionally, the legislation prohibits the disclosure of CBI to any person not authorized to receive it. Section 9 of the legislation, Conforming Amendments, makes a violation of these two requirements punishable through civil or criminal penalties or both. These sanctions are similar to penalties for unauthorized disclosure by Federal employees and Federal information protection laws that apply to the private sector, including the Health Insurance Portability and Accountability Act (42 USC 1320d-5).

Third, H.R. 2576 requires any manufacturer, processor, or distributor in commerce when submitting information to the Administrator to designate the information it believes qualifies for protection under the law. This designation, which applies only to information submitted to the Administrator after the date of enactment, must be made in writing and include: (1) a justification for each designation of confidentiality; (2) a certification that the information is not otherwise publically available; and (3) copies of all submitted information, one with the claimed CBI redacted and one with no redactions. In addition, information protected from public disclosure pursuant to these new requirements is required to be made public ten years after its initial grant of protection unless the requester submits a written renewal request that contains the necessary elements of the initial CBI protection request submission.

H.R. 2576 does not extend these same requirements to information protected under TSCA section 14 as in effect before the date of enactment of this legislation. Notwithstanding the Committee's concern that a retrospective requirement could have been burdensome for both the Agency and for small businesses as both try to implement all the new requirements of this legislation, the Committee supports ensuring that only legitimate CBI is protected.

The Committee is aware that EPA has undertaken a significant effort in recent years to review past CBI claims using authority under current law. Nothing in this bill is intended to restrict that authority under current law or prevent the Agency from continuing to review past CBI claims. Similarly, nothing in this bill is intended to restrict the Agency's ability to challenge, deny, or modify designations of information as CBI under this section.

Fourth, the legislation requires EPA, sixty days before publicly releasing any information protected by TSCA section 14 or the

amendments made by this legislation, to notify the respective manufacturer, processor, or distributor in commerce of the date on which the information will be made public unless EPA prior to that date receives a valid request for protection. The Committee understands that in some cases it may be difficult for EPA to find the appropriate person with rightful claim to the CBI. The Committee inserted the requirement that EPA efforts be “appropriate and practicable” to ensure that the Agency makes a good faith effort to contact the proper party, but not engage in an endless search.

Fifth, the legislation clarifies that while health and safety studies about a specific chemical substance or mixture are not eligible for protection as CBI, those studies cannot reveal data that would disclose formulas, including molecular structures, for chemical substances and mixtures whose protection as confidential has been justified to EPA. The Committee expects that redactions or the use of approved generic names or unique identifiers will be employed to meaningfully inform the public without comprising trade secrets.

Last, this section creates a savings clause in a new TSCA section 14(g) that states that nothing in TSCA section 14 shall be construed to affect the applicability of State or Federal rules of evidence or procedure in any judicial proceeding.

#### *Section 7. Effect on State law*

As amended by section 7, section 18 describes three instances in which an action by the Administrator would preempt State law.

As in current law, section 18(a)(2)(A), continues to provide that if the Administrator requires testing of a chemical substance or mixture under TSCA section 4, no State or political subdivision may, after the effective date of the Administrator’s testing requirement, establish or continue in effect a requirement for testing of such substance or mixture for similar purposes.

Section 18(a)(2)(B) is a new paragraph to reflect changes in how TSCA operates under new section 6(b). It provides that if the Administrator makes a final determination under section 6(b) that a chemical substance will not present an unreasonable risk of injury to health or the environment under the intended conditions of use, no State or political subdivision of a State may, after the date the determination is published, establish or continue in effect any requirement that applies to such chemical substance under the conditions of use and is designed to protect against exposure to such chemical substance under the intended conditions of use considered by the Administrator in the chemical’s risk evaluation under section 6(b).

However, if a requirement of a State or political subdivision of a State is adopted under the authority of a Federal law or is adopted pursuant to a State or local requirement that protects air or water quality or is related to waste treatment or waste disposal, Federal preemption does not apply unless the requirement of a State or political subdivision of a State actually conflicts with a provision of Title I of TSCA or an action or determination made by the Administrator under TSCA Title I.

Section 18(a)(2)(C) replaces TSCA section 18(a)(2)(B), which provides that if the Administrator applies a requirement under section 5 or 6 to a chemical substance or mixture designed to protect against a risk of injury to health or the environment associated

with such chemical substance or mixture, no State or political subdivision of a State may, after the effective date of such requirement, establish or continue in effect any requirement that applies to such chemical substance or mixture (including a requirement that applies to an article because the article contains the chemical substance or mixture) and is designed to protect against exposure to the substance or mixture either under the intended conditions of use considered by the Administrator in the risk evaluation under section 6(b) or from a use identified in a notice received by the Administrator under section 5(a) or, in the case of a requirement imposed pursuant to section 6(i), is designed to protect against a risk of injury considered by the Administrator in imposing such a requirement, unless the State or political subdivision requirement is identical to the requirement imposed by the Administrator, is adopted under authority of a Federal law, or is adopted to protect air or water quality or is related to waste treatment or waste disposal. These exceptions do not apply if a provision of Title I of TSCA or an action or determination by the Administrator under Title I of TSCA actually conflicts with the requirement. Because State monitoring, information reporting, and disclosure requirements often are intended to detect leaks or other problems, inform regulatory agencies, or serve communities' right to know, but not to protect against exposure to a chemical substance, the Committee expects that these type of requirements generally would fall outside the scope of preemption.

In the case of an identical State requirement, section 7 adds a new TSCA section 18(a)(2)(i), which precludes a State from assessing a penalty for a specific violation for which the Administrator has assessed a penalty under TSCA section 16, Penalties. If a State has assessed a penalty for a specific violation, the Administrator may not assess a penalty for that violation in an amount that would cause the total of the Federal and State penalties to exceed the maximum amount that may be assessed for that violation under TSCA section 16.

Section 7 does not amend subsection 18(b) of TSCA, but adds a new subsection 18(c) to preserve certain State actions. First, nothing in Title I is to be construed to preempt enforcement of any action taken before August 1, 2015, under a requirement of a State or political subdivision of a State that prohibits or otherwise restricts the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or any action taken pursuant to any State law in effect on August 31, 2003, unless an action or determination of the Administrator under TSCA title I actually conflicts with the State action.

New section 18(c)(2) also preserves Federal and State tort law and State law governing interpretation of contracts.

New section 18(c)(3) expresses Congressional intent that Title I of TSCA not be interpreted as influencing civil actions for damages in State court, or the admissibility of evidence under State law unless a provision of TSCA Title I actually conflicts with the State court action.

New section (c)(4) clarifies that the term "requirements" when used in TSCA Title I does not include civil tort actions for damages under State law.

Finally, section 7(c) states that nothing in TSCA, or the amendments made to it by the TSCA Modernization Act, shall be construed as changing the preemptive effect of actions taken by the Administrator under TSCA before the date of enactment of the TSCA Modernization Act or under TSCA section 6(e). This simply means that an action taken by the Administrator under TSCA before enactment of the TSCA Modernization Act, and any action taken under section 6(e) after enactment will have the same preemptive effect that it would have had if the TSCA Modernization Act were not enacted.

The Committee has heard concerns that courts may read in conflicts between Federal rules and State laws where none exist. The phrase “actually conflicts” is not included to invoke a particular precedent. The Committee does not expect conflicts to be found broadly or frequently.

#### *Section 8. Administration of the Act*

This section adds or makes changes to three parts of TSCA section 26.

First, the legislation changes the fee provisions in TSCA section 26(b). Specifically, it replaces the cap on fees for data submission under sections 4 (for new test data) and 5 (data about a new chemical or new use of a chemical)—currently set at \$2,500 or \$100 for small businesses—with a requirement that fees be “sufficient and not more than reasonably necessary.” The legislation also mandates that fees for small businesses be lower. The Committee expects that EPA will publish for notice and comment any regulations, policies, and procedures for setting, adjusting, and charging fees. The Committee is sympathetic to claims that EPA needs an updated fee structure reflective of today’s marketplace in order to operate a modernized TSCA. The Committee expects EPA to act prudently with this new authority. The Committee believes this new authority strikes the right balance for matching resources to needs.

This section creates a “TSCA Service Fee Fund,” to be operated by the U.S. Treasury, where those user fees collected for sections 4 and 5 and for risk evaluations requested by the manufacturer of a chemical substance under section 6(b) would be deposited. Funds deposited are made available to EPA only for use in administering the provisions of law for which they were collected. The legislation requires biannual EPA reports to Congress on fee income and disbursements, as well as annual TSCA Service Fee Fund audits by the EPA Inspector General to examine fee reasonableness, Fund management, and the Fund’s financial stability.

Second, the legislation requires EPA, when making science-based decisions in sections 4, 5, and 6, to consider the quality of the science it is using. The Committee believes that high quality science is the foundation of good public policy.

The criteria in new TSCA section 26(h) are drawn from EPA’s June 2003 “A summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information.” The Committee believes this is a good baseline for the Agency to use in making scientific evaluations for the provisions of TSCA Title I. These factors relate to the soundness of the means used to generate information, its appropriateness for its intended use, the rel-



evance of the information to the question being asked, the degree of the data's clarity and completeness, the extent of variability and uncertainty in the underlying data, methods, or analysis of the data, and the use of independent verification, reliable study methods, and peer review.

In addition to these information quality guidelines, the legislation creates a new TSCA section 26(i), which requires the Administrator to make decisions based upon the weight of the scientific evidence. The term "weight of evidence" refers to a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance. This requirement is not intended to prevent the Agency from considering academic studies, or any other category of study. The Committee expects that when EPA makes a weight of the evidence decision it will fully describe its use and methods.

Third, this section requires the Administrator, not later than two years after the date of enactment of this legislation, to develop any policies, procedures, and guidance that are necessary to implement the new provisions added to TSCA by this legislation. The language also mandates that EPA review the adequacy of these policies, procedures, and guidance, including as it relates to using animal testing and non-animal alternatives for assessing and determining risk every five years. After completing this review, EPA must make changes to the policies and guidance if necessary to reflect new scientific developments or understandings. The Committee does not intend for this language to require updates to these documents every five years, but expects the Agency to update them as needed to reflect generally accepted scientific and risk assessment practices.

Last, this section requires the Administrator to report to Congress on the Agency's capacity to conduct and publish risk evaluations under section 6 and to issue related or required rulemakings (as well as the resources needed to carry out section 6), and what needs to be done to ensure future capacity exists to meet future section 6 demands.

#### *Section 9. Conforming amendments*

This section makes technical and conforming amendments to Title I of TSCA to effectuate the two changes made in the other parts of this legislation. The first conforming amendment relates to the addition of authority for EPA to order testing under TSCA section 4 using orders or consent agreements. The other conforming amendment strikes the references to parts of existing TSCA section 6 that no longer apply.

The legislation made a single conforming change to TSCA section 8. When H.R. 2576 was ordered reported, the Committee was aware of five specific issues about which regulated stakeholders recommended legislative language in H.R. 2576 to improve the implementation of some portions of TSCA section 8. These issues are: (1) resetting the TSCA section 8(b) inventory, (2) updating the standards for determining what constitutes a small manufacturer or processor for purposes of section 8(a) reporting, (3) limiting sec-

tion 8(a) reporting requirements for byproducts if EPA already has that information and if the reporting discourages recycling, (4) requiring that EPA under section 8(b) consider chemical substances with multiple nomenclature conventions as a single inventory listing for both existing and new chemical substances, and (5) getting quicker and clearer responses from EPA on petitions for partial exemption from TSCA section 8(a) reporting due to a designation as a "low current interest" under 40 C.F.R. 711.6(b)(2)(iv). The exclusion of these items from H.R. 2576 should not be interpreted as a lack of interest by the Committee in the issues. Rather, the omission from H.R. 2576 is predicated on the understanding of the Committee that these are matters that EPA already has administrative authority under TSCA to address, and new or amended legal authority may not be required to accomplish these improvements under section 8. If the Administrator fails to promptly and adequately address these concerns, the Committee will work with other Members of Congress and with the Administration to consider legislative remedies.

#### CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

### TOXIC SUBSTANCES CONTROL ACT

#### TITLE I—CONTROL OF TOXIC SUBSTANCES

\* \* \* \* \*

#### SEC. 3. DEFINITIONS.

As used in this Act:

(1) The term "Administrator" means the Administrator of the Environmental Protection Agency.

(2)(A) Except as provided in subparagraph (B), the term "chemical substance" means any organic or inorganic substance of a particular molecular identity, including—

(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and

(ii) any element or uncombined radical.

(B) Such term does not include—

(i) any mixture,

(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide,

(iii) tobacco or any tobacco product,

(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act),

(v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax pro-

vided by section 4182 or 4221 or any other provision of such Code), and

(vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

The term “food” as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act).

(3) The term “commerce” means trade, traffic, transportation, or other commerce (A) between a place in a State and any place outside of such State, or (B) which affects trade, traffic, transportation, or commerce described in clause (A).

(4) The terms “distribute in commerce” and “distribution in commerce” when used to describe an action taken with respect to a chemical substance or mixture or article containing a substance or mixture mean to sell, or the sale of, the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.

(5) The term “environment” includes water, air, and land and the interrelationship which exists among and between water, air, and land and all living things.

(6) The term “health and safety study” means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act.

(7) *The term “intended conditions of use” means the circumstances under which a chemical substance is intended, known, or reasonably foreseeable to be manufactured, processed, distributed in commerce, used, and disposed of.*

[(7)] (8) The term “manufacture” means to import into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedules of the United States), produce, or manufacture.

[(8)] (9) The term “mixture” means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.

[(9)] (10) The term “new chemical substance” means any chemical substance which is not included in the chemical substance list compiled and published under section 8(b).

(11) *The term “potentially exposed subpopulation” means a group of individuals within the general population who, due to either greater susceptibility or greater potential exposure, are likely to be at greater risk than the general population of adverse health effects from exposure to a chemical substance.*

[(10)] (12) The term “process” means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce—

(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or

(B) as part of an article containing the chemical substance or mixture.

[(11)] (13) The term “processor” means any person who processes a chemical substance or mixture.

[(12)] (14) The term “standards for the development of test data” means a prescription of—

(A) the—

(i) health and environmental effects, and

(ii) information relating to toxicity, persistence, and other characteristics which affect health and the environment,

for which test data for a chemical substance or mixture are to be developed and any analysis that is to be performed on such data, and

(B) to the extent necessary to assure that data respecting such effects and characteristics are reliable and adequate—

(i) the manner in which such data are to be developed,

(ii) the specification of any test protocol or methodology to be employed in the development of such data, and

(iii) such other requirements as are necessary to provide such assurance.

[(13)] (15) The term “State” means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

[(14)] (16) The term “United States”, when used in the geographic sense, means all of the States.

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

(a) TESTING REQUIREMENTS.—If the Administrator finds that—

(1)(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data[; or];

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data[; and]; or

(C) *testing of a chemical substance is necessary to conduct a risk evaluation under section 6(b); and*

(2) in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture;

the Administrator shall by rule, order, or consent agreement require that testing be conducted on such substance or mixture to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

(b)(1) TESTING REQUIREMENT RULE.—A [rule] rule, order, or consent agreement under subsection (a) shall include—

(A) identification of the chemical substance or mixture for which testing is required under the [rule] rule, order, or consent agreement,

(B) standards for the development of test data for such substance or mixture, and

(C) with respect to chemical substances which are not new chemical substances and to mixtures, a specification of the period (which period may not be of unreasonable duration) within which the persons required to conduct the testing shall submit to the Administrator data developed in accordance with the standards referred to in subparagraph (B).

In determining the standards and period to be included, pursuant to subparagraphs (B) and (C), in a [rule] rule, order, or consent agreement under subsection (a), the Administrator's considerations shall include the relative costs of the various test protocols and methodologies which may be required under the [rule] rule, order, or consent agreement and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the [rule] rule, order, or consent agreement. Any such [rule] rule, order, or consent agreement may require the submission to the Administrator of preliminary data during the period prescribed under subparagraph (C).

(2)(A) The health and environmental effects for which standards for the development of test data may be prescribed include carcino-

genesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment. The characteristics of chemical substances and mixtures for which such standards may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristic which may present such a risk. The methodologies that may be prescribed in such standards include epidemiologic studies, serial or hierarchical tests, in vitro tests, and whole animal tests, except that before prescribing epidemiologic studies of employees, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health.

(B) From time to time, but not less than once each 12 months, the Administrator shall review the adequacy of the standards for development of data prescribed in [rules] *rules, orders, and consent agreements* under subsection (a) and shall, if necessary, institute proceedings to make appropriate revisions of such standards.

(3)(A) A [rule] *rule, order, or consent agreement* under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph (B) to conduct tests and submit data to the Administrator on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such data on behalf of the persons making the designation.

(B) The following persons shall be required to conduct tests and submit data on a chemical substance or mixture subject to a [rule] *rule, order, or consent agreement* under subsection (a):

(i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the manufacture of such substance or mixture.

(ii) Each person who processes or intends to process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the processing of such substance or mixture.

(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the distribution in commerce, use, or disposal of such substance or mixture.

(4) Any [rule under subsection (a)] *rule, order, or consent agreement under subsection (a)* requiring the testing of and submission of data for a particular chemical substance or mixture shall expire at the end of the reimbursement period (as defined in subsection (c)(3)(B)) which is applicable to test data for such substance or mixture unless the Administrator [repeals the rule] *repeals the rule or order or modifies the consent agreement to terminate the requirement* before such date; and a [rule under subsection (a)] *rule, order, or consent agreement under subsection (a)* requiring the testing of and submission of data for a category of chemical substances or mixtures shall expire with respect to a chemical substance or mixture included in the category at the end of the reimbursement period (as so defined) which is applicable to test data for such substance or mixture unless the Administrator before such date [re-

peals the application of the rule] *repeals or modifies the application of the rule, order, or consent agreement* to such substance or mixture or [repeals the rule] *repeals the rule or order or modifies the consent agreement to terminate the requirement*.

(5) Rules issued under subsection (a) (and any substantive amendment thereto or repeal thereof) shall be promulgated pursuant to section 553 of title 5, United States Code, except that (A) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submission; (B) a transcript shall be made of any oral presentation; and (C) the Administrator shall make and publish with the rule the findings described in [paragraph (1)(A) or (1)(B)] *paragraph (1)(A), (1)(B), or (1)(C)* of subsection (a) and, in the case of a rule respecting a mixture, the finding described in paragraph (2) of such subsection.

(c) EXEMPTION.—(1) Any person required by a [rule] *rule or order* under subsection (a) to conduct tests and submit data on a chemical substance or mixture may apply to the Administrator (in such form and manner as the Administrator shall prescribe) for an exemption from such requirement.

(2) If, upon receipt of an application under paragraph (1), the Administrator determines that—

(A) the chemical substance or mixture with respect to which such application was submitted is equivalent to a chemical substance or mixture for which data has been submitted to the Administrator in accordance with [a rule under subsection (a) or for which data is being developed pursuant to such a rule] *a rule, order, or consent agreement under subsection (a) or for which data is being developed pursuant to such a rule, order, or consent agreement*, and

(B) submission of data by the applicant on such substance or mixture would be duplicative of data which has been submitted to the Administrator in accordance with [such rule or which is being developed pursuant to such rule] *such rule, order, or consent agreement or which is being developed pursuant to such rule, order, or consent agreement*,

the Administrator shall exempt, in accordance with paragraph (3) or (4), the applicant from conducting tests and submitting data on such substance or mixture under [the rule] *the rule or order* with respect to which such application was submitted.

(3)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the existence of previously submitted test data and if such exemption is granted during the reimbursement period for such test data (as prescribed by subparagraph (B)), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted such test data, for a portion of the costs incurred by such person in complying with the requirement to submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute. In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) For purposes of subparagraph (A), the reimbursement period for any test data for a chemical substance or mixture is a period—

(i) beginning on the date such data is submitted in accordance with a **[rule promulgated]** *rule, order, or consent agreement* under subsection (a), and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and which is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(4)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit test data on a chemical substance or mixture is granted on the basis of the fact that test data is being developed by one or more persons pursuant to a **[rule promulgated]** *rule, order, or consent agreement* under subsection (a), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to each such person who is developing such test data, for a portion of the costs incurred by each such person in complying with **[such rule]** *such rule, order, or consent agreement*, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to the costs of complying with **[such rule]** *such rule, order, or consent agreement*, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider the factors described in the second sentence of paragraph (3)(A). An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.



(B) If any exemption is granted under paragraph (2) on the basis of the fact that one or more persons are developing test data pursuant to a **[rule promulgated]** *rule, order, or consent agreement* under subsection (a) and if after such exemption is granted the Administrator determines that no such person has complied with **[such rule]** *such rule, order, or consent agreement*, the Administrator shall (i) after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption, and (ii) notify in writing such person of the requirements of **[the rule]** *the rule, order, or consent agreement* with respect to which such exemption was granted.

(d) NOTICE.—Upon the receipt of any test data pursuant to a **[rule]** *rule, order, or consent agreement* under subsection (a), the Administrator shall publish a notice of the receipt of such data in the Federal Register within 15 days of its receipt. Subject to section 14, each such notice shall (1) identify the chemical substance or mixture for which data have been received; (2) list the uses or intended uses of such substance or mixture and the information required by the applicable standards for the development of test data; and (3) describe the nature of the test data developed. Except as otherwise provided in section 14, such data shall be made available by the Administrator for examination by any person.

(e) PRIORITY LIST.—(1)(A) There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of a rule under subsection (a). In making such a recommendation with respect to any chemical substance or mixture, the committee shall consider all relevant factors, including—

(i) the quantities in which the substance or mixture is or will be manufactured,

(ii) the quantities in which the substance or mixture enters or will enter the environment,

(iii) the number of individuals who are or will be exposed to the substance or mixture in their places of employment and the duration of such exposure,

(iv) the extent to which human beings are or will be exposed to the substance or mixture,

(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to present an unreasonable risk of injury to health or the environment,

(vi) the existence of data concerning the effects of the substance or mixture on health or the environment,

(vii) the extent to which testing of the substance or mixture may result in the development of data upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted, and

(viii) the reasonably foreseeable availability of facilities and personnel for performing testing on the substance or mixture.

The recommendations of the committee shall be in the form of a list of chemical substances and mixtures which shall be set forth, either by individual substance or mixture or by groups of substances or mixtures, in the order in which the committee determines the Administrator should take action under subsection (a)

with respect to the substances and mixtures. In establishing such list, the committee shall give priority attention to those chemical substances and mixtures which are known to cause or contribute to or which are suspected of causing or contributing to cancer, gene mutations, or birth defects. The committee shall designate chemical substances and mixtures on the list with respect to which the committee determines the Administrator should, within 12 months of the date on which such substances and mixtures are first designated, initiate a proceeding under subsection (a). The total number of chemical substances and mixtures on the list which are designated under the preceding sentence may not, at any time, exceed 50.

(B) As soon as practicable but not later than nine months after the effective date of this Act, the committee shall publish in the Federal Register and transmit to the Administrator the list and designations required by subparagraph (A) together with the reasons for the committee's inclusion of each chemical substance or mixture on the list. At least every six months after the date of the transmission to the Administrator of the list pursuant to the preceding sentence, the committee shall make such revisions in the list as it determines to be necessary and shall transmit them to the Administrator together with the committee's reasons for the revisions. Upon receipt of any such revision, the Administrator shall publish in the Federal Register the list with such revision, the reasons for such revision, and the designations made under subparagraph (A). The Administrator shall provide reasonable opportunity to any interested person to file with the Administrator written comments on the committee's list, any revision of such list by the committee, and designations made by the committee, and shall make such comments available to the public. Within the 12-month period beginning on the date of the first inclusion on the list of a chemical substance or mixture designated by the committee under subparagraph (A) the Administrator shall with respect to such chemical substance or mixture either initiate a rulemaking proceeding under subsection (a) or if such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not initiating such a proceeding.

(2)(A) The committee established by paragraph (1)(A) shall consist of eight members as follows:

(i) One member appointed by the Administrator from the Environmental Protection Agency.

(ii) One member appointed by the Secretary of Labor from officers or employees of the Department of Labor engaged in the Secretary's activities under the Occupational Safety and Health Act of 1970.

(iii) One member appointed by the Chairman of the Council on Environmental Quality from the Council or its officers or employees.

(iv) One member appointed by the Director of the National Institute for Occupational Safety and Health from officers or employees of the Institute.

(v) One member appointed by the Director of the National Institute of Environmental Health Sciences from officers or employees of the Institute.

(vi) One member appointed by the Director of the National Cancer Institute from officers or employees of the Institute.

(vii) One member appointed by the Director of the National Science Foundation from officers or employees of the Foundation.

(viii) One member appointed by the Secretary of Commerce from officers or employees of the Department of Commerce.

(B)(i) An appointed member may designate an individual to serve on the committee on the member's behalf. Such a designation may be made only with the approval of the applicable appointing authority and only if the individual is from the entity from which the member was appointed.

(ii) No individual may serve as a member of the committee for more than four years in the aggregate. If any member of the committee leaves the entity from which the member was appointed, such member may not continue as a member of the committee, and the member's position shall be considered to be vacant. A vacancy in the committee shall be filled in the same manner in which the original appointment was made.

(iii) Initial appointments to the committee shall be made not later than the 60th day after the effective date of this Act. Not later than the 90th day after such date the members of the committee shall hold a meeting for the selection of a chairperson from among their number.

(C)(i) No member of the committee, or designee of such member, shall accept employment or compensation from any person subject to any requirement of this Act or of any rule promulgated or order issued thereunder, for a period of at least 12 months after termination of service on the committee.

(ii) No person, while serving as a member of the committee, or designee of such member, may own any stocks or bonds, or have any pecuniary interest, of substantial value in any person engaged in the manufacture, processing, or distribution in commerce of any chemical substance or mixture subject to any requirement of this Act or of any rule promulgated or order issued thereunder.

(iii) The Administrator, acting through attorneys of the Environmental Protection Agency, or the Attorney General may bring an action in the appropriate district court of the United States to restrain any violation of this subparagraph.

(D) The Administrator shall provide the committee such administrative support services as may be necessary to enable the committee to carry out its function under this subsection.

(f) REQUIRED ACTIONS.—Upon the receipt of—

(1) any test data required to be submitted under this Act, or

(2) any other information available to the Administrator,

which indicates to the Administrator that there may be 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 beings from cancer, gene mutations, or birth defects, the Administrator shall, within the 180-day period beginning on the date of the receipt of such data or information, initiate appropriate action under section 5, 6, or 7 to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding that such risk is not unreasonable. 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. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review under chapter 7 of title 5, United States Code. This subsection shall not take effect until two years after the effective date of this Act.

(g) PETITION FOR STANDARDS FOR THE DEVELOPMENT OF TEST DATA.—A person intending to manufacture or process a chemical substance for which notice is required under section 5(a) and who is not required under a [rule] *rule, order, or consent agreement* under subsection (a) to conduct tests and submit data on such substance may petition the Administrator to prescribe standards for the development of test data for such substance. The Administrator shall by order either grant or deny any such petition within 60 days of its receipt. If the petition is granted, the Administrator shall prescribe such standards for such substance within 75 days of the date the petition is granted. If the petition is denied, the Administrator shall publish, subject to section 14, in the Federal Register the reasons for such denial.

#### SEC. 5. MANUFACTURING AND PROCESSING NOTICES.

(a) IN GENERAL.—(1) Except as provided in subsection (h), no person may—

(A) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 8(b), or

(B) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use, unless such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of subsection (b).

(2) 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—

(A) the projected volume of manufacturing and processing of a chemical substance,

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

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

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(b) SUBMISSION OF TEST DATA.—(1)(A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit test data for such substance pursuant to a [rule promulgated] *rule, order, or consent agreement* under section 4 before the submission of such notice,

such person shall submit to the Administrator such data in accordance with [such rule] *such rule, order, or consent agreement* at the time notice is submitted in accordance with subsection (a)(1).

(B) If—

(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and

(ii) such person has been granted an exemption under section 4(c) from the requirements of a [rule promulgated] *rule or order* under section 4 before the submission of such notice, such person may not, before the expiration of the 90-day period which begins on [the date of the submission in accordance with such rule] *the required date of submission* of the test data the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(B).

(2)(A) If a person—

(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and

(ii) is not required by a [rule promulgated] *rule, order, or consent agreement* under section 4 before the submission of such notice to submit test data for such substance, such person shall submit to the Administrator data prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

(B) Data submitted pursuant to subparagraph (A) shall be data which the person submitting the data believes show that—

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(B), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

(3) Data submitted under paragraph (1) or (2) shall be made available, subject to section 14, for examination by interested persons.

(4)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including—

(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.

(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5, United States Code, except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, (ii) a transcript shall be kept of any oral presentation, and (iii) the Administrator shall make and publish with the rule the finding described in subparagraph (A).

(c) EXTENSION OF NOTICE PERIOD.—The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b) before which the manufacturing or processing of a chemical substance subject to such subsection may begin. Subject to section 14, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

(d) CONTENT OF NOTICE; PUBLICATIONS IN THE FEDERAL REGISTER.—(1) The notice required by subsection (a) shall include—

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 8(a)(2), and

(B) in such form and manner as the Administrator may prescribe, any test data in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and

(C) a description of any other data concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

Such a notice shall be made available, subject to section 14, for examination by interested persons.

(2) Subject to section 14, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) or of data under subsection (b), the Administrator shall publish in the Federal Register a notice which—

(A) identifies the chemical substance for which notice or data has been received;

(B) lists the uses or intended uses of such substance; and

(C) in the case of the receipt of data under subsection (b), describes the nature of the tests performed on such substance

and any data which was developed pursuant to subsection (b) or a **[rule]** *rule, order, or consent agreement* under section 4. A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c) has not expired, and (B) each chemical substance for which such notification period has expired since the last publication in the Federal Register of such list.

(e) REGULATION PENDING DEVELOPMENT OF INFORMATION.—(1)(A) If the Administrator determines that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

the Administrator may issue a proposed order, to take effect on the expiration of the notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c), to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities.

(B) A proposed order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c), and (ii) unless the Administrator has, on or before the issuance of the proposed order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

(C) If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the date such manufacturer or processor received the notice required by subparagraph (B)(ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect.

(2)(A)(i) Except as provided in clause (ii), if with respect to a chemical substance with respect to which notice is required by subsection (a), the Administrator makes the determination described in paragraph (1)(A) and if—

(I) the Administrator does not issue a proposed order under paragraph (1) respecting such substance, or

(II) the Administrator issues such an order respecting such substance but such order does not take effect because objections were filed under paragraph (1)(C) with respect to it, the Administrator, through attorneys of the Environmental Protection Agency, shall apply to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer or processor, as the case may be, of such substance is found, resides, or transacts business for an injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance (or to prohibit or limit any combination of such activities).

(ii) If the Administrator issues a proposed order under paragraph (1)(A) respecting a chemical substance but such order does not take effect because objections have been filed under paragraph (1)(C) with respect to it, the Administrator is not required to apply for an injunction under clause (i) respecting such substance if the Administrator determines, on the basis of such objections, that the determinations under paragraph (1)(A) may not be made.

(B) A district court of the United States which receives an application under subparagraph (A)(i) for an injunction respecting a chemical substance shall issue such injunction if the court finds that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance.

(C) Pending the completion of a proceeding for the issuance of an injunction under subparagraph (B) respecting a chemical substance, the court may, upon application of the Administrator made through attorneys of the Environmental Protection Agency, issue a temporary restraining order or a preliminary injunction to prohibit the manufacture, processing, distribution in commerce, use, or disposal of such a substance (or any combination of such activities) if the court finds that the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance may expire before such proceeding can be completed.

(D) After the submission to the Administrator of test data sufficient to evaluate the health and environmental effects of a chemical substance subject to an injunction issued under subparagraph (B) and the evaluation of such data by the Administrator, the district court of the United States which issued such injunction shall, upon petition, dissolve the injunction unless the Administrator has initiated a proceeding for the issuance of a rule under section 6(a)



respecting the substance. If such a proceeding has been initiated, such court shall continue the injunction in effect until the effective date of the rule promulgated in such proceeding or, if such proceeding is terminated without the promulgation of a rule, upon the termination of the proceeding, whichever occurs first.

(f) PROTECTION AGAINST UNREASONABLE RISKS.—(1) If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance with respect to which notice is required by subsection (a), or that any combination of such activities, presents or will present an unreasonable risk of injury to health or environment before a rule promulgated under section 6 can protect against such risk, the Administrator shall, before the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

(2) The Administrator may issue a proposed rule under section 6(a) to apply to a chemical substance with respect to which a finding was made under paragraph (1)—

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 6(a), or

(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register. Section 6(d)(2)(B) shall apply with respect to such rule.

(3)(A) The Administrator may—

(i) issue a proposed order to prohibit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1), or

(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance.

A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance.

(B) If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 6 can protect against such risk, the court shall issue an injunction to prohibit the manufacture, proc-

essing or distribution in commerce of such substance or to prohibit any combination of such activities.

(C) The provisions of subparagraphs (B) and (C) of subsection (e)(1) shall apply with respect to an order issued under clause (i) of subparagraph (A); and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B).

(D) If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C), the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment.

(g) STATEMENT OF REASONS FOR NOT TAKING ACTION.—If the Administrator has not initiated any action under this section or section 6 or 7 to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, with respect to which notification or data is required by subsection (a)(1)(B) or (b), before the expiration of the notification period applicable to the manufacturing or processing of such substance, the Administrator shall publish a statement of the Administrator's reasons for not initiating such action. Such a statement shall be published in the Federal Register before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

(h) EXEMPTIONS.—(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) to permit such person to manufacture or process a chemical substance for test marketing purposes—

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, and

(B) under such restrictions as the Administrator considers appropriate.

(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit data for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that—

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which data has been submitted to the Administrator as required by subsection (b)(2), and

(ii) submission of data by the applicant on such substance would be duplicative of data which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such data on such substance. No exemption which is granted under this subparagraph with respect to the submission of

data for a chemical substance may take effect before the beginning of the reimbursement period applicable to such data.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting data required under subsection (b)(2) for a chemical substance because of the existence of previously submitted data and if such exemption is granted during the reimbursement period for such data, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted the data on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b)(2) to submit such data, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

(C) For purposes of this paragraph, the reimbursement period for any previously submitted data for a chemical substance is a period—

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such data to the Administrator, and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such data,

whichever is later.

(3) The requirements of subsections (a) and (b) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(A) scientific experimentation or analysis, or

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

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment. A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with [paragraphs (2) and (3) of section 6(c)] *paragraph (2) of section 6(c)*.

(5) The Administrator may, upon application, make the requirements of subsections (a) and (b) 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.

(6) Immediately upon receipt of an application under paragraph (1) or (5) the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

(i) DEFINITION.—For purposes of this section, the terms “manufacture” and “process” mean manufacturing or processing for commercial purposes.

#### **SEC. 6. REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES.**

(a) SCOPE OF REGULATION.—If the Administrator [finds that there is a reasonable basis to conclude] *determines under subsection (b)* that 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, *or designates a chemical substance under subsection (i)(2)*, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary [to protect adequately against such risk using the least burdensome requirements] *so that the chemical substance or mixture no longer presents or will present an unreasonable risk, including an identified unreasonable risk to a potentially exposed subpopulation:*

(1) A requirement (A) prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement—

(A) prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

(6)(A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.

(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

(7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such risk of injury, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Any requirement (or combination of requirements) imposed under this subsection may be limited in application to specified geographic areas.

[(b) **QUALITY CONTROL.**—If the Administrator has a reasonable basis to conclude that a particular manufacturer or processor is manufacturing or processing a chemical substance or mixture in a manner which unintentionally causes the chemical substance or mixture to present or which will cause it to present an unreasonable risk of injury to health or the environment—

[(1) the Administrator may by order require such manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of such chemical substance or mixture; and

[(2) if the Administrator determines—

[(A) that such quality control procedures are inadequate to prevent the chemical substance or mixture from presenting such risk of injury, the Administrator may order the manufacturer or processor to revise such quality control procedures to the extent necessary to remedy such inadequacy; or

[(B) that the use of such quality control procedures has resulted in the distribution in commerce of chemical substances or mixtures which present an unreasonable risk of injury to health or the environment, the Administrator may order the manufacturer or processor to (i) give notice of such risk to processors or distributors in commerce of any such substance or mixture, or to both, and, to the extent reasonably ascertainable, to any other person in possession of or exposed to any such substance, (ii) to give public notice of such risk, and (iii) to provide such replacement or repurchase of any such substance or mixture as is necessary to adequately protect health or the environment.

A determination under subparagraph (A) or (B) of paragraph (2) shall be made on the record after opportunity for hearing in accordance with section 554 of title 5, United States Code. Any manufacturer or processor subject to a requirement to replace or repurchase a chemical substance or mixture may elect either to replace or repurchase the substance or mixture and shall take either such action in the manner prescribed by the Administrator.】

(b) *RISK EVALUATIONS.*—

(1) *IN GENERAL.*—*The Administrator shall conduct risk evaluations pursuant to this subsection to determine whether or not a chemical substance presents or will present, in the absence of requirements under subsection (a), an unreasonable risk of injury to health or the environment.*

(2) *APPLYING REQUIREMENTS.*—*The Administrator shall apply requirements with respect to a chemical substance through a rule under subsection (a) only if the Administrator determines through a risk evaluation under this subsection that the chemical substance presents or will present, in the absence of such requirements, an unreasonable risk of injury to health or the environment.*

(3) *CONDUCTING RISK EVALUATION.*—

(A) *REQUIRED RISK EVALUATIONS.*—*The Administrator shall conduct and publish the results of a risk evaluation under this subsection for a chemical substance if—*

*(i) the Administrator determines that the chemical substance may present an unreasonable risk of injury to health or the environment because of potential hazard and a potential route of exposure under the intended conditions of use; or*

*(ii) a manufacturer of the chemical substance requests such a risk evaluation.*

(B) *TSCA WORK PLAN CHEMICALS.*—*The Administrator may, without making a determination under subparagraph (A)(i), conduct and publish the results of a risk evaluation under this subsection for a chemical substance that, on the date of enactment of the TSCA Modernization Act of 2015, is listed in the TSCA Work Plan for Chemical Assessments published by the Administrator.*

(4) *REQUIREMENTS.*—*In conducting a risk evaluation under this subsection, the Administrator shall—*

(A) *integrate and assess information on hazards and exposures for all of the intended conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed subpopulations;*

(B) *not consider information on cost and other factors not directly related to health or the environment;*

(C) *take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the intended conditions of use of the chemical substance;*

(D) *describe the weight of the scientific evidence for identified hazard and exposure;*

(E) *consider whether the weight of the scientific evidence supports the identification of doses of the chemical substance below which no adverse effects can be expected to occur; and*

(F) *in the case of a risk evaluation requested by a manufacturer under paragraph (3)(A)(ii), ensure that the costs to the Environmental Protection Agency, including contractor costs, of conducting the risk evaluation are paid for by the manufacturer.*

(5) *DEADLINES.*—

(A) *RISK EVALUATIONS.*—*The Administrator shall conduct and publish a risk evaluation under this subsection for a chemical substance as soon as reasonably possible, subject to the availability of resources, but not later than 3 years after the date on which—*

(i) *the Administrator—*

(I) *makes a determination under paragraph (3)(A)(i); or*

(II) *begins the risk evaluation under paragraph (3)(B); or*

(ii) *a manufacturer requests the risk evaluation under paragraph (3)(A)(ii).*

(B) *SUBSECTION (a) RULES.*—*If, based on a risk evaluation conducted under this subsection, the Administrator determines that a chemical substance presents or will present, in the absence of a rule under subsection (a), an unreasonable risk of injury to health or the environment, the Administrator shall—*

(i) *propose a rule under subsection (a) for the chemical substance not later than 90 days after the date on which the risk evaluation regarding such chemical substance is published under subparagraph (A); and*

(ii) *publish in the Federal Register a final rule not later than 180 days after the date on which the risk*

*evaluation regarding such chemical substance is published under subparagraph (A).*

(C) *EXTENSION.—If the Administrator determines that additional information is necessary to make a risk evaluation determination under this subsection, the Administrator may extend the deadline under subparagraph (A) accordingly, except that the deadline may not be extended to a date that is later than—*

*(i) 90 days after receipt of such additional information; or*

*(ii) 2 years after the original deadline.*

(6) *DETERMINATIONS OF NO UNREASONABLE RISK.—*

(A) *NOTICE AND COMMENT.—Not later than 30 days before publishing a final determination under this subsection that a chemical substance does not and will not present an unreasonable risk of injury to health or the environment, the Administrator shall make a preliminary determination to such effect and provide public notice of, and an opportunity for comment regarding, such preliminary determination.*

(B) *POTENTIALLY EXPOSED SUBPOPULATIONS.—The Administrator shall not make a determination under this subsection that a chemical substance will not present an unreasonable risk of injury to health or the environment if the Administrator determines that the chemical substance, under the intended conditions of use, presents or will present an unreasonable risk of injury to 1 or more potentially exposed subpopulations.*

(C) *FINAL ACTION.—A final determination under this subsection that a chemical substance will not present an unreasonable risk of injury to health or the environment shall be considered a final agency action.*

(7) *MINIMUM NUMBER.—Subject to the availability of appropriations, the Administrator shall initiate 10 or more risk evaluations under paragraphs (3)(A)(i) or (3)(B) in each fiscal year beginning in the fiscal year of the date of enactment of the TSCA Modernization Act of 2015.*

(c) *PROMULGATION OF SUBSECTION (a) RULES.—*[(1) In promulgating any rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement with respect to—

[(A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture,

[(B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,

[(C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and

[(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient ex-



tent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule under subsection (a) to protect against such risk of injury unless the Administrator finds, in the Administrator's discretion, that it is in the public interest to protect against such risk under this Act. In making such a finding the Administrator shall consider (i) all relevant aspects of the risk, as determined by the Administrator in the Administrator's discretion, (ii) a comparison of the estimated costs of complying with actions taken under this Act and under such law (or laws), and (iii) the relative efficiency of actions under this Act and under such law (or laws) to protect against such risk of injury.】

(1) *REQUIREMENTS FOR RULE.*—*In promulgating any rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall—*

(A) *consider and publish a statement with respect to—*

(i) *the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;*

(ii) *the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to the chemical substance or mixture;*

(iii) *the benefits of the chemical substance or mixture for various uses; and*

(iv) *the reasonably ascertainable economic consequences of the rule, including consideration of the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;*

(B) *impose requirements under the rule that the Administrator determines, consistent with the information published under subparagraph (A), are cost-effective, except where the Administrator determines that additional or different requirements described in subsection (a) are necessary to protect against the identified risk;*

(C) *based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific use of a chemical substance or mixture and in setting an appropriate transition period for such action, determine whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect;*

(D) *exempt replacement parts designed prior to the date of publication in the Federal Register of the rule unless the Administrator finds such replacement parts contribute significantly to the identified risk, including identified risk to identified potentially exposed subpopulations; and*

(E) *in selecting among prohibitions and other restrictions to address an identified risk, apply prohibitions or other restrictions to articles on the basis of a chemical substance or*

*mixture contained in the article only to the extent necessary to protect against the identified risk.*

(2) *PROCEDURES*.—When prescribing a rule under subsection (a) the Administrator shall proceed 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 shall also (A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule; (B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available; (C) provide an opportunity for an informal hearing in accordance with paragraph (3); (D) promulgate, if appropriate, a final rule based on the matter in the rulemaking record (as defined in section 19(a)), and (E); and (D) make and publish with the rule the finding described in subsection (a).

(3) Informal hearings required by paragraph (2)(C) shall be conducted by the Administrator in accordance with the following requirements:

[(A) Subject to subparagraph (B), an interested person is entitled—

[(i) to present such person's position orally or by documentary submissions (or both), and

[(ii) if the Administrator determines that there are disputed issues of material fact it is necessary to resolve, to present such rebuttal submissions and to conduct (or have conducted under subparagraph (B)(ii)) such cross-examination of persons as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to such issues.

[(B) The Administrator may prescribe such rules and make such rulings concerning procedures in such hearings to avoid unnecessary costs or delay. Such rules or rulings may include (i) the imposition of reasonable time limits on each interested person's oral presentations, and (ii) requirements that any cross-examination to which a person may be entitled under subparagraph (A) be conducted by the Administrator on behalf of that person in such manner as the Administrator determines (I) to be appropriate, and (II) to be required for a full and true disclosure with respect to disputed issues of material fact.

[(C)(i) Except as provided in clause (ii), if a group of persons each of whom under subparagraphs (A) and (B) would be entitled to conduct (or have conducted) cross-examination and who are determined by the Administrator to have the same or similar interests in the proceeding cannot agree upon a single representative of such interests for purposes of cross-examination, the Administrator may make rules and rulings (I) limiting the representation of such interest for such purposes, and (II) governing the manner in which such cross-examination shall be limited.

[(ii) When any person who is a member of a group with respect to which the Administrator has made a determination under clause (i) is unable to agree upon group representation with the other members of the group, then such person shall not be denied under the authority of clause (i) the opportunity

to conduct (or have conducted) cross-examination as to issues affecting the person's particular interests if (I) the person satisfies the Administrator that the person has made a reasonable and good faith effort to reach agreement upon group representation with the other members of the group and (II) the Administrator determines that there are substantial and relevant issues which are not adequately presented by the group representative.

[(D) A verbatim transcript shall be taken of any oral presentation made, and cross-examination conducted in any informal hearing under this subsection. Such transcript shall be available to the public.

[(4)(A) The Administrator may, pursuant to rules prescribed by the Administrator, provide compensation for reasonable attorneys' fees, expert witness fees, and other costs of participating in a rule-making proceeding for the promulgation of a rule under subsection (a) to any person—

[(i) who represents an interest which would substantially contribute to a fair determination of the issues to be resolved in the proceeding, and

[(ii) if—

[(I) the economic interest of such person is small in comparison to the costs of effective participation in the proceeding by such person, or

[(II) such person demonstrates to the satisfaction of the Administrator that such person does not have sufficient resources adequately to participate in the proceeding without compensation under this subparagraph.

In determining for purposes of clause (i) if an interest will substantially contribute to a fair determination of the issues to be resolved in a proceeding, the Administrator shall take into account the number and complexity of such issues and the extent to which representation of such interest will contribute to widespread public participation in the proceeding and representation of a fair balance of interests for the resolution of such issues.

[(B) In determining whether compensation should be provided to a person under subparagraph (A) and the amount of such compensation, the Administrator shall take into account the financial burden which will be incurred by such person in participating in the rulemaking proceeding. The Administrator shall take such action as may be necessary to ensure that the aggregate amount of compensation paid under this paragraph in any fiscal year to all persons who, in rulemaking proceedings in which they receive compensation, are persons who either—

[(i) would be regulated by the proposed rule, or

[(ii) represent persons who would be so regulated,

may not exceed 25 per centum of the aggregate amount paid as compensation under this paragraph to all persons in such fiscal year.]

[(5) Paragraphs (1), (2), (3), and (4)] (3) *APPLICATION.*—*Paragraphs (1) and (2) of this subsection apply to the promulgation of a rule repealing, or making a substantive amendment to, a rule promulgated under subsection (a).*

(d) EFFECTIVE DATE.—(1) The Administrator shall specify in any rule under subsection (a) the date on which it shall take effect, which date shall be as soon as feasible.

(2)(A) The Administrator may declare a proposed rule under subsection (a) to be effective upon its publication in the Federal Register and until the effective date of final action taken, in accordance with subparagraph (B), respecting such rule if—

(i) the Administrator determines that—

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

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

(ii) 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 clause (i)(I), a court has in an action under section 7 granted relief with respect to such risk associated with such substance or mixture.

Such a proposed rule which is made so effective shall not, for purposes of judicial review, be considered final agency action.

(B) If the Administrator makes a proposed rule effective upon its publication in the Federal Register, the Administrator shall, as expeditiously as possible, give interested persons prompt notice of such action[, provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), for a hearing on such rule,] *in accordance with paragraph (2) of subsection (c)*, and either promulgate such rule (as proposed or with modifications) or revoke it[, and if such a hearing is requested, the Administrator shall commence the hearing within five days from the date such request is made unless the Administrator and the person making the request agree upon a later date for the hearing to begin, and after the hearing is concluded the Administrator shall, within ten days of the conclusion of the hearing, either promulgate such rule (as proposed or with modifications) or revoke it.]. *Any rule promulgated under subsection (a) shall provide for a reasonable transition period.*

(e) POLYCHLORINATED BIPHENYLS.—(1) Within six months after the effective date of this Act the Administrator shall promulgate rules to—

(A) prescribe methods for the disposal of polychlorinated biphenyls, and

(B) require polychlorinated biphenyls to be marked with clear and adequate warnings, and instructions with respect to their processing, distribution in commerce, use, or disposal or with respect to any combination of such activities.

Requirements prescribed by rules under this paragraph shall be consistent with the requirements of paragraphs (2) and (3).

(2)(A) Except as provided under subparagraph (B), effective one year after the effective date of this Act no person may manufacture, process, or distribute in commerce or use any polychlorinated biphenyl in any manner other than in a totally enclosed manner.

(B) The Administrator may by rule authorize the manufacture, processing, distribution in commerce or use (or any combination of such activities) of any polychlorinated biphenyl in a manner other than in a totally enclosed manner if the Administrator finds that such manufacture, processing, distribution in commerce, or use (or combination of such activities) will not present an unreasonable risk of injury to health or the environment.

(C) For the purposes of this paragraph, the term “totally enclosed manner” means any manner which will ensure that any exposure of human beings or the environment by the polychlorinated biphenyl will be insignificant as determined by the Administrator by rule.

(3)(A) Except as provided in subparagraphs (B), (C), and (D)—

(i) no person may manufacture any polychlorinated biphenyl after two years after the effective date of this Act, and

(ii) no person may process or distribute in commerce any polychlorinated biphenyl after two and one-half years after such date.

(B) Any person may petition the Administrator for an exemption from the requirements of subparagraph (A), and the Administrator may grant by rule such an exemption if the Administrator finds that—

(i) an unreasonable risk of injury to health or environment would not result, and

(ii) good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl.

An exemption granted under this subparagraph shall be subject to such terms and conditions as the Administrator may prescribe and shall be in effect for such period (but not more than 1 year from the date it is granted, except as provided in subparagraph (D)) as the Administrator may prescribe.

(C) Subparagraph (A) shall not apply to the distribution in commerce of any polychlorinated biphenyl if such polychlorinated biphenyl was sold for purposes other than resale before two and one-half years after the date of enactment of this Act.

(D) The Administrator may extend an exemption granted pursuant to subparagraph (B) that has not yet expired for a period not to exceed 60 days for the purpose of authorizing the Secretary of Defense and the Secretaries of the military departments to provide for the transportation into the customs territory of the United States of polychlorinated biphenyls generated by or under the control of the Department of Defense for purposes of their disposal, treatment, or storage in the customs territory of the United States if those polychlorinated biphenyls are already in transit from their storage locations but the Administrator determines, in the sole discretion of the Administrator, they would not otherwise arrive in the customs territory of the United States within the period of the original exemption. The Administrator shall promptly publish notice of such extension in the Federal Register.

(4) Any rule under paragraph (1), (2)(B), or (3)(B) shall be promulgated in accordance with [paragraphs (2), (3), and (4) of subsection (c)] *paragraph (2) of subsection (c)*.

(5) This subsection does not limit the authority of the Administrator, under any other provision of this Act or any other Federal law, to take action respecting any polychlorinated biphenyl.

(f) MERCURY.—

(1) PROHIBITION ON SALE, DISTRIBUTION, OR TRANSFER OF ELEMENTAL MERCURY BY FEDERAL AGENCIES.—Except as provided in paragraph (2), effective beginning on the date of enactment of this subsection, no Federal agency shall convey, sell, or distribute to any other Federal agency, any State or local government agency, or any private individual or entity any elemental mercury under the control or jurisdiction of the Federal agency.

(2) EXCEPTIONS.—Paragraph (1) shall not apply to—

(A) a transfer between Federal agencies of elemental mercury for the sole purpose of facilitating storage of mercury to carry out this Act; or

(B) a conveyance, sale, distribution, or transfer of coal.

(3) LEASES OF FEDERAL COAL.—Nothing in this subsection prohibits the leasing of coal.

(g) NON-RISK FACTORS.—*The Administrator shall not consider costs or other non-risk factors when deciding whether to initiate a rulemaking under subsection (a).*

(h) CRITICAL USE EXEMPTIONS.—

(1) CRITERIA FOR EXEMPTION.—*The Administrator may grant an exemption from a requirement of a subsection (a) rule for a specific use of a chemical substance or mixture, if—*

(A) *the requirement is not cost-effective with respect to the specific use, as determined by the Administrator pursuant to subsection (c)(1)(B); and*

(B) *the Administrator finds that—*

(i) *the specific use is a critical or essential use; or*

(ii) *the requirement, as applied with respect to the specific use, would significantly disrupt the national economy, national security, or critical infrastructure.*

(2) PROCEDURE.—*An exemption granted under paragraph (1) shall be—*

(A) *supported by clear and convincing evidence;*

(B) *preceded by public notice of the proposed exemption and an opportunity for comment; and*

(C) *followed by notice of the granted exemption—*

(i) *to the public, by the Administrator; and*

(ii) *to known commercial purchasers of the chemical substance or mixture with respect to which the exemption applies, by the manufacturers and processors of such chemical substance or mixture.*

(3) PERIOD OF EXEMPTION.—*An exemption granted under paragraph (1) shall expire after a period not to exceed 5 years, but may be renewed for one or more additional 5-year periods if the Administrator finds that the requirements of paragraph (1) continue to be met.*

(4) CONDITIONS.—*The Administrator shall impose conditions on any use for which an exemption is granted under paragraph (1) to reduce risk from the chemical substance or mixture to the greatest extent feasible.*

(i) *CHEMICALS THAT ARE PERSISTENT, BIOACCUMULATIVE, AND TOXIC.*—

(1) *IDENTIFICATION.*—Not later than 9 months after the date of enactment of the TSCA Modernization Act of 2015, the Administrator shall publish a list of those chemical substances that the Administrator has a reasonable basis to conclude are persistent, bioaccumulative, and toxic, not including any chemical substance that is a metal, a metal compound, or subject to subsection (e).

(2) *CONFIRMATION OF CONCERN.*—Not later than 2 years after the date of enactment of the TSCA Modernization Act of 2015, the Administrator shall designate as a PBT chemical of concern each chemical substance on the list published under paragraph (1)—

(A) that, with respect to persistence and bioaccumulation, scores high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012; and

(B) exposure to which is likely to the general population or to a potentially exposed subpopulation identified by the Administrator.

(3) *EXPEDITED ACTION.*—Notwithstanding subsection (b)(2), subject to the availability of appropriations, not later than 2 years after designating a chemical substance under paragraph (2), the Administrator shall promulgate a rule under subsection (a) with respect to the chemical substance to reduce likely exposure to the extent practicable.

(4) *RELATIONSHIP TO SUBSECTION (B).*—If, at any time prior to the date that is 90 days after the date on which the Administrator publishes the list under paragraph (1), the Administrator makes a finding under subsection (b)(3)(A)(i), or a manufacturer requests a risk evaluation under subsection (b)(3)(A)(ii), with respect to a chemical substance, such chemical substance shall not be subject to this subsection.

**SEC. 7. IMMINENT HAZARDS.**

(a) *ACTIONS AUTHORIZED AND REQUIRED.*—(1) The Administrator may commence a civil action in an appropriate district court of the United States—

(A) for seizure of an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture,

(B) for relief (as authorized by subsection (b)) against any person who manufactures, processes, distributes in commerce, or uses, or disposes of, an imminent hazardous chemical substance or mixture or any article containing such a substance or mixture, or

(C) for both such seizure and relief.

A civil action may be commenced under this paragraph notwithstanding the existence of [a rule under section 4, 5, 6, or title IV or an order under section 5 or title IV] *a rule under section 4, 5, or 6 or title IV, an order under section 4 or 5 or title IV, or a consent agreement under section 4*, and notwithstanding the pendency of any administrative or judicial proceeding under any provision of this Act.

(2) If the Administrator has not made a rule under section 6(a) immediately effective (as authorized by subsection 6(d)(2)(A)(i)) with respect to an imminently hazardous chemical substance or mixture, the Administrator shall commence in a district court of the United States with respect to such substance or mixture or article containing such substance or mixture a civil action described in subparagraph (A), (B), or (C) of paragraph (1).

(b) RELIEF AUTHORIZED.—(1) The district court of the United States in which an action under subsection (a) is brought shall have jurisdiction to grant such temporary or permanent relief as may be necessary to protect health or the environment from the unreasonable risk associated with the chemical substance, mixture, or article involved in such action.

(2) In the case of an action under subsection (a) brought against a person who manufactures, processes, or distributes in commerce a chemical substance or mixture or an article containing a chemical substance or mixture, the relief authorized by paragraph (1) may include the issuance of a mandatory order requiring (A) in the case of purchasers of such substance, mixture, or article known to the defendant, notification to such purchasers of the risk associated with it; (B) public notice of such risk; (C) recall; (D) the replacement or repurchase of such substance, mixture, or article; or (E) any combination of the actions described in the preceding clauses.

(3) In the case of an action under subsection (a) against a chemical substance, mixture, or article, such substance, mixture, or article may be proceeded against by process of libel for its seizure and condemnation. Proceedings in such an action shall conform as nearly as possible to proceedings in rem in admiralty.

(c) VENUE AND CONSOLIDATION.—(1)(A) An action under subsection (a) against a person who manufactures, processes, or distributes a chemical substance or mixture or an article containing a chemical substance or mixture may be brought in the United States District Court for the District of Columbia or for any judicial district in which any of the defendants is found, resides, or transacts business; and process in such an action may be served on a defendant in any other district in which such defendant resides or may be found. An action under subsection (a) against a chemical substance, mixture, or article may be brought in any United States district court within the jurisdiction of which the substance, mixture, or article is found.

(B) In determining the judicial district in which an action may be brought under subsection (a) in instances in which such action may be brought in more than one judicial district, the Administrator shall take into account the convenience of the parties.

(C) Subpoenas requiring attendance of witnesses in an action brought under subsection (a) may be served in any judicial district.

(2) Whenever proceedings under subsection (a) involving identical chemical substances, mixtures, or articles are pending in courts in two or more judicial districts, they shall be consolidated for trial by order of any such court upon application reasonably made by any party in interest, upon notice to all parties in interest.

(d) ACTION UNDER SECTION 6.—Where appropriate, concurrently with the filing of an action under subsection (a) or as soon thereafter as may be practicable, the Administrator shall initiate a proceeding for the promulgation of a rule under section 6(a).



(e) REPRESENTATION.—Notwithstanding any other provision of law, in any action under subsection (a), the Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator in such an action.

(f) DEFINITION.—For the purposes of subsection (a), the term “imminently hazardous chemical substance or mixture” means a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture, or that any combination of such activities, is likely to result in such injury to health or the environment before a final rule under section 6 can protect against such risk.

#### **SEC. 8. REPORTING AND RETENTION OF INFORMATION.**

(a) REPORTS.—(1) The Administrator shall promulgate rules under which—

(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii)) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require, and

(B) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process—

(i) a mixture, or

(ii) a chemical substance in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product,

shall maintain records and submit to the Administrator reports but only to the extent the Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of this Act.

The Administrator may not require in a rule promulgated under this paragraph the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that the maintenance of such records or the submission of such reports, or both, is necessary for the effective enforcement of this Act. For purposes of the compilation of the list of chemical substances required under subsection (b), the Administrator shall promulgate rules pursuant to this subsection not later than 180 days after the effective date of this Act.

(2) The Administrator may require under paragraph (1) maintenance of records and reporting with respect to the following insofar as known to the person making the report or insofar as reasonably ascertainable:

(A) The common or trade name, the chemical identity, and molecular structure of each chemical substance or mixture for which such a report is required.

(B) The categories or proposed categories of use of each such substance or mixture.

(C) The total amount of each substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.

(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.

(E) All existing data concerning the environmental and health effects of such substance or mixture.

(F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.

(G) In the initial report under paragraph (1) on such substance or mixture, the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method.

To the extent feasible, the Administrator shall not require under paragraph (1), any reporting which is unnecessary or duplicative.

(3)(A)(i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as the Administrator may require for publication of the first list of chemical substances required by subsection (b).

(ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture—

(I) subject to a rule proposed or promulgated under section 4, 5(b)(4), or 6, ~~or an order in effect under section 5(e)~~, *an order in effect under section 4 or 5(e), or a consent agreement under section 4, or*

(II) with respect to which relief has been granted pursuant to a civil action brought under section 5 or 7,

to maintain such records on such substance or mixture, and to submit to the Administrator such reports on such substance or mixture, as the Administrator may reasonably require. A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2).

(B) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of this paragraph and paragraph (1).

(b) INVENTORY.—(1) The Administrator shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States. Such list shall at least include each chemical substance which any person reports, under section 5 or subsection (a) of this section, is manufactured or processed in the United States. Such list may not include any chemical substance which was not manufactured or processed in the United States within three years before the effective date of the rules promulgated pursuant to the last sentence of subsection (a)(1). In the

case of a chemical substance for which a notice is submitted in accordance with section 5, such chemical substance shall be included in such list as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in the United States. The Administrator shall first publish such a list not later than 315 days after the effective date of this Act. The Administrator shall not include in such list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product.

(2) To the extent consistent with the purposes of this Act, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

(c) RECORDS.—Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture. Records of such adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. Any other record of such adverse reactions shall be retained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record. Records required to be maintained under this subsection shall include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of any duly designated representative of the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

(d) HEALTH AND SAFETY STUDIES.—The Administrator shall promulgate rules under which the Administrator shall require any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator—

(1) lists of health and safety studies (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person, or (C) reasonably ascertainable by such person, except that the Administrator may exclude certain types or categories of studies from the requirements of this subsection if the Administrator finds that submission of lists of such studies are unnecessary to carry out the purposes of this Act; and

(2) copies of any study contained on a list submitted pursuant to paragraph (1) or otherwise known by such person.

(e) NOTICE TO ADMINISTRATOR OF SUBSTANTIAL RISKS.—Any person who manufactures, processes, or distributes in commerce a

chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

(f) DEFINITIONS.—For purposes of this section, the terms “manufacture” and “process” mean manufacture or process for commercial purposes.

**SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.**

(a) LAWS NOT ADMINISTERED BY THE ADMINISTRATOR.—(1) If the Administrator has reasonable basis to conclude that 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 determines, in the Administrator’s discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—

(A)(i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and

(ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and

(B) to respond to the Administrator with respect to the matters described in subparagraph (A).

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested response within such time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made. The response of an agency shall be accompanied by a detailed statement of the findings and conclusions of the agency and shall be published in the Federal Register.

(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either—

(A) issues an order declaring that the activity or combination of activities specified in the description of the risk described in the report does not present the risk described in the report, or

(B) initiates, within 90 days of the publication in the Federal Register of the response of the agency under paragraph (1), action under the law (or laws) administered by such agency to protect against such risk associated with such activity or combination of activities,

the Administrator may not take any action under [section 6] section 6(a) or 7 with respect to such risk.

(3) If the Administrator has initiated action under [section 6] *section 6(a)* or 7 with respect to a risk associated with a chemical substance or mixture which was the subject of a report made to an agency under paragraph (1), such agency shall before taking action under the law (or laws) administered by it to protect against such risk consult with the Administrator for the purpose of avoiding duplication of Federal action against such risk.

(b) LAWS ADMINISTERED BY THE ADMINISTRATOR.—[The Administrator shall coordinate] *(1) The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.*

*(2) In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this title with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider the relevant risks, and compare the estimated costs and efficiencies, of the action to be taken under this title and an action to be taken under such other law to protect against such risk.*

(c) OCCUPATIONAL SAFETY AND HEALTH.—In exercising any authority under this Act, the Administrator shall not, for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

(d) COORDINATION.—In administering this Act, the Administrator shall consult and coordinate with the Secretary of Health, Education, and Welfare and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes. The Administrator shall, in the report required by section 30, report annually to the Congress on actions taken to coordinate with such other Federal departments, agencies, or instrumentalities, and on actions taken to coordinate the authority under this Act with the authority granted under other Acts referred to in subsection (b).

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## SEC. 11. INSPECTIONS AND SUBPOENAS.

(a) IN GENERAL.—For purposes of administering this Act, the Administrator, and any duly designated representative of the Administrator, may inspect any establishment, facility, or other premises

in which chemical substances, mixtures, or products subject to title IV are manufactured, processed, stored, or held before or after their distribution in commerce and any conveyance being used to transport chemical substances, mixtures, such products, or such articles in connection with distribution in commerce. Such an inspection may only be made upon the presentation of appropriate credentials and of a written notice to the owner, operator, or agent in charge of the premises or conveyance to be inspected. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness and shall be conducted at reasonable times, within reasonable limits, and in a reasonable manner.

(b) SCOPE.—(1) Except as provided in paragraph (2), an inspection conducted under subsection (a) shall extend to all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of this Act applicable to the chemical substances, mixtures, or products subject to title IV within such premises or conveyance have been complied with.

(2) No inspection under subsection (a) shall extend to—

- (A) financial data,
- (B) sales data (other than shipment data),
- (C) pricing data,
- (D) personnel data, or
- (E) research data (other than data required by this Act or under a **[rule promulgated]** *rule promulgated, order issued, or consent agreement entered into thereunder*),

unless, the nature and extent of such data are described with reasonable specificity in the written notice required by subsection (a) for such inspection.

(c) SUBPOENAS.—In carrying out this Act, the Administrator may by subpoena require the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, and other information that the Administrator deems necessary. Witnesses shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. In the event of contumacy, failure, or refusal of any person to obey any such subpoena, any district court of the United States in which venue is proper shall have jurisdiction to order any such person to comply with such subpoena. Any failure to obey such an order of the court is punishable by the court as a contempt thereof.

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#### SEC. 14. DISCLOSURE OF DATA.

(a) IN GENERAL.—Except as provided by subsection (b), any information reported to, or otherwise obtained by, the Administrator (or any representative of the Administrator) under this Act, which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section, shall, notwithstanding the provisions of any other section of this Act, not be disclosed by the Administrator or by any officer or employee of the United States, except that such information—

(1) shall be disclosed to any officer or employee of the United States—

(A) in connection with the official duties of such officer or employee under any law for the protection of health or the environment, or

(B) for specific law enforcement purposes;

(2) shall be disclosed to contractors with the United States and employees of such contractors if in the opinion of the Administrator such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States entered into on or after the date of enactment of this Act for the performance of work in connection with this Act and under such conditions as the Administrator may specify;

(3) shall be disclosed if the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment; **[or]**

(4) may be disclosed when relevant in any proceeding under this Act, except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding**[.]**;

*(5) may be disclosed to a State, local, or tribal government official upon request of the official for the purpose of administration or enforcement of a law; and*

*(6) shall be disclosed upon request—*

*(A) to a health or environmental professional employed by a Federal or State agency in response to an environmental release; or*

*(B) to a treating physician or other health care professional to assist in the diagnosis or treatment of 1 or more individuals.*

In any proceeding under section 552(a) of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 552(b)(3) of such title to sustain the Administrator's action.

(b) DATA FROM HEALTH AND SAFETY STUDIES.—(1) Subsection (a) does not prohibit the disclosure of—

(A) any health and safety study which is submitted under this Act with respect to—

(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, or

(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5, and

(B) any data reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the release of any **[data which discloses]** *data that disclose formulas (including molecular structures) of a chemical substance or mixture*, processes used in the manufacturing or processing of a chemical substance or **[mixture or,]** *mixture, or*, in the case of a mixture, **[the release of data dis-**

closing] the portion of the mixture comprised by any of the chemical substances in the mixture.

(2) If a request is made to the Administrator under subsection (a) of section 552 of title 5, United States Code, for information which is described in the first sentence of paragraph (1) and which is not information described in the second sentence of such paragraph, the Administrator may not deny such request on the basis of subsection (b)(4) of such section.

(c) **DESIGNATION AND RELEASE OF CONFIDENTIAL DATA.—** *DESIGNATING AND SUBSTANTIATING CONFIDENTIALITY.—*[(1) In submitting data under this Act, a manufacturer, processor, or distributor in commerce may (A) designate the data which such person believes is entitled to confidential treatment under subsection (a), and (B) submit such designated data separately from other data submitted under this Act. A designation under this paragraph shall be made in writing and in such manner as the Administrator may prescribe.] *(1)(A) In submitting information under this Act after date of enactment of the TSCA Modernization Act of 2015, a manufacturer, processor, or distributor in commerce shall designate the information which such person believes is entitled to protection under this section, and submit such designated information separately from other information submitted under this Act. A designation under this subparagraph shall be made in writing and in such manner as the Administrator may prescribe, and shall include—*

- (i) justification for each designation of confidentiality;*
- (ii) a certification that the information is not otherwise publicly available; and*
- (iii) separate copies of all submitted information, with 1 copy containing and 1 copy excluding the information to which the request applies.*

*(B) Designations made under subparagraph (A) after the date of enactment of the TSCA Modernization Act of 2015 shall expire after 10 years, at which time the information shall be made public unless the manufacturer, processor, or distributor in commerce has reasserted the claim for protection, in writing and in such manner as the Administrator may prescribe, including all of the elements required for the initial submission.*

*(C) Not later than 60 days prior to making information public under subparagraph (B), the Administrator shall notify, as appropriate and practicable, the manufacturer, processor, or distributor in commerce who designated the information under subparagraph (A) of the date on which such information will be made public unless a request for renewal is granted under subparagraph (B).*

*(2)(A) Except as provided by subparagraph (B), if the Administrator, for a reason other than the expiration of such designation pursuant to paragraph (1)(B), proposes to release for inspection data which has been designated under paragraph (1)(A), the Administrator shall notify, in writing and by certified mail, the manufacturer, processor, or distributor in commerce who submitted such data of the intent to release such data. If the release of such data is to be made pursuant to a request made under section 552(a) of title 5, United States Code, such notice shall be given immediately upon approval of such request by the Administrator. The Administrator may not release such data until the expiration of 30 days after the manufacturer, processor, or distributor in commerce sub-*



mitting such data has received the notice required by this subparagraph.

(B)(i) Subparagraph (A) shall not apply to the release of information under paragraph (1), (2), (3), ~~[(or (4)) (4), or (6)]~~ of subsection (a), except that the Administrator may not release data under paragraph (3) of subsection (a) unless the Administrator has notified each manufacturer, processor, and distributor in commerce who submitted such data of such release. Such notice shall be made in writing by certified mail at least 15 days before the release of such data, except that if the Administrator determines that the release of such data is necessary to protect against an imminent, unreasonable risk of injury to health or the environment, such notice may be made by such means as the Administrator determines will provide notice at least 24 hours before such release is made.

(ii) Subparagraph (A) shall not apply to the release of information described in subsection (b)(1) other than information described in the second sentence of such subsection.

(d) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.—(1) Any officer or employee of the United States or former officer or employee of the United States, who by virtue of such employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a), and who knowing that disclosure of such material is prohibited by such subsection, willfully discloses the material in any manner to any person not entitled to receive it, shall be guilty of a misdemeanor and fined not more than \$5,000 or imprisoned for not more than one year, or both. Section 1905 of title 18, United States Code, does not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this Act.

(2) For the purposes of paragraph (1), any contractor with the United States who is furnished information as authorized by subsection (a)(2), and any employee of any such contractor, shall be considered to be an employee of the United States.

(e) ACCESS BY CONGRESS.—Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, upon written request of any duly authorized committee of the Congress, to such committee.

(f) PROHIBITION.—*No person who receives information as permitted under subsection (a) may use such information for any purpose not specified in such subsection, nor disclose such information to any person not authorized to receive such information.*

(g) SAVINGS.—*Nothing in this section shall be construed to affect the applicability of State or Federal rules of evidence or procedure in any judicial proceeding.*

#### SEC. 15. PROHIBITED ACTS.

It shall be unlawful for any person to—

(1) fail or refuse to comply with ~~[(A) any rule promulgated or order issued under section 4,] [(B) any requirement prescribed by section 5 or 6,] [(C) any rule promulgated or order issued under section 5 or 6, or] [(D)] any requirement of this title or any rule promulgated, order issued, or consent agree-~~

*ment entered into under this title, or any requirement of title II or any rule promulgated or order issued under title II;*

(2) *use for commercial purposes a chemical substance or mixture which such person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 or 6, a rule or order under section 5 or 6, or an order issued in action brought under section 5 or 7;*

(3) *fail or refuse to (A) establish or maintain records, (B) submit reports, notices, or other information, or (C) permit access to or copying of records, as required by this Act or a rule thereunder; or*

(4) *fail or refuse to permit entry or inspection as required by section 11.*

\* \* \* \* \*

#### SEC. 18. PREEMPTION.

(a) EFFECT ON STATE LAW.—(1) Except as provided in paragraph (2), nothing in this Act shall affect the authority of any State or political subdivision of a State to establish or continue in effect regulation of any chemical substance, mixture, or article containing a chemical substance or mixture.

(2) Except as provided in subsection (b)—

(A) if the Administrator requires by a [rule promulgated] *rule, order, or consent agreement* under section 4 the testing of a chemical substance or mixture, no State or political subdivision may, after the effective date of [such rule] *such rule, order, or consent agreement*, establish or continue in effect a requirement for the testing of such substance or mixture for purposes similar to those for which testing is required under [such rule] *such rule, order, or consent agreement* [; and];

[(B) if the Administrator prescribes a rule or order under section 5 or 6 (other than a rule imposing a requirement described in subsection (a)(6) of section 6) which is applicable to a chemical substance or mixture, and which is designed to protect against a risk of injury to health or the environment associated with such substance or mixture, no State or political subdivision of a State may, after the effective date of such requirement, establish or continue in effect, any requirement which is applicable to such substance or mixture, or an article containing such substance or mixture, and which is designed to protect against such risk unless such requirement (i) is identical to the requirement prescribed by the Administrator, (ii) is adopted under the authority of the Clean Air Act or any other Federal law, or (iii) prohibits the use of such substance or mixture in such State or political subdivision (other than its use in the manufacture or processing of other substances or mixtures).]

(B) *if the Administrator makes a final determination under section 6(b) that a chemical substance will not present an unreasonable risk of injury to health or the environment under the intended condition of use, no State or political subdivision may, after the date of publication of such determination, establish or continue in effect any requirement that applies to such chemical substance under the intended conditions of use considered by the Administrator in the risk evaluation under section 6(b), and*

*is designed to protect against exposure to such chemical substance under the intended conditions of use, unless the requirement of the State or political subdivision—*

*(i) is adopted under the authority of a Federal law; or*

*(ii) is adopted to protect air or water quality or is related to waste treatment or waste disposal, except that this clause does not apply to such a requirement if a provision of this title, or an action or determination made by the Administrator under this title, actually conflicts with the requirement; and*

*(C) if the Administrator imposes a requirement, through a rule or order under section 5 or 6, that applies to a chemical substance or mixture (other than a requirement described in section 6(a)(6)) and is designed to protect against a risk of injury to health or the environment associated with such chemical substance or mixture, no State or political subdivision may, after the effective date of such requirement, establish or continue in effect any requirement that applies to such chemical substance or mixture (including a requirement that applies to an article because the article contains the chemical substance or mixture) and is designed to protect against exposure to the chemical substance or mixture either under the intended conditions of use considered by the Administrator in the risk evaluation under section 6(b) or from a use identified in a notice received by the Administrator under section 5(a), or, in the case of a requirement imposed pursuant to section 6(i), is designed to protect against a risk of injury considered by the Administrator in imposing such requirement, unless the requirement of the State or political subdivision—*

*(i) is identical to the requirement imposed by the Administrator;*

*(ii) is adopted under the authority of a Federal law; or*

*(iii) is adopted to protect air or water quality or is related to waste treatment or waste disposal, except that this clause does not apply to such a requirement if a provision of this title, or an action or determination made by the Administrator under this title, actually conflicts with the requirement.*

*(3) In the case of an identical requirement described in paragraph (2)(C)(i)—*

*(A) a State may not assess a penalty for a specific violation for which the Administrator has assessed a penalty under section 16; and*

*(B) if a State has assessed a penalty for a specific violation, the Administrator may not assess a penalty for that violation in an amount that would cause the total of the penalties assessed for the violation by the State and the Administrator combined to exceed the maximum amount that may be assessed for that violation by the Administrator under section 16.*

*(b) EXEMPTION.—Upon application of a State or political subdivision of a State the Administrator may by rule exempt from subsection (a)(2), under such conditions as may be prescribed in such rule, a requirement of such State or political subdivision designed to protect against a risk of injury to health or the environment as—*

sociated with a chemical substance, mixture, or article containing a chemical substance or mixture if—

(1) compliance with the requirement would not cause the manufacturing, processing, distribution in commerce, or use of the substance, mixture, or article to be in violation of the applicable requirement under this Act described in subsection (a)(2), and

(2) the State or political subdivision requirement (A) provides a significantly higher degree of protection from such risk than the requirement under this Act described in subsection (a)(2) and (B) does not, through difficulties in marketing, distribution, or other factors, unduly burden interstate commerce.

(c) SAVINGS.—

(1) *PRIOR STATE ACTIONS.*—*Nothing in this title, nor any risk evaluation, rule, order, standard, or requirement completed or implemented under this title, shall be construed to preempt or otherwise affect the authority of a State or political subdivision of a State to continue to enforce any action taken before August 1, 2015, under the authority of a State law that prohibits or otherwise restricts the manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance, or any action taken pursuant to a State law that was in effect on August 31, 2003, unless an action or determination made by the Administrator under this title actually conflicts with the action taken pursuant to such a State law.*

(2) *TORT AND CONTRACT LAW.*—*Nothing in this title, nor any risk evaluation, rule, order, standard, or requirement completed or implemented under this title, shall be construed to preempt or otherwise affect either Federal or State tort law or the law governing the interpretation of contracts of any State, including any remedy for civil relief, whether under statutory or common law, including a remedy for civil damages, and 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 relating to tort law.*

(3) *INTENT OF CONGRESS.*—*It is not the intent of Congress that this title, or rules, regulations, or orders issued pursuant to this title, be interpreted as influencing, in either a plaintiff's or defendant's favor, the disposition of any civil action for damages in a State court, or the authority of any court to make a determination in an adjudicatory proceeding under applicable State law with respect to the admissibility of evidence, unless a provision of this title actually conflicts with the State court action.*

(4) *APPLICATION.*—*For purposes of this title, the term “requirements” does not include civil tort actions for damages under State law.*

#### **SEC. 19. JUDICIAL REVIEW.**

(a) *IN GENERAL.*—(1) **[(A) Not later than 60 days after the date of the promulgation of a rule] Not later than 60 days after the date on which a rule is promulgated under section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV, or the date on which an order is issued under section 4, any person may file a petition for judicial review of [such rule] such rule or order with the United States**

Court of Appeals for the District of Columbia Circuit or for the circuit in which such person resides or in which such person's principal place of business is located. Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of [such a rule] *such a rule or order* if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

[(B) Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of an order issued under subparagraph (A) or (B) of section 6(b)(1) if any district court of the United States would have had jurisdiction of such action but for this subparagraph.]

(2) Copies of any petition filed under paragraph (1)(A) shall be transmitted forthwith to the Administrator and to the Attorney General by the clerk of the court with which such petition was filed. The provisions of section 2112 of title 28, United States Code, shall apply to the filing of the rulemaking record of proceedings on which the Administrator based [the rule] *the rule or order* being reviewed under this section and to the transfer of proceedings between United States courts of appeals.

(3) For purposes of this section, the term "rulemaking record" means—

(A) [the rule] *the rule or order* being reviewed under this section;

(B) in the case of [a rule under section 4(a)] *a rule or order under section 4(a)*, the finding required by such section, in the case of a rule under section 5(b)(4), the finding required by such section, in the case of a rule under section 6(a) the finding required by section 5(f) or 6(a), as the case may be, in the case of a rule under section 6(a), the statement required by section 6(c)(1), and in the case of a rule under section 6(e), the findings required by paragraph (2)(B) or (3)(B) of such section, as the case may be and in the case of a rule under title IV, the finding required for the issuance of such a rule;

(C) any transcript required to be made of oral presentations made in proceedings for the promulgation of [such rule] *such rule or order*;

(D) any written submission of interested parties respecting the promulgation of [such rule] *such rule or order*; and

(E) any other information which the Administrator considers to be relevant [to such rule] *to such rule or order* and which the Administrator identified, on or before [the date of the promulgation of such rule] *the date on which such rule is promulgated or such order is issued*, in a notice published in the Federal Register.

(b) ADDITIONAL SUBMISSIONS AND PRESENTATIONS; MODIFICATIONS.—If in an action under this section to [review a rule] *review a rule, or an order under section 4*, the petitioner or the Administrator applies to the court for leave to make additional oral submissions or written presentations respecting [such rule] *such rule or order* and shows to the satisfaction of the court that such submissions and presentations would be material and that there were reasonable grounds for the submissions and failure to make such sub-

missions and presentations in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity to make such submissions and presentations. The Administrator may modify or set aside **the rule** *the rule or order* being reviewed or make a **new rule** *new rule or order* by reason of the additional submissions and presentations and shall file such modified or **new rule** *new rule or order* with the return of such submissions and presentations. The court shall thereafter review such new or **modified rule** *modified rule or order*.

(c) STANDARD OF REVIEW.—(1)(A) Upon the filing of a petition under subsection (a)(1) for judicial review of **a rule** *a rule, or an order under section 4*, the court shall have jurisdiction (i) to grant appropriate relief, including interim relief, as provided in chapter 7 of title 5, United States Code, and (ii) except as otherwise provided in subparagraph (B), to review **such rule** *such rule or order* in accordance with chapter 7 of title 5, United States Code.

(B) Section 706 of title 5, United States Code, shall apply to review of **a rule** *a rule or order* under this section, except that—

(i) in the case of review of a rule under section 4(a), 5(b)(4), 6(a), or 6(e), or *an order under section 4*, the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside **such rule** *such rule or order* if the court finds that **the rule** *the rule or order* is not supported by substantial evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole~~;~~**;** and

**[(ii) in the case of review of a rule under section 6(a), the court shall hold unlawful and set aside such rule if it finds that—**

**[(I) a determination by the Administrator under section 6(c)(3) that the petitioner seeking review of such rule is not entitled to conduct (or have conducted) cross-examination or to present rebuttal submissions, or**

**[(II) a rule of, or ruling by, the Administrator under section 6(c)(3) limiting such petitioner's cross-examination or oral presentations,**

has precluded disclosure of disputed material facts which was necessary to a fair determination by the Administrator of the rulemaking proceeding taken as a whole; and section 706(2)(D) shall not apply with respect to a determination, rule, or ruling referred to in subclause (I) or (II); and~~]~~**]**

**[(iii) (ii) the court may not review the contents and adequacy of—**

**(I) any statement required to be made pursuant to section 6(c)(1), or**

**(II) any 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.

The term “evidence” as used in clause (i) means any matter in the rulemaking record.

(C) A determination, rule, or ruling of the Administrator described in subparagraph (B)(ii) may be reviewed only in an action under this section and only in accordance with such subparagraph.

(2) The judgment of the court affirming or setting aside, in whole or in part, **[any rule]** *any rule or order* reviewed in accordance with this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

(d) FEES AND COSTS.—The decision of the court in an action commenced under subsection (a), or of the Supreme Court of the United States on review of such a decision, may include an award of costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate.

(e) OTHER REMEDIES.—The remedies as provided in this section shall be in addition to and not in lieu of any other remedies provided by law.

#### SEC. 20. CITIZENS' CIVIL ACTIONS.

(a) IN GENERAL.—Except as provided in subsection (b), any person may commence a civil action—

(1) against any person (including (A) the United States, and (B) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of this Act or any rule promulgated under section 4, 5, or 6, or title II or IV, or **[order issued under section 5]** *order issued under section 4 or 5* or title II or IV to restrain such violation, or

(2) against the Administrator to compel the Administrator to perform any act or duty under this Act which is not discretionary.

Any civil action under paragraph (1) shall be brought in the United States district court for the district in which the alleged violation occurred or in which the defendant resides or in which the defendant's principal place of business is located. Any action brought under paragraph (2) shall be brought in the United States District Court for the District of Columbia, or the United States district court for the judicial district in which the plaintiff is domiciled. The district courts of the United States shall have jurisdiction over suits brought under this section, without regard to the amount in controversy or the citizenship of the parties. In any civil action under this subsection process may be served on a defendant in any judicial district in which the defendant resides or may be found and subpoenas for witnesses may be served in any judicial district.

(b) LIMITATION.—No civil action may be commenced—

(1) under subsection (a)(1) to restrain a violation of this Act or rule or order under this Act—

(A) before the expiration of 60 days after the plaintiff has given notice of such violation (i) to the Administrator, and (ii) to the person who is alleged to have committed such violation, or

(B) if the Administrator has commenced and is diligently prosecuting a proceeding for the issuance of an order under section 16(a)(2) to require compliance with this Act or with such rule or order or if the Attorney General has commenced and is diligently prosecuting a civil action in a court of the United States to require compliance with this Act or with such rule or order, but if such proceeding or civil action is commenced after the giving of notice, any

person giving such notice may intervene as a matter of right in such proceeding or action; or

(2) under subsection (a)(2) before the expiration of 60 days after the plaintiff has given notice to the Administrator of the alleged failure of the Administrator to perform an act or duty which is the basis for such action or, in the case of an action under such subsection for the failure of the Administrator to file an action under section 7, before the expiration of ten days after such notification.

Notice under this subsection shall be given in such manner as the Administrator shall prescribe by rule.

(c) GENERAL.—(1) In any action under this section, the Administrator, if not a party, may intervene as a matter of right.

(2) The court, in issuing any final order in any action brought pursuant to subsection (a), may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(3) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this Act or any rule or order under this Act or to seek any other relief.

(d) CONSOLIDATION.—When two or more civil actions brought under subsection (a) involving the same defendant and the same issues or violations are pending in two or more judicial districts, such pending actions, upon application of such defendants to such actions which is made to a court in which any such action is brought, may, if such court in its discretion so decides, be consolidated for trial by order (issued after giving all parties reasonable notice and opportunity to be heard) of such court and tried in—

(1) any district which is selected by such defendant and in which one of such actions is pending,

(2) a district which is agreed upon by stipulation between all the parties to such actions and in which one of such actions is pending, or

(3) a district which is selected by the court and in which one of such actions is pending.

The court issuing such an order shall give prompt notification of the order to the other courts in which the civil actions consolidated under the order are pending.

#### **SEC. 21. CITIZENS' PETITIONS.**

(a) IN GENERAL.—Any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 6, or 8 or an [order under section 5(e) or 6(b)(2)] *order under section 4 or 5(e)*.

(b) PROCEDURES.—(1) Such petition shall be filed in the principal office of the Administrator and shall set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under section 4, 6, or 8 or an [order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)] *order under section 4 or 5(e)*.

(2) The Administrator may hold a public hearing or may conduct such investigation or proceeding as the Administrator deems appro-



priate in order to determine whether or not such petition should be granted.

(3) Within 90 days after filing of a petition described in paragraph (1), the Administrator shall either grant or deny the petition. If the Administrator grants such petition, the Administrator shall promptly commence an appropriate proceeding in accordance with section 4, 5, 6, or 8. If the Administrator denies such petition, the Administrator shall publish in the Federal Register the Administrator's reasons for such denial.

(4)(A) If the Administrator denies a petition filed under this section (or if the Administrator fails to grant or deny such petition within the 90-day period) the petitioner may commence a civil action in a district court of the United States to compel the Administrator to initiate a rulemaking proceeding as requested in the petition. Any such action shall be filed within 60 days after the Administrator's denial of the petition or, if the Administrator fails to grant or deny the petition within 90 days after filing the petition, within 60 days after the expiration of the 90-day period.

(B) In an action under subparagraph (A) respecting a petition to initiate a proceeding to issue a rule under section 4, 6, or 8 or an **[order under section 5(e) or 6(b)(2)]** *order under section 4 or 5(e)*, the petitioner shall be provided an opportunity to have such petition considered by the court in a de novo proceeding. If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

(i) in the case of a petition to initiate a proceeding for the issuance of a rule under section 4 or an **[order under section 5(e)]** *order under section 4 or 5(e)*—

(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order; and

(II) in the absence of such information, the substance may present an unreasonable risk to health or the environment, or the substance is or will be produced in substantial quantities and it enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to it; or

(ii) in the case of a petition to initiate a proceeding for the issuance of a rule under section 6 or 8 **[or an order under section 6(b)(2)]**, there is a reasonable basis to conclude that the issuance of such a rule or order is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment;

the court shall order the Administrator to initiate the action requested by the petitioner. If the court finds that the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act and there are insufficient resources available to the Administrator to take the action requested by the petitioner, the court may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes.

(C) The court in issuing any final order in any action brought pursuant to subparagraph (A) may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(5) The remedies under this section shall be in addition to, and not in lieu of, other remedies provided by law.

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#### **SEC. 24. EMPLOYMENT EFFECTS.**

(a) **IN GENERAL.**—The Administrator shall evaluate on a continuing basis the potential effects on employment (including reductions in employment or loss of employment from threatened plant closures) of—

(1) the issuance of a rule or order under section 4, 5, or 6, or

(2) a requirement of section 5 or 6.

(b)(1) **INVESTIGATIONS.**—Any employee (or any representative of an employee) may request the Administrator to make an investigation of—

(A) a discharge or layoff or threatened discharge or layoff of the employee, or

(B) adverse or threatened adverse effects on the employee's employment,

allegedly resulting from a rule or order under section 4, 5, or 6 or a requirement of section 5 or 6. Any such request shall be made in writing, shall set forth with reasonable particularity the grounds for the request, and shall be signed by the employee, or representative of such employee, making the request.

(2)(A) Upon receipt of a request made in accordance with paragraph (1) the Administrator shall (i) conduct the investigation requested, and (ii) if requested by any interested person, hold public hearings on any matter involved in the investigation unless the Administrator, by order issued within 45 days of the date such hearings are requested, denies the request for the hearings because the Administrator determines there are no reasonable grounds for holding such hearings. If the Administrator makes such a determination, the Administrator shall notify in writing the person requesting the hearing of the determination and the reasons therefor and shall publish the determination and the reasons therefor in the Federal Register.

(B) If public hearings are to be held on any matter involved in an investigation conducted under this subsection—

(i) at least five days' notice shall be provided the person making the request for the investigation and any person identified in such request, *and*

[(ii) such hearings shall be held in accordance with section 6(c)(3), and]

[(iii)] (ii) each employee who made or for whom was made a request for such hearings and the employer of such employee shall be required to present information respecting the applicable matter referred to in paragraph (1)(A) or (1)(B) together with the basis for such information.

(3) Upon completion of an investigation under paragraph (2), the Administrator shall make findings of fact, shall make such recommendations as the Administrator deems appropriate, and shall make available to the public such findings and recommendations.

(4) This section shall not be construed to require the Administrator to amend or repeal any rule or order in effect under this Act.

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#### SEC. 26. ADMINISTRATION OF THE ACT.

(a) COOPERATION OF FEDERAL AGENCIES.—Upon request by the Administrator, each Federal department and agency is authorized—

(1) to make its services, personnel, and facilities available (with or without reimbursement) to the Administrator to assist the Administrator in the administration of this Act; and

(2) to furnish to the Administrator such information, data, estimates, and statistics, and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary for the administration of this Act.

(b) FEES.—(1) The Administrator may, by rule, require the payment **[of a reasonable fee]** from any person required to submit data under section 4 or 5 *of a fee that is sufficient and not more than reasonably necessary*, or who requests a risk evaluation under section 6(b)(3)(A)(ii), to defray the cost of administering **[this Act]** *the provision of this title for which such fee is collected.* **[Such rules shall not provide for any fee in excess of \$2,500 or, in the case of a small business concern, any fee in excess of \$100.]** *Such rules shall provide for lower fees for small business concerns.* In setting a fee under this paragraph, the Administrator shall take into account the ability to pay of the person required to submit the data and the cost to the Administrator of reviewing such data. Such rules may provide for sharing such a fee in any case in which the expenses of testing are shared under section 4 or 5.

(2) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the persons which qualify as small business concerns for purposes of paragraph (1).

(3) FUND.—

(A) ESTABLISHMENT.—*There is established in the Treasury of the United States a revolving fund, to be known as the TSCA Service Fee Fund (in this paragraph referred to as the "Fund"), consisting of such amounts as are deposited in the Fund under this paragraph.*

(B) COLLECTION AND DEPOSIT OF FEES.—*The Administrator shall collect the fees described in paragraph (1) and deposit those fees in the Fund.*

(C) CREDITING AND AVAILABILITY OF FEES.—*On request by the Administrator, the Secretary of the Treasury shall transfer from the Fund to the Administrator amounts appropriated to pay or recover the full costs incurred by the Environmental Protection Agency, including contractor costs, in carrying out the provisions of this title for which the fees are collected under paragraph (1).*

(D) *USE OF FUNDS BY ADMINISTRATOR.*—Amounts equivalent to fees collected by the Administrator and deposited in the Fund under this section shall be available without fiscal year limitation to the Administrator, subject to the availability of appropriations, for use only in administering the provisions of this title for which the fees are collected.

(E) *ACCOUNTING AND AUDITING.*—

(i) *ACCOUNTING.*—The Administrator shall biennially prepare and submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes an accounting of the fees paid to the Administrator under this paragraph and amounts disbursed from the Fund for the period covered by the report, as reflected by financial statements provided in accordance with sections 3515 and 3521 of title 31, United States Code.

(ii) *AUDITING.*—

(I) *IN GENERAL.*—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of a covered executive agency.

(II) *COMPONENTS OF AUDIT.*—The annual audit required in accordance with sections 3515 and 3521 of title 31, United States Code, of the financial statements of activities carried out using amounts from the Fund shall include an analysis of—

(aa) the fees collected and amounts disbursed under this subsection;

(bb) the reasonableness of the fees in place as of the date of the audit to meet current and projected costs of administering the provisions of the title for which the fees are collected; and

(cc) the number of requests for a risk evaluation made by manufacturers under section 6(b)(3)(A)(ii).

(III) *FEDERAL RESPONSIBILITY.*—The Inspector General of the Environmental Protection Agency shall conduct the annual audit described in subclause (II) and submit to the Administrator a report that describes the findings and any recommendations of the Inspector General resulting from the audit.

(c) *ACTION WITH RESPECT TO CATEGORIES.*—(1) Any action authorized or required to be taken by the Administrator under any provision of this Act with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this Act with respect to a category of chemical substances or mixtures, any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category.

(2) For purposes of paragraph (1):

(A) The term “category of chemical substances” means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body

or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

(B) The term “category of mixtures” means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in the mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act.

(d) ASSISTANCE OFFICE.—The Administrator shall establish in the Environmental Protection Agency an identifiable office to provide technical and other nonfinancial assistance to manufacturers and processors of chemical substances and mixtures respecting the requirements of this Act applicable to such manufacturers and processors, the policy of the Agency respecting the application of such requirements to such manufacturers and processors, and the means and methods by which such manufacturers and processors may comply with such requirements.

(e) FINANCIAL DISCLOSURES.—(1) Except as provided under paragraph (3), each officer or employee of the Environmental Protection Agency and the Department of Health, Education, and Welfare who—

(A) performs any function or duty under this Act, and

(B) has any known financial interest (i) in any person subject to this Act or any rule or order in effect under this Act, or (ii) in any person who applies for or receives any grant or contract under this Act,

shall, on February 1, 1978, and on February 1 of each year thereafter, file with the Administrator or the Secretary of Health, Education, and Welfare (hereinafter in this subsection referred to as the “Secretary”), as appropriate, a written statement concerning all such interests held by such officer or employee during the preceding calendar year. Such statement shall be made available to the public.

(2) The Administrator and the Secretary shall—

(A) act within 90 days of the effective date of this Act—

(i) to define the term “known financial interests” for purposes of paragraph (1), and

(ii) to establish the methods by which the requirement to file written statements specified in paragraph (1) will be monitored and enforced, including appropriate provisions for review by the Administrator and the Secretary of such statements; and

(B) report to the Congress on June 1, 1978, and on June 1 of each year thereafter with respect to such statements and the actions taken in regard thereto during the preceding calendar year.

(3) The Administrator may by rule identify specific positions with the Environmental Protection Agency, and the Secretary may by rule identify specific positions with the Department of Health, Education, and Welfare, which are of a nonregulatory or nonpolicy-making nature, and the Administrator and the Secretary may by

rule provide that officers or employees occupying such positions shall be exempt from the requirements of paragraph (1).

(4) This subsection does not supersede any requirement of chapter 11 of title 18, United States Code.

(5) Any officer or employee who is subject to, and knowingly violates, this subsection or any rule issued thereunder, shall be fined not more than \$2,500 or imprisoned not more than one year, or both.

(f) STATEMENT OF BASIS AND PURPOSE.—Any final order issued under this Act shall be accompanied by a statement of its basis and purpose. The contents and adequacy of any such statement shall not be subject to judicial review in any respect.

(g) ASSISTANT ADMINISTRATOR.—(1) The President, by and with the advice and consent of the Senate, shall appoint an Assistant Administrator for Toxic Substances of the Environmental Protection Agency. Such Assistant Administrator shall be a qualified individual who is, by reason of background and experience, especially qualified to direct a program concerning the effects of chemicals on human health and the environment. Such Assistant Administrator shall be responsible for (A) the collection of data, (B) the preparation of studies, (C) the making of recommendations to the Administrator for regulatory and other actions to carry out the purposes and to facilitate the administration of this Act, and (D) such other functions as the Administrator may assign or delegate.

(2) The Assistant Administrator to be appointed under paragraph (1) shall be in addition to the Assistant Administrators of the Environmental Protection Agency authorized by section 1(d) of Reorganization Plan No. 3 of 1970.

(h) SCIENTIFIC STANDARDS.—*In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall consider, as applicable—*

*(1) the extent to which the scientific and technical procedures, measures, methods, or models employed to generate the information are reasonable for and consistent with the use of the information;*

*(2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;*

*(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;*

*(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, or models, are evaluated and characterized; and*

*(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, or models.*

(i) WEIGHT OF SCIENTIFIC EVIDENCE.—*The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence.*

(j) AVAILABILITY OF INFORMATION.—*Subject to section 14, the Administrator shall make available to the public all notices, determinations, findings, rules, and orders of the Administrator under this title.*

(k) POLICIES, PROCEDURES, AND GUIDANCE.—

(1) *DEVELOPMENT.*—Not later than 2 years after the date of enactment of the TSCA Modernization Act of 2015, the Administrator shall develop any policies, procedures, and guidance the Administrator determines are necessary to carry out the amendments to this Act made by the TSCA Modernization Act of 2015.

(2) *REVIEW.*—Not later than 5 years after the date of enactment of the TSCA Modernization Act of 2015, and not less frequently than once every 5 years thereafter, the Administrator shall—

(A) review the adequacy of the policies, procedures, and guidance developed under paragraph (1), including with respect to animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this title; and

(B) revise such policies, procedures, and guidance as the Administrator determines necessary to reflect new scientific developments or understandings.

(I) *REPORT TO CONGRESS.*—

(1) *INITIAL REPORT.*—Not later than 6 months after the date of enactment of the TSCA Modernization Act of 2015, the Administrator shall submit to the Committees on Energy and Commerce and Appropriations of the House of Representatives and the Committees on Environment and Public Works and Appropriations of the Senate a report containing an estimation of—

(A) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under subparagraphs (A)(i) and (B) of section 6(b)(3), and the resources necessary to initiate the minimum number of risk evaluations required under section 6(b)(7);

(B) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under section 6(b)(3)(A)(ii), the likely demand for such risk evaluations, and the anticipated schedule for accommodating that demand;

(C) the capacity of the Environmental Protection Agency to promulgate rules under section 6(a) as required based on risk evaluations conducted and published under section 6(b); and

(D) the actual and anticipated efforts of the Environmental Protection Agency to increase the Agency's capacity to conduct and publish risk evaluations under section 6(b).

(2) *SUBSEQUENT REPORTS.*—The Administrator shall update and resubmit the report described in paragraph (1) not less frequently than once every 5 years.

#### **SEC. 27. DEVELOPMENT AND EVALUATION OF TEST METHODS.**

(a) *IN GENERAL.*—The Secretary of Health, Education, and Welfare in consultation with the Administrator and acting through the Assistant Secretary for Health, may conduct, and make grants to public and nonprofit private entities and enter into contracts with public and private entities for, projects for the development and evaluation of inexpensive and efficient methods (1) for determining and evaluating the health and environmental effects of chemical substances and mixtures, and their toxicity, persistence, and other characteristics which affect health and the environment, and (2)

which may be used for the development of test data to meet the requirements of ~~rules promulgated~~ *rules, orders, or consent agreements* under section 4. The Administrator shall consider such methods in prescribing under section 4 standards for the development of test data.

(b) APPROVAL BY SECRETARY.—No grant may be made or contract entered into under subsection (a) unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be submitted in such form and manner and contain such information as the Secretary may require. The Secretary may apply such conditions to grants and contracts under subsection (a) as the Secretary determines are necessary to carry out the purposes of such subsection. Contracts may be entered into under such subsection without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

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#### SEC. 30. ANNUAL REPORT.

The Administrator shall prepare and submit to the President and the Congress on or before January 1, 1978, and on or before January 1 of each succeeding year a comprehensive report on the administration of this Act during the preceding fiscal year. Such report shall include—

(1) a list of the testing required under section 4 during the year for which the report is made and an estimate of the costs incurred during such year by the persons required to perform such tests;

(2) the number of notices received during such year under section 5, the number of such notices received during such year under such section for chemical substances subject to a section 4 ~~rule~~ *rule, order, or consent agreement*, and a summary of any action taken during such year under section 5(g);

(3) a list of rules issued during such year under section 6;

(4) a list, with a brief statement of the issues, of completed or pending judicial actions under this Act and administrative actions under section 16 during such year;

(5) a summary of major problems encountered in the administration of this Act; and

(6) such recommendations for additional legislation as the Administrator deems necessary to carry out the purposes of this Act.

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