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94TH CONGRESS }  
2d Session }

SENATE

{ REPORT  
No. 94-1302

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## TOXIC SUBSTANCES CONTROL ACT

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SEPTEMBER 24, 1976.—Ordered to be printed

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Mr. MAGNUSON, from the committee of conference,  
submitted the following

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### CONFERENCE REPORT

[To accompany S. 3149]

The committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 3149) to regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment insert the following:

#### **SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.**

*This Act may be cited as the "Toxic Substances Control Act".*

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#### **TABLE OF CONTENTS**

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## SEC. 2. FINDINGS, POLICY, AND INTENT.

### (a) FINDINGS.—The Congress finds that—

(1) human beings and the environment are being exposed each year to a large number of chemical substances and mixtures;

(2) among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment; and

(3) the effective regulation of interstate commerce in such chemical substances and mixtures also necessitates the regulation of intrastate commerce in such chemical substances and mixtures.

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

(1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;

(2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and

(3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

(c) INTENT OF CONGRESS.—It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this Act.

## 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 provided 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 "manufacture" means to import into the customs territory of the United States (as defined in general headnote 2 of the Tariff Schedules of the United States), produce, or manufacture.

(8) 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) 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).

(10) 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) The term "processor" means any person who processes a chemical substance or mixture.

(12) 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) 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) 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

(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 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 under subsection (a) shall include—

(A) identification of the chemical substance or mixture for which testing is required under the rule.

(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 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 and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule. Any such rule 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 carcinogenesis, 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, sub-acute 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 under subsection (a) and shall, if necessary, institute proceedings to make appropriate revisions of such standards.

(3)(A) A rule 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 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) 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 before such date; and a rule 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 repeals the application of the rule to such substance or mixture or repeals the rule.

(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 submissions; (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) 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 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, 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,

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 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 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 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, 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, 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 under subsection (a) and if after such exemp-

tion is granted the Administrator determines that no such person has complied with such rule, 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 with respect to which such exemption was granted.

(d) NOTICE.—Upon the receipt of any test data pursuant to a rule 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 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 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 with 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.

SEC. 5 (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 under section 4 before the submission of such notice, such person shall submit to the Administrator such data in accordance with such rule 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(e) from the requirements of a rule promulgated 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 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 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 355 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 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 injunc-

tion 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, processing, 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 ex-

emption 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

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.

(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 extent 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 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.

(2) 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) 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 hear-

ing 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 rule-making 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) 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 wide-

spread 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, 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.

(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 to a polychlorinated biphenyl will be insignificant as determined by the Administrator by rule.

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

(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 one year from the date it is granted) 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.

(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).

(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.

#### 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 imminently 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, or 6 or an order under section 5, 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 unreason-

able 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 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 the 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 such 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 Administration 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), 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 or 7 with respect to such risk.

(3) If the Administrator has initiated action under section 6 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 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.

(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).

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

(a) **AUTHORITY.**—The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare and with other heads of appropriate departments and agencies, conduct such research, development, and monitoring as is necessary to carry out the purposes of this Act. The Administrator may enter into contracts and may make grants for research, development, and monitoring under this subsection. Contracts may be entered into under this subsection without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 14 U.S.C. 5).

(b) **DATA SYSTEMS.**—(1) The Administrator shall establish, administer, and be responsible for the continuing activities of an interagency committee which will design, establish, and coordinate an efficient and effective system, within the Environmental Protection Agency, for the collection, dissemination to other Federal departments and agencies, and use of data submitted to the Administrator under this Act.

(2) (A) The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare and other heads of appropriate departments and agencies design, establish, and coordinate an efficient and effective system for the retrieval of toxicological and other scientific data which could be useful to the Administrator in carrying out the purposes of this Act. Systematized retrieval shall be developed for use by all Federal and other departments and agencies with responsibilities in the area of regulation or study of chemical substances and mixtures and their effect on health or the environment.

(B) The Administrator, in consultation and cooperation with the Secretary of Health, Education, and Welfare may make grants and enter into contracts for the development of a data retrieval system described in subparagraph (A). Contracts may be entered into under this subparagraph without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5).

(c) **SCREENING TECHNIQUES.**—The Administrator shall coordinate, with the Assistant Secretary for Health of the Department of Health, Education, and Welfare, research undertaken by the Administrator and directed toward the development of rapid, reliable, and economical screening techniques for carcinogenic, mutagenic, teratogenic, and ecological effects of chemical substances and mixtures.

(d) **MONITORING.**—The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare, establish and be responsible for research aimed at the development, in cooperation with local, State, and Federal agencies, of monitoring techniques and instruments which may be used in the detection of toxic chemical substances and mixtures and which are reliable, economical, and capable of being implemented under a wide variety of conditions.

(e) **BASIC RESEARCH.**—The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare, establish research programs to develop the fundamental scientific basis of the screening and monitoring techniques described in subsections (c) and (d), the bounds of the reliability of such techniques, and the opportunities for their improvement.

(f) **TRAINING.**—The Administrator shall establish and promote programs and workshops to train or facilitate the training of Federal laboratory and technical personnel in existing or newly developed screening and monitoring techniques.

(g) **EXCHANGE OF RESEARCH AND DEVELOPMENT RESULTS.**—The Administrator shall, in consultation with the Secretary of Health, Education, and Welfare and other heads of appropriate departments and agencies, establish and coordinate a system for exchange among Federal, State, and local authorities of research and development results respecting toxic chemical substances and mixtures, including a system to facilitate and promote the development of standard data format and analysis and consistent testing procedures.

#### **SEC. 11. INSPECTIONS AND SUBPOENAS.**

**SEC. 11. (a) IN GENERAL.**—For purposes of administering this

(a) **IN GENERAL.**—For purposes of administering this Act, the Administrator, and any duly designated representative of the Administra-

tor may inspect any establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce and any conveyance being used to transport chemical substances, mixtures, 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 or mixtures 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 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.

#### SEC. 12. EXPORTS.

(a) **IN GENERAL.**—(1) Except as provided in paragraph (2) and subsection (b), this Act (other than section 8) shall not apply to any chemical substance, mixture, or to an article containing a chemical substance or mixture, if—

(A) it can be shown that such substance, mixture, or article is being manufactured, processed, or distributed in commerce for export from the United States, unless such substance, mixture, or article was, in fact, manufactured, processed, or distributed in commerce, for use in the United States, and

(B) such substance, mixture, or article (when distributed in commerce), or any container in which it is enclosed (when so

distributed), bears a stamp or label stating that such substance, mixture, or article is intended for export.

(2) Paragraph (1) shall not apply to any chemical substance, mixture, or article if the Administrator finds that the substance, mixture, or article will present an unreasonable risk of injury to health within the United States or to the environment of the United States. The Administrator may require, under section 4, testing of any chemical substance or mixture exempted from this Act by paragraph (1) for the purpose of determining whether or not such substance or mixture presents an unreasonable risk of injury to health within the United States or to the environment of the United States.

(b) **NOTICE.**—(1) If any person exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under section 4 or 5(b), such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of the availability of the data submitted to the Administrator under such section for such substance or mixture.

(2) If any person exports or intends to export to a foreign country a chemical substance or mixture for which an order has been issued under section 5 or a rule has been proposed or promulgated under section 5 or 6, or with respect to which an action is pending, or relief has been granted under section 5 or 7, such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of such rule, order, action, or relief.

#### SEC. 13. ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES.

(a) **IN GENERAL.**—(1) The Secretary of the Treasury shall refuse entry into the customs territory of the United States (as defined in general headnote 2 to the Tariff Schedules of the United States) of any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry if—

- (A) it fails to comply with any rule in effect under this Act, or
- (B) it is offered for entry in violation of section 5 or 6, a rule or order under section 5 or 6, or an order issued in a civil action brought under section 5 or 7.

(2) If a chemical substance, mixture, or article is refused entry under paragraph (1), the Secretary of the Treasury shall notify the consignee of such entry refusal, shall not release it to the consignee, and shall cause its disposal or storage (under such rules as the Secretary of the Treasury may prescribe) if it has not been exported by the consignee within 90 days from the date of receipt of notice of such refusal, except that the Secretary of the Treasury may, pending a review by the Administrator of the entry refusal, release to the consignee such substance, mixture, or article on execution of bond for the amount of the full invoice of such substance, mixture, or article (as such value is set forth in the customs entry), together with the duty thereon. On failure to return such substance, mixture, or article for any cause to the custody of the Secretary of the Treasury when demanded, such consignee shall be liable to the United States for liquidated damages equal to the full amount of such bond. All charges for storage, cartage, and labor on and for disposal of substances, mixtures,

or articles which are refused entry or release under this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future entry made by such owner or consignee.

(b) *RULES.*—The Secretary of the Treasury, after consultation with the Administrator, shall issue rules for the administration of subsection (a) of this section.

#### 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.

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 processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing 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.*—(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.

(2) (A) Except as provided by subparagraph (B), if the Administrator 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 submitting 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) 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 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 mis-

demeanor 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.

#### 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, or (C) any rule promulgated or order issued under section 5 or 6;

(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 an 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. 16. PENALTIES.

(a) CIVIL.—(1) Any person who violates a provision of section 15 shall be liable to the United States for a civil penalty in an amount not to exceed \$25,000 for each such violation. Each day such a violation continues shall, for purposes of this subsection, constitute a separate violation of section 15.

(2)(A) A civil penalty for a violation of section 15 shall be assessed by the Administrator by an order made on the record after opportunity (provided in accordance with this subparagraph) for a hearing in accordance with section 554 of title 5, United States Code. Before issuing such an order, the Administrator shall give written notice to the person to be assessed a civil penalty under such order of the Administrator's proposal to issue such order and provide such person an opportunity to request, within 15 days of the date the notice is received by such person, such a hearing on the order.

(B) In determining the amount of a civil penalty, the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Administrator may compromise, modify, or remit, with or without conditions, any civil penalty which may be imposed under this subsection. The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(3) Any person who requested in accordance with paragraph (2)(A) a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 30-day period beginning on the date the order making such assessment was issued.

(4) If any person fails to pay an assessment of a civil penalty—

(A) after the order making the assessment has become a final order and if such person does not file a petition for judicial review of the order in accordance with paragraph (3), or

(B) after a court in an action brought under paragraph (3) has entered a final judgment in favor of the Administrator, the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 30-day period referred to in paragraph (3) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(b) CRIMINAL.—Any person who knowingly or willfully violates any provision of section 15 shall, in addition to or in lieu of any civil penalty which may be imposed under subsection (a) of this section for such violation, be subject, upon conviction, to a fine of not more than \$25,000 for each day of violation, or to imprisonment for not more than one year, or both.

#### SEC. 17. SPECIFIC ENFORCEMENT AND SEIZURE.

(a) SPECIFIC ENFORCEMENT.—(1) The district courts of the United States shall have jurisdiction over civil actions to—

(A) restrain any violation of section 15,

(B) restrain any person from taking any action prohibited by section 5 or 6 or by a rule or order under section 5 or 6,

(C) compel the taking of any action required by or under this Act, or

(D) direct any manufacturer or processor of a chemical substance or mixture manufactured or processed in violation of section 5 or 6 or a rule or order under section 5 or 6 and distributed in commerce, (i) to give notice of such fact 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, (ii) to give public notice of such risk of injury, and (iii) to either replace or repurchase such substance or mixture, whichever the person to which the requirement is directed elects.

(2) A civil action described in paragraph (1) may be brought—

(A) in the case of a civil action described in subparagraph (A) of such paragraph, in the United States district court for the judicial

district wherein any act, omission, or transaction constituting a violation of section 15 occurred or wherein the defendant is found or transacts business, or

(B) in the case of any other civil action described in such paragraph, in the United States district court for the judicial district wherein the defendant is found or transacts business.

In any such civil action process may be served on a defendant in any judicial district in which a defendant resides or may be found. Subpoenas requiring attendance of witnesses in any such action may be served in any judicial district.

(b) SEIZURE.—Any chemical substance or mixture which was manufactured, processed, or distributed in commerce in violation of this Act or any rule promulgated or order issued under this Act or any article containing such a substance or mixture shall be liable to be proceeded against, by process of libel for the seizure and condemnation of such substance, mixture, or article, in any district court of the United States within the jurisdiction of which such substance, mixture, or article is found. Such proceedings shall conform as nearly as possible to proceedings in rem in admiralty.

#### 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 under section 4 the testing of a chemical substance or mixture, no State or political subdivision may, after the effective date of such rule, 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; 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 of processing of other substances of mixtures).

(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 associated 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.

#### SEC. 19. JUDICIAL REVIEW.

(a) IN GENERAL.—(1) (A) Not later than 60 days after the date of the promulgation of a rule under section 4(a), 5(a) (2), 5(b) (4), 6(a) 6(e), or 8, any person may file a petition for judicial review of such rule 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 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 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 being reviewed under this section;

(B) in the case of a rule 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;

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

(D) any written submission of interested parties respecting the promulgation of such rule; and

(E) any other information which the Administrator considers to be relevant to such rule and which the Administrator identi-

fed, on or before the date of the promulgation of such rule, 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 the petitioner or the Administrator applies to the court for leave to make additional oral submissions or written presentations respecting such rule 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 submissions 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 being reviewed or make a new rule by reason of the additional submissions and presentations and shall file such modified or new rule with the return of such submissions and presentations. The court shall thereafter review such new or modified rule.

(c) **STANDARD OF REVIEW.**—(1) (A) Upon the filing of a petition under subsection (a) (1) for judicial review of a rule, 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 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 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), 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 if the court finds that the rule is not supported by substantial evidence in the rulemaking record (as defined in subsection (a) (3)) taken as a whole;

(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) 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 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) **FEEES 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 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 order issued under section 5 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).

(b) PROCEDURE.—(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).

(2) The Administrator may hold a public hearing or may conduct such investigation or proceeding as the Administrator deems appropriate 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), 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)—

(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 at-

toneys 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.

#### NATIONAL DEFENSE WAIVER

SEC. 22. The Administrator shall waive compliance with any provision of this Act upon a request and determination by the President that the requested waiver is necessary in the interest of national defense. The Administrator shall maintain a written record of the basis upon which such waiver was granted and make such record available for in camera examination when relevant in a judicial proceeding under this Act. Upon the issuance of such a waiver, the Administrator shall publish in the Federal Register a notice that the waiver was granted for national defense purposes, unless, upon the request of the President, the Administrator determines to omit such publication because the publication itself would be contrary to the interests of national defense, in which event the Administrator shall submit notice thereof to the Armed Services Committees of the Senate and the House of Representatives.

#### EMPLOYEE PROTECTION

SEC. 23. (a) IN GENERAL.—No employer may discharge any employee or otherwise discriminate against any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee) has—

(1) commenced, caused to be commenced, or is about to commence or cause to be commenced a proceeding under this Act;

(2) testified or is about to testify in any such proceeding; or

(3) assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this Act.

(b) REMEDY.—(1) Any employee who believes that the employee has been discharged or otherwise discriminated against by any person in violation of subsection (a) of this section may, within 30 days after such alleged violation occurs, file (or have any person file on the employee's behalf) a complaint with the Secretary of Labor (hereinafter in this section referred to as the "Secretary") alleging such discharge or discrimination. Upon receipt of such a complaint, the Secretary shall notify the person named in the complaint of the filing of the complaint.

(2)(A) Upon receipt of a complaint filed under paragraph (1), the Secretary shall conduct an investigation of the violation alleged in the complaint. Within 30 days of the receipt of such complaint, the Secretary shall complete such investigation and shall notify in writing the complainant (and any person acting on behalf of the complainant) and the person alleged to have committed such violation of the results of the investigation conducted pursuant to this paragraph. Within ninety days of the receipt of such complaint the Secretary shall, unless the proceeding

on the complaint is terminated by the Secretary on the basis of a settlement entered into by the Secretary and the person alleged to have committed such violation, issue an order either providing the relief prescribed by subparagraph (B) or denying the complaint. An order of the Secretary shall be made on the record after notice and opportunity for agency hearing. The Secretary may not enter into a settlement terminating a proceeding on a complaint without the participation and consent of the complainant.

(B) If in response to a complaint filed under paragraph (1) the Secretary determines that a violation of subsection (a) of this section has occurred, the Secretary shall order (i) the person who committed such violation to take affirmative action to abate the violation, (ii) such person to reinstate the complainant to the complainant's former position together with the compensation (including back pay), terms, conditions, and privileges of the complainant's employment, (iii) compensatory damages, and (iv) where appropriate, exemplary damages. If such an order issued, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney's fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(c) REVIEW.—Any employee or employer adversely affected or aggrieved by an order issued under subsection (b) may obtain review of the order in the United States Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred. The petition for review must be filed within sixty days from the issuance of the Secretary's order. Review shall conform to chapter 7 of title 5 of the United States Code.

(2) An order of the Secretary, with respect to which review could have been obtained under paragraph (1), shall not be subject to judicial review in any criminal or other civil proceeding.

(d) ENFORCEMENT.—Whenever a person has failed to comply with an order issued under subsection (b)(2), the Secretary shall file a civil action in the United States district court for the district in which the violation was found to occur to enforce such order. In actions brought under this subsection, the district courts shall have jurisdiction to grant all appropriate relief, including injunctive relief and compensatory and exemplary damages. Civil actions brought under this subsection shall be heard and decided expeditiously.

(e) EXCLUSION.—Subsection (a) of this section shall not apply with respect to any employee who, acting without direction from the employee's employer (or any agent of the employer), deliberately causes a violation of any requirement of this Act.

#### EMPLOYMENT EFFECTS

SEC. 24. (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,

(ii) such hearings shall be held in accordance with section 6(c)(3), and

(iii) 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.

#### SEC. 25. STUDIES.

(a) *INDEMNIFICATION STUDY.*—The Administrator shall conduct a study of all Federal laws administered by the Administrator for the purpose of determining whether and under what conditions, if any, indemnification should be accorded any person as a result of any action taken by the Administrator under any such law. The study shall—

(1) include an estimate of the probable cost of any indemnification programs which may be recommended;

(2) include an examination of all viable means of financing the cost of any recommended indemnification; and

(3) be completed and submitted to Congress within two years from the effective date of enactment of this Act.

The General Accounting Office shall review the adequacy of the study submitted to Congress pursuant to paragraph (3) and shall report the results of its review to the Congress within six months of the date such study is submitted to Congress.

(b) *CLASSIFICATION, STORAGE, AND RETRIEVAL STUDY.*—The Council on Environmental Quality, in consultation with the Administrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate Federal departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical substances and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such substances. A report on such study shall be completed and submitted to Congress not later than 18 months after the effective date of enactment of this Act.

#### 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) *FEEES.*—(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 to defray the cost of administering this Act. 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. 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).

(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 nonpolicymaking 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 (A) be in addition to the Assistant Administrators of the Environmental Protection Agency authorized by section 1(d) of Reorganization Plan No. 3 of 1970, and (B) be compensated at the rate of pay authorized for such Assistant Administrators.

#### 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 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).

(c) ANNUAL REPORTS.—(1) The Secretary shall prepare and submit to the President and the Congress on or before January 1 of each year a report of the number of grants made and contracts entered into under this section and the results of such grants and contracts.

(2) The Secretary shall periodically publish in the Federal Register reports describing the progress and results of any contract entered into or grant made under this section.

**SEC. 28. STATE PROGRAMS.**

(a) *IN GENERAL.*—For the purpose of complementing (but not reducing) the authority of, or actions taken by, the Administrator under this Act, the Administrator may make grants to States for the establishment and operation of programs to prevent or eliminate unreasonable risks within the States to health or the environment which are associated with a chemical substance or mixture and with respect to which the Administrator is unable or is not likely to take action under this Act for their prevention or elimination. The amount of a grant under this subsection shall be determined by the Administrator, except that no grant for any State program may exceed 75 per centum of the establishment and operation costs (as determined by the Administrator) of such program during the period for which the grant is made.

(b) *APPROVAL BY ADMINISTRATOR.*—(1) No grant may be made under subsection (a) unless an application therefor is submitted to and approved by the Administrator. Such an application shall be submitted in such form and manner as the Administrator may require and shall—

(A) set forth the need of the applicant for a grant under subsection (a),

(B) identify the agency or agencies of the State which shall establish or operate, or both, the program for which the application is submitted,

(C) describe the actions proposed to be taken under such program,

(D) contain or be supported by assurances satisfactory to the Administrator that such program shall, to the extent feasible, be integrated with other programs of the applicant for environmental and public health protection,

(E) provide for the making of such reports and evaluations as the Administrator may require, and

(F) contain such other information as the Administrator may prescribe.

(2) The Administrator may approve an application submitted in accordance with paragraph (1) only if the applicant has established to the satisfaction of the Administrator a priority need, as determined under rules of the Administrator, for the grant for which the application has been submitted. Such rules shall take into consideration the seriousness of the health effects in a State which are associated with chemical substances or mixtures, including cancer, birth defects, and gene mutations, the extent of the exposure in a State of human beings and the environment to chemical substances and mixtures, and the extent to which chemical substances and mixtures are manufactured, processed, used, and disposed of in a State.

(c) *ANNUAL REPORTS.*—Not later than six months after the end of each of the fiscal years 1979, 1980, and 1981, the Administrator shall submit to the Congress a report respecting the programs assisted by grants under subsection (a) in the preceding fiscal year and the extent to which the Administrator has disseminated information respecting such programs.

(d) *AUTHORIZATION.*—For the purpose of making grants under subsection (a) there are authorized to be appropriated \$1,500,000 for the fiscal year ending September 30, 1977, \$1,500,000 for the fiscal year ending September 30, 1978, and \$1,500,000 for the fiscal year ending

September 30, 1979. Sums appropriated under this subsection shall remain available until expended.

**SEC. 29. AUTHORIZATION FOR APPROPRIATIONS.**

There are authorized to be appropriated to the Administrator for purposes of carrying out this Act (other than sections 27 and 28 and subsections (a) and (c) through (g) of section 10 thereof) \$10,100,000 for the fiscal year ending September 30, 1977, \$12,625,000 for the fiscal year ending September 30, 1978, \$16,200,000 for the fiscal year ending September 30, 1979. No part of the funds appropriated under this section may be used to construct any research laboratories.

**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, 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.

**SEC. 31. EFFECTIVE DATE.**

Except as provided in section 4(f), this Act shall take effect on January 1, 1977.

And the House agree to the same.

WARREN G. MAGNUSON,  
VANCE HARTKE,  
PHILIP A. HART,  
JOHN A. DURKIN,  
JOHN V. TUNNEY,  
HOWARD BAKER,  
TED STEVENS,

*Managers on the Part of the Senate.*

HARLEY O. STAGGERS,  
JOHN M. MURPHY,  
W. S. STUCKEY,  
BOB ECKHARDT,  
RALPH H. METCALFE,  
WILLIAM BRODHEAD,  
JAMES H. SCHEUER,  
SAMUEL L. DEVINE,  
JAMES T. BROYHILL,  
MATTHEW J. RINALDO,

*Managers on the Part of the House.*

## JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 3149) to regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes, submit the following joint statement to the House and the Senate in explanation of the effect of the action agreed upon by the managers and recommended in the accompanying conference report:

The House amendment struck out all of the Senate bill after the enacting clause and inserted a substitute text.

The Senate recedes from its disagreement to the amendment of the House with an amendment which is a substitute for the Senate bill and the House amendment. The differences between the Senate bill, the House amendment, and the substitute agreed to in conference are noted below, except for clerical corrections, conforming changes made necessary by agreements reached by the conferees, and minor drafting and clarifying changes.

### FINDINGS, POLICY, AND INTENT

#### *Senate bill (section 2)*

Section 2(a) outlines Congressional policy underlying the Toxic Substances Control Act. Congress finds that: human beings and the environment are exposed to numerous chemical substances and mixtures; some of these may cause or contribute to an unreasonable risk of injury to health or the environment; and the effective regulation of such substances and mixtures in interstate commerce necessitates regulation of intrastate commerce as well.

Subsection (b) sets forth that it is the policy of the United States that adequate data on the health and environmental effects of such chemical substances and mixtures should be developed. Such data development should be the responsibility of those who manufacture and process such chemical substances and mixtures. Adequate authority should exist to regulate chemical substances and mixtures, but the exercise of such authority should not unduly impede technological innovation.

Subsection (c) contains a declaration of Congressional intent as to how the Administrator shall fulfill the responsibilities under this Act. The Administrator shall carry out this Act in a reasonable and prudent manner and consider the environmental, economic, and social impact of any action taken or proposed under this Act.

#### *House amendment (section 2)*

The House amendment is nearly identical to the Senate bill. However, the House amendment confines its data development man-

date to hazardous or potentially hazardous substances and mixtures, in contrast to the broader mandate contained in the Senate bill.

*Conference substitute (section 2)*

The conference substitute follows the Senate provision. Adequate data should be developed concerning the health and environmental effects of chemical substances and mixtures. Such data development should be the responsibility of those who manufacture or process such substances and mixtures. Adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment and to take action with respect to chemical substances and mixtures which are imminent hazards.

DEFINITIONS

*Senate bill (section 3)*

The Senate bill includes definitions for the Act, the principal ones of which are as follows:

1. Chemical substance is defined as (i) any organic or inorganic substance of a particular molecular identity including a combination of such substances occurring as a result of a chemical reaction, or (ii) any element or uncombined radical. The term specifically excludes any mixture; any pesticide; tobacco and tobacco products; special nuclear materials or by-product materials as defined in the Atomic Energy Act of 1954; articles which if sold would be subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (i.e., pistols, firearms, revolvers, shells and cartridges); any substance found in or on any food, drug, cosmetic or device and any substance produced for research and development purposes intended only for use in or on any food, drug cosmetic or device.

2. The term "environment" includes human beings and their environment, water, atmosphere, and land and the interrelationships which exist among and between these.

3. "Manufacture" means to import, produce, or manufacture for commercial purposes.

4. The term "mixture" means any combination of two or more chemical substances if such substances do not react chemically with each other and if the combination is not a result of the chemical reaction. Mixture also includes combinations of substances which occur in nature.

The Senate bill authorizes the Administrator to exclude from coverage of the Act any chemical substance or mixture if the Administrator determines, by rule, that the substance or mixture does not present an unreasonable risk of injury to health or the environment. However, the exclusion shall not apply to section 7 or section 8(e) of the Senate bill.

*House amendment (section 3)*

1. The House definition of "chemical substance" is similar to that of the Senate bill, except that the term includes organic or inorganic substances or combinations of such substances occurring in nature. The exclusions from the definition of chemical substances are similar to the Senate bill, although the House amendment specifically excludes food additives along with foods, drugs, cosmetics, and devices.

2. The House amendment defines "environment" to include water, air and land, and the interrelationships which exist among and between water, air and land, and all living things.

3. The House amendment, like the Senate bill, defines manufacture to mean import, produce, or manufacture, but the definition is not limited to such activities done for commercial purposes.

4. The term "mixture" is defined to mean 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. However, certain reaction-produced combinations are included in the term "mixture" in order to prevent disparate treatment of identical combinations simply because of the number of steps used in the manufacture of the combination. If each of the chemical substances comprising the combination is not a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction occurring at the time the substances comprising the combination were combined, then the combination is included within the term "mixture".

The House bill does not contain general authority for the Administrator to exclude any chemical substance or mixture from the provisions of the bill. However, section 5(i)(5) of the House amendment authorizes the Administrator to exclude any chemical substance from the notification requirements of section 5 if the Administrator determines, by rule, that the substance will not cause or significantly contribute to an unreasonable risk to health or the environment.

*Conference substitute (section 3)*

The conference substitute adopts the definitions contained in the House amendment.

The conferees recognize that virtually no chemical substance exists in a completely pure state and intend that any reference to a chemical substance includes all impurities and concomitant products, including incidental reaction products, contaminants, co-products, and trace materials. Thus the definition of term "chemical substance" shall be applied to chemical substances as actually produced and marketed. For example, when the Administrator promulgates a rule under section 6(a) to regulate a particular substance, such rule will apply to the identified substance, including all the impurities and other concomitant products, without explicitly identifying such impurities and concomitant products within the rule.

It is expected that the Administrator will develop guidelines for the purpose of clarifying the extent to which impurities and concomitant products will be included within a reference to "chemical substance" as it relates to the various provisions of the Act. While impurities and concomitant products are included within references to a "chemical substance" under the Act, the Administrator is obviously authorized to move against them separately under the applicable provisions of the Act.

TESTING OF CHEMICAL SUBSTANCES AND MIXTURES

The term "health and safety study" is important as it describes information to which various provisions of the Act are applicable. For

example, section 8(d) requires manufacturers, processors, and distributors in commerce to list such studies with the Administrator. Moreover, section 14(b) contains provisions concerning the availability of health and safety studies to the public.

The conference substitute defines health and safety study to mean any study of any effect of a chemical substance or mixture on health or the environment, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, chemical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act.

It is intended that the term be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included but other information relating to the effects of a chemical substance or mixture on health and the environment is also included. Any data which bears on the effects of a chemical substance on health or the environment would be included.

WARREN G. MAGUNSON,  
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JAMES T. BROYHILL,  
MATTHEW J. RINALDO,

*Managers on the Part of the House.*

*Senate bill (section 4)*

Section 4 authorizes the Administrator to require testing of chemical substances and mixtures to ascertain potential effects on human health and the environment. Under subsection (a), the Administrator must, by rule, require the testing of a chemical substance or mixture if the Administrator finds (1) that the chemical substance or mixture may present an unreasonable risk of injury to health or the environment, or that there may be significant human or environmental exposure because substantial quantities will be produced and such substance or mixture may perhaps present an adverse effect on health or the environment; (2) there are insufficient data or experience to reasonably determine or predict its health and environmental effects; and (3) testing is necessary to develop such data. If no reliable data is available to the Administrator, the finding that such substance or mixture may perhaps present an adverse effect on health or the environment shall be presumed. In the case of a mixture, the bill requires an

additional finding that testing the chemical substances which comprise the mixture is not a more efficient and reasonable method to determine effects on health and the environment. When requiring tests under subsection (a), the Administrator shall consider reasonably ascertainable costs and other burdens associated with conducting tests and publish such considerations in the Federal Register.

Subsection (b) sets forth the required contents of the testing rule and provides an illustrative list of health and environmental effects for which test standards may be required. This subsection also describes some of the methodologies which the testing rule may prescribe. In addition, it describes which manufacturers and processors will be required to conduct the testing.

The Administrator shall review and, if appropriate, revise the standards for development of data at least once per year. Testing rules shall be issued in accordance with the rulemaking procedures of section 553, of title 5, United States Code, except that the Administrator shall allow interested persons the opportunity to make oral presentations of data, views, or arguments in addition to written submissions. A transcript of such oral presentations is required.

Subsection (c) provides a procedure whereby persons may apply to the Administrator for an exemption from a testing requirement rule in order to avoid submission of duplicative data. If an exemption is granted, a cost-sharing procedure is provided. A person providing reimbursement may have access to test data, subject to the confidentiality provisions of section 14.

Subsection (d) requires the Administrator to publish a notice of receipt of test data in the Federal Register and to make the data available to the public within 15 days of receipt.

Subsection (e) establishes an interagency advisory committee comprised of qualified and appropriate Federal officials to make recommendations to the Administrator regarding testing priorities.

The committee shall submit a list of chemical substances and mixtures in the order in which the committee determines the Administrator should promulgate testing rules under subsection (a). Within 12 months after the inclusion of a chemical on such list, the Administrator shall either initiate a rulemaking proceeding under subsection (a) or publish reasons for not initiating a proceeding in the Federal Register. Subsection (e) also contains specific conflict of interest provisions applicable to members of the interagency advisory committee.

Subsection (f) specifies required actions by the Administrator in response to test data or other information which indicate that a substance or mixture has a potential to induce cancer, gene mutations, or birth defects at levels for which human exposure exists or may exist with appropriate safety margins. The Administrator shall either take appropriate action under section 5(e), 6(a), or 7 within 180 days after the date of receipt of such data or information or publish in the Federal Register a finding that no unreasonable risk of injury is presented and reasons for making such a finding. Such requirement shall not take effect until two years after enactment.

*House amendment (section 4)*

Like the Senate bill, the House amendment requires that the Administrator find that there are insufficient data and experience upon which

to determine or predict the effects of the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture. It also requires a finding that testing of the substance or mixture is necessary to develop such data. However, the House bill differs from the Senate bill in that it requires a finding that a chemical substance or mixture may "cause or significantly contribute" to an unreasonable risk, whereas the Senate bill requires a finding that the substance or mixture may "present" an unreasonable risk.

Section 4(a)(1)(B) of the House amendment sets forth a second set of conditions under which the Administrator shall require testing. If the Administrator finds (1)(A) that a chemical substance or mixture is or will be produced in substantial quantities; and (B)(i) either that 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 the substance or mixture, (2) there is an insufficiency of data, and (3) testing is necessary to develop the data, the Administrator shall, by rule, require testing.

The House amendment requires the Administrator to consult with the Director of the National Institute for Occupational Safety and Health before prescribing epidemiologic studies under the testing requirement rule. The House bill requires the Administrator to make and publish findings under subsection (a)(1)(A) or (a)(1)(B) before the issuance of a rule ordering persons to conduct tests. The House amendment also provides for the expiration of a testing requirement rule at the end of the reimbursement period.

The House amendment provides for exceptions from the testing rule in order to avoid submission of duplicative data. If an exemption is granted, reimbursement requirements similar to those in the Senate bill apply, except that the reimbursement period may last as long as five years, instead of the two-year period in the Senate bill. In promulgating rules to use in determining fair and equitable reimbursement, the House amendment does not require the Administrator to consult with the Attorney General and the Federal Trade Commission.

With respect to the interagency committee's priority list submitted to the Administrator, the House amendment does not require the Administrator either to initiate a rulemaking proceeding or to publish in the Federal Register the Administrator's reasons for not initiating such a proceeding. The House amendment does not include the conflict of interest provisions found in the Senate bill relating to members of the interagency advisory committee.

#### *Conference substitute (section 4)*

The conference substitute is similar to the House amendment with respect to the findings which the Administrator must make in order to require a manufacturer or processor to test a chemical substance or mixture, except that the term "presents" is used in lieu of "cause or significantly contribute to". The conference substitute includes this term throughout the bill when speaking of a risk.

In using the term, the conferees intend that the Administrator be able to address substances and mixtures which indirectly present unreasonable risks, as well as those which directly present such risks. Further, the conferees do not intend that a substance or mixture must be the single factor which results in the presentation of the risk.

Often times an unreasonable risk will be presented because of the interrelationship or cumulative impact of a number of different substances or mixtures. The conferees intend that the Administrator have authority to protect health and the environment in such situations.

In following the House language, the conference substitute requires testing not only (1) in situations in which a substance or mixture may present an unreasonable risk, but also (2) in situations in which there may be substantial environmental or significant or substantial human exposure to a substance or mixture about which there is inadequate information to predict effects on health or the environment.

In the first situation, the conferees intend to focus the Administrator's attention on those chemical substances and mixtures about which there is a basis for concern, but about which there is inadequate information to reasonably predict or determine their effects on health or the environment. The Administrator need not show that the substance or mixture does or will present a risk.

The second situation reflects the conferees' recognition that there are certain situations in which testing should be conducted even though there is an absence of information indicating that the substance or mixture *per se* may be hazardous.

The conference substitute follows the House amendment with respect to the contents of the testing rule. The Senate provision concerning which manufacturers and processors are required to conduct the testing and submit test data is included. Like both the Senate bill and the House amendment, the conference substitute permits the Administrator to grant exemptions from a testing rule. To grant an exemption, the Administrator must determine whether the chemical substance or mixture is equivalent to a chemical substance or mixture for which test data is already being developed. In making this determination the conferees expect the Administrator to look at any contaminants in the chemical substance or mixture for which an exemption is being sought and ascertain whether any contaminants present might cause differences in test data which would be significant and which would, therefore, cause the Administrator to determine that the chemical substances or mixtures in that instance were not equivalent. It also follows the House amendment concerning reimbursement, except that the Administrator must consult with the Attorney General and the Federal Trade Commission in issuing rules which establish the general criteria for determining reimbursement.

The conference substitute retains a modified version of the Senate provision on the interagency committee which is established to make recommendations concerning testing priorities to the Administrator.

The Administrator shall provide administrative services to support such activities. These services shall encompass such things as clerical staff assistance and supplies. The conferees recognize the importance of the interagency committee recommendations and expect the interagency committee to deliberate with care; therefore, the conferees intend that members of the interagency committee shall be given adequate support services by EPA. They also shall be relieved of responsibilities within the entity they represent to the extent necessary to carry out their duties to the committee. Each entity represented shall provide its member with professional and research services. Here,

as in all places in the bill where specific officers of the Federal Government are referred to by title, the conferees intend that such references be construed to mean successors to such offices as affected by any reorganization plan or the like.

The interagency committee may designate a maximum of 50 substances or mixtures with respect to which the Administrator should initiate a testing rulemaking proceeding within a year. No more than 50 substances or mixtures may be so designated at any one time. If the Administrator does not take such action within a year, the Administrator must publish in the Federal Register an explanation as to why such action has not been taken.

The conferees have given discretion to the interagency committee as to how many substances or mixtures should be designated. Although the committee may designate up to 50 substances or mixtures at any one time, the conferees wish to stress that the committee need not designate the maximum number. While it is intended that the recommendations of the interagency committee be given great weight by the Administrator, it should be emphasized that the decision to require testing rests with the Administrator.

The conferees do not intend that, in complying with the requirements of the statute, the Administrator divert from the regulatory activities of the Agency an inordinate amount of resources to justify the failure to require testing.

If the Administrator receives information which indicates to the Administrator that there may be a reasonable basis to conclude that a 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 initiate appropriate action under section 5, 6, or 7 to protect against the risk or publish in the Federal Register a finding that the risk is not unreasonable. Such action must be taken within 180 days of the receipt of the data, except that the Administrator may extend that period for an additional 90 days for good cause. This requirement does not take effect until two years after the date of enactment.

The conference substitute adopts a provision contained in the House amendment which enables any person who intends to manufacture or process a chemical substance which is not subject to a rule under section 4(a) to petition the Administrator to prescribe standards for the development of test data for such substance. The Administrator must grant or deny the petition within sixty days. If the petition is granted, the Administrator shall prescribe such standards within seventy-five days of the date on which the petition is granted. Any denial of such a petition must be published in the Federal Register.

#### MANUFACTURING AND PROCESSING NOTICES

##### *Senate bill (section 5)*

The Senate bill requires any manufacturer of a new chemical substance to notify the Administrator at least ninety days prior to the commencement of commercial manufacture of the new substance. The notice is to include the common and the trade name of the substance, its chemical identity and molecular structure, categories or proposed cate-

gories of use, reasonable estimates of the amount to be manufactured or processed, a description of the by-products, estimates of the number of people who will be exposed to the substance in their places of employment, and existing data concerning environmental and health effects of the substance.

In addition, if a testing rule applicable to the substance is in effect prior to submission of the notice, the manufacturer is required to submit along with the notification, the test data required to be developed by the testing rule.

The ninety day notification period may be extended by the Administrator for an additional ninety days for good cause shown. Notice of such extension must be published in the Federal Register.

Similar notification is required of any person intending to manufacture or process a chemical substance for a distribution in commerce, use, or disposal that has been identified by the Administrator, by rule, as a significant new use, distribution, or disposal. The Administrator is, by rule, to establish criteria defining a significant new distribution in commerce, use, or disposal. In establishing such criteria, the Administrator is to take into account the projected volume of production and category or categories of uses, increases in magnitude and duration of human or environmental exposure, routes of exposure, and the human health and environmental effects.

The Senate bill authorizes the Administrator to issue immediately effective administrative orders during the notification period to halt or limit the manufacture, processing, distribution in commerce, use or disposal of new chemical substances subject to the notification requirements in two situations.

First, the Administrator is required to issue such an order if the Administrator finds that a testing requirement under section 4(a) should be established or modified. The order is to remain in effect until an expedited rulemaking proceeding under section 4(a) to require testing can be completed, the testing performed and the test data submitted. Second, if the Administrator finds that a new substance presents or is likely to present an unreasonable risk of injury to health or the environment, the Administrator is also required to issue an immediately effective order. If such an order is issued, the Administrator must conduct an expedited rulemaking proceeding in accordance with the provisions of section 6(c) (2) and (3).

If the Administrator does not take action to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of a new substance during the notification period, the Administrator is required to publish a statement of reasons in the Federal Register for not taking such action. The statement must be published prior to the expiration of the notification period. Manufacture or processing of the new substance may commence following publication of the Administrator's statement. Failure to take action against a substance is an action subject to judicial review.

The Senate bill provides certain exemptions from the requirement to submit manufacturing and processing notice. The Administrator is authorized to grant such an exemption for test marketing or other specially limited purposes. In addition, the Administrator may exempt chemical substances which are intermediate reaction products



formed during the manufacture of another chemical substance and to which there is no human or environmental exposure. In addition, the notification provisions of the Senate bill do not apply to any chemical substance manufactured in small quantities solely for scientific experimentation or analysis or for chemical research or analysis, including such research or analysis for the development of a product. However, the Administrator may, by rule, require notification prior to the manufacture or processing of such a substance upon a finding that the substance may cause or contribute to an unreasonable risk of injury to health or the environment. Although the section, by its terms, does not apply to mixtures, the Administrator is authorized to specify any mixture which shall be subject to the provisions of the section.

*House amendment (section 5)*

Like the Senate bill, the House amendment requires manufacturers of new chemical substance to notify the Administrator ninety days prior to the commencement of commercial manufacture of such new substance. The notice is to include information similar to that required by the Senate bill, including test data required to be developed by any applicable testing rule which has been promulgated under section 4 prior to the submission of the notice.

In addition, the House amendment requires the Administrator to compile and maintain a list of chemical substances which cause or significantly contribute to or may cause or significantly contribute to an unreasonable risk to health or the environment. If a person intends to manufacture a new chemical substance included on this list and if no testing rule applicable to the substance has been issued under section 4, the person must submit to the Administrator information which the person believes indicates that the chemical substance will not cause or significantly contribute to an unreasonable risk. Such information must be submitted along with the notice.

The House amendment also requires manufacturers or processors of an existing chemical substance for a new use which has been designated by the Administrator, by rule, as a significant new use, to provide similar notice ninety days prior to such manufacture or processing. The House amendment does not require notification prior to the manufacture or processing of a chemical substance for a significant new distribution in commerce or disposal.

In instances in which there is inadequate information to evaluate the effects of a new substance or of an existing substance for a significant new use, the Administrator is authorized to seek a court injunction to halt manufacture, processing or distribution in commerce. The Federal district courts are empowered to grant injunctions if the court finds that (1) there is inadequate information to reasonably evaluate the health and environmental effects of the new substance and (2) in the absence of such information, the substance may cause or significantly contribute to an unreasonable risk. If an injunction is granted, the Administrator shall conduct an expedited rulemaking proceeding to determine if a lesser restriction (rather than a total halt of manufacture, processing or distribution) would be adequate to protect health or the environment until adequate test data is developed and evaluated.

The House amendment does not require the Administrator to publish a statement of reasons for not taking action during the notification period to prohibit or limit the manufacture, processing, distribution, use or disposal of a new substance or of an existing substance manufactured or processed for a significant new use.

The House amendment also provides for exemptions from the notification requirements. The Administrator is authorized to provide an exemption for the manufacture and processing of a substance for test marketing purposes. The House bill specifically exempts from the notification requirements those chemical substances manufactured or processed in small quantities for scientific experimentation or analysis or for chemical research or analysis on such substance or another substance, including research and analysis for the development of a substance or another substance into a commercial product. However, all persons engaged in such experimentation, research or analysis for a manufacturer or processor must be notified of any risk to health which the manufacturer or processor has reason to believe may be associated with the substance.

The House amendment authorizes the Administrator, by rule, to exempt a manufacturer or processor of any new chemical substance from all or part of the requirements of this section if the Administrator determines that such chemical substance will not cause or significantly contribute to an unreasonable risk to health or the environment. The House amendment also contains an exemption clarifying that a chemical substance which, except for its inert ingredients, is identical to a chemical substance contained on the section 8(b) inventory will not be treated as a new chemical substance.

The House amendment does not authorize the Administrator to specify that a manufacturer of a mixture shall be subject to the notification requirements.

*Conference substitute (section 5)*

*In general.*—Section 5 sets out the notification requirements with which manufacturers of new chemical substances and manufacturers and processors of existing substances for significant new uses must comply. The requirements are intended to provide the Administrator with an opportunity to review and evaluate information with respect to the substance to determine if manufacture, processing, distribution in commerce, use or disposal should be limited, delayed or prohibited because data is insufficient to evaluate the health and environmental effects or because the substance or the new use presents or will present an unreasonable risk of injury to health or the environment.

The provisions of the section reflect the conferees recognition that the most desirable time to determine the health and environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs before commercial production begins. Not only is human and environmental harm avoided or alleviated, but the cost of any regulatory action in terms of loss of jobs and capital investment is minimized. For these reasons the conferees have given the Administrator broad authority to act during the notification period.

Any person who intends to manufacture a new chemical substance or manufacture or process a chemical substance for a use which the Administrator, by rule, has determined is a significant new use, must

give the Administrator at least 90 days notice before beginning such manufacture or processing. The 90-day period shall begin upon receipt of the notice by the Administrator or the Administrator's duly designated representative.

The conferees have not included the Senate provision which requires notification of significant new distributions or disposals. However, the conference substitute requires that the Administrator consider the reasonably anticipated manner and method of manufacturing, processing, distribution in commerce and disposal of a substance in determining when a use will be considered a significant new use. Thus, the conferees intend that any potential threats to health or the environment from the manufacture, processing, distribution in commerce, or disposal of a substance associated with a new use be considered by the Administrator when determining the significance of a new use. In addition, the Administrator shall consider the projected volume of manufacturing and processing of the substance for a use, the extent to which a use changes the type or form of exposure of human beings or the environment to a substance, and the extent to which such use increases the magnitude and duration of human or environmental exposure to a substance. Thus, a significant increase in the projected volume of manufacture or processing for a substance, a significant change in the type or form of human or environmental exposure, or a significant increase in the magnitude or duration of human or environmental exposure could be the basis for determining that a use is a significant new use.

*Submission of test data.*—Subsection (b) describes the instances in which a person subject to a notification requirement with respect to a chemical substance under subsection (a) must submit test data to the Administrator before manufacture of the substance or manufacture or processing of the substance for a significant new use can begin. If a rule under section 4 respecting a substance has been promulgated before submission of the notice required by subsection (a), then a person who is required by the section 4 rule to submit test data for the substance must submit such test data at the time the notice is submitted in accordance with subsection (a). This assures that the Administrator will have at least 90 days to evaluate the test data before the manufacture or processing begins. If a person has been granted an exemption from a testing rule under section 4 applicable to a new substance or to a significant new use of an existing substance, such person shall not begin manufacture or processing until 90 days after the date of submission of the test data on which the exemption is based.

It should be noted that if a testing rule under section 4 respecting a substance has not been promulgated prior to the submission of a notice required by section 5, the Administrator may promulgate a testing rule under section 4 for such substance without taking separate action under this section. However, such a rule would not delay the manufacture or processing of the substance.

The conferees adopted a provision from the House bill to insure that information respecting the health and environmental effects of any chemical substance which the Administrator has identified as a suspect chemical substance is submitted at the time of notification. Under

the conference substitute the Administrator may, by rule, compile a list of chemical substances the manufacture, processing, distribution in commerce, use or disposal of which presents or may present an unreasonable risk of injury to health or environment. If a testing rule under section 4 has not been promulgated with respect to such substance before the submission of the notice, then the person submitting the notice must submit to the Administrator data which the person believes shows the manufacture, processing, distribution in commerce, use and disposal of the substance or any combination of such activities will not present an unreasonable risk to health or the environment.

*Extension of notice period.*—The Administrator, for good cause, may extend the 90 day notification period for additional periods not to exceed in the aggregate 90 days. Notice of any extension together with the reasons for it shall be published in the Federal Register and shall constitute final agency action subject to judicial review.

The conferees intend that the Administrator have a large degree of flexibility in extending the notification period, so that manufacture or processing may begin as soon as the Administrator has sufficient information to evaluate the substance. For example, if the Administrator expects that sufficient data will be available 30 days after the original notification period will expire, then the conferees expect that the Administrator will settle on an extension period which will reasonably accommodate production of that data and time for administrative consideration. If production of the data is delayed, of course the Administrator may extend the original extension period. However, in no case may the extensions exceed a total of 90 days. Every time that the notification period is extended, the Administrator must publish notice of the extension in the Federal Register along with reasons therefor.

*Content of notice; publications in the Federal Register.*—The conference substitute requires the notice required under subsection (a) to include certain information described in section 8(a) (Reporting and Retention of Information) whether or not the Administrator has required its submission under that section; any test data in the possession or control of the person giving the notice which is related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use or disposal of the substance; and a description of any other data concerning the health and environmental effects of the substance, insofar as known to the person making the report or insofar as reasonably ascertainable. The notice shall be made available, subject to section 14, for examination by interested persons.

In order that the public receive timely notification of any new chemical substance or any significant new use of an existing chemical substance, the conference substitute includes a provision which requires the Administrator to publish in the Federal Register a notice which identifies the chemical substance, lists the uses or intended uses of the substance, and describes the nature of tests performed on such substance and any data developed pursuant to subsection (b) or a rule under section 4. Such publication must occur within 5 days after the Administrator receives notice from the person who intends to manufacture or process.

The conference substitute also requires the Administrator to publish monthly a list of each chemical substance for which notice has been

received under subsection (a) and for which the notification period has not expired. The Administrator must also include on the list those substances for which the notification period has expired since the last monthly publication.

*Regulation pending development of information.*—Subsection (e) sets out the procedures under which the Administrator can halt or limit the manufacture, processing, distribution in commerce, use, or disposal of a new substance or an existing substance for a significant new use when there is insufficient information to evaluate the health and environmental effects of the substance.

Action to prohibit or limit manufacture, processing, distribution in commerce, use, or disposal is required in instances in which the Administrator determines that:

(1) Information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the substance, and

(2) (a). In the absence of information sufficient to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of the substance may present an unreasonable risk of injury to health or the environment, or

(b). The substance is or will be produced in substantial quantities, and (i) 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 the substance.

If the Administrator makes the above determination at least 45 days before the expiration of the notification period, then the Administrator may issue a proposed order to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of the substance. A limitation on manufacture or processing could, of course, include a labeling requirement. The proposed order will take effect upon the expiration of the notification period unless the manufacturer or processor subject to the order files objections with the Administrator, specifying with particularity the provision of the order deemed objectionable and stating the grounds for the objection. To prevent the order from becoming effective, the objections must be filed within 30 days after the manufacturer or processor has received in writing from the Administrator a notice of the proposed order. The conferees wish to stress that the Administrator must provide actual notice in writing to the manufacturer or processor who will be subject to the order. Notice is not to be published in the Federal Register, but is, of course, available to the public if it is not prohibited from disclosure under section 14.

This provision thus represents a melding of the Senate bill and the House amendment. In order to insure that timely action may be taken by the Administrator, the conference substitute authorizes the Administrator to issue an administrative order to take effect immediately upon the expiration of the notification period. However, to protect against unilateral action by the administrator without an adequate basis for action, the conference substitute borrows the procedure from section 701(e) of the Federal Food, Drug, and Cosmetic Act which permits the filing of objections by manufacturers and processors spe-

cifying with particularity the provisions of the order deemed objectionable and stating the grounds for the objections.

If such objections are filed, then the Administrator is instructed to seek an injunction in a Federal district court to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of the substance. Of course, if the objections filed with the Administrator indicate to the Administrator that the injunction is not necessary, then the Administrator is not required to seek the injunction.

If the court finds in such injunction action that (1) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the substance, and (2) (A) in the absence of such information, the manufacture, processing, distribution in commerce, use, or disposal of the substance may present an unreasonable risk of injury to health or the environment or (B) such 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 the substance, then the court shall grant an injunction. The conferees intend that this two-part standard totally supplant the traditional elements which a party must ordinarily show before a court will exercise its equitable jurisdiction to grant an injunction. The conferees do not intend that the Administrator be required to make any showing other than that which is required for the court to make the two findings described above. Application of any other standard by the court would frustrate the purposes of this section that suspect chemicals be adequately tested to determine their health and environmental effects before commercial manufacture or processing begins.

The conference substitute authorizes such courts to grant a temporary restraining order or a preliminary injunction to prohibit manufacture, processing or distribution of a new substance or of an existing substance for a significant new use if the court finds that the notification period may expire before the action for an injunction can be completed. The conferees recognize that a manufacturer or processor, merely by beginning to manufacture, process, or distribute a new chemical or an existing chemical for a significant new use, could defeat the objective of section 5 to totally prevent environmental or human exposure to suspect new chemical substances or significant new uses of existing chemical substances until adequate testing can be performed and the data evaluated. Therefore, the conferees intend that the court freely exercise the authority to grant preliminary relief as is necessary to preserve the status quo in order to insure that the policy of this section can be fulfilled.

After submission of adequate test data to the Administrator and evaluation of such data, the district courts may, upon petition, dissolve the injunction unless the Administrator has initiated a proceeding under section 6(a) with respect to the substance. In such a situation, the injunction shall remain in effect until the effective date of a rule under section 6(a) or until the section 6 proceeding is terminated, whichever occurs first.

*Protection against unreasonable risk.*—Section 5(f) of the conference substitute requires the Administrator to take immediate action

to prohibit or limit human or environmental exposure to a new chemical substance or to an existing chemical substance for a significant new use in certain situations. In section 5(f) the conference substitute authorizes the Administrator to issue a proposed rule under section 6(a), but such rule is to be effective upon its publication in the Federal Register. Such action is authorized in instances in which there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the substance presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 6(a) could protect against the risk. The conferees recognize, of course, that there is authority in section 6(d) under which the Administrator may make a proposed section 6(a) rule immediately effective. However, to invoke the section 6(d) authority the Administrator must find an imminent, unreasonable risk of serious or widespread injury. With respect to new chemical substances or substances for significant new uses, immediate action is authorized under section 5(f) when there is an imminent, unreasonable risk of injury, regardless of whether the injury will be serious or widespread.

The section 6(a) rule proposed and made immediately effective pursuant to the authority of this section may (A) limit the amount of a substance which may be manufactured, processed, or distributed in commerce, (B) contain any of the requirements described in paragraph (2), (3), (4), (5), (6), or (7) of subsection 6(a), or (C) contain any combination of the requirements described in clauses (A) and (B). Immediately following the publication in the Federal Register of a section 6(a) rule as authorized by this section, the Administrator must conduct an expedited rulemaking proceeding in accordance with the provisions of section 6(d) (2).

A rule under section 6(a) authorized by this section may not totally prohibit the manufacture, processing, or distribution in commerce of a new substance or an existing substance for a significant new use. In order to totally prohibit the manufacture, processing, or distribution in commerce of a new substance, or of an existing substance for a significant new use, the Administrator must either issue a proposed order which shall be subject to all the procedures applicable to the situation when there is an insufficiency of information, as described above, or obtain a court injunction. If the court finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use or disposal of a new substance or of an existing substance for a significant new use presents or will present an unreasonable risk of injury to health or the environment, the court shall issue an injunction. Again, the conferees intend that the court will not use the normal equity standard to determine if an injunction should be issued. Instead, the standard set out in section 5(f) (3) (B) of the conference substitute is intended to totally replace the normal injunction standard.

The conferees recognize that there will be instances in which there are a limited number of practical uses for a chemical substance and that by issuing an immediately effective proposed rule prohibiting those uses, the Administrator could effectively prohibit manufacture or processing altogether. The conferees view such a prohibition as a

total prohibition of manufacture or processing and intend that the Administrator comply with the procedures of section 5 (f) (3) in order to obtain a total prohibition on manufacture or processing. The authority to issue an immediately effective rule to prohibit manufacture or processing for a use should be utilized only when there is more than one practical use of a substance and when the prohibition does not effectively ban all such uses. Likewise, the conferees do not intend that the Administrator utilize the authority to issue an immediately effective proposed rule so severely limiting the amount of a substance which may be manufactured, processed, or distributed in commerce as to effectively prohibit manufacture, processing, or distribution.

*Statement of reasons for not taking action.*—If, within the notification period, the Administrator has not initiated action under this section or section 6 or 7 to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of certain new chemical substances or of existing chemical substances for significant new uses, then subsection (g) requires the Administrator to issue a statement of reasons in the Federal Register for not initiating such action. The statement must be published prior to the expiration of the notification period. The chemical substances for which such a statement is required are those for which the Administrator, because of prior administrative action with respect to such chemical substances, has indicated there may be particular cause for concern. Specifically, a statement of reasons for not initiating action is required if a testing rule under section 4 applies to a new substance or an existing substance for a significant new use, or if a substance is listed under section 5(b) (4). In addition, if notification is required because a use constitutes a significant new use and, if no action is initiated during the notification period, the Administrator must issue a statement of reasons for not initiating such action.

Publication of the statement of reasons in accordance with this subsection is not a prerequisite to the manufacture or processing of the substance with respect to which the statement is to be published. Thus, the Administrator, merely by not issuing the statement of reasons, cannot delay the beginning of manufacture or processing of a new substance or a substance for a significant new use. Nonetheless, the Administrator must perform this non-discretionary duty and will subject himself not only to criticism by the Congress for not doing so, but may also subject himself to suit under section 20 of this Act or other provisions of law relating to the required performance of non-discretionary duties.

*Exemptions.*—Subsection (h) describes the situations in which a chemical substance may be manufactured or processed without regard to the notice and test data submission requirements of subsections (a) and (b). Paragraph (1) provides the authority for granting an exemption for test marketing purposes. Under paragraph (2) an exemption from the test data submission requirements of subsection (b) may be obtained if submission of data for the substance to be exempted would be duplicative of data already submitted to the Administrator. Paragraph (3) adopts the language in the House amendment specifically exempting from the notification requirements those chemical substances manufactured or processed or proposed to be manufactured or processed in small quantities (as defined by the

Administrator by rule) for scientific experimentation or analysis or for chemical research or analysis, including research and analysis for the development of the substance or another chemical substance into a commercial product. All persons engaged in such experimentation, research, or analysis for a manufacturer or processor must be notified or any risk to health which the manufacturer or processor or Administrator has reason to believe may be associated with the substance.

Under paragraph (4), the Administrator may, upon application and by rule, exempt the manufacturer of a 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 the substance will not present an unreasonable risk of injury to health or the environment. A rule granting such an exemption must be promulgated in accordance with paragraphs (2), (3), and (4) of section 6(c).

Paragraph (5) authorizes the Administrator to make the requirements of subsection (a) and (b) inapplicable with respect to the manufacture or processing of a chemical substance which may temporarily exist as a result of a chemical reaction in the manufacture or processing of a mixture or another chemical substance and to which there is not or will not be any human or environmental exposure.

The conference substitute deletes the provision in the House amendment which clarified that a chemical substance is not to be treated as a new chemical substance solely because of the change in proportions of inert ingredients. This provision of the House amendment was deleted because under the definition of "mixture" in section 3 of the conference substitute the same result would occur, as any change in inert ingredients would constitute a new mixture not a new chemical substance. Mixtures are not covered by section 5.

*Definition.*—The terms "manufacture" and "process" as used in this section mean to manufacture or to process for commercial purposes. Since the term "manufacture" is defined to include import, persons who intend to import substances for commercial purposes will be treated in the same manner as domestic manufacturers under section 5.

#### REGULATION OF CHEMICAL SUBSTANCES AND MIXTURES

##### *Senate bill (section 6)*

The Senate bill requires the Administrator to impose restrictions on a chemical substance or mixture if the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal presents or is likely to present an unreasonable risk of injury to health or the environment. The Administrator shall impose one or more of several specified requirements as is necessary to adequately protect against the risk, using the least burdensome of effective controls.

A range of requirements is provided, from complete prohibitions on the manufacturing, processing, or distribution in commerce to labeling requirements. Among these is the authority to regulate the manner or method of use or disposal of such substance or mixture and the authority to require manufacturers or processors to replace or repurchase substances or mixtures found to present unreasonable risks.

The Senate bill also contains the authority to limit the amount of a substance or mixture which may be manufactured, processed, or dis-

tributed in commerce, or which may be manufactured, processed, or distributed in commerce for a particular use. A procedure for assigning permissible quotas if the applicable parties are unable to agree is provided. Supervision by the Attorney General and the Federal Trade Commission is provided for any voluntary efforts to establish quotas.

The Senate bill authorizes the Administrator to order manufacturers or processors to submit descriptions of relevant quality control procedures if the Administrator has good cause to believe that the manufacture or processing causes the adulteration of a chemical substance or mixture. If the Administrator determines that the quality control procedures of the manufacturer or processor are inadequate, the Administrator may order revisions in the quality control procedures to the extent necessary to remedy the inadequacy.

The Senate bill also requires the Administrator to consider relevant factors in imposing restrictions and to make findings with respect to certain factors.

The Senate bill contains a specific rulemaking procedure for rules imposing restrictions under this section. The procedure is an informal one, similar to the procedures in section 553 of title 5, United States Code, but there are exceptions, including an opportunity for an informal hearing. An opportunity for appropriate cross-examination in the hearing is provided under the supervision of the Administrator. Participants in a rulemaking proceeding may be compensated by the Administrator under specified criteria.

The Administrator may specify the date on which a rule under this section becomes effective, which shall be as soon as administratively feasible.

The Administrator may waive the required notice and comment period in those situations where compliance with the rulemaking provisions would present an unreasonable risk of death, serious or substantial personal injury, or serious or substantial environmental harm.

Finally, the Senate bill provides for the control of polychlorinated biphenyls (PCBs). Effective one year after the date of enactment of the Act, PCBs may not be used in any manner other than a totally enclosed manner, except that the Administrator may, by rule, authorize exceptions if the Administrator finds that no unreasonable risk of injury to health or the environment is presented. Effective two years after the date of enactment, the manufacture of any polychlorinated biphenyl would become unlawful. Effective two and one-half years after such date, the processing or distribution in commerce of PCB's would become unlawful, except that the Administrator may make exceptions if no unreasonable risk of injury to health or the environment is presented. Disposal regulations concerning PCB's shall be promulgated within six months after the date of enactment.

##### *House amendment (section 6)*

The standard for taking action against unreasonable risks under this section in the House amendment is slightly different from that contained in the Senate bill. If the Administrator finds that there is a reasonable basis on which to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of such actions causes or significantly contributes to, or will cause or significantly contribute to, an unrea-

sonable risk to health or the environment, the Administrator shall impose requirements as necessary to protect against the risk. The requirements generally are similar to the requirements of the Senate bill, with several exceptions. The Administrator may not regulate the manner or method of use. Nor may the Administrator impose replacement or repurchase requirements for substances regulated. Requirements regulating the manner or method of disposal may not require any person to take an action in violation of a State or local law. Also, a person subject to a disposal requirement shall notify the State in which a required disposal may occur of such requirement. The House amendment does not contain authority to impose manufacturing or processing quotas.

The House amendment provides a procedure for protecting against unintentional contamination of a chemical substance due to the manner of manufacturing or processing. Quality control procedures may be required to be submitted. If found inadequate, the Administrator may order such procedures to be changed. In addition, if the quality control procedures have resulted in the distribution in commerce of substances or mixtures which cause or significantly contribute to an unreasonable risk to health or the environment, the Administrator may require manufacturers or processors to give notice and to replace or repurchase any such substance or mixture as is necessary to protect health or the environment.

In promulgating any rule under section 6(a), the Administrator shall consider all relevant factors and make findings with respect to certain factors.

The Administrator shall not promulgate a rule under this section if the risk could be eliminated or reduced to a sufficient extent under another federal law administered by the Administrator unless the Administrator makes a finding that it is in the public interest to do so, taking into consideration a number of enumerated factors.

The rulemaking procedures of the House amendment are generally similar to those contained in the Senate bill.

The Administrator may make a rule immediately effective if an unreasonable risk of serious or widespread harm to health or the environment will occur prior to the completion of the rulemaking proceedings, and making the rule so effective is necessary to protect the public interest. If a proposed rule totally prohibits the manufacture, processing or distribution of a chemical substance or mixture, a court must have previously taken action against a substance or mixture in an imminent hazard proceeding under section 7. An expedited rulemaking procedure is provided for immediately effective rules.

The provision of the House amendment relating to PCBs is similar to the Senate bill with a few exceptions. For example, the prohibitions effective in one year apply only to the manufacture, processing or distribution in commerce for a use other than a use in a totally enclosed manner. In addition, exemptions from the prohibitions relating to the manufacture, processing, and distribution of PCB's may be granted, if the Administrator determines that the exemption is necessary to protect health or the environment, and good faith efforts have been made to develop substitutes.

*Conference substitute (section 6)*

The conference substitute requires the Administrator to take action under this section against chemical substances or mixtures for which there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substances or mixtures, or any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment. Requirements shall be imposed to the extent necessary to protect against the risk.

The requirements must be the least burdensome feasible for those subject to the requirement and for society while providing for an adequate margin of protection against the unreasonable risk.

The requirements which may be imposed are similar to those included in both the Senate bill and the House amendment. The Administrator may impose requirements regulating the manner or method of the commercial use of a substance a mixture and also requirements regulating the manner or method of disposal of a substance or mixture or an article containing a substance or mixture by the manufacturer or processor or by any other person who uses or disposes of it for commercial purposes. The provision of the House amendment that a disposal requirement may not require any person to take action in violation of any State law or political subdivision is included. The conference substitute also includes the Senate provision which authorizes the Administrator to require replacement or repurchase by manufacturers or processors of substances or mixtures with respect to which action has been taken under this section.

The provisions of the House bill relating to quality control are included.

The provisions of the Senate bill which authorize the Administrator to assign manufacturing or processing quotas are not included.

The conferees appreciate that if the Administrator chooses to impose a production limitation on any chemical substance, such limitation, if not carefully drawn, could produce monopoly profits. The conferees believe that the Administrator should consult with the Attorney General and the Federal Trade Commission in order to avoid any anticompetitive consequences.

The conference substitute requires the Administrator to consider certain enumerated factors and to publish a statement in the Federal Register with respect to them at the time of promulgation of a rule under section 6(a). Specifically, the Administrator must consider and publish a statement concerning the effects of the substance or mixture on health and the magnitude of human exposure to such substance or mixture; the effects of the substance or mixture on the environment and the magnitude of environmental exposure to such substance or mixture; the benefits of such substance or mixture for various uses and the availability of substitutes for such uses; and the reasonably ascertainable economic consequences of the rule, after consideration of the effects on the national economy, small business, innovation, the environment, and the public health. This requirement was contained in both the Senate bill and the House amendment. The purpose in requiring such a statement is to assure that the basis for the Administrator's rule are publicly enumerated. By requiring the statements,

the conferees intend to emphasize key considerations which must be addressed. The conferees do not intend that the statement be detailed or voluminous. A succinct and precise statement of these key considerations will suffice. Of course, the statements will provide part of the rulemaking record for judicial review of a rule promulgated under section 6(a).

Moreover, if the Administrator determines that a risk may be eliminated or reduced to a sufficient extent by actions taken under another Federal law administered by the Administrator, action may not be taken under this section unless the Administrator finds, in the Administrator's discretion, that it is in the public interest to take action under this Act. By committing such determination to the Administrator's discretion, the conferees intend that such determination not be subject to judicial review.

The House provision relating to compensation for the costs of participating in a rulemaking proceeding and the provisions relating to the effective date of a rule are included. Generally rules are to be effective as soon as procedurally and administratively feasible. However, proposed rules may be declared to be immediately effective by the Administrator in certain instances. The rule may be declared immediately effective if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a substance or mixture is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before the normal effective date and making the rule immediately effective is necessary to protect the public interest. In the case of a rule to prohibit the manufacture, processing, or the distribution, a court must have granted relief in an imminent hazard action under section 7. An expedited rulemaking procedure is provided if a rule is made immediately effective.

The conference substitute includes procedures contained in both bills for prescribing rules. In general, rules under this section are to be prescribed in accordance with the informal rulemaking procedures of section 553 of title 5, United States Code, except that an opportunity for an oral hearing and for limited cross-examination is provided. The procedures are patterned after those contained in section 18 of the Magnuson-Moss Warranty-Federal Trade Commission Improvements Act.

The Senate bill, unlike the House amendment, specifically authorizes the Administrator to conduct cross-examination on behalf of the participants to the proceeding. Although the conference substitute retains the Senate provision, the conferees expect that in most instances the participants themselves would conduct the cross-examination, subject to the Administrator's time limitations and other rules.

When the Act states that the transcripts shall be available to the public, the conferees intend that such availability be construed in a reasonable manner. No person may be denied access to such information, but at the same time the Administrator shall not be required to assume the burden of copying what may be a formidable amount of material. Therefore, the conferees intend that the Administrator furnish copies of transcripts as long as a supply exists within EPA. However, if the amount of material is vast, or if EPA has run out of copies, then the person may inspect the transcript which shall be available at every regional office of EPA. EPA may photocopy a reasonable num-

ber of pages, such as 200, but shall in all cases afford any person the opportunity to photocopy as much of the transcript as the person desires. The cost of copying pages beyond a reasonable number shall be borne by the person; however, the Administrator shall not charge an unreasonable fee per page.

Generally, the provisions of the Senate bill relating to the control of polychlorinated biphenyls are included. The standard that must be satisfied before exemptions from the complete ban on polychlorinated biphenyls are granted contains elements of both the House and Senate provisions. Exemptions may be granted only if the Administrator finds that there is no unreasonable risk to health or the environment, and that good faith efforts have been made to develop a substitute. So that existing PCBs may be reused rather than disposed of, the prohibitions do not apply to distributions in commerce of PCBs sold for purposes other than resale before the effective date of the prohibition on distribution of PCBs.

#### IMMINENT HAZARDS

##### *Senate bill (section 7)*

The Senate bill authorizes the Administrator to initiate a judicial proceeding against an imminently hazardous chemical substance or mixture or against any person who manufactures, processes, distributes in commerce, uses or disposes of such substance or mixture or against both. The court is authorized to grant such temporary or permanent relief as is necessary to protect against the hazard. Such relief may include seizure and condemnation of the imminently hazardous substance or mixture. Further, the court is specifically authorized to require manufacturers, processors, or distributors to provide notice of the hazard to purchasers of the substance or mixture and to the public, and to recall and replace or repurchase the substance or mixture. Under the Senate bill an imminent hazard is considered to exist when the evidence is sufficient to show that a situation exists in which the continued use of a substance or mixture would be likely to result in unreasonable adverse effects on the environment or an unreasonable hazard to the survival of an endangered species. An unreasonable adverse effect is defined to mean an unreasonable risk to man or the environment taking into account the economic, social, and environmental costs and benefits of the use of the substance or mixture.

##### *House amendment (section 7)*

The House amendment differs from the Senate bill in three ways. First, in addition to authorizing action against imminently hazardous substances and mixtures, the House amendment explicitly authorizes actions against articles containing such substances or mixtures. Second, if the Administrator has not acted under section 6(d) of the House amendment which authorizes immediate administrative action against an imminent hazard, the Administrator is required to take action under section 7. Third, the House amendment differs from the Senate bill in its definition of an imminent hazard. Under the House amendment an imminently hazardous chemical substance or mixture is one which causes or significantly contributes to an imminent and unreasonable risk of serious or widespread harm to health or the environment. Such risk shall be considered imminent if it is shown that the

manufacture, processing, distribution in commerce, use or disposal of a substance or mixture is likely to result in an unreasonable risk of serious or widespread harm to health or the environment before a final rule under section 6 can protect against the risk.

*Conference substitute (section 7)*

The conference substitute follows the House language with a clarification (contained in the Senate bill) that relief is authorized against persons who use or dispose of an imminently hazardous substance or mixture in addition to persons who manufacture, process, or distribute in commerce such substances or mixtures. If the Administrator has not used the authority provided in section 6(d)(2)(A)(i) to make a section 6(a) rule immediately effective in order to protect against an imminently hazardous substance or mixture, the Administrator must bring an action under section 7. The conferees have imposed such a nondiscretionary duty upon the Administrator to insure that protection is provided against imminently hazardous substances, mixtures, and articles containing such substances and mixtures.

The conferees wish to note that while the unreasonable risk of injury must be imminent, the physical manifestations of the injury itself need not be. Rather, an imminent hazard may be found at any point in the chain of events which may ultimately result in injury to health or the environment. The observance of actual injury is not essential to establish that an imminent hazard exists. The conferees intend that action under the imminent hazard section be able to occur early enough to prevent the final injury from materializing. In using the term "widespread injury" the conferees do not intend that the imminent hazard authority with respect to widespread harm be limited to instances in which the risk of injury is geographically widespread. Rather an unreasonable risk of harm affecting a substantial number of people, even though it is within a rather limited geographic area, should be deemed adequate to satisfy the requirement of an unreasonable risk of widespread injury to health. Of course if the risk of injury to health or environment is serious, it need not be widespread.

REPORTING AND RETENTION OF INFORMATION

*Senate bill (section 8)*

Section 8 sets forth requirements for reporting and retention of information. Under subsection (a) the Administrator shall issue rules which require each person who manufactures or processes a chemical substance or mixture to maintain records and to make such reports as the Administrator may reasonably require. Such rules shall require manufacturers or processors of chemical substances or mixtures who produce such substances or mixtures in small quantities solely for scientific experimentation or analysis for chemical research or analysis to maintain records and to submit reports only to the extent necessary for the effective enforcement of the Act. This subsection also contains an illustrative list of the kinds of information which the Administrator may require from manufacturers or processors of chemical substances.

To determine which substances are new chemical substances for the purpose of the pre-market notification provisions of section 5, sub-

section (b) requires the Administrator to publish an inventory of existing chemical substances or mixtures which any person report to be commercially manufactured or processed within the United States under subsection (a) or under section 5(a). The Administrator shall publish such list not later than 270 days after the date of enactment.

Subsection (c) requires any person who manufactures, processes, or distributes chemical substances or mixtures to maintain records of adverse reactions to health or the environment alleged to have been caused by any such substance or mixture. These records shall be maintained for 5 years from the date the information was reported to such person, except that reports dealing with adverse reactions of employees shall be retained for 30 years.

Subsection (d) requires the Administrator to promulgate rules with respect to the submission of lists of health and safety studies conducted or initiated by any manufacturer, processor, or distributor in commerce of any chemical substance or mixture. The Administrator may require the submission of any study appearing on the list.

Subsection (e) requires manufacturers, processors, or distributors in commerce of a chemical substance or mixture as well as their liability insurers to inform the Administrator when they receive information which supports the conclusion that such substance or mixture causes or contributes to an unreasonable risk of injury to health or the environment. Such persons are relieved of such requirement when they have reason to believe that the Administrator has been adequately informed of the risk.

*House amendment (section 8)*

Subsection (a) of the House amendment is substantially similar to the Senate bill except that it exempts small manufacturers or processors from the reporting requirements. The Administrator may, by rule, require such persons to maintain records and submit reports on a chemical substance or mixture subject to a rule or a proposed rule under section 4, 5(c), 5(g), or 6. In addition, if relief has been granted in an imminent hazard proceeding under section 7, the Administrator may, by rule, require a small manufacturer or processor to maintain records and submit reports. After consultation with the Administrator of the Small Business Administration, the Administrator, shall, by rule, prescribe standards for determining which manufacturers and processors will be considered "small" manufacturers and processors.

As a further limitation, section 8(a)(1)(B) specifies that the Administrator may not require 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 such recordkeeping or reporting is necessary for the effective enforcement of the Act.

With respect to the inventory of existing chemical substances required by subsection (b), the House amendment provides that the inventory shall include at least each chemical substance which any person reports under section 5 or under section 8(a) was commercially manufactured or processed in the United States within 3 years before the effective date of the rules promulgated under section 8(a). The House amendment requires the publication of such inventory within 1 year after the effective date of the Act.



Subsection (c) differs from the Senate bill in that it allows the Administrator to determine, by rule, the requirements respecting the maintenance of records of adverse reactions to health or the environment alleged to have been caused by a substance or mixture. The Administrator may require that records relating to adverse reactions to employee health be retained for up to 50 years.

Subsection (d) concerning submission of lists of health and safety studies is similar to the Senate bill.

Subsection (e) of the House amendment does not require liability insurers to report to the Administrator information which supports the conclusion that a substance or mixture may cause or significantly contribute to an unreasonable risk of injury. Manufacturers, processors, and distributors must report information relating to a substantial risk to health or the environment unless they have actual knowledge that the Administrator has been adequately informed of such risk.

Subsection (f) of the House amendment provides definitions of "manufacture" and "process" for the purposes of section 8.

*Conference substitute (section 8)*

The conference substitute follows with some modification the House amendment of section 8 which outlines the policies and procedures for reporting and retention of information. Subsection (a) identifies which persons must, pursuant to rules promulgated by the Administrator, maintain records and make reports. The conference substitute provides an illustrative list of the kinds of activities for which recordkeeping and reporting may be required. The list includes such information as the identity of the chemical, categories of use, amounts manufactured or processed, by products, existing data, employees exposed, and the manner or method of disposal. The information specified may be required by the Administrator "insofar as known to the person making the report or insofar as reasonably ascertainable". The conferees intend that the "reasonably ascertainable" standard be an objective, rather than a subjective one. Thus, the manufacturer or processor must provide information of which a reasonable person similarly situated might be expected to have knowledge.

The conference substitute retains the exemptions in the House amendment relating to reporting by small businesses. The intent of the conferees is to protect small manufacturers and processors from unreasonably burdensome reporting requirements. However, the conferees do not intend to deny the Administrator access to information which may be necessary either to determine whether a rule or order should be promulgated or to enforce a final rule or order. Therefore, the conferees have specifically authorized the Administrator to obtain reports from small manufacturers and processors of a chemical substance or mixture with respect to which a rule has been proposed or promulgated under section 4, 5(b)(4), or 6, or with respect to which an order or rule is in effect under section 5(e) or 5(f). Thus, once a rule has been proposed, the Administrator may, by rule, issued in accordance with the informal rulemaking procedures of section 553 of title 5, United States Code, require reporting from small manufacturers and processors. Under such procedures, the Administrator will

be able to obtain timely access to needed information. Similarly, reporting may be obtained from small manufacturers and processors of a substance or mixture with respect to which relief has been granted in a civil action under section 5 or 7.

The conference substitute adopts, with some clarification, the House amendment in subsection (b) which requires the Administrator to compile, keep current, and publish an inventory of chemical substances and mixtures manufactured or processed in the United States. The conference committee compromised on the date that the Administrator shall first publish the inventory, which publication shall take place 315 days after the effective date of the Act.

The conference substitute accepts the substance of the Senate bill in subsection (c), which states that records of significant adverse reactions (as defined by the Administrator by rule) shall be retained for five years after such reactions are reported. Under this provision an officer or employee designated by the Administrator may inspect the records maintained on adverse reactions. The conferees intend that persons under contract with the Administrator be considered employees of the Administrator. Such contractors and their employees may have access to records for purposes of this section and throughout the Act. The conferees recognize the special dangers presented to persons who are exposed to substances on a daily basis; therefore, records of adverse occupational effects must be retained for thirty years.

The seriousness, duration, and the frequency of reactions should be taken into account in establishing what constitutes a significant adverse reaction. For example, if an individual reports that a chemical substance causes his or her eyes to become inflamed and to tear, such reaction may be attributed to an isolated allergic reaction. However, if several persons report a similar reaction, then the reaction may indeed be significant. Because the ultimate significance of adverse reactions is difficult to predict, the conferees intend that the requirement to retain records err on the side of safety. Some very serious neurological disorders, for instance, at first present what appear to be trifling symptoms.

The conference substitute includes the Senate version of subsection (d) concerning health and safety studies with slight modifications. As with the provision concerning adverse reactions, the conferees emphasize the importance of gaining information which errs on the side of too much rather than too little. Of course, the Administrator is to avoid imposing unnecessary or overly burdensome reporting requirements. In cases where test results are submitted, supporting data and the sources for such data must be included.

The conference substitute follows the House amendment for subsection (e) which provides that any manufacturer, processor, or distributor of a chemical substance or mixture who obtains information supporting the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall notify the Administrator, unless such person has actual knowledge that the Administrator already possesses the information.

*Senate bill (section 9)*

Section 9(a) of the Senate bill provides that if the Administrator (A) has reason to believe that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture causes or contributes to, or is likely to cause or contribute to an unreasonable risk of injury to health or the environment, and (B) 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 EPA, then the Administrator must request the agency which administers such law to issue an order. Such agency shall consider all data submitted by the Administrator and issue an order declaring whether or not the manufacture, processing, distribution in commerce, use, or disposal of such substance or mixture causes or contributes to or is likely to cause or contribute to such a risk. If such agency makes such determination it shall also determine if such risk may be prevented or reduced to a sufficient extent by action taken under the law (or laws) administered by the agency.

The Administrator may specify the time within which the other agency must issue the order, but such time may not be less than 90 days from the date the request was made. The other agency must issue a report including a detailed statement of its findings and conclusions in response to the Administrator's request.

The Administrator shall not take any action under section 6 or 7 of this Act if such other agency (A) issues an order declaring that there is no unreasonable risk of injury, or (B) initiates action under the law (or laws) administered by such agency within 90 days of publication in the Federal Register of its report in response to the EPA request.

Section 9(a) of the Senate bill also states that nothing in this section shall prevent the Administrator from making any subsequent request or taking subsequent action under the Toxic Substances Control Act with respect to such risks if the requirements of section 9(a) are satisfied.

Section 9(a) of the Senate bill provides that if the Administrator has initiated action under section 6 or 7 of this bill with respect to a risk of injury which is the subject of a request to another agency, such other agency must consult with the Administrator to avoid duplication of Federal action against such risk before taking action under the law or laws it administers.

Section 9(b) of the Senate bill directs the Administrator to coordinate actions taken under this bill with actions taken under other Federal laws administered wholly or partially by the Administrator. The Administrator must use the authorities contained in such other Federal laws to protect against any risk to health or the environment associated with a chemical substance or mixture unless the Administrator, in the Administrator's discretion, determines that such risk might be more appropriately protected against under this Act. Section 9(b) does not relieve the Administrator of any duties or responsibilities imposed by other Federal law. Nor does section 9(b) affect any final action taken under such other Federal law or the extent to which

human health or the environment is protected under such other law.

Section 9(c) of the Senate bill states that, in exercising any authority under this bill, 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.

Section 9(d) of the Senate bill requires the Administrator to consult and coordinate with the Secretary of Health, Education, and Welfare and the heads of other appropriate Federal agencies, departments or instrumentalities for the purpose of achieving the maximum enforcement of this legislation while imposing the least burdens of duplicative requirements on those subject to the bill, and for other purposes. The Administrator shall report annually to the Congress on actions taken to so coordinate authority under this bill with the authority granted under other EPA-administered laws and laws administered by other Federal agencies.

Section 9(e) of the Senate bill provides that nothing in section 9 limits any requirement of section 4, 5 (other than section 5(e)(2)), or 8, or rules promulgated thereunder.

*House amendment (section 9)*

Section 9(a) of the House bill is similar to section 9(a) of the Senate bill; however, there are certain differences. First, the Administrator's determination that an unreasonable risk to health or the environment may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator is not discretionary. Second, if such a determination is made, the Administrator shall submit a report to the agency administering such other law. Such report shall describe such risk and include a specification of the activity or activities which the Administrator has reason to believe caused or contributed to such risk.

Such report shall request such agency to determine whether the risk might be prevented or reduced to a sufficient extent by action taken under such law. Conditioned upon such a determination shall be a request that the agency issue an order declaring whether the activity or activities specified in the Administrator's description caused or significantly contributed to such risk, which determination and order shall be reported to the Administrator.

Like the Senate bill, section 9(b) of the House bill requires the Administrator to coordinate actions taken under this legislation with actions taken under other laws administered in whole or in part by the Administrator; however, the language of the House bill differs regarding the Administrator's authority to regulate a risk to health or the environment associated with a chemical substance or mixture. Unless the Administrator determines that it is in the public interest to protect against such risk by actions taken under this Act, the House amendment requires the Administrator to use the authorities contained in other laws, if such risk could be eliminated or reduced to a sufficient extent.

Sections 9(c) and (d) of the House amendment are identical to the Senate bill. The House amendment contains no provision similar to section 9(e) of the Senate bill.

*Conference substitute (section 9)*

The conferees have drawn from both the Senate bill and the House amendment to assure that overlapping or duplicative regulation is avoided while attempting to provide for the greatest possible measure of protection to health and the environment.

Section 9(a) establishes the relationship between the Act and Federal laws not administered by the Administrator. If the Administrator has a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture presents or will present an unreasonable risk of injury and if the Administrator makes a discretionary determination (which is not subject to judicial review) that the risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, then the Administrator must give the other agency an opportunity to act to protect against the risk before the Administrator uses the authorities in section 6 or 7 to protect against the risk.

If the Administrator determines that another Federal law contains authorities adequate to prevent or reduce the suspected risk to a sufficient extent, the Administrator shall submit to the agency which administers the law a report which describes the risk, including a specification of the activity or combination of activities associated with the substance or mixture which the Administrator believes presents the risk. The report must also include a detailed statement of the information on which it is based. The report shall also request the agency to determine if the risk described in the report may be prevented or sufficiently reduced by action taken under its law and, if such determination is affirmative, to issue an order declaring whether or not the activity specified in the report presents an unreasonable risk.

The agency receiving the request from the Administrator must respond to the Administrator within such time as the Administrator specifies. However, the Administrator must give the other agency at least 90 days.

Section 9(a) prohibits the Administrator from acting under section 6 or 7 with respect to the risk about which the Administrator notified the other agency if the other agency takes one of two alternative courses of action. First, if the other agency issues an order declaring that the activity specified in the Administrator's report does not present the unreasonable risk described in the report, then the Administrator may not take action under section 6 or 7 with respect to such risk. Alternatively, if within 90 days of the publication in the Federal Register of the other agency's response, the other agency initiates action to protect against such risk, then the Administrator is precluded from taking action under section 6 or 7 with respect to such risk. If the other agency does not take one of these actions, then the Administrator is permitted to act under section 6 or 7 to protect against the risk.

The conferees recognize that the other agency may not because of time constraints be able to initiate formal regulatory action to protect against the risk within the specified time period. As long as the other agency has officially initiated an action which will culminate as soon as

practicable in effective regulatory action to protect against the unreasonable risk and sets forth a general time schedule of steps for such action, the requirement should be deemed satisfied. However, the requirement that the other agency initiate action to protect against the risk is not satisfied by the mere open-ended possibility of action by the other agency.

Subsection (b) establishes the relationship between this Act and other laws administered in whole or in part by the Administrator. Subsection (b) requires the Administrator to coordinate actions taken under this Act with actions taken under other Federal laws administered by the Administrator.

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 the authorities contained in other Federal laws, then the Administrator shall use such other authorities unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk under this Act. While it is clear that the Administrator's determination that it is in the public interest to use this Act, is a completely discretionary decision not subject to judicial review in any manner, it is expected that the Administrator will review the other authorities and present the results of that review at the same time the Administrator takes action under this Act. While the Administrator's decision to use this Act, notwithstanding the other authorities, is unreviewable by any court, a reviewing court is expected to require that the Administrator have examined the other authorities and present the results of that examination when making the finding that it is in the public interest to use this Act. Of course, the requirement to examine other EPA laws and to make determinations applies only when the Administrator takes regulatory action to protect against an unreasonable risk under this Act. It does not apply when the Administrator takes action necessary for the administration or enforcement of the Act, such as issuing recordkeeping requirements.

This provision is not to be construed to relieve the Administrator of any requirement imposed by other Federal laws upon the Administrator, and of course nothing in this Act shall affect any final action taken under other Federal laws administered by the Administrator or in any way affect the extent to which health or the environment is to be protected under such other Federal laws.

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

*Senate bill (section 10)*

Section 10 authorizes the Administrator to conduct research and monitoring in cooperation with the Secretary of Health, Education, and Welfare and the heads of other appropriate agencies, as is necessary to carry out the purposes of the Act.

The Administrator shall undertake and support programs of research and monitoring of polychlorinated biphenyls to develop safe methods of disposal. The Administrator shall also establish, administer, and assume responsibility for the activities of an interagency

committee to construct within the EPA an efficient system for the collection, dissemination, and use of data submitted to the Administrator under this Act among other Federal agencies. This interagency committee shall also direct its attention to coordinating the regulation of chemical substances among the federal agencies. The Administrator shall design, establish, and coordinate an effective system for the retrieval of toxicological and other scientific data which could be useful to the Administrator in carrying out this Act. This section also authorizes the Administrator to make grants and to enter into contracts in order to carry out his responsibilities under this section.

*House amendment (section 10)*

The House version of section 10 is substantially similar to the Senate bill. However, the House amendment omits the requirement that the Administrator undertake and support programs of research and monitoring of polychlorinated biphenyls. The House amendment contains additional specific provisions for various research programs such as the development of rapid, reliable and economical screening and monitoring techniques for carcinogenic, mutagenic, teratogenic, and ecological effects of chemical substances and mixtures.

*Conference substitute (section 10)*

The conference substitute includes provisions found in both the Senate bill and the House amendment, but generally follows the language from the House version. Subsection (a) requires the Administrator to conduct such research, development, and monitoring as is necessary to carry out the purposes of this Act. In doing so, the Administrator must consult and cooperate with the Secretary of Health, Education, and Welfare and with heads of other appropriate departments and agencies. The Administrator may enter into contracts and make grants for the purpose of research and development in this area.

Subsection (b) authorizes the establishment of an interagency committee whose primary responsibility shall be to design an efficient system within the Environmental Protection Agency for the collection of data (submitted to the Administrator under this Act), the dissemination of such data to other instrumentalities of the Federal Government, and the use of such data.

Subsection (b) specifies that an efficient and effective data retrieval system shall be developed. The conferees emphasize that sufficient data is necessary for successful implementation of this Act, yet they also acknowledge the burden placed on industry by excessive or duplicative reporting. It is essential that toxicological and other relevant scientific data already in the possession of the Federal Government be made available to the Administrator. The efficient exchange of information among Federal agencies and departments will facilitate implementation of this Act, and every effort should be made to achieve this goal and to avoid duplicative requirements in information-gathering.

Subsections (c), (d), (e), (f), and (g) of the conference substitute adopt provisions from the House amendment which concern research and development in the area of data collection. The conferees do not intend that such projects should detract from the primary purposes of the Act, but rather that those purposes should be enhanced by

allowing the development of proper tools. Thus the purpose of these subsections is to provide the means to an end. They should in no case detract from the main purposes of the Act nor from other equally important research conducted by the Administrator, but should contribute to the achievement of those purposes where appropriate. Of course, such research and development should not duplicate any research and development already being conducted by other Federal agencies and departments. Thus, careful coordination and consultation with such departments and agencies is required.

INSPECTIONS AND SUBPOENAS

*Senate bill (section 11)*

The Senate bill authorizes the Administrator or any duly designated representative to inspect any establishment, facility or other premises in which chemical substances or mixtures are manufactured, processed, stored or held before or after distribution in commerce. Inspections are also authorized of conveyances used to transport chemical substances or mixtures in connection with distribution in commerce. Inspections may extend to all things within the premises or conveyances inspected bearing on whether the requirements of the Act have been complied with.

The Senate bill also authorizes the Administrator to issue subpoenas to require the attendance and testimony of witnesses and the production of reports, papers, documents, and answers to questions or other information necessary for the Administrator carry out his or her duties under the Act.

*House amendment (section 11)*

The House amendment contains a similar provision authorizing inspections for the purpose of enforcement of the Act. However, the House amendment provides that no inspection shall extend to financial data, sales data other than shipment data, pricing data, personnel data, or research data (other than research data required by the Act) unless the nature and extent of the data are described with reasonable specificity in the written notice presented to the owner, operator or agent in charge of the premises or conveyance to be inspected. The House amendment contained no subpoena authority.

*Conference substitute (section 11)*

The conference substitute includes the provision from the Senate bill with the addition of the House provision relating to inspections of financial data, sales data other than shipment data, pricing data, personnel data or research data (other than research data required by the Act or pursuant to any rule issued under the Act).

The conferees recognize that the Administrator will have access to much information under section 5 and section 8 of the Act. Therefore, the conferees expect that the Administrator will use the subpoena authority only when information otherwise available through voluntary means or under other provisions of this Act is inadequate to meet the Administrator's needs under this Act.

It should be noted that the conferees intend that representatives of the Administrator authorized to make inspections should have the

opportunity to record the results of such inspections because such records might be required at some later date; therefore, it is intended that persons making the inspection shall be allowed, for example, to photocopy records or photograph premises.

#### EXPORTS

##### *Senate bill (section 12)*

This section outlines the policy for chemical substances and mixtures manufactured, processed, sold, or held for sale solely for export from the United States. Subsection (a) provides that unless the Administrator finds that such substances or mixtures will cause or contribute to an unreasonable risk to the health of persons within the United States or the environment of the United States, such substances are exempt from the Act (other than the reporting requirements of section 8) if proper labeling shows that they are intended for export use only.

However, subsection (b) allows the Administrator to require testing under section 4 to see if such substance or mixture may cause or contribute to a risk of health within the United States or to the environment of the United States. Subsection (b) also requires that any person engaged in export activities shall notify the Administrator if such activities involve chemical substances or mixtures for which data is required under section 4 or 5 or for which a rule has been proposed or promulgated under section 5 or 6 or for which action is pending or relief has been granted under section 7. Should any such circumstance arise, the Administrator shall furnish the appropriate foreign government with relevant information pertaining to the chemical substance subject to the limitations of section 14.

##### *House amendment (section 12)*

Except for minor differences in language, the House amendment follows the Senate provision. The House provision also specifically covers articles containing chemical substances.

##### *Conference substitute (section 12)*

The conference substitute follows the policy set forth in both the Senate and House provisions to protect the health and environment of persons in the United States and to provide information to foreign governments regarding chemical substances and mixtures, so that such foreign governments can protect their own citizens.

#### ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES

##### *Senate bill (section 13)*

The Senate bill instructs the Secretary of the Treasury to refuse entry into the United States of any chemical substance or mixture offered for entry if it fails to conform with any requirement of the Act or any rule in effect under the Act or if it is otherwise prohibited from being distributed in commerce. If a substance or mixture is refused entry, the Secretary of the Treasury is required to notify the consignee of the entry refusal. If the substance or mixture is not exported within 90 days, the Secretary is to cause the disposal or storage of the substance or mixture.

##### *House amendment (section 13)*

The House amendment contains a similar provision.

##### *Conference substitute (section 13)*

The conference substitute adopts the provision found in both the Senate bill and the House amendment relating to entry into the customs territory of the United States. Although the Secretary of the Treasury is authorized to cause the disposal of substances and mixtures which have been refused entry and are not exported within 90 days, the conferees intend that the Secretary consult with the Administrator before determining the disposal methods for the substance or mixture.

#### DISCLOSURE OF DATA

##### *Senate bill (section 14)*

The Senate bill provides generally that all information obtained by the Administrator under this Act shall be subject to the Freedom of Information Act (5 U.S.C. 552). The Freedom of Information Act makes such information available to the public upon request, unless the information requested falls into one of nine exceptions.

The Senate bill also requires the disclosure of data in certain further specified situations. If officers or employees of the United States request information in connection with their official duties under laws protecting human health or the environment or for specific law enforcement purposes, then the Administrator must disclose the information to them.

Likewise, the Administrator must disclose information to the public whenever the Administrator determines it is necessary to protect human health or the environment. If the Administrator determines that disclosure of information is necessary for a contractor or the contractor's employee to perform official duties satisfactorily under contracts for the United States in connection with this Act, then the Administrator must disclose the information. Finally, the Administrator must disclose information to any duly authorized committee of Congress upon written request.

##### *House amendment (section 14)*

The House amendment contains some similarities to, but also some differences from, the Senate bill. Whereas the Senate bill states that the Freedom of Information Act applies except in certain areas where disclosure is mandatory, the House bill statutorily prohibits the disclosure of information which falls into one of the exemption categories (subsection (b) (4) (5 U.S.C. 552(b) (4))) of the Freedom of Information Act.

Subsection (b) (4) of that Act encompasses matters that are trade secrets and commercial or financial information obtained from a person and privileged or confidential. The Administrator may not disclose information under that classification except to officers or employees of the United States in connection with their duties to protect health or the environment or for specified law enforcement purposes or to contractors with the United States or their employees in connection with this Act. Such information may be disclosed when relevant to a proceeding under this Act, but the disclosure must pre-

serve confidentiality as much as possible without impairing the proceeding.

Subsection (b)(1) specifically provides that disclosure of any health and safety study for any chemical substance or mixture which is already being distributed or for which testing is required under section 4 or for which notification is required under section 5, is not prohibited. Data in such a study which discloses a manufacturing process or the proportions of a mixture may not be disclosed if such process or proportions would otherwise be entitled to protection from disclosure.

Subsection (c) authorizes any person who submits data under the bill to designate information he believes is entitled to confidential treatment under section (a). Designated information may not be released for 30 days after notification of release has been received by the person submitting such data.

*Conference substitute (section 14)*

The conference substitute adopts elements of both the Senate bill and the House amendment. The prohibition against disclosure of information exempt from mandatory disclosure under section (a) of section 552 of title 5, United States Code, by reason of its falling within the exemption under subsection (b)(4) of such section, is included. Section 14 applies to any release of information obtained under the Act.

Mandatory exceptions from this prohibition are also provided. Disclosure of information described in section 552(b)(4) of title 5 is required in the following situations:

(1) To officers or employees of the United States in connection with their official duties to protect health or the environment, and for specific law enforcement purposes.

(2) To contractors with the United States when the Administrator determines it to be necessary for the satisfactory performance of their duties in connection with this Act and under such conditions as necessary to preserve confidentiality as the Administrator may specify.

(3) If the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury to health or the environment.

In addition, the Administrator may disclose such information when relevant under a proceeding under this Act, except that disclosure under such proceeding shall be made in such a manner as to preserve confidentiality to the extent practicable without impairing the hearing. It is intended that the Administrator exercise due care to prevent the release of confidential information to competitors of persons submitting data merely because the competitors have joined the proceeding.

In any proceeding under section 552(a) of title 5 to obtain information which the Administrator has refused to release on the basis that disclosure is prohibited by section 14(a) of this Act, the Administrator may not rely on section 552(b)(3) of title 5 to sustain the refusal to disclose the information. Thus the Administrator will have to show that the information falls within section 552(b)(4) of title 5. Of course, section 552 of title 5 is the vehicle through which the public can obtain information from the Federal government, and all the provi-

sions of that section will apply to requests for information obtained under this Act.

The conference substitute specifically provides that disclosure of any health and safety study or information from such a study on any substance or mixture which is already being distributed or for which testing is required under section 4 or for which notification is required under section 5, is not prohibited. Data in such a study which discloses manufacturing processes or the proportions of a mixture may not be disclosed if such processes or proportions would otherwise be entitled to protection from disclosure. However, any restriction on the release of such data will not apply to the health and safety study in which it is contained or from which it is derived. To comply with such restriction the Administrator need only to exclude such data when releasing such study.

If a request is made to the Administrator for health and safety study information which is not entitled to protection, the Administrator may not deny a request under section 552 of title 5, United States Code, on the basis that such information is included in the exceptions to mandatory disclosure enumerated in subsection (b)(3) or (b)(4) of such section. It is also intended that the Administrator not use exception (b)(7) of section 552 of title 5, relating to matters under investigation, in an excessive manner as a device for withholding information submitted under this Act. In order to be withheld under that exception, the information must be the subject of an ongoing, active investigation.

In submitting data, a person may designate data which the person believes is entitled to confidential treatment under this Act and submit it separately. If the Administrator proposes to release for inspection designated data, the Administrator must give 30 days notice to the person who submitted the information. Thirty days advance notice need not be given when information is to be released under one of the mandatory exceptions described above or when disclosure is not prohibited because the information is health and safety data. When disclosure is proposed because it is necessary to protect health and the environment from an unreasonable risk, the Administrator shall provide the person submitting the data written notice by certified mail of the proposed release at least 15 days prior to the release. The purpose of this provision is to provide the person submitting the data an opportunity to seek to stop the proposed release if that person disputes the Administrator's determination. The conferees recognize that there may arise emergency situations in which the Administrator determines that earlier release is necessary. In such cases, where the occurrence of the unreasonable risk is imminent, the Administrator need give notice only 24 hours prior to release. The required notice need not be given in writing but may be made by some other means such as telephone or telegraph.

The criminal penalties for wrongful disclosure contained in the House bill have been included in the conference substitute.

PROHIBITED ACTS

*Senate bill (section 15)*

The Senate bill makes it unlawful for any person to fail or refuse to comply with any rule or order promulgated under section

4, 5, or 6, or any requirement prescribed by section 5 or 6. It also makes it unlawful for any person to use or dispose of a chemical substance or mixture which the person knew or had reason to know was manufactured, processed or distributed in commerce in violation of section 5 or a rule or order under section 6. Failure or refusal to establish or maintain records, submit reports, notices, or other information or to permit access to, or copying of, records is also unlawful. Finally, the Senate amendment makes unlawful the failure or refusal to permit entry or inspection as required by section 11.

*House amendment (section 15)*

The House amendment makes it unlawful for any person to fail or refuse to comply with any rule or order promulgated under section 4, 5 or 6 or any requirement prescribed by section 5. It also makes it unlawful for any person to use for commercial purposes a chemical substance or mixture which the person using such substance or mixture knew or had reason to know was manufactured, processed or distributed in commerce in violation of section 5, a rule or order under section 5 or 6 or an order issued in an action brought under section 5 or 7. The House provisions respecting maintenance of records, submission of reports, entry, and inspections are identical to the Senate bill.

*Conference substitute (section 15)*

The conference substitute incorporates the provisions of the House bill with a conforming amendment making violations of the provisions of section 6 relating to polychlorinated biphenyls an unlawful act.

PENALTIES

*Senate bill (section 16)*

This section outlines the penalties and procedures for assessing penalties against persons who violate section 15. Subsection (a) provides for civil penalties of up to \$25,000 per day per violation. Taking relevant factors into account, the Administrator shall assess the amount of such civil penalties in an order made on the record after the opportunity for an adjudicative hearing and proper notification of the person in violation of this Act. Such person may file a petition for judicial review of an order assessing civil penalties in U.S. Court of Appeals within thirty days; however, if a person fails to pay such assessment after it has become a final and unappealable order or after the Court of Appeals has found in favor of the Administrator, then the Attorney General shall recover the amount assessed.

Subsection (b) provides for criminal penalties of up to \$25,000 per day or up to one year's imprisonment, or both, per violation for any person who knowingly or willfully violates this Act.

*House amendment (section 16)*

The House amendment follows subsections (a) and (b) of the Senate provision. In addition, subsection (c) of the House Amendment provides that the Administrator may require a person who has manufactured, processed, or distributed a chemical substance or mixture in violation of regulations issued under paragraphs (1) or (2) of section 6(a) to give notice of the risk associated with that substance to any person who may be exposed to it and to the public at large.

The Administrator may also require such person to either replace or repurchase the substance found to be in violation. The Administrator may choose any or all of the remedies set forth in subsection (c); however, in each case the order must be made on the record with full opportunity for an agency hearing.

*Conference substitute (section 16)*

The conference substitute adopts the provisions found in both bills concerning civil and criminal penalties for violations of this Act. Under subsection (a), the Administrator shall assess the amount of civil penalties up to \$25,000 per day per violation; however, the Administrator must take into account such factors as the gravity and extent of the violation, the ability to pay of the person held in violation, and any prior history of violations under this Act.

Criminal penalties may be imposed on persons who "knowingly or willfully" violate any provision of section 15, which sets forth unlawful acts.

SPECIFIC ENFORCEMENT AND SEIZURE

*Senate bill (section 17)*

The Senate bill grants the United States district courts jurisdiction, upon application of the Administrator or the Attorney General, to restrain any violation of section 15, to restrain any person from manufacturing or processing a chemical substance before the expiration of the notification period under section 5, and to restrain any person from taking any action prohibited by a requirement prescribed under section 5 or 6 or rules or orders issued under section 5 or 6. In addition, the courts are granted jurisdiction to direct any manufacturer or processor of a chemical substance or mixture who is not in compliance with any order issued under section 5(e) or any rule issued under section 4 or 6 to give notice of such fact to persons within the chain of distribution and to the public, and to either replace or repurchase the substance or mixture. The Senate provision also authorizes the district courts to compel the taking of any action required by or under the Act. In addition, the Senate bill provides that any substance or mixture manufactured or processed or distributed in commerce in violation of the Act or any rule or order promulgated under the Act shall be liable to be proceeded against for seizure and condemnation.

*House amendment (section 17)*

The House amendment grants jurisdiction to the district courts to restrain any violation of section 15, to restrain any person from manufacturing or processing a substance before the expiration of the notification period under section 5, and to restrain any person from taking action prohibited by section 5 or a rule or order under section 5 or 6. Jurisdiction is also granted to compel the taking of any action required by or under this Act. The seizure authority in the House amendment is similar to that found in the Senate bill, except that seizure and condemnation of articles containing chemical substances or mixtures manufactured, processed or distributed in commerce in violation of the Act or any rule or order promulgated under the Act is specifically authorized.

*Conference substitute*

The conference substitute grants the district courts of the United States jurisdiction to restrain any violation of section 15, to restrain any person from manufacturing or processing a substance before the expiration of the notification period under section 5, and to restrain any person from taking any action prohibited by section 5 or 6 or a rule or order under section 5 or 6. The provision also grants such courts jurisdiction over actions to direct any manufacturer or processor of a chemical substance or mixture manufactured or processed in violation of any order issued under section 5 or any rule or order issued under section 6 to give notice of the risk associated with the substance or mixture to persons in the chain of distribution and to the public. The courts also have jurisdiction to require manufacturers or processors to either replace or repurchase the substance or mixture, whichever the person to whom the requirement is directed elects. The conference substitute also grants jurisdiction to compel the taking of any action required by or under the Act. The seizure authority in the conference substitute is identical to that contained in the House amendment.

## PREEMPTION

*Senate bill (section 18)*

This section outlines the relationship between State authority and the authority under this Act to regulate chemical substances or mixtures. Subsection (a) asserts the State's authority to regulate, with certain limitations. No State may require testing which duplicates testing required by the Administrator under a section 4 testing rule. Further, if the Administrator has prescribed a requirement under section 5 or 6 to protect against a particular risk associated with a chemical substance or mixture, a State may not prescribe any different requirement (other than a total ban) with respect to that risk unless the State obtains permission from the Administrator to do so.

The Administrator may, by rule, grant such permission if the Administrator finds that compliance with the State requirement would not result in a violation of this Act, would result in a significantly higher degree of protection, and would not unduly burden interstate commerce.

*House amendment (section 18)*

The House amendment is similar to the Senate bill. However, rules promulgated under section 6(a)(5) do not preempt State laws. Moreover, rules promulgated under other Federal authorities such as the Clean Air Act, are not preempted by requirements under this Act.

Like the Senate bill, the House amendment authorizes the Administrator to exempt, by rule, States from prohibitions under subsection (a) in the same manner as the Senate bill.

*Conference substitute (section 18)*

The conference substitute provides that no State or political subdivision may establish similar requirements for the testing of a substance or mixture after the Administrator has issued a rule under section 4 respecting the substance or mixture. Nor may any State regulate any risk associated with a substance or mixture if the Administrator has prescribed a rule or order under section 5 or 6, which is

designed to protect against the risk to health or the environment, unless the rule (A) is identical to that issue under this Act, (B) is adopted under the authority of another Federal law, or (C) prohibits the use of such substance or mixture other than in its use in the manufacture or processing of other chemical substances or mixtures.

In addition to the specific exemptions from the preemption provision, the conference substitute provides a means whereby a State or political subdivision may seek an exemption from the preemptive effects of a Federal requirement in order to provide a higher degree of protection for their citizens than that provided by a requirement under this Act. The Administrator may, by rule, grant an exemption if compliance with the State or local requirement will not cause a violation of the applicable requirement under this Act, if the State or local requirement will provide a significantly higher degree of protection from the risk, and if the State or local requirement will not unduly burden interstate commerce.

## JUDICIAL REVIEW

*Senate bill (section 19)*

The Senate's provision authorized pre-enforcement judicial review of any rule under the Act or an order issued under section 5(e). Any rule promulgated under section 3(b), 5 or 6 shall not be affirmed unless the rule (A) is identical to that issued under this Act, (B) is

*House amendment (section 19)*

The House provision authorizes pre-enforcement judicial review of rules issued under section 4, 5 or 6(a). Such rules shall not be affirmed unless supported by substantial evidence based on the record taken as a whole.

*Conference substitute (section 19)*

Section 19 of the conference substitute provides for judicial review in the courts of appeals of the United States for certain rules promulgated under the Act. The jurisdiction for pre-enforcement review and review of determinations of the Administrator relating to cross-examination is exclusively vested in such courts. Not later than 60 days after the date of promulgation of a rule under section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8 any person may file a petition for judicial review of the rule in the appropriate U.S. court of appeals.

The section specifically defines the rulemaking record to include the rule being reviewed (which would include the statement of basis and purpose pursuant to section 553(c) of title 5, United States Code), any transcript required to be made of an oral presentation, any written submission of interested parties, and any other information which the Administrator considers to be relevant to the rule and with respect to which the Administrator published a notice in the Federal Register identifying the information on or before the date of the promulgation of such rule. In addition certain findings and statements required to be made with respect to specific rules must also be included in the rulemaking record. In the case of a rule under section 4(a), the finding required, by that section must be included in the record. In the case of a rule under section 5(b)(4), the finding required to be made



by that section must be included in that record. In the case of a rule under section 6(a), the finding required by section 5(f) or section 6(a), as the case may be, and the statement required by section 6(c)(1) must be included in the rulemaking record.

The section includes authority for the submission of additional data and oral or written views and for the modification of the rule being reviewed.

Generally section 706 of title 5, United States Code, applies to review of a rule under this section. However, in the case of review of a rule under section 4(a), 5(b)(4), 6(a) or 6(e), the bill provides that the courts shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole. This provision is in lieu of paragraph 2(E) of section 706 of title 5. It is the intent of the conferees that the traditional presumption of validity of an agency rule is to remain in effect. The conferees recognize that in rulemaking proceedings such as those contained in this bill, which are essentially informal and which involve both determinable facts and policy judgments derived therefrom, the traditional standard for review is that of "arbitrary and capricious". However, the conferees have adopted the "substantial evidence" test because they intend that the reviewing court focus on the rulemaking record to see if the Administrator's action is supported by that record. Of course, the conferees do not intend that the court substitute its judgment for that of the Administrator.

Further, in the case of review of a rule under section 6(a), the court shall set the rule aside if it finds that action by the Administrator in excluding or limiting cross-examination or rebuttal submissions precluded disclosure of disputed issues of material fact necessary for a fair determination of the rulemaking proceeding taken as a whole. Also, in review of such rules, section 706(2)(D) will not apply with respect to review of the Administrators actions respecting limitations or exclusions of cross-examination or rebuttal submissions, and review of such actions can occur only during preenforcement judicial review.

Section 19 also provides that the court may not review the contents and adequacy of any statement required to be made pursuant to section 6(c)(1) or any statement of basis and purpose required by section 553(c) of title 5 of United States Code to be incorporated in the rule except as part of a review of a rulemaking record taken as a whole.

Section 19 provides that in a judicial review proceeding under this section the court may award the costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. In addition, in any review of such an action the Supreme Court may also award such costs of suit and reasonable fees.

The section also provides that the remedies provided in section 19 shall be in addition to, and not in lieu of, any other remedies provided by law. This provision should not be construed, however, to negate the provision in this section which specifically provides that the United States courts of appeals shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) if any district court of the United States would have had jurisdiction of such an action but for the provisions of this section.

#### CITIZEN'S CIVIL ACTIONS

##### *Senate bill (section 20)*

Subsection (a) authorizes any person to commence a civil action in specified district courts against (A) any person including the United States or any governmental agency or instrumentality alleged to be in violation of this Act or any rule or order prescribed under sections 4, 5, or 6(a). Such suits may also be brought to compel the Administrator to perform any nondiscretionary act or duty.

Subsections (b), (c), and (d) specify certain procedural provisions. No action may begin until the Administrator and the alleged violator have received proper notice of the alleged violation. If the Administrator has instituted a civil action against an alleged violator to compel compliance, then no action may be brought under this section. However, if the Administrator does not commence such action until after the person bringing the citizen's civil action has notified the alleged violator of intention to sue under this Act, then the person who gave such notification may intervene in the suit brought by the Administrator. The Administrator may intervene in any civil action under this section to which the Administrator is not a party. The court may award the costs of the suit and reasonable fees for attorneys and expert witnesses. The court may also consolidate two or more civil actions involving the same defendant, the same issues, or the same alleged violations when appropriate.

##### *House amendment (section 20)*

The House amendment contains the same provision as the Senate bill.

##### *Conference substitute (section 20)*

The conference substitute contains the provision included in both the Senate bill and the House amendment with a clarification that citizen's civil actions may also be brought for violations of an order under section 5 or 6.

#### CITIZENS' PETITIONS

##### *Senate bill (section 21)*

Section 21 of the Senate bill authorizes any person to petition the Administrator to issue a rule or order or to take other action for the purpose of protecting against an unreasonable risk of injury to health or the environment. If the petition is denied or not acted upon within 90 days, the petitioner may bring a civil action in a United States district court to compel the Administrator to initiate the requested action. If the petitioner demonstrates by a preponderance of the evidence in a *de novo* proceeding that the action requested in the petition conforms to the applicable requirements of the Act, the court shall order the Administrator to initiate the requested action.

##### *House amendment (section 21)*

The House amendment authorizes any person to petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 5(c), or 6(a). If the petition is denied, the petitioner may file a civil action to compel the Administrator

to initiate the rulemaking proceeding. If the petitioner requests the issuance of a rule under section 4, 5(c), or 6(a) (as opposed to the modification or repeal of such a rule) the petitioner has an opportunity for a *de novo* proceeding before the court. If the petitioner makes the requisite showings for the applicable provision, the court must order the Administrator to initiate the requested action unless the court finds that the failure of the Administrator to initiate the requested action was not unreasonable.

*Conference substitute (section 21)*

The conference substitute authorizes any person to petition the Administrator to initiate a proceeding for the issuance, amendment or repeal of an action under section 4, 5(e), 6, or 8 of the Act. It should be noted that a petition under this section may be used to initiate a proceeding under section 5(f) since a proceeding under that section is for the issuance of a rule under section 6(a). The Administrator must grant or deny any petition under this section within 90 days after it is filed.

The conference substitute thereafter provides for different judicial review of the Administrator's denial of a petition, depending upon whether such petition seeks the issuance of a rule or order or the amendment or repeal of an existing rule or order.

The substitute affords greater rights to a person petitioning for the issuance of a rule or order because in such a situation the Administrator will not previously have addressed the issue by rule or order. If the Administrator denies or fails to respond to a petition for the issuance of a rule or order, the petitioner may commence a civil action in a United States district court to compel the Administrator to take the action requested in the petition. In the court, the petitioner is entitled to a *de novo* proceeding. If the petitioner demonstrates to the court by a preponderance of the evidence that there is an adequate basis for the issuance of the rule or order requested, the court shall order the Administrator to initiate the requested action.

The court may defer requiring the Administrator to take the requested action if it finds that the extent of risk of injury to health or the environment alleged by the petitioner is less than those risks of injury which the Administrator is addressing under this Act and there are insufficient resources to do both. If a deferral is granted, the conferees anticipate that the Administrator may seek extensions as needed.

The conference substitute provides different treatment for review of petitions for amendment or repeal of rules or orders, because the Administrator already will have addressed the general subject matter in an existing rule or order and the Administrator's determination will have been subject to review under section 19 of this Act. Therefore, the conferee's main interest is to make certain that any such petitioner receive timely consideration of such petition. By requiring the Administrator to act on any such petition within 90 days, the conferees will facilitate such a petitioner's right to seek judicial review should the Administrator deny the petition. Otherwise, the Administrator could avoid any judicial review simply by failing to take any action.

The conferees believe that a petition for amendment or repeal of an existing rule or order should contain newly discovered, noncumulative

material which was not presented for the Administrator's consideration in promulgating the rule or order. Failure to include such information would be an adequate basis for denying the petition.

At the same time, the conferees do not intend that the Administrator be subjected to constant petitions challenging rules or orders for which adequate judicial review is provided under section 19. Therefore, if the Administrator denies a petition to amend or repeal an action under section 4, 5(e), 6, or 8, the conference substitute permits review of such denial only under the Administrative Procedure Act.

NATIONAL DEFENSE WAIVER

*Senate bill (section 22)*

The Senate bill directs the Administrator to waive compliance with any provision of this Act upon the request of the Secretary of Defense and a determination by the President that the interest of national defense requires such a waiver. The Administrator shall maintain a written record of the basis for the waiver. In addition, the Administrator shall publish notice of the waiver in the Federal Register, unless the Administrator determines, upon request from the Secretary of Defense, that such publication is contrary to national defense interests, in which case, the Administrator shall notify the Armed Services Committees of the Senate and the House of Representatives.

*House amendment (section 22)*

The House amendment is similar to the policies and procedures of the Senate bill except that only the President, not the Secretary of Defense, is authorized to request a national defense waiver from the Administrator and to request that publication of the waiver not be placed in the Federal Register for national defense reasons.

*Conference substitute (section 22)*

The conference substitute includes the provision of the House amendment.

EMPLOYEE PROTECTION

*Senate bill (section 23)*

Section 23 of the Senate bill provides protection for employees who cooperate with the Administrator in carrying out the Act. The provision prohibits any employer from discharging any employee or otherwise discriminating against the employee with respect to compensation, terms, conditions, or privileges of employment because the employee commenced, caused to be commenced, or is about to commence a proceeding under the Act. Protection is provided for employees who have testified or are about to testify in any proceeding under the Act or who have assisted or participated in a proceeding or any other action to carry out the purposes of the Act. The Secretary of Labor shall conduct investigations of alleged violations and issue orders to require any person who violates the prohibitions to take affirmative action to remedy any such violation. Any person adversely affected by an order of the Secretary may obtain judicial review of the order in the United States court of appeals for the circuit in which the violation allegedly occurred. The Secretary is authorized to enforce the orders in the dis-

strict court of the United States for the district in which the violation occurred.

*House amendment (section 23)*

The House amendment contains an identical provision.

*Conference substitute (section 23)*

The conference substitute adopts the provision found in both the Senate bill and House amendment.

EMPLOYMENT EFFECTS

*Senate bill (section 23(f))*

The Administrator shall conduct continuing evaluation of the effect on employment of rules or orders under this Act. Any employee who is discharged or whose employment is threatened or who is otherwise discriminated against as a result of any action under this Act may request investigation of the matter by the Administrator. The Administrator shall investigate the matter. If any interested party requests a hearing, the Administrator shall conduct a public hearing in accordance with section 554 of title 5, United States Code, at which the parties are required to present information on any employment effects.

Upon receipt of the investigation report, the Administrator shall make findings of fact as to the employment effects and shall make appropriate recommendations which shall be available to the public.

*House amendment (section 24)*

The House amendment is similar to the Senate bill. The House provision differs from the Senate's primarily as to whether and how a hearing requested by an interested person shall be conducted.

Upon request, the Administrator must hold a public hearing unless the Administrator determines that there are no reasonable grounds for such hearing. The hearing need not be a formal adjudicative hearing under 5 U.S.C. 554. Provision is made for subpoenas, oaths, and payment of witness fees in connection with any investigation or public hearing conducted under this section.

*Conference substitute (section 24)*

The conference substitute follows the House amendment with two modifications. First, if the Administrator determines that there are no reasonable grounds for holding a hearing, the Administrator must so find, by order, within 45 days of the date within which time such hearing is requested. Second, if a hearing is held, it shall be in accordance with the requirements of section 6(c)(3) of this Act.

STUDIES

*Senate bill (section 24)*

The Senate bill requires the General Accounting Office to conduct a study of all Federal laws administered by the Administrator to determine whether and under what conditions, if any, indemnification should be accorded any person as a result of action taken by the Administrator under such laws. The Senate bill also requires the Council on Environmental Quality to coordinate a study of the feasibility of

establishing a standard classification system of chemical substances and related substances and a standard method for storing and obtaining rapid access to information respecting such substances.

*House amendment (section 25)*

The House amendment contains a similar provision except that the indemnification study shall be conducted by the Administrator and reviewed by the General Accounting Office.

*Conference substitute (section 25)*

The conference substitute includes the House provision.

ADMINISTRATION OF THE ACT

*Senate bill (section 26)*

Subsection (a) gives authority to each federal department and agency to cooperate with the Administrator, upon request, by sharing services of personnel, facilities, and information in order to carry out the purposes of this Act.

Subsection (b) provides that the Administrator may, by rule, require payment from any person submitting data pursuant to section 4 or 5 to help defray administrative costs, provided that no such fee exceeds \$2,500.

Under subsection (c), the Administrator may act with respect to categories of chemical substances or mixtures. For purposes of this section, a category includes chemical substances or mixtures grouped by virtue of similarity of chemical structure, physical, chemical, or biological properties, use or mode of entry into the human body or environment, or some other suitable grouping.

Under subsection (d), any proposed or final rule or order under this Act shall be accompanied by a statement of purpose and justification, which identifies the basis for the action. This statement shall become part of the "record of the proceedings" for purposes of judicial review under section 19(a).

Subsection (e) directs the President to appoint by and with the advice and consent of the Senate, an Assistant Administrator of the Environmental Protection Agency to administer this Act. The Assistant Administrator shall be qualified to direct a program concerning the effects of chemicals on health and the environment by reason of background and experience.

*House amendment (section 26)*

The House amendment contains provisions similar to the Senate bill concerning cooperation among federal agencies and fees to be paid by persons submitting data under section 4 or 5 to defray administrative costs, except that no small businesses shall be required to pay administrative fees exceeding \$100. The House amendment also includes a provision on categories similar to that in the Senate bill.

No provision is made in the House amendment for appointment of an Assistant Administrator for Toxic Substances. However, the House amendment establishes an office within the Environmental Protection Agency to provide technical and other nonfinancial assistance to manufacturers and processors of chemical substances and mixtures concerning the requirements and application of this Act.

The House amendment does not contain a specific provision requiring that each proposed or final rule or order be accompanied by a statement of purpose or justification.

The House amendment in section 29 provides that each officer and employee of the Environmental Protection Agency and the Secretary of Health, Education, and Welfare who perform any function or duty under the bill and who has any known financial interest in any person subject to the bill or in any person who applied for or received any financial assistance pursuant to the bill must, beginning February 1, 1977, annually file with the appropriate agency or department a statement concerning all such interests during the preceding calendar year. Such statement must be available to the public.

The House amendment also directs the Administrator and the Secretary, within 90 days after enactment, to define "known financial interest" and to establish methods to monitor, enforce, and review the filing of such statements. They are also directed to report each year to Congress on June 1 regarding such disclosures and actions taken concerning them during the preceding calendar year.

Officers or employees in designated positions of a nonregulatory or nonpolicymaking nature may be exempted, by rule, from the requirements of this section.

The House amendment states that any officer or employer who is subject to, and knowingly violates, this section or any regulations issued thereunder is to be fined not more than \$2,500 or imprisoned for not more than one year, or both.

*Conference substitute (section 26)*

The conference substitute incorporates provisions from both the Senate bill and the House amendment. Subsection (a) gives authority to each federal agency and department to cooperate with the Administrator to carry out the purposes of this Act.

The Administrator is authorized to require, by rule, payment of reasonable fees from any person required to submit data under sections 4 and 5 in order to defray the costs of administering this Act. In no case shall such fees exceed \$2,500, or \$100 in the case of a small business. In all cases when setting such fees, the Administrator shall take into account the ability to pay of persons submitting data.

The conference substitute includes the House provision concerning categories in subsection (c). The conferees expect that the Administrator will find the authority to categorize especially helpful in promulgating rules under section 5(a)(2) concerning what constitutes significant new use of chemical substances.

The conference substitute adopts the provision from the House amendment which establishes an office within EPA to provide technical and other nonfinancial assistance to manufacturers, processors of chemicals, and others. The purpose of the office is to help manufacturers and processors understand the requirements of the Act in order to assist in its efficient implementation and to avoid unnecessary confusion, which might prove detrimental to the chemical industry and the public interest.

The conference substitute adopts the House provision on financial disclosures for which the Senate bill had no comparable provision.

The procedures and penalties are designed to make sure that persons who perform regulatory functions under this Act divulge any known financial interest such persons may have in any person subject to this Act.

Subsection (f) of the conference substitute modifies the requirement in the Senate amendment that each proposed or final rule or order be accompanied by a statement of basis and purpose to apply only to final orders.

The conference substitute includes the provision found in the Senate bill that the President appoint, with the advice and consent of the Senate, an Assistant Administrator for Toxic Substances who shall direct a program concerning the effects of chemicals on human health and the environment and perform other duties and responsibilities under this Act.

While the Assistant Administrator for Toxic Substances will be assigned responsibilities pursuant to this Act, the Administrator may assign additional duties. Of course this position will be in addition to the existing five assistant administrator positions established by Reorganization Plan No. 3 of 1970.

DEVELOPMENT AND EVALUATION OF TEST METHODS

*Senate bill*

The Senate bill contains no provision respecting development and evaluation of test methods.

*House amendment (section 27)*

The House amendment authorizes the Secretary of Health, Education, and Welfare, in consultation with the Administrator and acting through the Office of the Assistant Secretary for Health, to conduct projects for the development and evaluation of inexpensive and efficient methods for determining and evaluating the health and environmental effects of chemical substances and mixtures.

*Conference substitute (section 27)*

The House provision is included.

STATE PROGRAMS

*Senate bill (section 25)*

Section 25 authorizes the Administrator to assist up to three states in the establishment of demonstration programs to complement federal efforts under the Act. Subsection (a) describes the functions of such programs. Subsection (b) requires the Administrator to submit annual reports to the Congress on the demonstration programs. Subsection (c) authorizes appropriation of funds to assist the states in funding the demonstration programs. Grants shall not exceed 75 percent of the cost of any demonstration program. Subsection (d) provides that assistance shall be available to those states which can establish a priority need for such assistance. The Senate bill authorizes a maximum appropriation of \$2 million for the fiscal year ending September 30, 1977, \$2 million for the fiscal year ending September 30, 1978, and \$2 million for the fiscal year ending September 30, 1979.

*House amendment (section 28)*

The House amendment is similar to the Senate bill, but differs in that grants are authorized only to assist states in addressing risks associated with substances and mixtures which the Administrator is unable to address.

The House amendment does not restrict the number of programs which the Administrator may approve. The House amendment authorizes an annual appropriation of \$1 million for the fiscal years ending September 30, 1978, September 30, 1979 and September 30, 1980.

*Conference substitute (section 28)*

The conference substitute generally follows the House amendment with some modification. The Administrator may make grants to States to establish programs to prevent or eliminate unreasonable risks associated with chemical substances or mixtures against which the Administrator is not able or not likely to take action under this Act. The conferees agreed to a compromise on the authorization for such programs of \$1.5 million for each of the fiscal years 1977 through 1979.

## AUTHORIZATION FOR APPROPRIATIONS

*Senate bill (section 27)*

Section 27 of the Senate bill authorizes to be appropriated to the Administrator \$11,100,000 for the fiscal year ending June 30, 1976, \$2,600,000 for the period beginning July 1, 1976 and ending September 30, 1976, and \$10,100,000 for the fiscal year ending September 30, 1977. This section prohibits using funds for construction of research laboratories.

Section 27(b) of the Senate bill requires that the Administrator submit concurrently to the Congress any budget requests, supplemental budget estimates, legislative recommendations, prepared testimony for Congressional hearings, or comments on legislation to the President or to the Office of Management and Budget connected with this Act.

*House amendment (section 30)*

The House amendment authorizes to be appropriated \$12,625,000 for the fiscal year ending September 30, 1978, \$16,200,000 for the fiscal year ending September 30, 1979, and \$17,350,000 for the fiscal year ending September 30, 1980. The House amendment contained no provision relating to simultaneous submissions.

*Conference substitute (section 29)*

The conference substitute authorizes to be appropriated to carry out the purposes of this Act as follows: \$10,100,000 for the fiscal year ending September 30, 1977; \$12,625,000 for the fiscal year ending September 30, 1978; and \$16,200,000 for the fiscal year ending September 30, 1979.

The conference substitute contains no provision for simultaneous submission of materials to Congress and the Office of Management and Budget.

## ANNUAL REPORT

*Senate bill (section 28)*

The Senate bill requires the Administrator to submit to both the President and the Congress a comprehensive annual report. The report shall include (1) a list of the testing required under section 4 and an estimate of the costs incurred by the person required to perform the tests; (2) the number of notices received under section 5, the number of notices received under section 5 for chemical substances subject to a section 4 rule, and a summary of any action taken during the premarket notification period; (3) a list of rules issued under section 6; (4) a list, with a brief statement of the issues, of completed or pending judicial actions under the bill; (5) a summary of major problems encountered in administration of the bill; and (6) such recommendations for additional legislation as the Administrator deems necessary to carry out the purposes of the bill.

*House amendment (section 31)*

The House amendment is almost identical to the Senate bill. The only difference occurs with respect to the date that the Administrator must submit the first annual report. The House amendment specifies that the Administrator shall submit the first annual report on or before January 1, 1979.

*Conference substitute (section 30)*

The conference substitute generally follows the provision of the Senate bill. The first submission is due on or before January 1, 1978.

## REVIEW

*Senate bill*

The Senate bill contained no rule review provision.

*House amendment (section 32)*

Section 32 of the House amendment provides that either House of Congress may veto a rule issued by the Administrator, the Secretary of the Treasury, or the Secretary of Health, Education, and Welfare under this Act, by adopting a resolution of disapproval within 60 days.

*Conference substitute*

The House recesses.

## EFFECTIVE DATE

*Senate bill*

The Senate bill contained no specific provision specifying an effective date; therefore, the legislation is to take effect upon enactment.

*House amendment (section 33)*

The House amendment provides that the legislation shall take effect October 1, 1977.

*Conference substitute*

The conference substitute establishes the effective date as January 1, 1977, except that section 4(f) shall not become effective for two years.

# Ninety-fourth Congress of the United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Monday, the nineteenth day of January,  
one thousand nine hundred and seventy-six*

## An Act

To regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes.

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

### SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

This Act may be cited as the "Toxic Substances Control Act".

#### TABLE OF CONTENTS

Sec. 1.	Short title and table of contents.
Sec. 2.	Findings, policy, and intent.
Sec. 3.	Definitions.
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Sec. 9.	Relationship to other Federal laws.
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Sec. 28.	State programs.
Sec. 29.	Authorization for appropriations.
Sec. 30.	Annual report.
Sec. 31.	Effective date.

### SEC. 2. FINDINGS, POLICY, AND INTENT.

#### (a) FINDINGS.—The Congress finds that—

(1) human beings and the environment are being exposed each year to a large number of chemical substances and mixtures;

(2) among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment; and

(3) the effective regulation of interstate commerce in such chemical substances and mixtures also necessitates the regulation of intrastate commerce in such chemical substances and mixtures.

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

(1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environ-

ment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;

(2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and

(3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

(c) **INTENT OF CONGRESS.**—It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this Act.

### 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 provided 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 "manufacture" means to import into the customs territory of the United States (as defined in general headnote 2 of the Tariff Schedules of the United States), produce, or manufacture.

(8) 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) 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).

(10) 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) The term "processor" means any person who processes a chemical substance or mixture.

(12) 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) 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) 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

(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 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 under subsection (a) shall include—

(A) identification of the chemical substance or mixture for which testing is required under the rule,

(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 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 and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule. Any such rule 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 carcinogenesis, 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 under subsection (a) and shall, if necessary, institute proceedings to make appropriate revisions of such standards.

(3) (A) A rule 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 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) 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 before such date;

and a rule 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 repeals the application of the rule to such substance or mixture or repeals the rule.

(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 submissions; (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) 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 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, 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,

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 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 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 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, 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, 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 under subsection (a) and if after such exemption is granted the Administrator determines that no such person has complied with such rule, 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 with respect to which such exemption was granted.

(d) Notice.—Upon the receipt of any test data pursuant to a rule 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 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 under section 4 before the submission of such notice, such person shall submit to the Administrator such data in accordance with such rule 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 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 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 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 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 pro-

ceeding 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, processing, 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).

(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 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, 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:

(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.

(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 extent 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.

(2) 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) 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-examina-

tion 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 rulemaking 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 rule-making 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) Paragraph (1), (2), (3), and (4) 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, 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.

(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 to a polychlorinated biphenyl will be insignificant as determined by the Administrator by rule.

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

(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 one year from the date it is granted) 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.

(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).

(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.

**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 imminently 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, or 6 or an order under section 5, 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 the 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 such 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), 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 or 7 with respect to such risk.

(3) If the Administrator has initiated action under section 6 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 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.

(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).

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

(a) **AUTHORITY.**—The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare and with other heads of appropriate departments and agencies, conduct such research, development, and monitoring as is necessary to carry out the purposes of this Act. The Administrator may enter into contracts and may make grants for research, development, and monitoring under this subsection. Contracts may be entered into under this subsection without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 14 U.S.C. 5).

(b) **DATA SYSTEMS.**—(1) The Administrator shall establish, administer, and be responsible for the continuing activities of an interagency committee which shall design, establish, and coordinate an efficient and effective system, within the Environmental Protection Agency, for the collection, dissemination to other Federal departments and agencies, and use of data submitted to the Administrator under this Act.

(2) (A) The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare and other heads of appropriate departments and agencies design, establish, and coordinate an efficient and effective system for the retrieval of toxicological and other scientific data which could be useful to the Administrator in carrying out the purposes of this Act. Systematized retrieval shall be developed for use by all Federal and other departments and agencies

with responsibilities in the area of regulation or study of chemical substances and mixtures and their effect on health or the environment.

(B) The Administrator, in consultation and cooperation with the Secretary of Health, Education, and Welfare, may make grants and enter into contracts for the development of a data retrieval system described in subparagraph (A). Contracts may be entered into under this subparagraph without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5).

(c) **SCREENING TECHNIQUES.**—The Administrator shall coordinate, with the Assistant Secretary for Health of the Department of Health, Education, and Welfare, research undertaken by the Administrator and directed toward the development of rapid, reliable, and economical screening techniques for carcinogenic, mutagenic, teratogenic, and ecological effects of chemical substances and mixtures.

(d) **MONITORING.**—The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare, establish and be responsible for research aimed at the development, in cooperation with local, State, and Federal agencies, of monitoring techniques and instruments which may be used in the detection of toxic chemical substances and mixtures and which are reliable, economical, and capable of being implemented under a wide variety of conditions.

(e) **BASIC RESEARCH.**—The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare, establish research programs to develop the fundamental scientific basis of the screening and monitoring techniques described in subsections (c) and (d), the bounds of the reliability of such techniques, and the opportunities for their improvement.

(f) **TRAINING.**—The Administrator shall establish and promote programs and workshops to train or facilitate the training of Federal laboratory and technical personnel in existing or newly developed screening and monitoring techniques.

(g) **EXCHANGE OF RESEARCH AND DEVELOPMENT RESULTS.**—The Administrator shall, in consultation with the Secretary of Health, Education, and Welfare and other heads of appropriate departments and agencies, establish and coordinate a system for exchange among Federal, State, and local authorities of research and development results respecting toxic chemical substances and mixtures, including a system to facilitate and promote the development of standard data format and analysis and consistent testing procedures.

#### **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 or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce and any conveyance being used to transport chemical substances, mixtures, 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 or mixtures 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 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.

#### **SEC. 12. EXPORTS.**

(a) **IN GENERAL.**—(1) Except as provided in paragraph (2) and subsection (b), this Act (other than section 8) shall not apply to any chemical substance, mixture, or to an article containing a chemical substance or mixture, if—

(A) it can be shown that such substance, mixture, or article is being manufactured, processed, or distributed in commerce for export from the United States, unless such substance, mixture, or article was, in fact, manufactured, processed, or distributed in commerce, for use in the United States, and

(B) such substance, mixture, or article (when distributed in commerce), or any container in which it is enclosed (when so distributed), bears a stamp or label stating that such substance, mixture, or article is intended for export.

(2) Paragraph (1) shall not apply to any chemical substance, mixture, or article if the Administrator finds that the substance, mixture, or article will present an unreasonable risk of injury to health within the United States or to the environment of the United States. The Administrator may require, under section 4, testing of any chemical substance or mixture exempted from this Act by paragraph (1) for the purpose of determining whether or not such substance or mixture presents an unreasonable risk of injury to health within the United States or to the environment of the United States.

(b) **NOTICE.**—(1) If any person exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under section 4 or 5(b), such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of the availability of the data submitted to the Administrator under such section for such substance or mixture.

(2) If any person exports or intends to export to a foreign country a chemical substance or mixture for which an order has been issued

under section 5 or a rule has been proposed or promulgated under section 5 or 6, or with respect to which an action is pending, or relief has been granted under section 5 or 7, such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of such rule, order, action, or relief.

**SEC. 13. ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES.**

(a) **IN GENERAL.**—(1) The Secretary of the Treasury shall refuse entry into the customs territory of the United States (as defined in general headnote 2 to the Tariff Schedules of the United States) of any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry if—

(A) it fails to comply with any rule in effect under this Act, or

(B) it is offered for entry in violation of section 5 or 6, a rule or order under section 5 or 6, or an order issued in a civil action brought under section 5 or 7.

(2) If a chemical substance, mixture, or article is refused entry under paragraph (1), the Secretary of the Treasury shall notify the consignee of such entry refusal, shall not release it to the consignee, and shall cause its disposal or storage (under such rules as the Secretary of the Treasury may prescribe) if it has not been exported by the consignee within 90 days from the date of receipt of notice of such refusal, except that the Secretary of the Treasury may, pending a review by the Administrator of the entry refusal, release to the consignee such substance, mixture, or article on execution of bond for the amount of the full invoice of such substance, mixture, or article (as such value is set forth in the customs entry), together with the duty thereon. On failure to return such substance, mixture, or article for any cause to the custody of the Secretary of the Treasury when demanded, such consignee shall be liable to the United States for liquidated damages equal to the full amount of such bond. All charges for storage, cartage, and labor on and for disposal of substances, mixtures, or articles which are refused entry or release under this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future entry made by such owner or consignee.

(b) **RULES.**—The Secretary of the Treasury, after consultation with the Administrator, shall issue rules for the administration of subsection (a) of this section.

**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 Administra-

tor 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.

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 processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing 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.—(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.

(2) (A) Except as provided by subparagraph (B), if the Administrator 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 submitting 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) 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.

#### 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, or (C) any rule promulgated or order issued under section 5 or 6;

(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. 16. PENALTIES.**

(a) CIVIL.—(1) Any person who violates a provision of section 15 shall be liable to the United States for a civil penalty in an amount not to exceed \$25,000 for each such violation. Each day such a violation continues shall, for purposes of this subsection, constitute a separate violation of section 15.

(2) (A) A civil penalty for a violation of section 15 shall be assessed by the Administrator by an order made on the record after opportunity (provided in accordance with this subparagraph) for a hearing in accordance with section 554 of title 5, United States Code. Before issuing such an order, the Administrator shall give written notice to the person to be assessed a civil penalty under such order of the Administrator's proposal to issue such order and provide such person an opportunity to request, within 15 days of the date the notice is received by such person, such a hearing on the order.

(B) In determining the amount of a civil penalty, the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Administrator may compromise, modify, or remit, with or without conditions, any civil penalty which may be imposed under this subsection. The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(3) Any person who requested in accordance with paragraph (2) (A) a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 30-day period beginning on the date the order making such assessment was issued.

(4) If any person fails to pay an assessment of a civil penalty—

(A) after the order making the assessment has become a final order and if such person does not file a petition for judicial review of the order in accordance with paragraph (3), or

(B) after a court in an action brought under paragraph (3) has entered a final judgment in favor of the Administrator, the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 30-day period referred to in paragraph (3) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(b) CRIMINAL.—Any person who knowingly or willfully violates any provision of section 15 shall, in addition to or in lieu of any civil penalty which may be imposed under subsection (a) of this section for such violation, be subject, upon conviction, to a fine of not more than \$25,000 for each day of violation, or to imprisonment for not more than one year, or both.

**SEC. 17. SPECIFIC ENFORCEMENT AND SEIZURE.**

(a) SPECIFIC ENFORCEMENT.—(1) The district courts of the United States shall have jurisdiction over civil actions to—

(A) restrain any violation of section 15,



(B) restrain any person from taking any action prohibited by section 5 or 6 or by a rule or order under section 5 or 6,

(C) compel the taking of any action required by or under this Act, or

(D) direct any manufacturer or processor of a chemical substance or mixture manufactured or processed in violation of section 5 or 6 or a rule or order under section 5 or 6 and distributed in commerce, (i) to give notice of such fact 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, (ii) to give public notice of such risk of injury, and (iii) to either replace or repurchase such substance or mixture, whichever the person to which the requirement is directed elects.

(2) A civil action described in paragraph (1) may be brought—

(A) in the case of a civil action described in subparagraph (A) of such paragraph, in the United States district court for the judicial district wherein any act, omission, or transaction constituting a violation of section 15 occurred or wherein the defendant is found or transacts business, or

(B) in the case of any other civil action described in such paragraph, in the United States district court for the judicial district wherein the defendant is found or transacts business.

In any such civil action process may be served on a defendant in any judicial district in which a defendant resides or may be found. Subpoenas requiring attendance of witnesses in any such action may be served in any judicial district.

(b) SEIZURE.—Any chemical substance or mixture which was manufactured, processed, or distributed in commerce in violation of this Act or any rule promulgated or order issued under this Act or any article containing such a substance or mixture shall be liable to be proceeded against, by process of libel for the seizure and condemnation of such substance, mixture, or article, in any district court of the United States within the jurisdiction of which such substance, mixture, or article is found. Such proceedings shall conform as nearly as possible to proceedings in rem in admiralty.

#### 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 under section 4 the testing of a chemical substance or mixture, no State or political subdivision may, after the effective date of such rule, 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; 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 mix-

ture, 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) **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 associated 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.

#### SEC. 19. JUDICIAL REVIEW.

(a) **IN GENERAL.**—(1) (A) Not later than 60 days after the date of the promulgation of a rule under section 4(a), 5(a) (2), 5(b) (4), 6(a), 6(e), or 8, any person may file a petition for judicial review of such rule 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 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 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 being reviewed under this section;

(B) in the case of a rule 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;

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

(D) any written submission of interested parties respecting the promulgation of such rule; and

(E) any other information which the Administrator considers to be relevant to such rule and which the Administrator identified, on or before the date of the promulgation of such rule, 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 the petitioner or the Administrator applies to the court for leave to make additional oral submissions or written presentations respecting such rule 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 submissions 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 being reviewed or make a new rule by reason of the additional submissions and presentations and shall file such modified or new rule with the return of such submissions and presentations. The court shall thereafter review such new or modified rule.

(c) **STANDARD OF REVIEW.**—(1) (A) Upon the filing of a petition under subsection (a) (1) for judicial review of a rule, 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 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 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), 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 if the court finds that the rule is not supported by substantial evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;

(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) 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 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 order issued under section 5 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).

(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).

(2) The Administrator may hold a public hearing or may conduct such investigation or proceeding as the Administrator deems appropriate 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), 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)—

(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.

**SEC. 22. NATIONAL DEFENSE WAIVER.**

The Administrator shall waive compliance with any provision of this Act upon a request and determination by the President that the requested waiver is necessary in the interest of national defense. The Administrator shall maintain a written record of the basis upon which such waiver was granted and make such record available for in camera examination when relevant in a judicial proceeding under this Act. Upon the issuance of such a waiver, the Administrator shall publish in the Federal Register a notice that the waiver was granted for national defense purposes, unless, upon the request of the President, the Administrator determines to omit such publication because the publication itself would be contrary to the interests of national defense, in which event the Administrator shall submit notice thereof to the Armed Services Committees of the Senate and the House of Representatives.

**SEC. 23. EMPLOYEE PROTECTION.**

(a) **IN GENERAL.**—No employer may discharge any employee or otherwise discriminate against any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee) has—

- (1) commenced, caused to be commenced, or is about to commence or cause to be commenced a proceeding under this Act;
- (2) testified or is about to testify in any such proceeding; or
- (3) assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this Act.

(b) **REMEDY.**—(1) Any employee who believes that the employee has been discharged or otherwise discriminated against by any person in violation of subsection (a) of this section may, within 30 days after such alleged violation occurs, file (or have any person file on the employee's behalf) a complaint with the Secretary of Labor (hereinafter in this section referred to as the "Secretary") alleging such discharge or discrimination. Upon receipt of such a complaint, the Secretary shall notify the person named in the complaint of the filing of the complaint.

(2) (A) Upon receipt of a complaint filed under paragraph (1), the Secretary shall conduct an investigation of the violation alleged in the complaint. Within 30 days of the receipt of such complaint, the Secretary shall complete such investigation and shall notify in writing the complainant (and any person acting on behalf of the complainant) and the person alleged to have committed such violation of the results of the investigation conducted pursuant to this paragraph. Within ninety days of the receipt of such complaint the Secretary shall, unless the proceeding on the complaint is terminated by the Secretary on the basis of a settlement entered into by the Secretary and the person alleged to have committed such violation, issue an order either providing the relief prescribed by subparagraph (B) or denying the complaint. An order of the Secretary shall be made on the record after notice and opportunity for agency hearing. The Secretary may not enter into a settlement terminating a proceeding on a complaint without the participation and consent of the complainant.

(B) If in response to a complaint filed under paragraph (1) the Secretary determines that a violation of subsection (a) of this section has occurred, the Secretary shall order (i) the person who committed such violation to take affirmative action to abate the violation, (ii)

such person to reinstate the complainant to the complainant's former position together with the compensation (including back pay), terms, conditions, and privileges of the complainant's employment, (iii) compensatory damages, and (iv) where appropriate, exemplary damages. If such an order issued, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney's fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(c) **REVIEW.**—(1) Any employee or employer adversely affected or aggrieved by an order issued under subsection (b) may obtain review of the order in the United States Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred. The petition for review must be filed within sixty days from the issuance of the Secretary's order. Review shall conform to chapter 7 of title 5 of the United States Code.

(2) An order of the Secretary, with respect to which review could have been obtained under paragraph (1), shall not be subject to judicial review in any criminal or other civil proceeding.

(d) **ENFORCEMENT.**—Whenever a person has failed to comply with an order issued under subsection (b) (2), the Secretary shall file a civil action in the United States district court for the district in which the violation was found to occur to enforce such order. In actions brought under this subsection, the district courts shall have jurisdiction to grant all appropriate relief, including injunctive relief and compensatory and exemplary damages. Civil actions brought under this subsection shall be heard and decided expeditiously.

(e) **EXCLUSION.**—Subsection (a) of this section shall not apply with respect to any employee who, acting without direction from the employee's employer (or any agent of the employer), deliberately causes a violation of any requirement of this Act.

#### **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



(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 to defray the cost of administering this Act. 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. 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).

(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 nonpolicymaking 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 (A) be in addition to the Assistant Administrators of the Environmental Protection Agency authorized by section 1(d) of Reorganization Plan No. 3 of 1970, and (B) be compensated at the rate of pay authorized for such Assistant Administrators.

**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 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).

(c) **ANNUAL REPORTS.**—(1) The Secretary shall prepare and submit to the President and the Congress on or before January 1 of each year a report of the number of grants made and contracts entered into under this section and the results of such grants and contracts.

(2) The Secretary shall periodically publish in the Federal Register reports describing the progress and results of any contract entered into or grant made under this section.

**SEC. 28. STATE PROGRAMS.**

(a) **IN GENERAL.**—For the purpose of complementing (but not reducing) the authority of, or actions taken by, the Administrator under this Act, the Administrator may make grants to States for the establishment and operation of programs to prevent or eliminate unreasonable risks within the States to health or the environment which are associated with a chemical substance or mixture and with respect to which the Administrator is unable or is not likely to take action under this Act for their prevention or elimination. The amount of a grant under this subsection shall be determined by the Administrator, except that no grant for any State program may exceed 75 per centum of the establishment and operation costs (as determined by the Administrator) of such program during the period for which the grant is made.

(b) **APPROVAL BY ADMINISTRATOR.**—(1) No grant may be made under subsection (a) unless an application therefor is submitted to and approved by the Administrator. Such an application shall be submitted in such form and manner as the Administrator may require and shall—

(A) set forth the need of the applicant for a grant under subsection (a),

(B) identify the agency or agencies of the State which shall establish or operate, or both, the program for which the application is submitted,

(C) describe the actions proposed to be taken under such program,

(D) contain or be supported by assurances satisfactory to the Administrator that such program shall, to the extent feasible, be integrated with other programs of the applicant for environmental and public health protection,

(E) provide for the making of such reports and evaluations as the Administrator may require, and

(F) contain such other information as the Administrator may prescribe.

(2) The Administrator may approve an application submitted in accordance with paragraph (1) only if the applicant has established to the satisfaction of the Administrator a priority need, as determined under rules of the Administrator, for the grant for which the application has been submitted. Such rules shall take into consideration the seriousness of the health effects in a State which are associated with chemical substances or mixtures, including cancer, birth defects, and gene mutations, the extent of the exposure in a State of human beings and the environment to chemical substances and mixtures, and the extent to which chemical substances and mixtures are manufactured, processed, used, and disposed of in a State.

(c) ANNUAL REPORTS.—Not later than six months after the end of each of the fiscal years 1979, 1980, and 1981, the Administrator shall submit to the Congress a report respecting the programs assisted by grants under subsection (a) in the preceding fiscal year and the extent to which the Administrator has disseminated information respecting such programs.

(d) AUTHORIZATION.—For the purpose of making grants under subsection (a) there are authorized to be appropriated \$1,500,000 for the fiscal year ending September 30, 1977, \$1,500,000 for the fiscal year ending September 30, 1978, and \$1,500,000 for the fiscal year ending September 30, 1979. Sums appropriated under this subsection shall remain available until expended.

**SEC. 29. AUTHORIZATION FOR APPROPRIATIONS.**

There are authorized to be appropriated to the Administrator for purposes of carrying out this Act (other than sections 27 and 28 and subsections (a) and (c) through (g) of section 10 thereof) \$10,100,000 for the fiscal year ending September 30, 1977, \$12,625,000 for the fiscal year ending September 30, 1978, \$16,200,000 for the fiscal year ending September 30, 1979. No part of the funds appropriated under this section may be used to construct any research laboratories.

**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, 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.

**SEC. 31. EFFECTIVE DATE.**

Except as provided in section 4(f), this Act shall take effect on January 1, 1977.

*Speaker of the House of Representatives.*

*Vice President of the United States and  
President of the Senate.*