1988—Par. (7). Pub. L. 100–418 substituted ''general note 2 of the Harmonized Tariff Schedule of the United States'' for ''general headnote 2 of the Tariff Schedules of the United States''.

1986—Par. (2)(B)(v). Pub. L. 99–514 substituted ''Internal Revenue Code of 1986'' for ''Internal Revenue Code of 1954''.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–418 effective Jan. 1, 1989, and applicable with respect to articles entered on or after such date, see section 1217(b)(1) of Pub. L. 100–418, set out as an Effective Date note under section 3001 of Title 19, Customs Duties.

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94–469, set out as a note under section 2601 of this title.

§ 2603. Testing of chemical substances and mixtures

(a) Testing requirements

(1) If the Administrator finds that—

(A)(i)(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 is insufficient information 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 information; or

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

(II) there is insufficient information 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 information; and

(B) 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, or, in the case of a chemical substance or mixture described in subparagraph (A)(i), by rule, order, or consent agreement, require that testing be conducted on such substance or mixture to develop information with respect to the health and environmental effects for which there is an insufficiency of information and experience and which is 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.

(2) ADDITIONAL TESTING AUTHORITY.—In addition to the authority provided under paragraph (1), the Administrator may, by rule, order, or consent agreement—

(A) require the development of new information relating to a chemical substance or mixture if the Administrator determines that the information is necessary—

(i) to review a notice under section 2604 of this title or to perform a risk evaluation under section 2605(b) of this title;

(ii) to implement a requirement imposed in a rule, order, or consent agreement under subsection (e) or (f) of section 2604 of this title or in a rule promulgated under section 2605(a) of this title;

(iii) at the request of a Federal implementing authority under another Federal law, to meet the regulatory testing needs of that authority with regard to toxicity and exposure; or

(iv) pursuant to section 2611(a)(2) of this title; and

(B) require the development of new information for the purposes of prioritizing a chemical substance under section 2605(b) of this title only if the Administrator determines that such information is necessary to establish the priority of the substance, subject to the limitations that—

(i) not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, order, or consent agreement under this subparagraph, the Administrator shall designate the chemical substance as a high-priority substance or a low-priority substance; and

(ii) information required by the Administrator under this subparagraph shall not be required for the purposes of establishing or implementing a minimum information requirement of broader applicability.

(3) STATEMENT OF NEED.—When requiring the development of new information relating to a chemical substance or mixture under paragraph (2), the Administrator shall identify the need for the new information, describe how information reasonably available to the Administrator was used to inform the decision to require new information, explain the basis for any decision that requires the use of vertebrate animals, and, as applicable, explain why issuance of an order is warranted instead of promulgating a rule or entering into a consent agreement.

(4) TIERED TESTING.—When requiring the development of new information under this subsection, the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are nec-

essary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first conducting screening-level testing.

(b) Testing requirement rule, order, or consent agreement

(1) A rule, order, or consent agreement under subsection (a) shall include—

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

(B) protocols and methodologies for the development of information 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 information developed in accordance with the protocols and methodologies referred to in subparagraph (B).

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

(2)(A) The health and environmental effects for which protocols and methodologies for the development of information 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. Protocols and methodologies for the development of information may also be prescribed for the assessment of exposure or exposure potential to humans or the environment. The characteristics of chemical substances and mixtures for which such protocols and methodologies 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 protocols and methodologies include epidemiologic studies, serial or tiered testing, 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 protocols and methodologies for development of information prescribed in rules, orders, and consent agreements under subsection (a) and shall, if necessary, institute proceedings to make appropriate revisions of such protocols and methodologies.

(3)(A) A rule or order under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph (B) or (C), as applicable, to conduct tests and submit information 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 information on behalf of the persons making the designation.

(B) The following persons shall be required to conduct tests and submit information on a chemical substance or mixture subject to a rule under subsection (a)(1):

(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)(i)(II) or (a)(1)(A)(ii)(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)(i)(II) or (a)(1)(A)(ii)(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)(i)(II) or (a)(1)(A)(ii)(II) with respect to the distribution in commerce, use, or disposal of such substance or mixture.

(C) A rule or order under paragraph (1) or (2) of subsection (a) may require the development of information by any person who manufactures or processes, or intends to manufacture or process, a chemical substance or mixture subject to the rule or order.

(4) Any rule, order, or consent agreement under subsection (a) requiring the testing of and submission of information 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 information for such substance or mixture unless the Administrator repeals the rule or order or modifies the consent agreement to terminate the requirement before such date; and a rule, order, or consent agreement under subsection (a) requiring the testing of and submission of information 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 information for such substance or mixture unless the Administrator before such date repeals or modifies the application of the rule, order, or consent agreement to such substance or mixture or repeals the rule or order or modifies the consent agreement to terminate the requirement.

(c) Exemption

(1) Any person required by a rule or order under subsection (a) to conduct tests and submit information 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 information has been submitted to the Administrator in accordance with a rule, order, or consent agreement under subsection (a) or for which information is being developed pursuant to such a rule, order, or consent agreement, and

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

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

(3)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit information on a chemical substance or mixture is granted on the basis of the existence of previously submitted information and if such exemption is granted during the reimbursement period for such information (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 information, for a portion of the costs incurred by such person in complying with the requirement to submit such information, 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 information for a chemical substance or mixture is a period—

(i) beginning on the date such information is submitted in accordance with a rule, order, or consent agreement under subsection (a), and

(ii) ending—

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

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

whichever is later.

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

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

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

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

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

(d) Notice

Upon the receipt of any information pursuant to a rule, order, or consent agreement under subsection (a), the Administrator shall publish a notice of the receipt of such information in the Federal Register within 15 days of its receipt. Subject to section 2613 of this title, each such notice shall (1) identify the chemical substance

or mixture for which information has been received; (2) list the uses or intended uses of such substance or mixture and the information required by the applicable protocols and methodologies for the development of information; and (3) describe the nature of the information developed. Except as otherwise provided in section 2613 of this title, such information 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 development of information 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 information 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 information 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 January 1, 1977, 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 preceeding[1] 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 issue an order, enter into a consent agreement, or initiate a rulemaking proceeding under subsection (a), or, if such an order or consent agreement is not issued or such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not issuing such an order, entering into such a consent agreement, or initiating such a proceeding.

(2)(A) The committee established by paragraph (1)(A) shall consist of ten 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 [29 U.S.C. 651 et seq.].

(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.

(ix) One member appointed by the Chairman of the Consumer Product Safety Commission

[1] So in original. Probably should be ''preceding''.

from Commissioners or employees of the Commission.

(x) One member appointed by the Commissioner of Food and Drugs from employees of the Food and Drug Administration.

(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 January 1, 1977. 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 chapter 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 chapter 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 information required to be submitted under this chapter, 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 a significant risk of serious or widespread harm to human beings, the Administrator shall, within the 180-day period beginning on the date of the receipt of such information, initiate applicable action under section 2604, 2605, or 2606 of this title to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding, made without consideration of costs or other nonrisk factors, 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. This subsection shall not take effect until two years after January 1, 1977.

(g) Petition for protocols and methodologies for the development of information

A person intending to manufacture or process a chemical substance for which notice is required under section 2604(a) of this title and who is not required under a rule, order, or consent agreement under subsection (a) to conduct tests and submit information on such substance may petition the Administrator to prescribe protocols and methodologies for the development of information 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 protocols and methodologies 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 2613 of this title, in the Federal Register the reasons for such denial.

(h) Reduction of testing on vertebrates

(1) In general

The Administrator shall reduce and replace, to the extent practicable, scientifically justified, and consistent with the policies of this subchapter, the use of vertebrate animals in the testing of chemical substances or mixtures under this subchapter by—

(A) prior to making a request or adopting a requirement for testing using vertebrate animals, and in accordance with subsection (a)(3), taking into consideration, as appropriate and to the extent practicable and scientifically justified, reasonably available existing information, including—

(i) toxicity information;

(ii) computational toxicology and bioinformatics; and

(iii) high-throughput screening methods and the prediction models of those methods; and

(B) encouraging and facilitating—

(i) the use of scientifically valid test methods and strategies that reduce or replace the use of vertebrate animals while providing information of equivalent or better scientific quality and relevance that will support regulatory decisions under this subchapter;

(ii) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide scientifically valid and useful information on other chemical substances in the category; and

(iii) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests, provided that such consortia make all information from such testing available to the Administrator.

(2) Implementation of alternative testing methods

To promote the development and timely incorporation of new scientifically valid test methods and strategies that are not based on vertebrate animals, the Administrator shall—

(A) not later than 2 years after June 22, 2016, develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing and provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment of chemical substances or mixtures through, for example—

(i) computational toxicology and bioinformatics;

(ii) high-throughput screening methods;

(iii) testing of categories of chemical substances;

(iv) tiered testing methods;

(v) in vitro studies;

(vi) systems biology;

(vii) new or revised methods identified by validation bodies such as the Interagency Coordinating Committee on the Validation of Alternative Methods or the Organization for Economic Co-operation and Development; or

(viii) industry consortia that develop information submitted under this subchapter;

(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

(C) include in the strategic plan developed under subparagraph (A) a list, which the Administrator shall update on a regular basis, of particular alternative test methods or strategies the Administrator has identified that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information of equivalent or better scientific reliability and quality to that which would be obtained from vertebrate animal testing;

(D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific reliability and relevance of the test methods and strategies that may be identified pursuant to subparagraph (C);

(E) beginning on the date that is 5 years after June 22, 2016, and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing the plan developed under subparagraph (A) and goals for future alternative test methods and strategies implementation; and

(F) prioritize and, to the extent consistent with available resources and the Administrator's other responsibilities under this subchapter, carry out performance assessment, validation, and translational studies to accelerate the development of scientifically valid test methods and strategies that reduce, refine, or replace the use of vertebrate animals, including minimizing duplication, in any testing under this subchapter.

(3) Voluntary testing

(A) In general

Any person developing information for submission under this subchapter on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative test method or strategy identified by the Administrator pursuant to paragraph (2)(C), if the Administrator has identified such a test method or strategy for the development of such information, before conducting new vertebrate animal testing.

(B) Effect of paragraph

Nothing in this paragraph shall, under any circumstance, limit or restrict the submission of any existing information to the Administrator.

(C) Relationship to other law

A violation of this paragraph shall not be a prohibited act under section 2614 of this title.

(D) Review of means

This paragraph authorizes, but does not require, the Administrator to review the means by which a person conducted testing described in subparagraph (A).

(Pub. L. 94–469, title I, § 4, Oct. 11, 1976, 90 Stat. 2006; renumbered title I, Pub. L. 99–519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 114–182, title I, §§ 4, 19(d), June 22, 2016, 130 Stat. 449, 505.)

Editorial Notes

REFERENCES IN TEXT

The Occupational Safety and Health Act of 1970, referred to in text, is Pub. L. 91–596, Dec. 29, 1970, 84 Stat. 1590, as amended, which is classified principally to chapter 15 (§ 651 et seq.) of Title 29, Labor. For complete classification of this Act to the Code, see Short Title note set out under section 651 of Title 29 and Tables.

AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114–182, § 4(2)(B)(x), in concluding provisions, inserted ", or, in the case of a chemical substance or mixture described in subparagraph (A)(i), by rule, order, or consent agreement," after "shall by rule", substituted "information" for "data" in two places, and substituted "and which is relevant" for "and which are relevant".

Pub. L. 114–182, § 4(2)(B)(v), substituted "such information" for "such data" in two places.

Pub. L. 114–182, § 4(2)(B)(iii), substituted "there is insufficient information" for "there are insufficient data" in two places.

Pub. L. 114–182, § 4(2)(A), substituted "(1) If the Administrator finds" for "If the Administrator finds".

Subsec. (a)(1)(A)(i)(I). Pub. L. 114–182, § 4(2)(B)(i), substituted "(A)(i)(I)" for "(1)(A)(i)".

Subsec. (a)(1)(A)(i)(II). Pub. L. 114–182, §4(2)(B)(ii), substituted ''(II)'' for ''(ii)''.

Subsec. (a)(1)(A)(i)(III). Pub. L. 114–182, §4(2)(B)(iv), substituted ''(III)'' for ''(iii)''.

Subsec. (a)(1)(A)(ii)(I). Pub. L. 114–182, §4(2)(B)(viii), which directed amendment of subsec. (a)(1) by substituting ''(bb)'' for ''(II)'', was executed by making the substitution in text of subsec. (a)(1)(A)(ii)(I) after ''quantities or'', to reflect the probable intent of Congress.

Pub. L. 114–182, §4(2)(B)(vii), which directed amendment of subsec. (a)(1) by substituting ''(aa)'' for ''(I)'', was executed by making the substitution in text of subsec. (a)(1)(A)(ii)(I) after ''quantities, and'', to reflect the probable intent of Congress.

Pub. L. 114–182, §4(2)(B)(vi), substituted ''(ii)(I)'' for ''(B)(i)''.

Subsec. (a)(1)(A)(ii)(II). Pub. L. 114–182, §4(2)(B)(ii), substituted ''(II)'' for ''(ii)''.

Subsec. (a)(1)(A)(ii)(III). Pub. L. 114–182, §4(2)(B)(iv), substituted ''(III)'' for ''(iii)''.

Subsec. (a)(1)(B). Pub. L. 114–182, §4(2)(B)(ix), substituted ''(B)'' for ''(2)''. Former subpar. (B) redesignated subpar. (A)(ii).

Subsec. (a)(2) to (4). Pub. L. 114–182, §4(2)(C), added pars. (2) to (4). Former par. (2) redesignated par. (1)(B).

Subsec. (b). Pub. L. 114–182, §19(d)(1)(A)(i), which directed amendment of subsec. (b)(1) by inserting '', order, or consent agreement'' at end of paragraph heading, was executed by making the insertion at end of subsec. (b) heading to reflect the probable intent of Congress.

Pub. L. 114–182, §4(1), substituted ''protocols and methodologies'' for ''standards'' wherever appearing except after ''various test'' in concluding provisions of par. (1).

Subsec. (b)(1). Pub. L. 114–182, §19(d)(1)(A)(ii), substituted ''rule, order, or consent agreement'' for ''rule'' wherever appearing.

Pub. L. 114–182, §4(3)(A)(iii), substituted ''information'' for ''data'' in concluding provisions.

Subsec. (b)(1)(B). Pub. L. 114–182, §4(3)(A)(i), substituted ''information'' for ''test data''.

Subsec. (b)(1)(C). Pub. L. 114–182, §4(3)(A)(ii), substituted ''information'' for ''data''.

Subsec. (b)(2)(A). Pub. L. 114–182, §4(3)(B)(i), inserted ''Protocols and methodologies for the development of information may also be prescribed for the assessment of exposure or exposure potential to humans or the environment.'' after ''health or the environment.'' and substituted ''information may be'' for ''test data may be'' and ''tiered testing'' for ''hierarchical tests''.

Subsec. (b)(2)(B). Pub. L. 114–182, §19(d)(1)(B), substituted ''rules, orders, and consent agreements'' for ''rules''.

Pub. L. 114–182, §4(3)(B)(ii), substituted ''information'' for ''data''.

Subsec. (b)(3). Pub. L. 114–182, §4(3)(C)(i), substituted ''information'' for ''data'' wherever appearing in subpars. (A) and (B).

Subsec. (b)(3)(A). Pub. L. 114–182, §19(d)(1)(C), substituted ''rule or order'' for ''rule''.

Pub. L. 114–182, §4(3)(C)(ii), inserted ''or (C), as applicable,'' after ''subparagraph (B)''.

Subsec. (b)(3)(B). Pub. L. 114–182, §4(3)(C)(iv), substituted ''subsection (a)(1)'' for ''subsection (a)'' in introductory provisions.

Pub. L. 114–182, §4(3)(C)(iii), substituted ''(a)(1)(A)(i)(II) or (a)(1)(A)(ii)(II)'' for ''(a)(1)(A)(ii) or (a)(1)(B)(ii)'' in cls. (i) to (iii).

Subsec. (b)(3)(C). Pub. L. 114–182, §4(3)(C)(v), added subpar. (C).

Subsec. (b)(4). Pub. L. 114–182, §19(d)(1)(D), substituted ''rule, order, or consent agreement under subsection (a)'' for ''rule under subsection (a)'' in two places, ''repeals the rule or order or modifies the consent agreement to terminate the requirement'' for ''repeals the rule'' in two places, and ''repeals or modifies the application of the rule, order, or consent agreement'' for ''repeals the application of the rule''.

Pub. L. 114–182, §4(3)(D), substituted ''of information'' for ''of data'' in two places and ''to information'' for ''to test data'' in two places.

Subsec. (b)(5). Pub. L. 114–182, §4(3)(E), struck out par. (5) which read as follows: ''Rules issued under subsection (a) (and any substantive amendment thereto or repeal thereof) shall be promulgated pursuant to section 553 of title 5 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.''

Subsec. (c)(1). Pub. L. 114–182, §19(d)(2)(A), substituted ''rule or order'' for ''rule''.

Pub. L. 114–182, §4(4)(A), substituted ''information'' for ''data''.

Subsec. (c)(2). Pub. L. 114–182, §19(d)(2)(B)(iii), substituted ''the rule or order'' for ''the rule'' in concluding provisions.

Pub. L. 114–182, §4(4)(B), substituted ''information'' for ''data'' wherever appearing.

Subsec. (c)(2)(A). Pub. L. 114–182, §19(d)(2)(B)(i), substituted ''a rule, order, or consent agreement under subsection (a) or for which information is being developed pursuant to such a rule, order, or consent agreement'' for ''a rule under subsection (a) or for which data is being developed pursuant to such a rule''. Amendment was executed as if the amendment by Pub. L. 114–182, §4(4)(B), had not applied, to reflect the probable intent of Congress. See above.

Subsec. (c)(2)(B). Pub. L. 114–182, §19(d)(2)(B)(ii), substituted ''such rule, order, or consent agreement or which is being developed pursuant to such rule, order, or consent agreement'' for ''such rule or which is being developed pursuant to such rule''.

Subsec. (c)(3)(A). Pub. L. 114–182, §4(4)(C)(i), substituted ''information'' for ''test data'' wherever appearing.

Subsec. (c)(3)(A)(i). Pub. L. 114–182, §4(4)(C), substituted ''submitted such information'' for ''submitted such test data'' and ''submit such information'' for ''submit such data''.

Subsec. (c)(3)(B). Pub. L. 114–182, §4(4)(C)(i), substituted ''information'' for ''test data'' in introductory provisions.

Subsec. (c)(3)(B)(i). Pub. L. 114–182, §19(d)(2)(C), substituted ''rule, order, or consent agreement'' for ''rule promulgated''.

Pub. L. 114–182, §4(4)(C)(ii), substituted ''such information'' for ''such data''.

Subsec. (c)(3)(B)(ii)(II). Pub. L. 114–182, §4(4)(C)(ii), substituted ''such information'' for ''such data''.

Subsec. (c)(4). Pub. L. 114–182, §19(d)(2)(D)(i), (ii), substituted ''pursuant to a rule, order, or consent agreement'' for ''pursuant to a rule promulgated'' in two places and ''such rule, order, or consent agreement'' for ''such rule'' wherever appearing.

Pub. L. 114–182, §4(4)(D), substituted ''information'' for ''test data'' wherever appearing.

Subsec. (c)(4)(B). Pub. L. 114–182, §19(d)(2)(D)(iii), substituted ''the rule or order'' for ''the rule''.

Subsec. (d). Pub. L. 114–182, §19(d)(3), substituted ''rule, order, or consent agreement'' for ''rule''.

Pub. L. 114–182, §4(5), substituted ''any information'' for ''any test data'', ''development of information'' for ''development of test data'', ''nature of the information'' for ''nature of the test data'', and ''for which information has'' for ''for which data have'', and substituted ''such information'' for ''such data'' in two places.

Pub. L. 114–182, §4(1), substituted ''protocols and methodologies'' for ''standards''.

Subsec. (e)(1)(A). Pub. L. 114–182, §4(6)(A)(i)(I), substituted ''development of information'' for ''promulgation of a rule'' in introductory provisions.

Subsec. (e)(1)(A)(vi), (vii). Pub. L. 114–182, § 4(6)(A)(i)(II), substituted ''information'' for ''data''.

Subsec. (e)(1)(B). Pub. L. 114–182, § 4(6)(A)(ii), substituted ''issue an order, enter into a consent agreement, or initiate a rulemaking proceeding under subsection (a), or, if such an order or consent agreement is not issued or such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not issuing such an order, entering into such a consent agreement, or initiating such a proceeding'' for ''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''.

Subsec. (e)(2)(A). Pub. L. 114–182, § 4(6)(B)(i), substituted ''ten members'' for ''eight members'' in introductory provisions.

Subsec. (e)(2)(A)(ix), (x). Pub. L. 114–182, § 4(6)(B)(ii), added cls. (ix) and (x).

Subsec. (f). Pub. L. 114–182, § 4(7)(B), in concluding provisions, struck out ''or will present'' after ''mixture presents'' and ''from cancer, gene mutations, or birth defects'' after ''human beings'', substituted ''applicable'' for ''appropriate'', and inserted '', made without consideration of costs or other nonrisk factors,'' after ''publish in the Federal Register a finding''.

Subsec. (f)(1). Pub. L. 114–182, § 4(7)(A), substituted ''information'' for ''test data''.

Subsec. (g). Pub. L. 114–182, § 19(d)(4), substituted ''rule, order, or consent agreement'' for ''rule''.

Pub. L. 114–182, § 4(8), substituted ''Petition for protocols and methodologies for the development of information'' for ''Petition for standards for the development of test data'' in heading and ''submit information'' for ''submit data'' and ''development of information'' for ''development of test data'' in text.

Pub. L. 114–182, § 4(1), substituted ''protocols and methodologies'' for ''standards'' in two places.

Subsec. (h). Pub. L. 114–182, § 4(9), added subsec. (h).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective Jan. 1, 1977, except as provided in subsec. (f) of this section, see section 31 of Pub. L. 94–469, set out as a note under section 2601 of this title.

§ 2604. Manufacturing and processing notices

(a) In general

(1)(A) Except as provided in subparagraph (B) of this paragraph and subsection (h), no person may—

(i) 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 2607(b) of this title, or

(ii) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use.

(B) A person may take the actions described in subparagraph (A) if—

(i) 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, or imposed pursuant to, subsection (b), (e), or (f); and

(ii) the Administrator—

(I) conducts a review of the notice; and

(II) makes a determination under subparagraph (A), (B), or (C) of paragraph (3) and takes the actions required in association with that determination under such subparagraph within the applicable review period.

(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.

(3) REVIEW AND DETERMINATION.—Within the applicable review period, subject to section 2617 of this title, the Administrator shall review such notice and determine—

(A) that the relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall take the actions required under subsection (f);

(B) that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use; or

(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, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator; 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,

in which case the Administrator shall take the actions required under subsection (e); or

(C) that the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant