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).

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 by the Administrator under the conditions of use, in which case the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use.

(4) FAILURE TO RENDER DETERMINATION.—

(A) FAILURE TO RENDER DETERMINATION.—If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 2625(b) of this title, and the Administrator shall not be relieved of any requirement to make such determination.

(B) LIMITATIONS.—(i) A refund of applicable fees under subparagraph (A) shall not be made if the Administrator certifies that the submitter has not provided information required under subsection (b) or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable review period.

(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.

(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section.

(5) ARTICLE CONSIDERATION.—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(A)(ii) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.

(b) Submission of information

(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 information for such substance pursuant to a rule, order, or consent agreement under section 2603 of this title before the submission of such notice, such person shall submit to the Administrator such information in accordance with such rule, order, or consent agreement at the time notice is submitted in accordance with subsection (a)(1).

(B) If—

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

(ii) such person has been granted an exemption under section 2603(c) of this title from the requirements of a rule or order under section 2603 of this title 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 information 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)(i) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(A)(ii).

(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, order, or consent agreement under section 2603 of this title before the submission of such notice to submit information for such substance,

such person may submit to the Administrator information prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

(B) Information submitted pursuant to subparagraph (A) shall be information which the person submitting the information believes shows that—

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

(3) Information submitted under paragraph (1) or (2) of this subsection or under subsection (e) shall be made available, subject to section 2613 of this title, 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, without consideration of costs or other nonrisk factors.

(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.

(c) Extension of review 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). Subject to section 2613 of this title, 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 2607(a)(2) of this title, and

(B) in such form and manner as the Administrator may prescribe, any information 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 information 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 2613 of this title, for examination by interested persons.

(2) Subject to section 2613 of this title, 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 information under subsection (b), the Administrator shall publish in the Federal Register a notice which—

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

(B) lists the uses of such substance identified in the notice; and

(C) in the case of the receipt of information under subsection (b), describes the nature of the tests performed on such substance and any information which was developed pursuant to subsection (b) or a rule, order, or consent agreement under section 2603 of this title.

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 applicable review period has not expired, and (B) each chemical substance for which such period has expired since the last publication in the Federal Register of such list.

(e) Regulation pending development of information

(1)[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); 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 subpopulation identified as relevant by the Administrator under the conditions of use; 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 shall issue an order, to take effect on the expiration of the applicable review period, 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 to the extent necessary to protect against 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, and the submitter of the notice may commence manufacture of the chemical substance, or manufacture or process-

[1] So in original. There is no par. (2).

ing of the chemical substance for a significant new use, including while any required information is being developed, only in compliance with the order.

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

(f) Protection against unreasonable risks

(1) If the Administrator determines that a chemical substance or significant new use with respect to which notice is required by subsection (a) presents an unreasonable risk of injury to health or environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use, the Administrator shall, before the expiration of the applicable review period, 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 2605(a) of this title 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 2605(a) of this title, 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 2605(d)(3)(B) of this title shall apply with respect to such rule.

(3)(A) The Administrator may issue an order to prohibit or limit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1). Such order shall take effect on the expiration of the applicable review period.

(B) The provisions of subparagraph (B) of subsection (e)(1) shall apply with respect to an order issued under subparagraph (A).

(4) TREATMENT OF NONCONFORMING USES.—Not later than 90 days after taking an action under paragraph (2) or (3) or issuing an order under subsection (e) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the action or order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(5) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B) to address workplace exposures.

(g) Statement on Administrator finding

If the Administrator finds in accordance with subsection (a)(3)(C) that a chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, then notwithstanding any remaining portion of the applicable review period, the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for the significant new use, and the Administrator shall make public a statement of the Administrator's finding. Such a statement shall be submitted for publication in the Federal Register as soon as is practicable 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, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific conditions of use identified in the application, 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 information 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 information has been submitted to the Administrator as required by subsection (b)(2), and

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

the Administrator shall exempt the applicant from the requirement to submit such information on such substance. No exemption which is granted under this subparagraph with respect to the submission of information for a chemical substance may take effect before the beginning of the reimbursement period applicable to such information.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting information required under subsection (b)(2) for a chemical substance because of the existence of previously submitted information and if such exemption is granted during the reimbursement period for such information, 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 information 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 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, 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 information 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 information 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 information,

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, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use.

(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) Definitions

(1) For purposes of this section, the terms ''manufacture'' and ''process'' mean manufacturing or processing for commercial purposes.

(2) For purposes of this chapter, the term ''requirement'' as used in this section shall not displace any statutory or common law.

(3) For purposes of this section, the term ''applicable review period'' means the period starting on the date the Administrator receives a notice under subsection (a)(1) and ending 90 days after that date, or on such date as is provided for in subsection (b)(1) or (c).

(Pub. L. 94–469, title I, §5, Oct. 11, 1976, 90 Stat. 2012; renumbered title I, Pub. L. 99–519, §3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 114–182, title I, §§5, 19(e), June 22, 2016, 130 Stat. 454, 506.)

AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114–182, §5(1)(A), designated existing provisions as subpar. (A) and redesignated former subpars. (A) and (B) as cls. (i) and (ii), respectively; substituted ''Except as provided in subparagraph (B) of this paragraph and'' for ''Except as provided in'' in introductory provisions; substituted ''significant new use.'' for ''significant new use,'' at end of cl. (ii); struck out concluding provisions ''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).''; and added subpar. (B).

Subsec. (a)(3) to (5). Pub. L. 114–182, §5(1)(B), added pars. (3) to (5).

Subsec. (b). Pub. L. 114–182, §5(2)(A), substituted ''information'' for ''test data'' in heading.

Subsec. (b)(1)(A). Pub. L. 114–182, §19(e)(1)(A), substituted ''a rule, order, or consent agreement'' for ''a rule promulgated'' and ''such rule, order, or consent agreement'' for ''such rule''.

Pub. L. 114–182, §5(2)(B)(i), substituted ''submit information'' for ''submit test data'' and ''such information'' for ''such data''.

Subsec. (b)(1)(B). Pub. L. 114–182, §5(2)(B)(ii), in concluding provisions, substituted ''information'' for ''test data'', ''subsection (a)(1)(A)(i)'' for ''subsection (a)(1)(A)'', and ''subsection (a)(1)(A)(ii)'' for ''subsection (a)(1)(B)''.

Subsec. (b)(1)(B)(ii). Pub. L. 114–182, §19(e)(1)(B), substituted ''rule or order'' for ''rule promulgated''.

Subsec. (b)(2)(A). Pub. L. 114–182, §5(2)(C)(i)(II), (III), in concluding provisions, substituted ''may'' for ''shall'' and ''information prescribed'' for ''data prescribed''.

Subsec. (b)(2)(A)(ii). Pub. L. 114–182, §19(e)(1)(C), substituted ''rule, order, or consent agreement'' for ''rule promulgated''.

Pub. L. 114–182, §5(2)(C)(i)(I), substituted ''information'' for ''test data''.

Subsec. (b)(2)(B). Pub. L. 114–182, §5(2)(C)(ii)(I)–(III), in introductory provisions, substituted ''Information'' for ''Data'', ''be information'' for ''be data'', ''the information'' for ''the data'', and ''shows'' for ''show''.

Subsec. (b)(2)(B)(i). Pub. L. 114–182, §5(2)(C)(ii)(IV), substituted ''subsection (a)(1)(A)(i)'' for ''subsection (a)(1)(A)''.

Subsec. (b)(2)(B)(ii). Pub. L. 114–182, §5(2)(C)(ii)(V), substituted ''subsection (a)(1)(A)(ii)'' for ''subsection (a)(1)(B)''.

Subsec. (b)(3). Pub. L. 114–182, §5(2)(D), substituted ''Information'' for ''Data'' and ''paragraph (1) or (2) of this subsection or under subsection (e)'' for ''paragraph (1) or (2)''.

Subsec. (b)(4)(A)(i). Pub. L. 114–182, §5(2)(E)(i), inserted '', without consideration of costs or other nonrisk factors'' after ''health or the environment''.

Subsec. (b)(4)(C). Pub. L. 114–182, §5(2)(E)(ii), struck out '', 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)'' before period at end.

Subsec. (c). Pub. L. 114–182, §5(3), substituted ''review'' for ''notice'' in heading and struck out ''before which the manufacturing or processing of a chemical substance subject to such subsection may begin'' after ''subsection (a) or (b)'' in text.

Subsec. (d)(1)(B). Pub. L. 114–182, §5(4)(A), substituted ''information'' for ''test data''.

Subsec. (d)(1)(C). Pub. L. 114–182, §5(4)(B), substituted ''information'' for ''data''.

Subsec. (d)(2). Pub. L. 114–182, §5(4)(B), substituted ''information'' for ''data'' wherever appearing.

Subsec. (d)(2)(B). Pub. L. 114–182, §5(4)(C), substituted ''uses of such substance identified in the notice'' for ''uses or intended uses of such substance''.

Subsec. (d)(2)(C). Pub. L. 114–182, §19(e)(2), substituted ''rule, order, or consent agreement'' for ''rule''.

Subsec. (d)(3). Pub. L. 114–182, §5(4)(D), substituted ''for which the applicable review period'' for ''for which the notification period prescribed by subsection (a), (b), or (c)'' and ''such period'' for ''such notification period''.

Subsec. (e)(1)(A). Pub. L. 114–182, §5(5)(A)(iii)(III), inserted before period at end of concluding provisions ''to the extent necessary to protect against 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, and the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, including while any required information is being developed, only in compliance with the order''.

Pub. L. 114–182, §5(5)(A)(iii)(II), which directed substitution of ''applicable review period'' for ''notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), (c)'' in concluding provisions, was executed by making the substitution for ''notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c)'' to reflect the probable intent of Congress.

Pub. L. 114–182, §5(5)(A)(iii)(I), substituted ''shall issue an order'' for ''may issue a proposed order'' in concluding provisions.

Subsec. (e)(1)(A)(i). Pub. L. 114–182, §5(5)(A)(i), substituted ''; or'' for ''; and'' at end.

Subsec. (e)(1)(A)(ii)(I). Pub. L. 114–182, §5(5)(A)(ii), inserted ''without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use;'' after ''health or the environment,''.

Subsec. (e)(1)(B). Pub. L. 114–182, §5(5)(B)(iii), substituted ''of the order'' for ''of the proposed order''.

Pub. L. 114–182, §5(5)(B)(ii), which directed substitution of ''applicable review period'' for ''notification period applicable to the manufacture or processing of such substance under subsection (a), (b), (c)'', was executed by making the substitution for ''notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c)'' to reflect the probable intent of Congress.

Pub. L. 114–182, §5(5)(B)(i), substituted ''An order'' for ''A proposed order''.

Subsec. (e)(1)(C). Pub. L. 114–182, §5(5)(C), struck out subpar. (C) which read as follows: ''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.''

Subsec. (e)(2). Pub. L. 114–182, §5(5)(D), struck out par. (2) which related to injunctions to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance.

Subsec. (f)(1). Pub. L. 114–182, §5(6)(A), substituted ''determines that a chemical substance or significant new use with'' for ''finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance with'', '', without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use,'' for ''before a rule promulgated under section 2605 of this title can protect against such risk,'' and ''applicable review period'' for ''notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance'' and struck out '', or that any combination of such activities,'' after ''required by subsection (a)'' and ''or will present'' after ''presents''.

Subsec. (f)(2). Pub. L. 114–182, §5(6)(B), substituted ''Section 2605(d)(3)(B)'' for ''Section 2605(d)(2)(B)'' in concluding provisions.

Subsec. (f)(3)(A). Pub. L. 114–182, §5(6)(C)(i), substituted ''Administrator may'' for ''Administrator may—'', struck out cl. (i) designation before ''issue'', substituted ''an order to prohibit or limit the'' for ''a proposed order to prohibit the'' and ''under paragraph

(1). Such order shall take effect on the expiration of the applicable review period.'' for ''under paragraph (1), or'', and struck out cl. (ii) and concluding provisions which read as follows:

''(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.''

Subsec. (f)(3)(B), (C). Pub. L. 114–182, §5(6)(C)(ii), (iii), redesignated subpar. (C) as (B), substituted ''subparagraph (B)'' for ''subparagraphs (B) and (C)'', struck out ''clause (i) of'' after ''order issued under'' and ''; and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B)'' after ''subparagraph (A)'', and struck out former subpar. (B) which read as follows: ''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 2605 of this title 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.''

Subsec. (f)(3)(D). Pub. L. 114–182, §5(6)(C)(iv), struck out subpar. (D) which read as follows: ''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.''

Subsec. (f)(4), (5). Pub. L. 114–182, §5(6)(D), added pars. (4) and (5).

Subsec. (g). Pub. L. 114–182, §5(7), amended subsec. (g) generally. Prior to amendment, text read as follows: ''If the Administrator has not initiated any action under this section or section 2605 or 2606 of this title 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.''

Subsec. (h)(1)(A). Pub. L. 114–182, §5(8)(A), inserted '', including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific conditions of use identified in the application'' after ''health or the environment''.

Subsec. (h)(2). Pub. L. 114–182, §5(8)(B), substituted ''information'' for ''data'' wherever appearing.

Subsec. (h)(4). Pub. L. 114–182, §5(8)(C), substituted ''environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use'' for ''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 2605(c) of this title''.

Subsec. (i). Pub. L. 114–182, §5(9), amended subsec. (i) generally. Prior to amendment, text read as follows: ''For purposes of this section, the terms 'manufacture' and 'process' mean manufacturing or processing for commercial purposes.''

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.

§ 2605. Prioritization, risk evaluation, and regulation of chemical substances and mixtures

(a) Scope of regulation

If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 2617 of this title, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk:

(1) A requirement (A) prohibiting or otherwise restricting 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 or otherwise restricting 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 minimum 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 minimum 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 or monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.