

**15 USC 2605: Prioritization, risk evaluation, and regulation of chemical substances and mixtures**

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**From Title 15-COMMERCE AND TRADE**

CHAPTER 53-TOXIC SUBSTANCES CONTROL

SUBCHAPTER I-CONTROL OF TOXIC SUBSTANCES

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## **§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.

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

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

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

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

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

**(b) Risk evaluations****(1) Prioritization for risk evaluations****(A) Establishment of process**

Not later than 1 year after June 22, 2016, the Administrator shall establish, by rule, a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time. The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.

**(B) Identification of priorities for risk evaluation****(i) High-priority substances**

The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.

**(ii) Low-priority substances**

The Administrator shall designate a chemical substance as a low-priority substance if the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance.

**(C) Information request and review and proposed and final prioritization designation**

The rulemaking required in subparagraph (A) shall ensure that the time required to make a priority designation of a chemical substance be no shorter than nine months and no longer than 1 year, and that the process for such designations includes-

(i) a requirement that the Administrator request interested persons to submit relevant information on a chemical substance that the Administrator has initiated the prioritization process on, before proposing a priority designation for the chemical substance, and provide 90 days for such information to be provided;

(ii) a requirement that the Administrator publish each proposed designation of a chemical substance as a high- or low-priority substance, along with an identification of the information, analysis, and basis used to make the proposed designations, and provide 90 days for public comment on each such proposed designation; and

(iii) a process by which the Administrator may extend the deadline in clause (i) for up to three months in order to receive or evaluate information required to be submitted in accordance with section 2603(a)(2)(B) of this title, subject to the limitation that if the information available to the Administrator at the end of such an extension remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the chemical substance as a high-priority substance.

**(2) Initial risk evaluations and subsequent designations of high- and low-priority substances****(A) Initial risk evaluations**

Not later than 180 days after June 22, 2016, the Administrator shall ensure that risk evaluations are being conducted on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments and shall publish the list of such chemical substances during the 180 day period.

**(B) Additional risk evaluations**

Not later than three and one half years after June 22, 2016, the Administrator shall ensure that risk evaluations are being conducted on at least 20 high-priority substances and that at least 20 chemical substances have been designated as low-priority substances, subject to the limitation that at least 50 percent of all chemical substances on which risk evaluations are being conducted by the Administrator are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.

**(C) Continuing designations and risk evaluations**

The Administrator shall continue to designate priority substances and conduct risk evaluations in accordance with this subsection at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines under paragraph (4)(G).

**(D) Preference**

In designating high-priority substances, the Administrator shall give preference to-

- (i) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a Persistence and Bioaccumulation Score of 3; and
- (ii) chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

**(E) Metals and metal compounds**

In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007, or a successor document that addresses metals risk assessment and is peer reviewed by the Science Advisory Board.

**(3) Initiation of risk evaluations; designations****(A) Risk evaluation initiation**

Upon designating a chemical substance as a high-priority substance, the Administrator shall initiate a risk evaluation on the substance.

**(B) Revision**

The Administrator may revise the designation of a low-priority substance based on information made available to the Administrator.

**(C) Ongoing designations**

The Administrator shall designate at least one high-priority substance upon the completion of each risk evaluation (other than risk evaluations for chemical substances designated under paragraph (4)(C)(ii)).

**(4) Risk evaluation process and deadlines****(A) In general**

The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance 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 to the risk evaluation by the Administrator, under the conditions of use.

**(B) Establishment of process**

Not later than 1 year after June 22, 2016, the Administrator shall establish, by rule, a process to conduct risk evaluations in accordance with subparagraph (A).

**(C) Requirement**

The Administrator shall conduct and publish risk evaluations, in accordance with the rule promulgated under subparagraph (B), for a chemical substance-

- (i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and
- (ii) subject to subparagraph (E), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (B), be subjected to a risk evaluation.

**(D) Scope**

The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider, and, for each designation of a high-priority substance, ensure not less than 12 months between the initiation of the prioritization process for the chemical substance and the publication of the scope of the risk evaluation for the chemical substance, and for risk evaluations conducted on chemical substances that have been identified under paragraph (2)(A) or selected under subparagraph (E)(iv)(II) of this paragraph, ensure not less than 3 months before the Administrator publishes the scope of the risk evaluation.

**(E) Limitation and criteria****(i) Percentage requirements**

The Administrator shall ensure that, of the number of chemical substances that undergo a risk evaluation under clause (i) of subparagraph (C), the number of chemical substances undergoing a risk evaluation under clause (ii) of subparagraph (C) is-

- (I) not less than 25 percent, if sufficient requests are made under clause (ii) of subparagraph (C); and
- (II) not more than 50 percent.

**(ii) Requested risk evaluations**

Requests for risk evaluations under subparagraph (C)(ii) shall be subject to the payment of fees pursuant to section 2625(b) of this title, and the Administrator shall not expedite or otherwise provide special treatment to such risk evaluations.

**(iii) Preference**

In deciding whether to grant requests under subparagraph (C)(ii), the Administrator shall give preference to requests for risk evaluations on chemical substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

**(iv) Exceptions**

- (I) Chemical substances for which requests have been granted under subparagraph (C)(ii) shall not be subject to section 2617(b) of this title.
- (II) Requests for risk evaluations on chemical substances which are made under subparagraph (C)(ii) and that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments shall be granted at the discretion of the Administrator and not be subject to clause (i)(II).

**(F) Requirements**

In conducting a risk evaluation under this subsection, the Administrator shall-

- (i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;
- (ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;
- (iii) not consider costs or other nonrisk factors;
- (iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and
- (v) describe the weight of the scientific evidence for the identified hazard and exposure.

**(G) Deadlines**

The Administrator-

- (i) shall complete a risk evaluation for a chemical substance as soon as practicable, but not later than 3 years after the date on which the Administrator initiates the risk evaluation under subparagraph (C); and
- (ii) may extend the deadline for a risk evaluation for not more than 6 months.

**(H) Notice and comment**

The Administrator shall provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation.

**(c) Promulgation of subsection (a) rules****(1) Deadlines**

If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A), the Administrator-

- (A) shall propose in the Federal Register a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published;
- (B) shall publish in the Federal Register a final rule not later than 2 years after the date on which the final risk evaluation regarding the chemical substance is published; and
- (C) may extend the deadlines under this paragraph for not more than 2 years, subject to the condition

that the aggregate length of extensions under this subparagraph and subsection (b)(4)(G)(ii) does not exceed 2 years, and subject to the limitation that the Administrator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

## **(2) Requirements for rule**

### **(A) Statement of effects**

In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to-

- (i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;
- (ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;
- (iii) the benefits of the chemical substance or mixture for various uses; and
- (iv) the reasonably ascertainable economic consequences of the rule, including consideration of-
  - (I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;
  - (II) the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and
  - (III) the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

### **(B) Selecting requirements**

In selecting among prohibitions and other restrictions, the Administrator shall factor in, to the extent practicable, the considerations under subparagraph (A) in accordance with subsection (a).

### **(C) Consideration of alternatives**

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

### **(D) Replacement parts**

#### **(i) In general**

The Administrator shall exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication in the Federal Register of the rule under subsection (a), unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation conducted under subsection (b)(4)(A), to the general population or to an identified potentially exposed or susceptible subpopulation.

#### **(ii) Definitions**

In this subparagraph-

- (I) the term "complex consumer goods" means electronic or mechanical devices composed of multiple manufactured components, with an intended useful life of 3 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, and the components of which would be impracticable to redesign or replace; and
- (II) the term "complex durable goods" means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use.

### **(E) Articles**

In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or

mixture from the article or category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

### **(3) Procedures**

When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5 (without regard to any reference in such section to sections 556 and 557 of such title), and shall also-

- (A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule;
- (B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available;
- (C) promulgate a final rule based on the matter in the rulemaking record; and
- (D) make and publish with the rule the determination described in subsection (a).

### **(d) Effective date**

#### **(1) In general**

In any rule under subsection (a), the Administrator shall-

- (A) specify the date on which it shall take effect, which date shall be as soon as practicable;
- (B) except as provided in subparagraphs (C) and (D), specify mandatory compliance dates for all of the requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in a case of a use exempted under subsection (g);
- (C) specify mandatory compliance dates for the start of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in the case of a use exempted under subsection (g);
- (D) specify mandatory compliance dates for full implementation of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable; and
- (E) provide for a reasonable transition period.

#### **(2) Variability**

As determined by the Administrator, the compliance dates established under paragraph (1) may vary for different affected persons.

(3)(A) The Administrator may declare a proposed rule under subsection (a) to be effective, and compliance with the proposed requirements to be mandatory, upon publication in the Federal Register of the proposed rule and until the compliance dates applicable to such requirements in a final rule promulgated under section 2605(a) of this title or until the Administrator revokes such proposed rule, in accordance with subparagraph (B), if-

- (i) the Administrator determines that-
  - (I) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before such effective date without consideration of costs or other non-risk factors; and
  - (II) making such proposed rule so effective is necessary to protect the public interest; and

(ii) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under clause (i)(I), a court has in an action under section 2606 of this title granted relief with respect to such risk associated with such substance or mixture.

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

(B) If the Administrator makes a proposed rule effective upon its publication in the Federal Register, the Administrator shall, as expeditiously as possible, give interested persons prompt notice of such action in accordance with subsection (c), and either promulgate such rule (as proposed or with modifications) or revoke it.

### **(e) Polychlorinated biphenyls**

(1) Within six months after January 1, 1977, the Administrator shall promulgate rules to-

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

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

(2)(A) Except as provided under subparagraph (B), effective one year after January 1, 1977, no person may manufacture, process, or distribute in commerce or use any polychlorinated biphenyl in any manner other than in a totally enclosed manner.

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

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

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

(i) no person may manufacture any polychlorinated biphenyl after two years after January 1, 1977, and

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

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

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

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

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

(C) Subparagraph (A) shall not apply to the distribution in commerce of any polychlorinated biphenyl if such polychlorinated biphenyl was sold for purposes other than resale before two and one half years after October 11, 1976.

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

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

#### **(f) Mercury**

##### **(1) Prohibition on sale, distribution, or transfer of elemental mercury by Federal agencies**

Except as provided in paragraph (2), effective beginning on October 14, 2008, no Federal agency shall convey, sell, or distribute to any other Federal agency, any State or local government agency, or any private individual or entity any elemental mercury under the control or jurisdiction of the Federal agency.

##### **(2) Exceptions**

Paragraph (1) shall not apply to-

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

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

##### **(3) Leases of Federal coal**

Nothing in this subsection prohibits the leasing of coal.

#### **(g) Exemptions**

##### **(1) Criteria for exemption**

The Administrator may, as part of a rule promulgated under subsection (a), or in a separate rule, grant an exemption from a requirement of a subsection (a) rule for a specific condition of use of a chemical substance or mixture, if the Administrator finds that-

(A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;

(B) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or

(C) the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

**(2) Exemption analysis and statement**

In proposing an exemption under this subsection, the Administrator shall analyze the need for the exemption, and shall make public the analysis and a statement describing how the analysis was taken into account.

**(3) Period of exemption**

The Administrator shall establish, as part of a rule under this subsection, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis, and, by rule, may extend, modify, or eliminate an exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or modification or is no longer necessary.

**(4) Conditions**

As part of a rule promulgated under this subsection, the Administrator shall include conditions, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption.

**(h) Chemicals that are persistent, bioaccumulative, and toxic**

**(1) Expedited action**

Not later than 3 years after June 22, 2016, the Administrator shall propose rules under subsection (a) with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments-

(A) that the Administrator has a reasonable basis to conclude are toxic and that with respect to persistence and bioaccumulation score high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation, initiated a review under section 5, or entered into a consent agreement under section 2603 of this title, prior to June 22, 2016; and

(B) exposure to which under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator.

**(2) No risk evaluation required**

The Administrator shall not be required to conduct risk evaluations on chemical substances that are subject to paragraph (1).

**(3) Final rule**

Not later than 18 months after proposing a rule pursuant to paragraph (1), the Administrator shall promulgate a final rule under subsection (a).

**(4) Selecting restrictions**

In selecting among prohibitions and other restrictions promulgated in a rule under subsection (a) pursuant to paragraph (1), the Administrator shall address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance and shall reduce exposure to the substance to the extent practicable.

**(5) Relationship to subsection (b)**

If, at any time prior to the date that is 90 days after June 22, 2016, the Administrator makes a designation under subsection (b)(1)(B)(i), or receives a request under subsection (b)(4)(C)(ii), such chemical substance shall not be subject to this subsection, except that in selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a), the Administrator shall both ensure that the chemical substance meets the rulemaking standard under subsection (a) and reduce exposure to the substance to the extent practicable.

**(i) Final agency action**

Under this section and subject to section 2617 of this title-

(1) a determination by the Administrator under subsection (b)(4)(A) that a chemical substance does not present an unreasonable risk of injury to health or the environment shall be issued by order and considered to be a final agency action, effective beginning on the date of issuance of the order; and



(2) a final rule promulgated under subsection (a), including the associated determination by the Administrator under subsection (b)(4)(A) that a chemical substance presents an unreasonable risk of injury to health or the environment, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule.

**(j) Definition**

For the purposes of this chapter, the term "requirement" as used in this section shall not displace statutory or common law.

( Pub. L. 94–469, title I, §6, Oct. 11, 1976, 90 Stat. 2020 ; renumbered title I, Pub. L. 99–519, §3(c)(1), Oct. 22, 1986, 100 Stat. 2989 ; amended Pub. L. 109–364, div. A, title III, §317(a), Oct. 17, 2006, 120 Stat. 2142 ; Pub. L. 110–414, §3, Oct. 14, 2008, 122 Stat. 4342 ; Pub. L. 114–182, title I, §6, June 22, 2016, 130 Stat. 460 .)

## AMENDMENTS

**2016**-Pub. L. 114–182, §6(1), substituted "Prioritization, risk evaluation, and regulation of chemical substances and mixtures" for "Regulation of hazardous chemical substances and mixtures" in section catchline.

Subsec. (a). Pub. L. 114–182, §6(2)(A)–(D), in introductory provisions, substituted "determines in accordance with subsection (b)(4)(A)" for "finds that there is a reasonable basis to conclude" and "so that the chemical substance or mixture no longer presents such risk" for "to protect adequately against such risk using the least burdensome requirements", struck out "or will present" after "presents", and inserted "and subject to section 2617 of this title, and in accordance with subsection (c)(2)," after "shall by rule".

Subsec. (a)(1)(A), (2)(A). Pub. L. 114–182, §6(2)(E), inserted "or otherwise restricting" after "prohibiting".

Subsec. (a)(3). Pub. L. 114–182, §6(2)(F), inserted "minimum" before "warnings" in two places.

Subsec. (a)(4). Pub. L. 114–182, §6(2)(G), substituted "or monitor or conduct tests" for "and monitor or conduct tests".

Subsec. (a)(7). Pub. L. 114–182, §6(2)(H), substituted "such determination" for "such unreasonable risk of injury" and for "such risk of injury".

Subsec. (b). Pub. L. 114–182, §6(3), amended subsec. (b) generally. Prior to amendment, subsec. (b) related to quality control procedures in the manufacturing or processing of a chemical substance or mixture to prevent unreasonable risk of injury to health or the environment.

Subsec. (c). Pub. L. 114–182, §6(4), amended subsec. (c) generally. Prior to amendment, subsec. (c) related to promulgation of subsection (a) rules.

Subsec. (d)(1), (2). Pub. L. 114–182, §6(5)(B), added pars. (1) and (2) and struck out former par. (1) which read as follows: "The Administrator shall specify in any rule under subsection (a) the date on which it shall take effect, which date shall be as soon as feasible.". Former par. (2) redesignated (3).

Subsec. (d)(3). Pub. L. 114–182, §6(5)(A), redesignated par. (2) as (3).

Subsec. (d)(3)(A). Pub. L. 114–182, §6(5)(C)(i)(I), in introductory provisions, substituted ", and compliance with the proposed requirements to be mandatory, upon publication in the Federal Register of the proposed rule and until the compliance dates applicable to such requirements in a final rule promulgated under section 2605(a) of this title or until the Administrator revokes such proposed rule, in accordance with subparagraph (B), if" for "upon its publication in the Federal Register and until the effective date of final action taken, in accordance with subparagraph (B), respecting such rule if".

Subsec. (d)(3)(A)(i)(I). Pub. L. 114–182, §6(5)(C)(i)(II), inserted "without consideration of costs or other non-risk factors" after "effective date".

Subsec. (d)(3)(B). Pub. L. 114–182, §6(5)(C)(ii), substituted "in accordance with subsection (c), and either promulgate such rule (as proposed or with modifications) or revoke it." for ", provide reasonable opportunity, in accordance with paragraphs (2) and (3) of subsection (c), for a hearing on such rule, and either promulgate such rule (as proposed or with modifications)

or revoke it; and if such a hearing is requested, the Administrator shall commence the hearing within five days from the date such request is made unless the Administrator and the person making the request agree upon a later date for the hearing to begin, and after the hearing is concluded the Administrator shall, within ten days of the conclusion of the hearing, either promulgate such rule (as proposed or with modifications) or revoke it."

Subsec. (e)(4). Pub. L. 114–182, §6(6), substituted "paragraph (3)" for "paragraphs (2), (3), and (4)".

Subsecs. (g) to (j). Pub. L. 114–182, §6(7), added subsec. (g) to (j).

2008-Subsec. (f). Pub. L. 110–414 added subsec. (f).

2006-Subsec. (e)(3)(A). Pub. L. 109–364, §317(a)(1), (b), temporarily substituted "subparagraphs (B), (C), and (D)" for "subparagraphs (B) and (C)" in introductory provisions. See Termination Date of 2006 Amendment note below.

Subsec. (e)(3)(B). Pub. L. 109–364, §317(a)(2), (b), temporarily substituted "but not more than 1 year from the date it is granted, except as provided in subparagraph (D)" for "but not more than one year from the date it is granted" in concluding provisions. See Termination Date of 2006 Amendment note below.

Subsec. (e)(3)(D). Pub. L. 109–364, §317(a)(3), (b), temporarily added subpar. (D) which read as follows: "The Administrator may extend an exemption granted pursuant to subparagraph (B) that has not yet expired for a period not to exceed 60 days for the purpose of authorizing the Secretary of Defense and the Secretaries of the military departments to provide for the transportation into the customs territory of the United States of polychlorinated biphenyls generated by or under the control of the Department of Defense for purposes of their disposal, treatment, or storage in the customs territory of the United States if those polychlorinated biphenyls are already in transit from their storage locations but the Administrator determines, in the sole discretion of the Administrator, they would not otherwise arrive in the customs territory of the United States within the period of the original exemption. The Administrator shall promptly publish notice of such extension in the Federal Register." See Termination Date of 2006 Amendment note below.

### **TERMINATION DATE OF 2006 AMENDMENT**

Pub. L. 109–364, div. A, title III, §317(b), Oct. 17, 2006, 120 Stat. 2142 , provided that: "The amendments made by subsection (a) [amending this section] shall cease to have effect on September 30, 2012. The termination of the authority to grant exemptions pursuant to such amendments shall not effect the validity of any exemption granted prior to such date."

### **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.