SHORT TITLE OF 2008 AMENDMENT

Pub. L. 110–414, §1, Oct. 14, 2008, 122 Stat. 4341, provided that: ''This Act [enacting section 6939f of Title 42, The Public Health and Welfare, amending sections 2605 and 2611 of this title, and enacting provisions set out as a note under section 2611 of this title] may be cited as the 'Mercury Export Ban Act of 2008'.''

SHORT TITLE OF 1992 AMENDMENT

Pub. L. 102–550, title X, §1021(c), Oct. 28, 1992, 106 Stat. 3924, provided that: ''This subtitle [subtitle B (§1021) of title X of Pub. L. 102–550, enacting sections 2681 to 2692 of this title and amending sections 2606, 2610, 2612, 2615, 2616, 2618, and 2619 of this title] may be cited as the 'Lead-Based Paint Exposure Reduction Act'.''

SHORT TITLE OF 1986 AMENDMENT

Pub. L. 99–519, §1, Oct. 22, 1986, 100 Stat. 2970, provided that: ''This Act [enacting sections 2641 to 2654 of this title and section 4022 of Title 20, Education, amending sections 2614, 2618, and 2619 of this title and sections 4014 and 4021 of Title 20, and enacting provisions set out as a note under section 4014 of Title 20] may be cited as the 'Asbestos Hazard Emergency Response Act of 1986'.''

SHORT TITLE

Pub. L. 94–469, §1, Oct. 11, 1976, 90 Stat. 2003; renumbered title I, Pub. L. 99–519, §3(c), Oct. 22, 1986, 100 Stat. 2989, provided that: ''This Act [enacting this chapter and provisions set out as notes under this section] may be cited as the 'Toxic Substances Control Act'.''

NO RETROACTIVITY OF PUB. L. 114–182 AMENDMENTS

Pub. L. 114–182, title I, §20, June 22, 2016, 130 Stat. 510, provided that: ''Nothing in sections 1 through 19 [amending this section, sections 2602 to 2611, 2613 to 2615, 2617 to 2620, 2623, 2625 to 2627, and 2629 of this title, and section 6939f of Title 42, The Public Health and Welfare, repealing section 2624 of this title, and enacting provisions set out as a note under this section], or the amendments made by sections 1 through 19, shall be interpreted to apply retroactively to any State, Federal, or maritime legal action filed before the date of enactment of this Act [June 22, 2016].''

FEDERAL COMPLIANCE WITH POLLUTION CONTROL STANDARDS

For provisions relating to the responsibility of the head of each Executive agency for compliance with applicable pollution control standards, see Ex. Ord. No. 12088, Oct. 13, 1978, 43 F.R. 47707, set out as a note under section 4321 of Title 42, The Public Health and Welfare.

§ 2602. Definitions

As used in this chapter:

(1) the[1] term ''Administrator'' means the Administrator of the Environmental Protection Agency.

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

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

(ii) any element or uncombined radical.

(B) Such term does not include—

(i) any mixture,

(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide,

(iii) tobacco or any tobacco product,

(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 [42 U.S.C. 2011 et seq.] and regulations issued under such Act),

(v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986 [26 U.S.C. 4181] (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code) and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges), and

(vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

The term ''food'' as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act [21 U.S.C. 453(e) and (f)]), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act [21 U.S.C. 601(j)]), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act [21 U.S.C. 1033]).

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

(4) The term ''conditions of use'' means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

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

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

(7) The term ''guidance'' means any significant written guidance of general applicability prepared by the Administrator.

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

[1] So in original. Probably should be capitalized.

(9) The term ''manufacture'' means to import into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States), produce, or manufacture.

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

(11) The term ''new chemical substance'' means any chemical substance which is not included in the chemical substance list compiled and published under section 2607(b) of this title.

(12) The term ''potentially exposed or susceptible subpopulation'' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

(13) The term ''process'' means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce—

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

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

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

(15) The term ''protocols and methodologies for the development of information'' means a prescription of—

(A) the—

(i) health and environmental effects, and

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

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

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

(i) the manner in which such information are[2] to be developed,

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

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

(16) The term ''State'' means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

(17) The term ''United States'', when used in the geographic sense, means all of the States.

(Pub. L. 94–469, title I, §3, Oct. 11, 1976, 90 Stat. 2004; Pub. L. 99–514, §2, Oct. 22, 1986, 100 Stat. 2095; renumbered title I, Pub. L. 99–519, §3(c)(1), Oct. 22, 1986, 100 Stat. 2989; Pub. L. 100–418, title I, §1214(e)(1), Aug. 23, 1988, 102 Stat. 1156; Pub. L. 114–92, div. A, title III, §315, Nov. 25, 2015, 129 Stat. 791; Pub. L. 114–182, title I, §§3, 19(c), June 22, 2016, 130 Stat. 448, 505.)

REFERENCES IN TEXT

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in par. (2)(B)(ii), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92–516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (§136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

The Atomic Energy Act of 1954, referred to in par. (2)(B)(iv), is act Aug. 1, 1946, ch. 724, as added by act Aug. 30, 1954, ch. 1073, §1, 68 Stat. 919, and amended, which is classified principally to chapter 23 (§2011 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 2011 of Title 42 and Tables.

The Harmonized Tariff Schedule of the United States, referred to in par. (9), is not set out in the Code. See Publication of Harmonized Tariff Schedule note set out under section 1202 of Title 19, Customs Duties.

For definition of Canal Zone, Governor of the Canal Zone, and Panama Canal Company, referred to in par. (16), see section 3602(b) of Title 22, Foreign Relations and Intercourse.

AMENDMENTS

2016—Pars. (4) to (7). Pub. L. 114–182, §3(1)–(3), added pars. (4) and (7) and redesignated former pars. (4) and (5) as (5) and (6), respectively. Former pars. (6) and (7) redesignated (8) and (9), respectively.

Par. (8). Pub. L. 114–182, §19(c)(1), substituted ''information'' for ''data''.

Pub. L. 114–182, §3(1), redesignated par. (6) as (8). Former par. (8) redesignated (10).

Pars. (9) to (14). Pub. L. 114–182, §3(1), (4), added par. (12) and redesignated former pars. (7) to (11) as (9), (10), (11), (13), and (14), respectively. Former pars. (12) to (14) redesignated (15) to (17), respectively.

Par. (15). Pub. L. 114–182, §19(c)(2)(A), (B), in introductory provisions, substituted ''protocols and methodologies for the development of information'' for ''standards for the development of test data''.

Pub. L. 114–182, §3(1), redesignated par. (12) as (15).

Par. (15)(A). Pub. L. 114–182, §19(c)(2)(C), substituted ''on such information'' for ''on such data'' in concluding provisions.

Pub. L. 114–182, §19(c)(2)(B), substituted ''for which information'' for ''for which test data'' in concluding provisions.

Par. (15)(B). Pub. L. 114–182, §19(c)(2)(C), substituted ''information'' for ''data'' wherever appearing.

Pars. (16), (17). Pub. L. 114–182, §3(1), redesignated pars. (13) and (14) as (16) and (17), respectively.

2015—Par. (2)(B)(v). Pub. L. 114–92 substituted ''and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges), and'' for '', and''.

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''.

[2] So in original. Probably should be ''is''.

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 necessary, 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—