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§ 2601. Findings, policy, and intent

(a) Findings

The Congress finds that—

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

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

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

(b) Policy

It is the policy of the United States that—

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

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

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

(c) Intent of Congress

It is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Ad-

ministrator takes or proposes to take under this chapter.

(Pub. L. 94-469, title I, §2, Oct. 11, 1976, 90 Stat. 2003; renumbered title I, Pub. L. 99-519, §3(c)(1), Oct. 22, 1986, 100 Stat. 2989.)

EFFECTIVE DATE

Section 31 of title I of Pub. L. 94-469; renumbered title I, Pub. L. 99-519, §3(c), Oct. 22, 1986, 100 Stat. 2989, provided that: "Except as provided in section 4(f) [section 2603(f) of this title], this Act [enacting this chapter] shall take effect on January 1, 1977."

SHORT TITLE OF 2010 AMENDMENT

Pub. L. 111-199, §1, July 7, 2010, 124 Stat. 1359, provided that: "This Act [enacting subchapter VI of this chapter and provisions set out as a note under section 2697 of this title] may be cited as the 'Formaldehyde Standards for Composite Wood Products Act'."

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

Section 1 of Pub. L. 99-519 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

Section 1 of title I of Pub. L. 94-469; 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'."

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<sup>1</sup> 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.

<sup>1</sup> So in original. Probably should be capitalized.

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

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

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

(7) 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.

(8) The term “mixture” means any combination of two or more chemical substances if the

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

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

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

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

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

(11) The term “processor” means any person who processes a chemical substance or mixture.

(12) The term “standards for the development of test data” means a prescription of—

(A) the—

(i) health and environmental effects, and

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

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

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

(i) the manner in which such data are to be developed,

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

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

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

(14) The term “United States”, when used in the geographic sense, means all of the States.

(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.)

#### 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. 921, and amended, which is classified generally 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. (7), 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. (13), see section 3602(b) of Title 22, Foreign Relations and Intercourse.

#### AMENDMENTS

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”.

#### 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.

### § 2603. Testing of chemical substances and mixtures

#### (a) Testing requirements

If the Administrator finds that—

(1)(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

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

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; and

(2) in the case of a mixture, the effects which the mixture’s manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reason-

ably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture;

the Administrator shall by rule require that testing be conducted on such substance or mixture to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

#### (b) Testing requirement rule

(1) A rule under subsection (a) of this section shall include—

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

(B) standards for the development of test data for such substance or mixture, and

(C) with respect to chemical substances which are not new chemical substances and to mixtures, a specification of the period (which period may not be of unreasonable duration) within which the persons required to conduct the testing shall submit to the Administrator data developed in accordance with the standards referred to in subparagraph (B).

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

(2)(A) The health and environmental effects for which standards for the development of test data may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment. The characteristics of chemical substances and mixtures for which such standards may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristic which may present such a risk. The methodologies that may be prescribed in such standards include epidemiologic studies, serial or hierarchical tests, in vitro tests, and whole animal tests, except that before prescribing epidemiologic studies of employees, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health.

(B) From time to time, but not less than once each 12 months, the Administrator shall review the adequacy of the standards for development of data prescribed in rules under subsection (a) of this section and shall, if necessary, institute proceedings to make appropriate revisions of such standards.