

### Subpart A—General Provisions

#### § 720.1 Scope.

This part establishes procedures for the reporting of new chemical substances by manufacturers and importers under section 5 of the Toxic Substances Control Act, 15 U.S.C. 2604. This part applies to microorganisms only to the extent provided by part 725 of this chapter. The rule defines the persons and chemical substances subject to the reporting requirements, prescribes the contents of section 5 notices, and establishes procedures for submitting notices. The rule also establishes EPA policy regarding claims of confidentiality for, and public disclosure of, various categories of information submitted in connection with section 5 notices.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993; 62 FR 17932, April 11, 1997]

#### § 720.3 Definitions.

(a)(1) For the purposes of this part, the terms *cosmetic*, *device*, *drug*, *food*, and *food additive* have the meanings contained in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.*, and the regulations issued under it. In addition, the term “food” includes poultry and poultry products, as defined in the Poultry Products Inspection Act, 21 U.S.C. 453 *et seq.*; meats and meat food products, as defined in the Federal Meat Inspection Act, 21 U.S.C. 60 *et seq.*; and eggs and egg products, as defined in the Egg Products Inspection Act, 21 U.S.C. 1033 *et seq.*

(2) The term *pesticide* has the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.* and the regulations issued under it.

(3) The terms *byproduct material*, *source material*, and *special nuclear material* have the meanings contained in the Atomic Energy Act of 1954, 42 U.S.C. 2014 *et seq.* and the regulations issued under it.

(b) *Act* means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

(c) *Article* means a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape

or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 720.36(g)(5), except that fluids and particles are not considered articles regardless of shape or design.

(d) *Byproduct* means a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.

(e) *Chemical substance* means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical, except that “chemical substance” does not include:

(1) Any mixture.

(2) Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide.

(3) Tobacco or any tobacco product.

(4) Any source material, special nuclear material, or byproduct material.

(5) Any pistol, firearm, revolver, shells, or cartridges.

(6) Any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

(f) *Commerce* means trade, traffic, transportation, or other commerce (1) between a place in a State and any place outside of such State, or (2) which affects trade, traffic, transportation, or commerce between a place in a State and any place outside of such State.

(g) *Customs territory of the United States* means the 50 States, Puerto Rico, and the District of Columbia.

(h) *Director* means the Director of the EPA Office of Pollution Prevention and Toxics.

(i) *Distribute in commerce* means to sell in commerce, to introduce or deliver for introduction into commerce, or to hold after introduction into commerce.

(j) *EPA* means the U.S. Environmental Protection Agency.