

the manufacture, processing, distribution, use, or disposal of any new chemical substance under the terms of this exemption if he or she determines that the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance may present an unreasonable risk of injury to health or the environment.

(n) *Enforcement.* (1) A failure to comply with any provision of this part is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Submitting materially misleading or false information in connection with the requirements of any provision of this part is a violation of this regulation and therefore a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(4) EPA may seek to enjoin the manufacture of a new chemical substance in violation of this exemption or act to seize any chemical substances manufactured in violation of the exemption under the authority of section 17 of the Act (15 U.S.C. 2616).

[47 FR 24317, June 4, 1982, as amended at 53 FR 12523, Apr. 15, 1988; 60 FR 34465, July 3, 1995; 62 FR 17932, April 11, 1997; 68 FR 906, Jan. 7, 2003; 71 FR 33642, June 12, 2006]

#### § 723.250 Polymers.

(a) *Purpose and scope.* (1) This section grants an exemption from certain of the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of certain polymers. This section does not apply to microorganisms subject to part 725 of this chapter.

(2) To manufacture a new chemical substance under the terms of this section, a manufacturer must:

(i) Determine that the substance meets the definition of polymer in paragraph (b) of this section.

(ii) Determine that the substance is not specifically excluded by paragraph (d) of this section.

(iii) Ensure that the substance meets the exemption criteria of paragraph (e) of this section.

(iv) Submit a report as required under paragraph (f) of this section.

(v) Comply with the recordkeeping requirements of paragraph (j) of this section.

(b) *Definitions.* In addition to the definitions under section 3 of the Act, 15 U.S.C. 2602, the following definitions apply to this part.

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

*Biopolymer* means a polymer directly produced by living or once-living cells or cellular components.

*Category of chemical substances* has the same meaning as in section 26(c)(2) of the Act (15 U.S.C. 2625).

*Cationic polymer* means a polymer that contains a net positively charged atom(s) or associated groups of atoms covalently linked to its polymer molecule.

*Chemical substance, Director, EPA, importer, impurity, Inventory, known to or reasonably ascertainable, manufacture, manufacturer, mixture, new chemical, person, possession or control, process and test data* have the same meanings as in § 720.3 of this chapter.

*Equivalent weight of a functional group* means the ratio of the molecular weight to the number of occurrences of that functional group in the molecule. It is the weight of substance that contains one formula-weight of the functional group.

*Fluorotelomers* means the products of telomerization, which is the reaction of a telogen (such as pentafluoroethyl iodide) with an ethylenic compound (such as tetrafluoroethylene) to form low molecular weight polymeric compounds, which contain an array of saturated carbon atoms covalently bonded to each other (C-C bonds) and to fluorine atoms (C-F bonds). This array is predominantly a straight chain, and depending on the telogen used produces a compound having an even number of carbon atoms. However, the carbon chain length of the fluorotelomer varies widely. The perfluoroalkyl groups formed by this process are usually, but do not have to be, connected to the polymer through a functionalized ethylene group as indicated by the following structural diagram: (Rf-CH<sub>2</sub>CH<sub>2</sub>-Anything).

*Internal monomer unit* means a monomer unit that is covalently bonded to at least two other molecules. Internal

monomer units of polymer molecules are chemically derived from monomer molecules that have formed covalent bonds between two or more other monomer molecules or other reactants.

*Monomer* means a chemical substance that is capable of forming covalent bonds with two or more like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process.

*Monomer Unit* means the reacted form of the monomer in a polymer.

*Number-average molecular weight* means the arithmetic average (mean) of the molecular weight of all molecules in a polymer.

*Oligomer* means a polymer molecule consisting of only a few monomer units (dimer, trimer, tetramer)

*Other reactant* means a molecule linked to one or more sequences of monomer units but which, under the relevant reaction conditions used for the particular process, cannot become a repeating unit in the polymer structure.

*Perfluoroalkyl carboxylate (PFAC)* means a group of saturated carbon atoms covalently bonded to each other in a linear, branched, or cyclic array and covalently bonded to a carbonyl moiety and where all carbon-hydrogen (C-H) bonds have been replaced with carbon-fluorine (C-F) bonds. The carbonyl moiety is also covalently bonded to a hetero atom, typically, but not necessarily oxygen (O) or nitrogen (N).

*Perfluoroalkyl sulfonate (PFAS)* means a group of saturated carbon atoms covalently bonded to each other in a linear, branched, or cyclic array and covalently bonded to a sulfonyl moiety and where all carbon - hydrogen (C-H) bonds have been replaced with carbon - fluorine (C-F) bonds. The sulfonyl moiety is also covalently bonded to a hetero atom, typically, but not necessarily oxygen (O) or nitrogen (N).

*Polyester* means a chemical substance that meets the definition of polymer and whose polymer molecules contain at least two carboxylic acid ester linkages, at least one of which links internal monomer units together.

*Polymer* means a chemical substance consisting of molecules characterized by the sequence of one or more types of

monomer units and comprising a simple weight majority of molecules containing at least 3 monomer units which are covalently bound to at least one other monomer unit or other reactant and which consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition, sequence means that the monomer units under consideration are covalently bound to one another and form a continuous string within the molecule, uninterrupted by units other than monomer units.

*Polymer molecule* means a molecule which contains a sequence of at least 3 monomer units which are covalently bound to at least one other monomer unit or other reactant.

*Reactant* means a chemical substance that is used intentionally in the manufacture of a polymer to become chemically a part of the polymer composition.

*Reactive functional group* means an atom or associated group of atoms in a chemical substance that is intended or can reasonably be anticipated to undergo further chemical reaction.

*Reasonably anticipated* means that a knowledgeable person would expect a given physical or chemical composition or characteristic to occur based on such factors as the nature of the precursors used to manufacture the polymer, the type of reaction, the type of manufacturing process, the products produced in polymerization, the intended uses of the substance, or associated use conditions.

(c) *Applicability.* This section applies to manufacturers of new chemical substances that otherwise must submit a premanufacture notice to EPA under § 720.22 of this chapter. New substances are eligible for exemption under this section if they meet the definition of "polymer" in paragraph (b) of this section, and the criteria in paragraph (e) of this section, and if they are not excluded from the exemption under paragraph (d) of this section.

(d) *Polymers that cannot be manufactured under this section—(1) Cationic*

*polymers.* A polymer cannot be manufactured under this section if the polymer is a cationic polymer as defined under paragraph (b) of this section or if the polymer is reasonably anticipated to become a cationic polymer in a natural aquatic environment (e.g., rivers, lakes) unless:

(i) The polymer is a solid material that is not soluble or dispersible in water and will be used only in the solid phase (e.g., polymers that will be used as ion exchange beads), or

(ii) The combined (total) functional group equivalent weight of cationic groups in the polymer is equal to or greater than 5,000.

(2) *Elemental limitations.* (i) A polymer manufactured under this section must contain as an integral part of its composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.

(ii) A polymer cannot be manufactured under this section if it contains as an integral part of its composition, except as impurities, any elements other than the following:

(A) The elements listed in paragraph (d)(2)(i) of this section.

(B) Sodium, magnesium, aluminum, potassium, calcium, chlorine, bromine, and iodine as the monatomic counterions  $\text{Na}^+$ ,  $\text{Mg}^{+2}$ ,  $\text{Al}^{+3}$ ,  $\text{K}^+$ ,  $\text{Ca}^{+2}$ ,  $\text{Cl}^-$ ,  $\text{Br}^-$ , or  $\text{I}^-$ .

(C) Fluorine, chlorine, bromine, and iodine covalently bound to carbon.

(D) Less than 0.20 weight percent of any combination of the atomic elements lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin, and zirconium.

(3) *Polymers which degrade, decompose, or depolymerize.* A polymer cannot be manufactured under this section if the polymer is designed or is reasonably anticipated to substantially degrade, decompose, or depolymerize, including those polymers that could substantially decompose after manufacture and use, even though they are not actually intended to do so. For the purposes of this section, degradation, decomposition, or depolymerization mean those types of chemical change that convert a polymeric substance into simpler, smaller substances, through processes including but not limited to oxidation,

hydrolysis, attack by solvents, heat, light, or microbial action.

(4) *Polymers manufactured or imported from monomers and reactants not on the TSCA Chemical Substance Inventory.* A polymer cannot be manufactured under this section if the polymer being manufactured or imported is prepared from monomers and/or other reactants (that are either charged to the reaction vessel or incorporated in the polymer at levels of greater than 2 weight percent) that are not already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

(5) *Water absorbing polymers with number average molecular weight (MW) 10,000 and greater.* A polymer cannot be manufactured under this section if the polymer being manufactured or imported is a water absorbing polymer and has a number average MW greater than or equal to 10,000 daltons. For purposes of this section, a water-absorbing polymer is a polymeric substance that is capable of absorbing its weight of water.

(6) *Polymers which contain certain perfluoroalkyl moieties consisting of a CF<sub>3</sub>- or longer chain length.* Except as provided in paragraph (d)(6)(i), after February 26, 2010, a polymer cannot be manufactured under this section if the polymer contains as an integral part of its composition, except as impurities, one or more of the following perfluoroalkyl moieties consisting of a CF<sub>3</sub>- or longer chain length: Perfluoroalkyl sulfonates (PFAS), perfluoroalkyl carboxylates (PFAC), fluorotelomers, or perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule.

(i) Any polymer that has been manufactured previously in full compliance with the requirements of this section prior to February 26, 2010 may no longer be manufactured under this section after January 27, 2012.

(ii) [Reserved]

(e) *Exemption criteria.* To be manufactured under this section, the polymer must meet one of the following criteria:

(1) *Polymers with number average MW greater than or equal to 1,000 and less*

than 10,000 daltons (and oligomer content less than 10 percent below MW 500 and less than 25 percent below MW 1,000). (i) The polymer must have a number average MW greater than or equal to 1,000 and less than 10,000 daltons and contain less than 10 percent oligomeric material below MW 500 and less than 25 percent oligomeric material below MW 1,000.

(ii) The polymer cannot contain reactive functional groups unless it meets one of the following criteria:

(A) The polymer contains only the following reactive functional groups: carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups that are considered "ordinary," (i.e., not specially activated either by being part of a larger functional group, such as a vinyl ether, or by other activating influences, e.g., strongly electron-withdrawing sulfone group with which the olefinic groups interact), butenedioic acid groups, those conjugated olefinic groups contained in naturally-occurring fats, oils, and carboxylic acids, blocked isocyanates (including ketoxime-blocked isocyanates), thiols, unconjugated nitrile groups, and halogens (except that reactive halogen-containing groups such as benzylic or allylhalides cannot be included).

(B) The polymer has a combined (total) reactive group equivalent weight greater than or equal to 1,000 for the following reactive functional groups: acidhalides; acid anhydrides; aldehydes, hemiacetals; methylolamides,- amines or,- ureas; alkoxy silanes with alkoxy greater than C<sub>2</sub>-alkoxy silanes; allyl ethers; conjugated olefins; cyanates; epoxides; imines; or unsubstituted positions *ortho* or *para* to phenolic hydroxyl; or

(C) If any reactive functional groups not included in paragraph (e)(1)(ii)(A) and (B) of this section are present, the combined (total) reactive group equivalent weight, including any groups listed in paragraph (e)(1)(ii)(B), is greater than or equal to 5,000.

(2) *Polymers with number average MW greater than or equal to 10,000 (and oligomer content less than 2 percent below MW 500 and less than 5 percent below MW 1,000)*. The polymer must have a number average MW greater than or equal to 10,000 daltons and contain less than 2 percent oligomeric material below MW 500 and less than 5 percent oligomeric material below MW 1000.

(3) *Polyester polymers*. The polymer is a polyester as defined in paragraph (b) of this section and is manufactured solely from one or more of the reactants in the following table 1:

TABLE 1—LIST OF REACTANTS FROM WHICH POLYESTER MAY BE MADE

Reactant	CAS No.
<b>Monobasic Acids and Natural Oils</b>	
Benzoic acid .....	65-85-0
Canola oil .....	120962-03-0
Coconut oil .....	8001-31-8*
Corn oil .....	8001-30-7*
Cottonseed oil .....	8001-29-4*
Dodecanoic acid .....	143-07-7
Fats and glyceridic oils, anchovy .....	128952-11-4*
Fats and glyceridic oils, babassu .....	91078-92-1*
Fats and glyceridic oils, herring .....	68153-06-0*
Fats and glyceridic oils, menhaden .....	8002-50-4*
Fats and glyceridic oils, sardine .....	93334-41-9*
Fats and glyceridic oils, oiticica .....	8016-35-1*
Fatty acids, C <sub>16-18</sub> and C <sub>18</sub> -unsatd. ....	67701-08-0*
Fatty acids, castor-oil .....	61789-44-4*
Fatty acids, coco .....	61788-47-4*
Fatty acids, dehydrated castor-oil .....	61789-45-5*
Fatty acids, linseed oil .....	68424-45-3*
Fatty acids, safflower oil .....	
Fatty acids, soya .....	68308-53-2*
Fatty acids, sunflower oil .....	84625-38-7*
Fatty acids, sunflower-oil, conjugated .....	68953-27-5*
Fatty acids, tall-oil .....	61790-12-3*
Fatty acids, tall-oil, conjugated* .....	
Fatty acids, vegetable oil .....	61788-66-7*
Glycerides, C <sub>16-18</sub> and C <sub>18</sub> -unsatd. ....	67701-30-8*
Heptanoic acid .....	111-14-8
Hexanoic acid .....	142-62-1

TABLE 1—LIST OF REACTANTS FROM WHICH POLYESTER MAY BE MADE—Continued

Reactant	CAS No.
Hexanoic acid, 3,3,5-trimethyl- .....	3302-10-1
Linseed oil .....	8001-26-1*
Linseed oil, oxidized .....	68649-95-6*
Nonanoic acid .....	112-05-0
Oils, Cannabis* .....	
Oils, palm kernel .....	8023-79-8*
Oils, perilla .....	68132-21-8*
Oils, walnut .....	8024-09-7
Safflower oil .....	8001-23-8*
Soybean oil .....	8001-22-7*
Sunflower oil .....	8001-21-6*
Tung oil .....	8001-20-5*
<b>Di and Tri Basic Acids:</b>	
1,2-Benzenedicarboxylic acid .....	88-99-3
1,3-Benzenedicarboxylic acid .....	121-91-5
1,3-Benzenedicarboxylic acid, dimethyl ester .....	1459-93-4
1,4-Benzenedicarboxylic acid .....	100-21-0
1,4-Benzenedicarboxylic acid, diethyl ester .....	636-09-9
1,4-Benzenedicarboxylic acid, dimethyl ester .....	120-61-6
1,2,4-Benzenetricarboxylic acid .....	528-44-9
Butanedioic acid .....	110-15-6
Butanedioic acid, diethyl ester .....	123-25-1
Butanedioic acid, dimethyl ester .....	106-65-0
2-Butenedioic acid (E)- .....	110-17-8
Decanedioic acid .....	111-20-6
Decanedioic acid, diethyl ester .....	110-40-7
Decanedioic acid, dimethyl ester .....	106-79-6
Dodecanedioic acid .....	693-23-2
Fatty acids, C <sub>18</sub> -unsatd., dimers .....	61788-89-4*
Heptanedioic acid .....	111-16-0
Heptanedioic acid, dimethyl ester .....	1732-08-7
Hexanedioic acid .....	124-04-9
Hexanedioic acid, dimethyl ester .....	627-93-0
Hexanedioic acid, diethyl ester .....	141-28-6
Nonanedioic acid .....	123-99-9
Nonanedioic acid, dimethyl ester .....	1732-10-1
Nonanedioic acid, diethyl ester .....	624-17-9
Octanedioic acid .....	(505-48-6)
Octanedioic acid, dimethyl ester .....	1732-09-8
Pentanedioic acid .....	(110-94-1)
Pentanedioic acid, dimethyl ester .....	1119-40-0
Pentanedioic acid, diethyl ester .....	818-38-2
Undecanedioic acid .....	1852-04-6
<b>Polyols</b>	
1,3-Butanediol .....	107-88-0
1,4-Butanediol .....	110-63-4
1,4-Cyclohexanedimethanol .....	105-08-8
1,2-Ethandiol .....	107-21-1
Ethanol, 2,2'-oxybis- .....	111-46-6
1,6-Hexanediol .....	629-11-8
1,3-Pentanediol, 2,2,4-trimethyl- .....	144-19-4
1,2-Propanediol, .....	57-55-6
1,3-Propanediol, 2,2-bis(hydroxymethyl)- .....	115-77-5
1,3-Propanediol, 2,2-dimethyl- .....	126-30-7
1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)- .....	77-99-6
1,3-Propanediol, 2-(hydroxymethyl)-2-methyl- .....	77-85-0
1,3-propanediol, 2-methyl .....	2163-42-0
1,2,3-Propanetriol .....	56-81-5
1,2,3-Propanetriol, homopolymer .....	25618-55-7
2-Propen-1-ol, polymer with ethenylbenzene .....	25119-62-4
<b>Modifiers</b>	
Acetic acid, 2,2'-oxybis- .....	110-99-6
1-Butanol .....	71-36-3**
Cyclohexanol .....	108-93-0
Cyclohexanol, 4,4'-(1-methylethylidene)bis- .....	80-04-6
Ethanol, 2-(2-butoxyethoxy)- .....	112-34-5
1-Hexanol .....	111-27-3
Methanol, hydrolysis products with trichlorohexylsilane and trichlorophenylsilane .....	72318-84-4*
1-Phenanthrenemethanol, tetradecahydro-1,4a-dimethyl-7-(1-methylethyl)- .....	13393-93-6
Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2,2'-[[1-methylethylidene]bis(4,1-phenyleneoxymethylene)] bis[oxirane].	25036-25-3

TABLE 1—LIST OF REACTANTS FROM WHICH POLYESTER MAY BE MADE—Continued

Reactant	CAS No.
Siloxanes and Silicones, di-Me, di-Ph, polymers with Ph silsesquioxanes, methoxy-terminated .....	68440-65-3*
Siloxanes and Silicones, di-Me, methoxy Ph, polymers with Ph silsesquioxanes, methoxy-terminated .....	68957-04-0*
Siloxanes and Silicones, Me Ph, methoxy Ph, polymers with Ph silsesquioxanes, methoxy- and Ph-terminated.	168957-06-2*
Silsesquioxanes, Ph Pr .....	168037-90-1*

\* Chemical substance of unknown or variable composition, complex reaction products, and biological materials (UVCB). The CAS Registry Numbers for UVCB substances are not used in CHEMICAL ABSTRACTS and its indexes.

\*\* These substances may not be used in a substance manufactured from fumaric or maleic acid because of potential risks associated with esters, which may be formed by reaction of these reactants.

(f) *Exemption report for polymers manufactured under the terms of this section.* For substances exempt under paragraphs (e)(1), (e)(2), and (e)(3) of this section a report of manufacture or import must be submitted (postmarked) by January 31 of the year subsequent to initial manufacture. The notice must include:

(1) *Manufacturer's name.* This includes the name and address of the manufacturer and the name and telephone number of a technical contact.

(2) *Number of substances manufactured.* Number of substances manufactured. The manufacturer must identify the number of polymers manufactured under terms of the exemption for the first time in the year preceding the notice.

(g) *Chemical identity information.* For substances exempt under paragraph (e) of this section the manufacturer must to the extent known to or reasonably ascertainable by the manufacturer identify the following and maintain the records in accordance with paragraph (j) of this section:

(1) A specific chemical name and CAS Registry Number (or EPA assigned Accession Number) for each "reactant," as that term is defined in paragraph (b) of this section, used at any weight in the manufacture of the polymer. For purposes of determining chemical identity, the manufacturer may determine whether a reactant is used at greater than two weight percent according to either the weight of the reactant charged to the reaction vessel or the weight of the chemically combined (incorporated) reactant in the polymer. Manufacturers who choose the "incorporated" method must have analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not

necessary), to demonstrate compliance with this paragraph. Reactants that introduce into the polymer elements, properties, or functional groups that would render the polymer ineligible for the exemption are not allowed at any level.

(2) A representative structural diagram, if possible.

(h) *Certification.* To manufacture a substance under the terms of this section, a manufacturer must as of the date of first manufacture, make the following certification statements and maintain them in accordance with paragraph (j) of this section:

(1) The substance is manufactured or imported for a commercial purpose other than for research and development.

(2) All information in the certification is truthful.

(3) The new chemical substance meets the definition of a polymer, is not specifically excluded from the exemption in paragraph (d) of this section, and meets the conditions of the exemption in paragraph (e) of this section.

(i) *Exemptions granted under superseded regulations.* Manufacturers granted exemptions under the superseded requirements of § 723.250 (as in effect on May 26, 1995) shall either continue to comply with those requirements or follow all procedural and recordkeeping requirements pursuant to this section. If an exemption holder continues to follow the superseded regulations, the Notice of Commencement requirements apply and the exempt polymer will continue to be listed on the Inventory with exclusion criteria and exemption category restrictions on residual monomer/reactant and low molecular weight species content limitations.

(j) *Recordkeeping.* (1) A manufacturer of a new polymer under paragraphs (e) of this section, must retain the records described in this paragraph at the manufacturing site for a period of 5 years from the date of commencement of manufacture or import.

(2) The records must include the following to demonstrate compliance with the terms of this section:

(i) Chemical identity information as required in paragraph (g) of this section.

(ii) Information to demonstrate that the new polymer is not specifically excluded from the exemption.

(iii) Records of production volume for the first 3 years of manufacture and the date of commencement of manufacture.

(iv) Information to demonstrate that the new polymer meets the exemption criteria in paragraphs (e)(1), (e)(2), or (e)(3) of this section.

(v) Analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not necessary), to demonstrate that the polymer meets the number-average MW exemption criteria in paragraphs (e)(1) or (e)(2) of this section. The analytical tests may include gel permeation chromatography (GPC), vapor pressure osmometry (VPO), or other such tests which will demonstrate that the polymer meets the number-average MW criterion.

(vi) Analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not necessary), to demonstrate that the polymer meets the criteria in paragraphs (e)(1) or (e)(2) of this section, meets the low MW content criteria in paragraphs (e)(1) or (e)(2) of this section.

(vii) If applicable, analytical data, or theoretical calculations (if it can be documented that an analytical determination cannot be made or is not necessary) required in paragraph (g) of this section for determining monomers or reactants charged to the reaction vessel at greater than 2 weight percent but incorporated at 2 weight percent or less in the manufactured polymer.

(viii) The certification statements as required under paragraph (h) of this section.

(3) The manufacturer must submit the records listed in paragraph (j)(2) of this section to EPA upon written request by EPA. The manufacturer must provide these records within 15 working days of receipt of this request. In addition, any person who manufactures a new chemical substance under the terms of this section, upon request of EPA, must permit such person at all reasonable times to have access to and to copy these records.

(k) *Submission of information.* Information submitted to EPA under this section must be sent in writing to: TSCA Document Control Officer, (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(1) *Compliance.* (1) A person who manufactures or imports a new chemical substance and fails to comply with any provision of this section is in violation of section 15 of the Act (15 U.S.C. 2614).

(2) Using for commercial purposes a chemical substance or mixture which a person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 of the Act is a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by this section and section 11 of the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(4) Failure or refusal to permit entry or inspection as required by section 11 of the Act is a violation of section 15 of the Act (15 U.S.C. 2614).

(5) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. Persons who submit materially misleading or false information in connection with the requirements of any provision of this section may be subject to penalties calculated as if they never filed their notices.

(6) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section or act to seize any chemical substance manufactured or processed in violation

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of this section or take other actions under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 2616).

(m) *Inspections.* EPA will conduct inspections under section 11 of the Act to assure compliance with section 5 and this section, to verify that information submitted to EPA under this section is true and correct, and to audit data submitted to EPA under this section.

(n) *Confidentiality.* If a manufacturer submits information to EPA under this section which the manufacturer claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA by bracketing, circling, or underlining it and stamping it with “CONFIDENTIAL” or some other appropriate designation. Any information so identified will be treated in accordance with the procedures in 40 CFR part 2. Any information not claimed confidential at the time of submission may be made available to the public without further notice.

[60 FR 16332, Mar. 29, 1995, as amended at 62 FR 17932, April 11, 1997; 75 FR 4305, Jan. 27, 2010]

**PART 725—REPORTING REQUIREMENTS AND REVIEW PROCESSES FOR MICROORGANISMS**

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- 725.160 Submission of health and environmental effects data.
- 725.170 EPA review of the MCAN.
- 725.190 Notice of commencement of manufacture or import.

**Subpart E—Exemptions for Research and Development Activities**

- 725.200 Scope and purpose.
- 725.205 Persons who may report under this subpart.
- 725.232 Activities subject to the jurisdiction of other Federal programs or agencies.
- 725.234 Activities conducted inside a structure.
- 725.235 Conditions of exemption for activities conducted inside a structure.
- 725.238 Activities conducted outside a structure.
- 725.239 Use of specific microorganisms in activities conducted outside a structure.
- 725.250 Procedural requirements for the TERA.
- 725.255 Information to be included in the TERA.
- 725.260 Submission of health and environmental effects data.
- 725.270 EPA review of the TERA.
- 725.288 Revocation or modification of TERA approval.

**Subpart F—Exemptions for Test Marketing**

- 725.300 Scope and purpose.