§ 707.72 Termination of reporting requirements.

(a) The reporting requirements of subpart D of this part are terminated for certain specific chemical substances and mixtures as set forth in this paragraph.

(1) When data required under part 766 of this chapter have been submitted to EPA for a specific chemical substance produced by a specific process, and the data show no positive test result as defined in §766.3 of this chapter, reporting is no longer required by persons who export or intend to export that substance produced by that process.

(2) [Reserved]

(b) [Reserved]

[52 FR 21437, June 5, 1987]

§ 707.75 Confidentiality.

(a) A person may assert a claim of confidentiality for any information which is submitted to EPA in a notice.

(b) Any claim of confidentiality must accompany the information at the time it is submitted to EPA. In the notice, the submitter must clearly identify the information that is claimed confidential by marking the specific information on each page with a label such as ''confidential business information'', ''proprietary'', or ''trade secret''.

(c) Notwithstanding any claim of confidentiality, information outlined in §707.70 will be included in the EPA notice to the foreign government. With this exception, EPA will disclose information that is covered by a claim of confidentiality asserted in accordance with this section only to the extent permitted by, and in accordance with, the procedures set forth in TSCA and part 2 of this chapter.

(d) Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

[45 FR 82850, Dec. 16, 1980, as amended at 88 FR 37172, June 7, 2023]

PART 710—COMPILATION OF THE TSCA CHEMICAL SUBSTANCE INVENTORY

Subpart A—General Provisions

Sec.

Subpart B—Commercial Activity Notification

Subpart C—Review Plan

AUTHORITY: 15 U.S.C. 2607(a) and (b).

Subpart A—General Provisions

§ 710.1 Scope and compliance.

(a) This part establishes regulations governing reporting and recordkeeping by certain persons who manufacture, import, or process chemical substances for commercial purposes under section 8(a) of the Toxic Substances Control Act (15 U.S.C. 2607(a)) (TSCA). Section 8(a) authorizes the Administrator to require reporting of information necessary for administration of the Act and requires EPA to issue regulations for the purpose of compiling and keeping current an inventory of chemical substances manufactured or processed for a commercial purpose, as required by section 8(b) of the Act. Following an initial reporting period, EPA published an initial inventory of chemical substances manufactured, processed, or imported for commercial purposes. In accordance with section 8(b), EPA periodically amends the inventory to include new chemical substances which are manufactured or imported for a commercial purpose and reported under

section 5(a)(1) of the Act. EPA also revises the categories of chemical substances and makes other amendments as appropriate.

(b) This part applies to the activities associated with the compilation of the TSCA Chemical Substance Inventory (Inventory) and the designation of chemical substances on the TSCA Inventory as active or inactive in U.S. commerce.

(c) Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under these reporting regulations. In addition, section 15(3) makes it unlawful for any person to fail to keep, and permit access to, records required by these regulations. Section 16 provides that any person who violates a provision of section 15 is liable to the United States for a civil penalty and may be criminally prosecuted. Pursuant to section 17, the Government may seek judicial relief to compel submission of section 8(a) information and to otherwise restrain any violation of section 15. (EPA does not intend to concentrate its enforcement efforts on insignificant clerical errors in reporting.)

(d) Each person who reports under these regulations must maintain records that document information reported under these regulations and, in accordance with the Act, permit access to, and the copying of, such records by EPA officials.

[68 FR 887, Jan. 7, 2003, as amended at 76 FR 50859, Aug. 16, 2011; 76 FR 54933, Sept. 6, 2011; 82 FR 37539, Aug. 11, 2017]

§ 710.3 Definitions.

For purposes of this part:

(a) The following terms will have the meaning contained in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.*, and the regulations issued under such Act: *Cosmetic*, *device*, *drug*, *food*, and *food additive*. 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*.

(b) The term *pesticide* will have the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.*, and the regulations issued thereunder.

(c) The following terms will have the meaning contained in the Atomic Energy Act of 1954, 42 U.S.C. 2014 *et seq.*, and the regulations issued thereunder: *Byproduct material*, *source material*, and *special nuclear material*.

(d) The following definitions also apply to this part:

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

Administrator means the Administrator of the U.S. Environmental Protection Agency, any employee or authorized representative of the Agency to whom the Administrator may either herein or by order delegate his/her authority to carry out his/her functions, or any other person who will by operation of law be authorized to carry out such functions.

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 § 710.4(d)(5); except that fluids and particles are not considered articles regardless of shape or design.

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

CASRN means Chemical Abstracts Service Registry Number.

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, but not including any derivative products;

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

(5) Any pistol, firearm, revolver, shells, and cartridges; and

(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.

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.

Customs territory of the United States means the 50 States, Puerto Rico, and the District of Columbia.

Distribute in commerce and *distribution in commerce* means to sell in commerce, to introduce or deliver for introduction into commerce, or to hold after its introduction into commerce.

Domestic means within the geographical boundaries of the 50 United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

EPA means the U.S. Environmental Protection Agency.

Importer means any person who imports any chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the United States. ''Importer'' includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his or her behalf. The term also includes, as appropriate,

(1) The consignee,

(2) The importer of record,

(3) the actual owner if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR 141.20, or

(4) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with subpart C of 19 CFR 144.

Impurity means a chemical substance which is unintentionally present with another chemical substance.

Intermediate means any chemical substance that is consumed, in whole or in part, in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rate(s) of such chemical reaction(s).

Inventory means the TSCA Chemical Substance Inventory, which is EPA's comprehensive list of confidential and non-confidential chemical substances manufactured or processed in the United States for nonexempt commercial purpose that EPA compiled and keeps current under section 8(b) of the Act.

Manufacture means to manufacture, produce, or import, for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances. When a chemical substance, manufactured other than by import, is: (1) Produced exclusively for another person who contracts for such production, and (2) that other person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process, then that chemical substance is co-manufactured by the producing manufacturer and the person contracting for such production.

Manufacture for commercial purposes means: (1) To manufacture, produce, or import with the purpose of obtaining an immediate or eventual commercial advantage, and includes, among other things, the ''manufacture'' of any amount of a chemical substance or mixture (i) for commercial distribution, including for test marketing, or (ii) for use by the manufacturer, including use for product research and development or as an intermediate. (2) The term also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts that are separated from that other substance or

mixture and impurities that remain in that substance or mixture. Byproducts and impurities without separate commercial value are nonetheless produced for the purpose of obtaining a commercial advantage, since they are part of the manufacture of a chemical substance for commercial purposes.

Manufacturer means a person who manufactures a chemical substance.

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 ''mixture'' does include (1) any combination which occurs, in whole or in part, as a result of a chemical reaction 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, and if all of the chemical substances comprising the combination are not new chemical substances, and (2) hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water, so long as the nonhydrated form is itself not a new chemical substance.

New chemical substance means any chemical substance which is not included on the Inventory.

Person includes any individual, firm, company, corporation, joint-venture, partnership, sole proprietorship, association, or any other business entity; any State or political subdivision thereof; any municipality; any interstate body; and any department, agency, or instrumentality of the Federal Government.

Process means to process for commercial purposes. Process includes the preparation of a chemical substance or mixture, after its manufacture, (1) 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 (2) as part of a mixture or article containing the chemical substance or mixture.

Process for commercial purposes means the preparation of a chemical substance or mixture after its manufacture for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included in this definition. If a chemical substance or mixture containing impurities is processed for commercial purposes, then the impurities also are processed for commercial purposes.

Processor means any person who processes a chemical substance or mixture.

Site means a contiguous property unit. Property divided only by a public right-of-way will be considered one site. More than one manufacturing plant may be located on a single site.

(1) For chemical substances manufactured under contract, *i.e.*, by a toll manufacturer, the site is the location where the chemical substance is physically manufactured.

(2) The site for an importer who imports a chemical substance described in § 710.25 is the U.S. site of the operating unit within the person's organization that is directly responsible for importing the chemical substance. The import site, in some cases, may be the organization's headquarters in the United States. If there is no such operating unit or headquarters in the United States, the site address for the importer is the U.S. address of an agent acting on behalf of the importer who is authorized to accept service of process for the importer.

Small quantities solely for research and development (or ''small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product'') means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes.

State means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

Technically qualified individual means a person:

(1) Who because of his/her education, training, or experience, or a combination of these factors, is capable of appreciating the health and environmental risks associated with the chemical substance which is used under his/her supervision,

(2) Who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research in order to minimize such risks, and

(3) Who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting the research and development activity. The responsibilities in this paragraph may be delegated to another individual, or other individuals, as long as each meets the criteria in paragraph (1) of this definition.

Test marketing means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.

United States, when used in the geographic sense, means all of the States, territories, and possessions of the United States.

[68 FR 888, Jan. 7, 2003, as amended at 69 FR 40791, July 7, 2004; 76 FR 50859, Aug. 16, 2011; 76 FR 54933, Sept. 6, 2011; 82 FR 37539, Aug. 11, 2017]

§ 710.4 Scope of the inventory.

(a) *Chemical substances subject to these regulations.* Only chemical substances which are manufactured, imported, or processed ''for a commercial purpose,'' as defined in § 710.3(d), are subject to these regulations.

(b) *Naturally occurring chemical substances automatically included.* Any chemical substance which is naturally occurring and:

(1) Which is (i) unprocessed or (ii) processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or

(2) Which is extracted from air by any means, will automatically be included in the inventory under the category ''Naturally Occurring Chemical Substances.'' Examples of such substances are: raw agricultural commodities; water, air, natural gas, and crude oil; and rocks, ores, and minerals.

(c) *Substances excluded by definition or section 8(b) of TSCA.* The following substances are excluded from the inventory:

(1) Any substance which is not considered a ''chemical substance'' as provided in subsection 3(2)(B) of the Act and in the definition of ''chemical substance'' in § 710.3(d);

(2) Any mixture as defined in § 710.3(d);

NOTE: A chemical substance that is manufactured as part of a mixture is subject to these reporting regulations. This exclusion applies only to the mixture and not to the chemical substances of which the mixture is comprised. The term ''mixture'' includes alloys, inorganic glasses, ceramics, frits, and cements, including Portland cement.

(3) Any chemical substance which is manufactured, imported, or processed solely in small quantities for research and development, as defined in § 710.3(d); and

(4) Any chemical substance not manufactured, processed or imported for a commercial purpose since January 1, 1975.

(d) *Chemical substances excluded from the inventory.* The following chemical substances are excluded from the inventory. Although they are considered to be manufactured or processed for a commercial purpose for the purpose of section 8 of the Act, they are not manufactured or processed for distribution in commerce as chemical substances *per se* and have no commercial purpose separate from the substance, mixture, or article of which they may be a part.

NOTE: In addition, chemical substances excluded here will not be subject to premanufacture notification under section 5 of the Act.

(1) Any impurity.

(2) Any byproduct which has no commercial purpose.

NOTE: A byproduct which has commercial value only to municipal or private organizations who (i) burn it as a fuel, (ii) dispose of

it as a waste, including in a landfill or for enriching soil, or (iii) extract component chemical substances which have commercial value, may be reported for the inventory, but will not be subject to premanufacture notification under section 5 of the Act if not included.

(3) Any chemical substance which results from a chemical reaction that occurs incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.

(4) Any chemical substance which results from a chemical reaction that occurs incidental to storage of another chemical substance, mixture, or article.

(5) Any chemical substance which results from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles such as adhesives, paints, miscellaneous cleansers or other housekeeping products, fuels and fuel additives, water softening and treatment agents, photographic films, batteries, matches, and safety flares, and which is not itself manufactured for distribution in commerce or for use as an intermediate.

(6) Any chemical substance which results from a chemical reaction that occurs upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints; or other chemical substances formed during manufacture of an article destined for the marketplace without further chemical change of the chemical substance except for those chemical changes that may occur as described elsewhere in this §710.4(d).

(7) Any chemical substance which results from a chemical reaction that occurs when (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or de-foamer, dispersant, precipitation inhibitor, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended or (ii) a chemical substance, solely intended to impart a specific physicochemical characteristic, functions as intended.

(8) Chemical substances which are not intentionally removed from the equipment in which they were manufactured.

NOTE: See note to definition of ''intermediate'' at §710.3(d) for explanation of ''equipment in which it was manufactured.''

[42 FR 64572, Dec. 23, 1977, as amended at 68 FR 889, Jan. 7, 2003]

Subpart B—Commercial Activity Notification

SOURCE: 82 FR 37540, Aug. 11, 2017, unless otherwise noted.

§ 710.23 Definitions.

The following definitions also apply to subpart B of this part.

Active substance means any interim active substance, any naturally occurring chemical substance as defined by §710.27(b), any chemical substance that was added to the Inventory on or after June 21, 2006 pursuant to a Notice of Commencement under §720.102 received by the Agency on or after June 21, 2006, and any chemical substance subject to commercial activity designation that the Administrator designates as active based on the receipt of a notice under this subpart.

Central Data Exchange or CDX means EPA's centralized electronic document reporting portal, or its successors.

Chemical Information Submission System or CISS means EPA's web-based reporting tool for preparing and submitting a Notice of Activity.

Chemical substance subject to commercial activity designation means a chemical substance that requires a designation as either an active or an inactive substance. A chemical substance is subject to commercial activity designation if it is not an interim active substance, it was added to the Inventory before June 21, 2006, it is not a naturally occurring chemical substance as defined by §710.27(b), and it has not yet been designated by the Administrator as either an active or an inactive substance.

e-NOA means EPA's software module within CISS for generating and completing Notice of Activity Forms A and B.

Existing claim for protection of specific chemical identity against disclosure is a claim for protection of the specific chemical identity of a chemical substance that is listed on the confidential portion of the Inventory, asserted prior to June 22, 2016.

Inactive substance means any chemical substance subject to commercial activity designation, that the Administrator designates as inactive based on the lack of receipt of a notice under this subpart, effective 90 days after the Administrator identifies the chemical substance for such designation.

Interim active substance means any chemical substance that was reported, pursuant to 40 CFR part 711, as having been manufactured in and of the calendar years: 2010, 2011, 2012, 2013, 2014, or 2015.

Known to or reasonably ascertainable by means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.

Notice of Activity Form A means the form for supplying retrospective notification under TSCA section 8(b)(4), for which the submission obligation is described in §710.25(a).

Notice of Activity Form B means the form for supplying forward-looking reporting under TSCA section 8(b)(5), for which the submission obligation is described in §710.25(c).

Lookback period means the period beginning on June 21, 2006 and ending on June 21, 2016.

Possession or *Control* means in the possession or control of any person, or of any subsidiary, partnership in which the person is a general partner, parent company, or any company or partnership which the parent company owns or controls, if the subsidiary, parent company, or other company or partnership is associated with the person in the research, development, test marketing, or commercial marketing of the chemical substance in question. Information is in the possession or control of a person if it is:

(1) In the person's own files including files maintained by employees of the person in the course of their employment.

(2) In commercially available data bases to which the person has purchased access.

(3) Maintained in the files in the course of employment by other agents of the person who are associated with research, development, test marketing, or commercial marketing of the chemical substance in question.

Reportable chemical substance means a chemical substance that is listed on the Inventory and that is either:

(1) A chemical substance subject to commercial activity designation for which notification is required or allowed under §710.25(a) and §710.25(b),

(2) A chemical substance that was added to the confidential portion of the Inventory before June 22, 2016, or (3) an inactive substance for which notification is required under §710.25(c).

Submission period means the applicable period for submitting a Notice of Activity under §710.25.

§710.25 Persons subject to the notification requirement.

The following persons are subject to the requirements of this subpart.

(a) *Who must submit the Notice of Activity Form A?* Any person who manufactured (including imported) a chemical substance subject to commercial activity designation at any time during the lookback period, except as provided in §710.27, must submit a Notice of Activity Form A as specified under §§710.29 and 710.30(a), unless such person has evidence in the form of a CDX receipt, documenting EPA's receipt of a Notice of Activity Form A from another person, for the same chemical substance, or unless the prior manufacturing of such a substance is not known to or reasonably ascertainable by the person. Evidence in the form of a CDX receipt for a Notice of Activity Form A is not a basis for exemption from the requirements of §710.25(c) if the chemical substance is ultimately designated as inactive due to withdrawal of the Notice of Activity Form A.

(b) *Who else may submit the Notice of Activity Form A?* Any person not required to submit a Notice of Activity Form A under §710.25(a), who manufactured (including imported) or processed a reportable chemical substance, at

any time during the lookback period, may submit a Notice of Activity Form A as specified under §§ 710.29 and 710.30(a).

(c) *Who must submit the Notice of Activity Form B?* Any person who intends to manufacture (including import) or process an inactive substance, except as provided in § 710.27, after the effective date of the Administrator's designation of such chemical substance as an inactive substance, must submit a Notice of Activity Form B as specified under §§ 710.29 and 710.30(b), unless the presence of the inactive substance on the confidential portion of the Inventory is not known to or reasonably ascertainable by the person.

§ 710.27 Activities for which notification is not required.

(a) *In general.* The following activities do not trigger notification requirements under this subpart:

(1) The manufacturing or processing of a chemical substance in small quantities solely for research and development.

(2) The import or processing of a chemical substance as part of an article.

(3) The manufacturing or processing of a chemical substance as described in § 720.30(g) or (h).

(4) The manufacturing or processing of a chemical substance solely for export from the United States as described in § 720.30(e) or § 721.3, except where the Administrator has made a finding described in TSCA section 12(a)(2).

(5) The manufacturing or processing of a chemical substance solely for test marketing purposes.

(b) *Manufacturing or processing naturally occurring chemical substances.* The following activities do not trigger notification requirements under this subpart:

(1) The manufacture of a naturally occurring chemical substance, as described in § 710.4(b). Some chemical substances can be manufactured both as described in § 710.4(b) and by means other than those described in § 710.4(b). If a person manufactures a chemical substance by means other than those described in § 710.4(b), this exemption is inapplicable, regardless of whether the chemical substance also could have been produced as described in § 710.4(b). This exemption does not cover the manufacture of a chemical substance from a naturally occurring chemical substance.

(2) The processing of a naturally occurring chemical substance only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water.

§ 710.29 Information required in the notification.

(a) *Reporting information to EPA.* A person who reports information to EPA under this subpart must do so using the e-NOA software module, the CISS reporting tool, and the CDX electronic reporting portal provided by EPA at the addresses set forth in § 710.39. For notices of activity under §§ 710.25(a) and 710.25(b), the submission must include all information described in paragraph (b) of this section. For a Notice of Activity under § 710.25(c), the submission must include all information described in paragraph (c) of this section. A person must submit a separate notice for each chemical substance that the person is required to report. Using e-NOA and CISS and registering in CDX are described in instructions available from EPA at the Web sites set forth in § 710.39.

(b) *Information to be reported on the Notice of Activity Form A.* A person submitting a Notice of Activity Form A under § 710.25(a) or § 710.25(b) must submit the information specified in § 710.29(d) for each reportable chemical substance. A person submitting information under § 710.25(a) or § 710.25(b) must report information to the extent that such information is known to or reasonably ascertainable by that person.

(c) *Information to be reported on a Notice of Activity Form B.* Any person submitting a Notice of Activity Form B under § 710.25(c) must provide the information described in this paragraph for each inactive substance intended to be manufactured or processed.

(1) Information specified in § 710.29(d).

(2) The anticipated date by which the inactive substance is to be manufactured or processed in the United

States. If the Notice of Activity Form B is filed prior to the effective date of the chemical substance's inactive designation, the most recent date of manufacturing or processing may be provided in lieu of an anticipated date.

(d) *Information to be reported on either the Notice of Activity Form A or Form B.*

(1) *Company.* The name and address of the submitting company.

(2) *Authorized official.* The name and address of the authorized official for the submitting company.

(3) *Technical contact.* The name and telephone number of a person who will serve as technical contact for the submitting company and who will be able to answer questions about the information submitted by the company to EPA.

(4) *Chemical-specific information.* The system described under §710.29(a) will provide a list of reportable chemical substances from which a person can select his or her chemical. The list will include the correct CASRN and CA Index name used to list a non-confidential chemical substance on the Inventory. For confidential substances on the Inventory, the list will include the TSCA Accession Number and generic name.

(i) If an importer submitting a notice cannot provide the information specified in §710.29(d)(4) because it is unknown to the importer and claimed as confidential by the supplier of the chemical substance or mixture, the importer must ask the supplier to provide the specific chemical identity information directly to EPA in a joint submission using the same e-NOA software module used for commercial activity reporting. Such request must refer the supplier to EPA's instructions for submitting chemical identity information electronically, using e-NOA, CISS, and CDX (see §710.39), and for clearly referencing the importer's submission. Contact information for the supplier, a trade name or other name for the chemical substance or mixture, and a copy of the request to the supplier must be included with the importer's submission.

(ii) If a manufacturer or processor submitting a notice cannot provide the information specified in §710.29(d)(4) because the reportable chemical substance is manufactured or processed using a reactant having a specific chemical identity that is unknown to the manufacturer or processor and claimed as confidential by its supplier, the manufacturer or processor must ask the supplier of the confidential reactant to provide the specific chemical identity of the confidential reactant directly to EPA in a joint submission using the same e-NOA software module used for commercial activity reporting. Such request must refer the supplier to EPA's instructions for submitting chemical identity information electronically using e-NOA, CISS, and CDX (see §710.39), and for clearly referencing the manufacturer's or processor's submission. Contact information for the supplier, a trade name or other name for the chemical substance, and a copy of the request to the supplier must be included with the manufacturer's or processor's submission with respect to the chemical substance.

(iii) Joint submissions must be submitted electronically using e-NOA, CISS, and CDX (see §710.39).

(5) *Certification statements.* The authorized official must certify that the submitted information has been completed in compliance with the requirements of this part as described in this paragraph.

(i) The certification must be signed and dated by the authorized official for the submitting company.

(ii) The following is required certification language for an authorized official submitting a Notice of Activity Form A under §710.25(a) or §710.25(b): ''I certify under penalty of law that this document and all attachments were prepared under my direction or supervision and the information contained therein, to the best of my knowledge, is true, accurate, and complete. I also certify that I have manufactured, imported, or processed the above chemical between the dates of June 21, 2006 and June 21, 2016. I am aware it is unlawful to knowingly submit incomplete, false and/or misleading information, and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment.''

(iii) The following is required certification language for an authorized official submitting a Notice of Activity Form B under §710.25(c): ''I certify under penalty of law that this document and all attachments were prepared under my direction or supervision and the information contained therein, to the best of my knowledge, is true, accurate, and complete. I also certify that I have intent to manufacture, import, or process the above chemical within 90 days of submission. I am aware it is unlawful to knowingly submit incomplete, false and/or misleading information, and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment.''

§ 710.30 When to submit notifications.

(a) *When must a Notice of Activity Form A be submitted?* The Notice of Activity Form A required to be submitted under §710.25(a) must be submitted during the applicable submission period.

(1) *Manufacturers.* The submission period for manufacturers under §§710.25(a) and 710.25(b) begins on August 11, 2017 and ends on February 7, 2018.

(2) *Processors.* The submission period for processors under §710.25(b) begins on August 11, 2017 and ends on October 5, 2018.

(3) *Withdrawal of a Notice of Activity Form A.* A Notice of Activity Form A submitted under §710.30(a)(1) or §710.30(a)(2) may be withdrawn by the submitter no later than October 5, 2018. If EPA receives a timely request to withdraw a previously submitted Notice of Activity Form A for a chemical substance subject to commercial activity designation, and EPA has not received a Notice of Activity Form A from another submitter for the same chemical substance, EPA will not designate the chemical substance as active. A Form A withdrawn under this paragraph will not satisfy the obligation under this rule to submit a Form A.

(b) *When must a Notice of Activity Form B be submitted?*—(1) *Manufacturers and processors.* The Notice of Activity Form B required to be submitted under §710.25(c) must be submitted before a person manufactures or processes the inactive substance, but not more than 90 days prior to the anticipated date of manufacturing or processing.

(2) *When else may a Notice of Activity Form B be submitted?* A Notice of Activity Form B that will later be required to be submitted under §710.25(c) may be submitted during the 90-day period between EPA's identification of a chemical substance for inactive designation and the effective date for such designation, by a person who is currently manufacturing or processing such chemical substance or who anticipates manufacturing or processing such chemical substance within 90 days following submission.

(3) *When may EPA execute a request to withdraw a Notice of Activity Form B?* If EPA receives a request to withdraw a previously submitted Notice of Activity Form B from the submitter of the Notice of Activity Form B and EPA has neither yet moved the subject chemical substance from the inactive to the active Inventory nor yet moved the subject chemical substance from the confidential portion of the Inventory to the public portion of the Inventory as a result of the original submission, then EPA may execute the request.

§ 710.33 Co-manufacturers and co-processors.

(a) *Notice of Activity submitted by co-manufacturers.* When, in a single instance of manufacturing or importing a particular volume of a chemical substance during the lookback period, two or more persons qualify as the manufacturer or importer of that volume, they may determine among themselves who should make the required submission under §710.25(a). If no notice is submitted as required under this subpart, EPA will hold each such person liable for failure to submit a notice.

(b) *Notice of Activity by prospective co-manufacturers or co-processors.* If two or more persons intend to manufacture, import, or process a particular volume of an inactive substance, such that multiple persons would qualify as the manufacturer, importer, or processor of that volume, they may determine among themselves who will submit the required notice under §710.25(c). If no notice is submitted as required under

this subpart, all of the persons remain subject to the reporting requirements, and EPA will hold each such person liable for a failure to submit a notice prior to the date of manufacturing, importing, or processing.

§ 710.35 Recordkeeping requirements.

Each person who is subject to the notification requirements of this part must retain records that document any information reported to EPA. Records relevant to a Notice of Activity under §§ 710.25(a) and 710.25(b) must be retained for a period of 5 years beginning on the last day of the submission period. Records relevant to a Notice of Activity under § 710.25(c) must be retained for a period of 5 years beginning on the day that the notice was submitted.

§ 710.37 Confidentiality claims.

(a) *Chemical identity*. A person submitting information under this part may request to maintain an existing claim of confidentiality for the specific chemical identity of a reportable chemical substance, but may do so only if the identity of the chemical substance is listed on the confidential portion of the Inventory as of the time the notice is submitted for that chemical substance under this part. A request to maintain an existing claim of confidentiality must be made at the time the information is submitted. If no person submitting the information specified in § 710.29(d)(4) for a particular chemical substance requests that the claim be maintained, EPA will treat the specific chemical identity of that chemical substance as not subject to a confidentiality claim and will move the chemical substance to the public portion of the Inventory. Except as set forth in this subsection, information claimed as confidential in accordance with this section will be treated and disclosed in accordance with the procedures in 40 CFR part 2, subpart B.

(1) *Notice of Activity Form A*. A person requesting to maintain an existing claim of confidentiality for specific chemical identity may submit with the notice answers to the questions in paragraphs (c)(1) and(c)(2) of this section, signed and dated by an authorized official. If these answers are submitted less than five years before the date on which substantiation is due pursuant to TSCA section 8(b)(4)(D)(i), the answers will be deemed to be substantiations made under TSCA section (8)(b)(4)(D)(i) and the person will be exempt from further substantiation requirements under TSCA section (8)(b)(4)(D)(i). Answers that do not include the answers to all applicable questions in paragraph (c) of this section will not be deemed to be substantiations made under the TSCA section (8)(b)(4)(D)(i) requirement.

(2) *Notice of Activity Form B*. A person requesting to maintain an existing claim of confidentiality for specific chemical identity must submit answers to the questions in paragraphs (c)(1) and (c)(2) of this section within 30 days of submitting the notice, signed and dated by an authorized official. If this information is not submitted within 30 days of submitting the notice, EPA will consider the confidentiality claim as deficient, so that the specific chemical identity is not subject to a confidentiality claim, and may make the information public without further notice.

(i) Persons who submitted the information described in paragraph (a)(2) of this section before May 5, 2020 must submit answers to the questions in paragraphs (c)(2)(ii) and (iii) of this section not later than June 4, 2020.

(ii) [Reserved]

(b) *Information other than specific chemical identity*. A person submitting information under this part may assert a claim of confidentiality for information other than specific chemical identity. Any such confidentiality claim must be made at the time the information is submitted. Except as set forth in this section, information claimed as confidential in accordance with this subsection will be treated and disclosed in accordance with 40 CFR part 2, subpart B. A person asserting a claim of confidentiality under this subsection must submit with the notice answers to the questions in paragraph (c)(1) of this section, signed and dated by an authorized official. If no claim is asserted at the time the information is submitted, or if the answers to the questions in paragraph (c)(1) of this section are not provided, EPA will consider the

information as not subject to a confidentiality claim and may make the information public without further notice.

(c) *Substantiation questions.* Persons asserting that information is exempt from substantiation pursuant to TSCA section 14(c)(2) must answer only the question in paragraph (c)(1)(i) of this section.

(1) *Substantiation questions for any confidentiality claim.* For any information with a confidentiality claim that you assert is exempt from substantiation pursuant to TSCA section 14(c)(2), answer only the question in paragraph (c)(1)(i) of this section. For all other information with a confidentiality claim, answer the questions in paragraphs (c)(1)(ii) through (vi) of this section. If more than one data element on Form A or Form B is claimed as confidential, you must answer the applicable questions individually for each data element. If the answer to a question applies for all confidentiality claims on the form, indicate this in your substantiation response.

(i) Do you believe that the information is exempt from substantiation pursuant to TSCA section 14(c)(2)? If you answered yes, you must individually identify the specific information claimed as confidential and specify the applicable exemption(s).

(ii) Will disclosure of the information likely result in substantial harm to your business's competitive position? If you answered yes, describe with specificity the substantial harmful effects that would likely result to your competitive position if the information is made available to the public.

(iii) To the extent your business has disclosed the information to others (both internally and externally), what precautions has your business taken? Identify the measures or internal controls your business has taken to protect the information claimed as confidential: Non-disclosure agreement required prior to access; access is limited to individuals with a need-to-know; information is physically secured; other internal control measure(s). If yes, explain.

(iv) Does the information appear in any public documents, including (but not limited to) safety data sheets, advertising or promotional material, professional or trade publication, or any other media or publications available to the general public? If you answered yes, explain why the information should be treated as confidential.

(v) Is the claim of confidentiality intended to last less than 10 years? If so, indicate the number of years (between 1–10 years) or the specific date/occurrence after which the claim is withdrawn.

(vi) Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this chemical substance? If you answered yes, explain the outcome of that determination and provide a copy of the previous confidentiality determination or any other information that will assist in identifying the prior determination.

(2) *Substantiation for confidentiality claims for specific chemical identity.* (i) Is the confidential chemical substance publicly known to have ever been offered for commercial distribution in the United States? If you answered yes, explain why the information should be treated as confidential.

(ii) Does this particular chemical substance leave the site of manufacture (including import) or processing in any form, *e.g.,* as a product, effluent, or emission? If yes, please explain what measures have been taken, if any, to guard against the discovery of its identity.

(iii) If the chemical substance leaves the site in a form that is available to the public or your competitors, can the chemical identity be readily discovered by analysis of the substance (*e.g.,* product, effluent, or emission), in light of existing technologies and any costs, difficulties, or limitations associated with such technologies? Please explain why or why not.

(d) *Confidentiality of substantiation.* If any of the information contained in the answers to the questions listed in paragraph (c)(1) or (c)(2) of this section is claimed as confidential business information, the submitter must clearly indicate such by marking the substantiation as confidential business information as provided in a Notice of Activity Form A or Form B.

(e) *Certification statement for claims.* An authorized official of a person submitting or substantiating a claim of confidentiality or a request to maintain an existing claim of confidentiality for specific chemical identity must certify that the submission complies with the requirements of this part by signing and dating the following certification statement: ''I certify that all claims for confidentiality made or sought to be maintained with this submission are true and correct, and all information submitted herein to substantiate such claims is true and correct. Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. 1001.'' I further certify that it is true and correct that:

(1) My company has taken reasonable measures to protect the confidentiality of the information;

(2) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(3) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(4) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

[82 FR 37540, Aug. 11, 2017, as amended at 85 FR 13067, Mar. 6, 2020]

§ 710.39 Electronic filing.

(a) EPA will accept information submitted under this subpart only if submitted in accordance with this section. All information must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, Notices of Activity and any associated information must be generated and completed using the e-NOA software module.

(b) Obtain instructions for registering in CDX as follows:

(1) *Web site.* The CDX Registration User Guide is available at *https://www.epa.gov/sites/production/files/documents/cdx__registration__guide__v0__02.pdf.* To register in CDX, go to *https://cdx.epa.gov* and follow the appropriate links.

(2) *Telephone.* Contact the EPA CDX Help Desk at 1–888–890–1995.

(3) *Email.* Email the EPA CDX Help Desk at *HelpDesk@epacdx.net.*

(c) Obtain instructions for using CISS and the e-NOA software module as follows:

(1) *Web site.* Go to the EPA New Chemicals under the Toxic Substances Control Act Web site at *https://www.epa.gov/reviewing-new-chemicalsunder-toxic-substances-control-act-tsca/how-submit-e-pmn* and follow the appropriate links.

(2) *Telephone.* Contact the EPA TSCA Hotline at 1–202–554–1404.

(3) *Email.* Email the EPA TSCA Hotline at *TSCA-Hotline@epa.gov.*

Subpart C—Review Plan

SOURCE: 85 FR 13068, Mar. 6, 2020, unless otherwise noted.

§ 710.41 Scope.

This subpart applies to the substantiation and review of claims of confidentiality asserted in Notices of Activity Form A to protect the specific chemical identities of chemical substances.

§ 710.43 Persons subject to substantiation requirement.

(a) *Who must substantiate.* Any person who filed a Notice of Activity Form A requesting to maintain an existing confidentiality claim for a specific chemical identity must substantiate that confidentiality claim as specified in §§ 710.45 and 710.47 unless eligible for an exemption in paragraph (b) of this section.

(b) *Exemptions.* (1) Any person who completed the voluntary substantiation process set forth in § 710.37(a)(1) is exempt from the substantiation requirement of this subpart pertaining to the submission of answers to the questions in § 710.45(b)(1) through (6). All remaining requirements of § 710.45 must be met in accordance with the deadline specified in § 710.47(a), including the requirement to submit answers to the questions in § 710.45(b)(7) and (8), signed and dated by an authorized official, and to complete the certification statement in § 710.37(e).

(2) A person who has previously substantiated the confidentiality claim for a specific chemical identity that the person requested to maintain in a Notice of Activity Form A, by submitting information that is responsive to all questions in § 710.45, is exempt from the substantiation requirement of this subpart if both of the following conditions are met:

(i) The previous substantiation was submitted to EPA on or after November 1, 2015; and

(ii) The person reports to EPA the submission date, submission type, and case number, transaction ID, or equivalent identifier for the previous submission that contained the substantiation, not later than the deadline specified in § 710.47.

§ 710.45 Contents of substantiation.

(a) *The submission.* A person substantiating a confidentiality claim for a specific chemical identity must submit written answers to the questions in paragraph (b) of this section, signed and dated by an authorized official, and complete the certification statement in § 710.37(e). If any of the information contained in the answers to the questions listed in paragraph (b) of this section is itself claimed as confidential, the submitter must clearly indicate such by marking that information as confidential business information.

(b) *Substantiation questions.* (1) Will disclosure of the information claimed as confidential likely cause substantial harm to your business's competitive position? If you answered yes, describe the substantial harmful effects that would likely result to your competitive position if the information is disclosed, including but not limited to how a competitor could use such information and the causal relationship between the disclosure and the harmful effects.

(2) To the extent your business has disclosed the information to others (both internally and externally), has your business taken precautions to protect the confidentiality of the disclosed information? If yes, please explain and identify the specific measures, including but not limited to internal controls, that your business has taken to protect the information claimed as confidential.

(3)(i) Is any of the information claimed as confidential required to be publicly disclosed under any other Federal law? If yes, please explain.

(ii) Does any of the information claimed as confidential otherwise appear in any public documents, including (but not limited to) safety data sheets; advertising or promotional material; professional or trade publications; state, local, or Federal agency files; or any other media or publications available to the general public? If yes, please explain why the information should be treated as confidential.

(iii) Does any of the information claimed as confidential appear in one or more patents or patent applications? If yes, please provide the associated patent number or patent application number (or numbers) and explain why the information should be treated as confidential.

(4) Is the claim of confidentiality intended to last less than 10 years? If yes, please indicate the number of years (between 1-10 years) or the specific date/occurrence after which the claim is withdrawn.

(5) Has EPA, another Federal agency, or court made any confidentiality determination regarding information associated with this chemical substance? If yes, please provide the circumstances associated with the prior determination, whether the information was found to be entitled to confidential treatment, the entity that made the decision, and the date of the determination.

(6) Is the confidential chemical substance publicly known (including by your competitors) to have ever been offered for commercial distribution in the United States? If yes, please explain why the specific chemical identity should still be afforded confidential status (*e.g.*, the chemical substance is publicly known only as being distributed in commerce for research and development purposes, but no other information about the current commercial distribution of the chemical substance in the United States is publicly available).

(7) Does this particular chemical substance leave the site of manufacture (including import) or processing in any form, *e.g.*, as a product, effluent, or

emission? If yes, please explain what measures have been taken, if any, to guard against the discovery of its identity.

(8) If the chemical substance leaves the site in a form that is available to the public or your competitors, can the chemical identity be readily discovered by analysis of the substance (*e.g.*, product, effluent, or emission), in light of existing technologies and any costs, difficulties, or limitations associated with such technologies? Please explain why or why not.

§ 710.47 When to submit substantiation or information on previous substantiation.

(a) All persons required to substantiate a confidentiality claim pursuant to § 710.43(a) or (b)(1) must submit their substantiation not later than November 1, 2020.

(b) All persons who seek an exemption under § 710.43(b)(2) must submit the information specified in § 710.43(b)(2)(ii) not later than November 1, 2020.

§ 710.49 Failure to report.

If neither the substantiation required under § 710.43(a) or (b)(1), nor the information specified in § 710.43(b)(2)(ii), is submitted to EPA in accordance with the provisions of this subpart, then EPA will deny the confidentiality claim in accordance with the procedures set forth in TSCA section 14(g)(2) and 40 CFR part 2, subpart B.

§ 710.51 Electronic filing.

EPA will accept information submitted under this subpart only if submitted in accordance with § 710.39.

§ 710.53 Recordkeeping requirements.

Each person who is subject to this part must retain records that document any information reported to EPA. Records must be retained for a period of 5 years beginning on the last day of the submission period.

§ 710.55 Claim review, duration of protection, TSCA Inventory maintenance, posting results, and extension.

(a) *Review criteria and procedures.* Except as set forth in this subpart, confidentiality claims for specific chemical identities asserted in Notices of Activity Form A will be reviewed and approved or denied in accordance with the criteria and procedures in TSCA section 14 and 40 CFR part 2, subpart B.

(b) *Duration of protection from disclosure.* Except as provided in 40 CFR part 2, subpart B, and section 14 of TSCA, a specific chemical identity that is the subject of an approved confidentiality claim under this subpart will be protected from disclosure for a period of 10 years from the date on which the confidentiality claim was first asserted by any submitter after June 22, 2016, unless, prior to the expiration of the period, the claimant notifies EPA that the person is withdrawing the confidentiality claim, in which case EPA will not protect the information from disclosure; or EPA otherwise becomes aware that the information does not qualify for protection from disclosure, in which case EPA will take the actions described in TSCA section 14(g)(2) to notify the claimant of EPA's intent to disclose the information.

(c) *Updating the TSCA Inventory.* EPA will periodically update the TSCA Inventory based on the results of the reviews of the confidentiality claims asserted in Notices of Activity Form A.

(d) *Posting of annual goals and numbers of reviews completed.* At the beginning of each calendar year until all reviews are completed, EPA will publish an annual goal for reviews and the number of reviews completed in the prior year on the Agency website. Determination of annual review goals will take into consideration the number of claims needing review, available resources, and a target completion date for all reviews under this subpart not later than February 19, 2024.

(e) *Extension.* If EPA determines that the target completion date in paragraph (d) of this section cannot be met based on the number of claims needing review and the available resources, then EPA will publish a document in the FEDERAL REGISTER announcing the extension of the deadline to complete its review of all confidentiality claims under this subpart for not more than two additional years, together with an explanation of the reasons for the extension.