the Agency as required by the EPA Administrator or appropriate designee. EPA will notify those responsible for reporting by letter or will announce any such requirements for submitting copies of records by a notice in the FEDERAL REGISTER. Such letter or notice will be signed by the Administrator or appropriate designee, and will specify which records or portion of records must be submitted. The reporting period will be specified by the letter or notice but in no case will such reporting period be less than 45 days from the date of the letter or the effective date of the notice.

(c) *How to report.* When required to report, firms must submit copies of records via CDX *https://cdx.epa.gov/* using the EPA provided electronic reporting application.

[48 FR 38187, Aug. 22, 1983, as amended at 49 FR 23183, June 5, 1984; 52 FR 20084, May 29, 1987; 53 FR 12523, Apr. 15, 1988; 58 FR 34204, June 23, 1993; 60 FR 34464, July 3, 1995; 71 FR 33641, June 12, 2006; 88 FR 37172, June 7, 2023]

§ 717.19 Confidentiality.

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

[88 FR 37172, June 7, 2023]

PART 720—PREMANUFACTURE NOTIFICATION

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AUTHORITY: 15 U.S.C. 2604, 2607, and 2613.

SOURCE: 48 FR 21742, May 13, 1983, unless otherwise noted.

Subpart A—General Provisions

§ 720.1 Scope.

This part establishes procedures for the reporting of new chemical substances by manufacturers 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. This part defines the persons and chemical substances subject to the reporting requirements, prescribes the contents of section 5 notices, and establishes procedures for submitting notices. This part 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, Apr. 11, 1997; 87 FR 39763, July 5, 2022; 89 FR 102789, Dec. 18, 2024]

§ 720.3 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*.

Applicable review period means the period starting on the date EPA receives a complete notice under section 5(a)(1) of the Act and ending 90 days after that date or on such date as is provided for in sections 5(b)(1) or 5(c) of the Act.

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 § 720.30(h)(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 or mixture.

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.

Central Data Exchange or *CDX* means EPA's centralized electronic document receiving system, or its successors.

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; or

(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.

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*.

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

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

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

EPA means the U.S. Environmental Protection Agency.

e-PMN software means electronic-PMN software created by EPA for use in preparing and submitting Premanufacture Notices (PMNs) and other TSCA section 5 notices and support documents electronically to the Agency.

Health and safety study or *study* means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological, or other studies of a chemical substance or mixture, and any test performed under the Act. Chemical identity is always part of a health and safety study.

(1) Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture on health or the environment is also included. Any data that bear on the effects of a chemical substance on health or the environment would be included.

(2) Examples include:

(i) Long- and short-term tests of mutagenicity, carcinogenicity, or teratogenicity; data on behavioral disorders; dermatoxicity; pharmacological effects; mammalian absorption, distribution, metabolism, and excretion; cumulative, additive, and synergistic effects; acute, subchronic, and chronic effects; and structure/activity analyses.

(ii) Tests for ecological or other environmental effects on invertebrates, fish, or other animals, and plants, including acute toxicity tests, chronic toxicity tests, critical life stage tests, behavioral tests, algal growth tests, seed germination tests, plant growth or damage tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies.

(iii) Assessments of human and environmental exposure, including workplace exposure, and impacts of a particular chemical substance or mixture on the environment, including surveys, tests, and studies of: Biological, photochemical, and chemical degradation; air, water, and soil transport; biomagnification and bioconcentration; and chemical and physical properties, *e.g.*, boiling point, vapor pressure, evaporation rates from soil and water, octanol/water partition coefficient, and water solubility.

(iv) Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture.

(v) Any assessments of risk to health and the environment resulting from the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance.

Importer means any person who imports a 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 19 CFR part 144, subpart C. (See ''principal importer.'')

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 reactions used for the intentional manufacture of another chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rates of such chemical reactions.

Inventory means the list of chemical substances manufactured or processed in the United States that EPA compiled and keeps current under section 8(b) of the Act.

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.

Manufacture means to produce or manufacture in the United States or import into the customs territory of the United States.

Manufacture for commercial purposes means:

(1) To manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes, among other things, ''manufacture'' of any amount of a chemical substance or mixture.

(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.

Manufacture solely for export means to manufacture for commercial purposes a chemical substance solely for export from the United States under the following restrictions on activities in the United States:

(1) Distribution in commerce is limited to purposes of export or processing solely for export as defined in § 721.3 of this chapter.

(2) The manufacturer and any person to whom the substance is distributed for purposes of export or processing solely for export (as defined in § 721.3 of this chapter), may not use the substance except in small quantities solely for research and development in accordance with § 720.36.

Manufacturer means a person who imports, produces, or manufactures a chemical substance. A person who extracts a component chemical substance from a previously existing chemical substance or a complex combination of substances is a manufacturer of that component chemical substance. A person who contracts with a manufacturer to manufacture or produce a chemical substance is also a manufacturer if:

(1) The manufacturer manufactures or produces the substance exclusively for that person; and

(2) That person specifies the identity of the substance and controls the total amount produced and the basic technology for the plant process.

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 ''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.

Nonisolated intermediate means any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the chemical substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

Person means any natural person, 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.

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.

Possession or control means in possession or control of the submitter, or of any subsidiary, partnership in which the submitter 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 submitter in the research, development, test marketing, or commercial marketing of the chemical substance in question. (A parent company owns or controls another company if the parent owns or controls 50 percent or more of the other company's voting stock. A parent company owns or controls any partnership in which it is a general partner). Information is included within this definition if it is:

(1) In files maintained by submitter's employees who are:

(i) Associated with research, development, test marketing, or commercial

marketing of the chemical substance in question.

(ii) Reasonably likely to have such data.

(2) Maintained in the files of other agents of the submitter who are associated with research, development, test marketing, or commercial marketing of the chemical substance in question in the course of their employment as such agents.

Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, the elderly, or overburdened communities.

Principal importer means the first importer who, knowing that a new chemical substance will be imported rather than manufactured domestically, specifies the identity of the chemical substance and the total amount to be imported. Only persons who are incorporated, licensed, or doing business in the United States may be principal importers.

Process means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce:

(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.

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

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 or processed or proposed to be manufactured 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 and the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

Support documents means material and information submitted to EPA in support of a TSCA section 5 notice, including but not limited to, correspondence, amendments (if notices for these amendments were submitted prior to January 19, 2016), and test data. The term ''support documents'' does not include orders under TSCA section 5(e) (either consent orders or orders imposed pursuant to TSCA section 5(e)(2)(B)).

Technically qualified individual means a person or persons:

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

(2) Who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research 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 a research and development activity.

Test data means data from a formal or informal test or experiment, including information concerning the objectives, experimental methods and materials, protocols, results, data analyses, recorded observations, monitoring data, measurements, and conclusions from a test or experiment.

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.

[89 FR 102789, Dec. 18, 2024]

Subpart B—Applicability

§ 720.22 Persons who must report.

(a)(1) Any person who intends to manufacture a new chemical substance in the United States for commercial purposes must submit a notice unless the substance is excluded under § 720.30.

(2) If a person contracts with a manufacturer to manufacture or produce a new chemical substance, and (i) the manufacturer manufactures or produces the substance exclusively for that person, and (ii) that person specifies the identity of the substance, and controls the total amount produced and the basic technology for the plant process, that person must submit the notice. If it is unclear who must report, EPA should be contacted to determine who must submit the notice.

(3) Only manufacturers that are incorporated, licensed, or doing business in the United States may submit a notice.

(b)(1) Any person who intends to import a new chemical substance into the United States for commercial purposes must submit a notice, unless the substance is excluded under § 720.30 or unless the substance is imported as part of an article.

(2) When several persons are involved in an import transaction, the notice must be submitted by the principal importer. If no one person fits the principal importer definition in a particular transaction, the importer should contact EPA to determine who must submit the notice for that transaction.

§ 720.25 Determining whether a chemical substance is on the Inventory.

(a) A new chemical substance is any chemical substance that is not currently listed on the Inventory.

(b)(1) A chemical substance is listed in the public portion of the Inventory by a specific chemical name (either a Chemical Abstracts (CA) Index Name or a CA Preferred Name) and a Chemical Abstracts Service (CAS) Registry Number if its identity is not confidential. If its identity is confidential, it is listed in the public portion of the Inventory by a TSCA Accession Number and a generic chemical name that masks the specific substance identity. The confidential substance is listed by its specific chemical name only in the confidential portion of the Inventory, which is not available to the public. A person who intends to manufacture (including import) a chemical substance not listed by specific chemical name in the public portion of the Inventory may ask EPA whether the substance is included in the confidential Inventory. EPA will answer such an inquiry only if EPA determines that the person has a *bona fide* intent to manufacture (including import) the chemical substance for commercial purposes.

(2) To establish a *bona fide* intent to manufacture (including import) a chemical substance, the person who proposes to manufacture the substance must submit the request to EPA via CDX. Prior to submission to EPA via CDX, such *bona fide* intents to manufacture (including import) must be generated and completed using e-PMN software. See § 720.40(a)(2)(ii) for information on how to access the e-PMN software. A *bona fide* intent to manufacture (including import) must contain:

(i) Except as provided in paragraphs (b)(3)(i) and (ii) of this section, the specific chemical identity of the substance that the person intends to manufacture (including import), using the currently correct CA Index name for the substance and the other correct chemical identity information in accordance with § 720.45(a) (1), (2), and (3).

(ii) A signed statement that the person intends to manufacture (including import) that chemical substance for commercial purposes.

(iii)(A) A brief description of the research and development activities conducted to date related to the substance, including the year in which the person first started to conduct research

or development activity on the substance, and the general types of research and development activities conducted thus far (e.g., synthesis, substance isolation/purification, formulating, product development, process development, end-use application, toxicity testing, etc.). The person must also indicate whether any pilot plant or production-scale plant evaluations have been conducted involving the manufacture or processing of the substance.

(B) If an importer is unable to provide the information requested in paragraph (b)(2)(iii)(A) of this section from the foreign manufacturer or supplier, the following information shall be submitted:

(*1*) A brief statement indicating how long the substance has been in commercial use outside of the United States.

(*2*) The name of a country in which it has been commercially used.

(*3*) Whether the importer believes that the substance has already been used commercially, in any country, for the same purpose or application that the importer is intending.

(iv) A specific description of the major intended application or use of the substance.

(v) An infrared spectrum of the substance, or alternative spectra or other data which identify the substance if infrared analysis is not suitable for the substance or does not yield a reasonable amount of structural information. When using alternative spectra or instrumental analysis, the person must submit a spectrum or instrumental readout for the substance.

(vi) The estimated date (month/year) in which the person intends to submit a Premanufacture Notice (PMN) for this substance if EPA informs the notice submitter that the substance is not on the Inventory.

(vii) The address of the facility under the control of the submitter at which the manufacture or processing of the substance would most likely occur. For an imported substance, the facility under the control of the importer at which processing of the substance would likely occur, if any.

(viii)(A) For substances intended to be manufactured in the United States, a description of the most probable manufacturing process that would be used by the submitter to produce the substance for non-exempt commercial purposes.

(B) For substances intended to be imported, a brief description of how the submitter is most likely to process or use the substance for a commercial purpose. If the substance is not expected to be processed or used at any facility under the importer's control, a statement to this effect must be included along with a description of how the substance will be processed or used at sites controlled by others, if this information is known or reasonably ascertainable.

(3)(i) If an importer cannot provide the chemical identity information required by paragraph (b)(2) (i) and (v) of this section because it is claimed confidential by its foreign manufacturer or supplier, the foreign manufacturer or supplier must supply the required information directly to EPA in accordance with § 720.45(a) (1), (2), and (3) and reference the importer's notice. If the appropriate supporting document from the foreign party is not received within 30 days after EPA receives the importer's notice, the notice will be considered incomplete.

(ii) If a manufacturer cannot provide all of the required information in accordance with § 720.45(a) (1), (2), and (3) because the new chemical substance is manufactured using a reactant that has a specific chemical identity claimed as confidential by its supplier, the notice must contain chemical identity information that is as complete as known by the manufacturer. In addition, a letter of support for the notice must then be sent to EPA by the chemical supplier of the confidential reactant, providing the specific chemical identity of the proprietary reactant. The letter of support must reference the manufacturer's notice. If the appropriate supporting document from the supplier is not received within 30 days after EPA receives the manufacturer's notice, the notice will be considered incomplete.

(4) EPA will review the information submitted by the proposed manufacturer (including importer) under this paragraph to determine whether it has

a *bona fide* intent to manufacture (including import) the chemical substance. If necessary, EPA will compare this information to the information requested for the confidential chemical substance under § 720.85(b)(3)(iii).

(5) If the proposed manufacturer (including importer) has shown a *bona fide* intent to manufacture (including import) the substance, and has provided sufficient unambiguous chemical identity information so EPA can make a conclusive determination of the chemical substance's Inventory status, EPA will search the confidential Inventory and inform the proposed manufacturer (including importer) whether the chemical substance is on the confidential Inventory.

(6) If the chemical substance is found on the confidential Inventory, EPA will notify the person(s) who originally reported the chemical substance that another person has demonstrated a *bona fide* intent to manufacture (including import) the substance and therefore was told that the chemical substance is on the Inventory.

(7) A disclosure of a confidential chemical identity to a person with a *bona fide* intent to manufacture (including import) the particular chemical substance will not be considered a public disclosure of confidential business information under section 14 of the Act.

(8) EPA will answer an inquiry on whether a particular chemical substance is on the confidential Inventory within 30 days after receipt of a complete submission under paragraph (b)(2) of this section.

(9) If the required chemical identity information has not been reported correctly or completely in the notice (except as provided under paragraph (b)(3)(ii) of this section) or if any other required data or information has been omitted or is incomplete, EPA will consider the whole notice to be incomplete. As soon as an incomplete notice is identified as such by EPA, the Agency will immediately return the notice directly to the submitter. The submitter must then resubmit the whole, completed *bona fide* notice to EPA in order to have the Agency perform the desired Inventory search and respond to the notice.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993; 60 FR 16309, Mar. 29, 1995; 80 FR 42745, July 20, 2015]

§ 720.30 Chemicals not subject to notification requirements.

The following substances are not subject to the notification requirements of this part:

(a) Any substance which is not a ''chemical substance'' as defined in § 720.3.

(b) Any mixture as defined in § 720.3.[1]

(c) Any new chemical substance which will be manufactured in small quantities solely for research and development under § 720.36.

(d) Any new chemical substance which will be manufactured solely for test-marketing purposes under an exemption granted under § 720.38.

(e) Any new chemical substance manufactured solely for export if, when the substance is distributed in commerce:

(1) The substance is labeled in accordance with section 12(a)(1)(B) of the Act.

(2) The manufacturer knows that the person to whom the substance is being distributed intends to export it or process it solely for export as defined in § 721.3 of this chapter.

(f) Any new chemical substance which is manufactured under the terms of a rule promulgated under section 5(h)(4) of the Act.

(g) Any byproduct if its only commercial purpose is for use by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes. (This exclusion only applies to the byproduct; it does not apply to the component substances extracted from the byproduct.)

(h) The chemical substances described below: (Although they are manufactured for commercial purposes

[1] A new chemical substance that is manufactured as part of a mixture is subject to the requirements of this part. This exclusion applies only to a mixture as a whole and not to any chemical substances which are part of the mixture.

under the Act, they are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part.)

(1) Any impurity.

(2) Any byproduct which is not used for commercial purposes.

(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 or disposal of another chemical substance, mixture, or article.

(5) Any chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, mixture, or article such as an adhesive, paint, miscellaneous cleanser or other housekeeping product, fuel additive, water softening and treatment agent, photographic film, battery, match, or safety flare, 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 any other chemical substance formed during the manufacture of an article destined for the marketplace without further chemical change of the chemical substance except for those chemical changes that occur as described elsewhere in this paragraph.

(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 defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, 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, which is intended solely to impart a specific physiochemical characteristic, functions as intended.

(8) Any nonisolated intermediate.

(i) Any chemical substance which is manufactured solely for non-commercial research and development purposes. Non-commercial research and development purposes include scientific experimentation, research, or analysis conducted by academic, government, or independent not-for-profit research organizations (e.g., universities, colleges, teaching hospitals, and research institutes), unless the activity is for eventual commercial purposes.

[48 FR 21742, May 13, 1983, as amended at 51 FR 15101, Apr. 22, 1986; 87 FR 39763, July 5, 2022; 89 FR 102792, Dec. 18, 2024]

§ 720.36 Exemption for research and development.

(a) This part does not apply to a chemical substance if the following conditions are met:

(1) The chemical substance is manufactured only in small quantities solely for research and development.

(2) The manufacturer notifies all persons in its employ or to whom it directly distributes the chemical substance, who are engaged in experimentation, research, or analysis on the chemical substance, including the manufacture, processing, use, transport, storage, and disposal of the substance associated with research and development activities, of any risk to health, identified under paragraph (b) of this section, which may be associated with the substance. The notification must be made in accordance with paragraph (c) of this section.

(3) The chemical substance is used by, or directly under the supervision of, a technically qualified individual.

(b)(1) To determine whether notification under paragraph (a)(2) of this section is required, the manufacturer must review and evaluate the following information to determine whether there is reason to believe there is any potential risk to health which may be associated with the chemical substance:

(i) Information in its possession or control concerning any significant adverse reaction by persons exposed to the chemical substance which may reasonably be associated with such exposure.

(ii) Information provided to the manufacturer by a supplier or any other person concerning a health risk believed to be associated with the substance.

(iii) Health and environmental effects data in its possession or control concerning the substance.

(iv) Information on health effects which accompanies any EPA rule or order issued under sections 4, 5, or 6 of the Act that applies to the substance and of which the manufacturer has knowledge.

(2) When the research and development activity is conducted solely in a laboratory and exposure to the chemical substance is controlled through the implementation of prudent laboratory practices for handling chemical substances of unknown toxicity, and any distribution, except for purposes of disposal, is to other such laboratories for further research and development activity, the information specified in paragraph (b)(1) of this section need not be reviewed and evaluated. (For purposes of this paragraph, a laboratory is a contained research facility where relatively small quantities of chemical substances are used on a nonproduction basis, and where activities involve the use of containers for reactions, transfers, and other handling of substances designed to be easily manipulated by a single individual.)

(c)(1) The manufacturer must notify the persons identified in paragraph (a)(2) of this section by means of a container labeling system, conspicuous placement of notices in areas where exposure may occur, written notification to each person potentially exposed, or any other method of notification which adequately informs persons of health risks which the manufacturer has reason to believe may be associated with the substance, as determined under paragraph (b)(1) of this section.

(2) If the manufacturer distributes a chemical substance manufactured under this section to persons not in its employ, the manufacturer must in written form:

(i) Notify those persons that the substance is to be used only for research and development purposes.

(ii) Provide the notice of health risks specified in paragraph (c)(1) of this section.

(3) The adequacy of any notification under this section is the responsibility of the manufacturer.

(d) A chemical substance is not exempt from reporting under this part if any amount of the substance, including as part of a mixture, is processed, distributed in commerce, or used, for any commercial purpose other than research and development, except where the chemical substance is processed, distributed in commerce, or used only as an impurity or as part of an article.

(e) Quantities of the chemical substance, or of mixtures or articles containing the chemical substance, remaining after completion of research and development activities may be:

(1) Disposed of as a waste in accordance with applicable Federal, state, and local regulations, or

(2) Used for the following commercial purposes:

(i) Burning it as a fuel.

(ii) Reacting or otherwise processing it to form other chemical substances for commercial purposes, including extracting component chemical substances.

(f) Quantities of research and development substances existing solely as impurities in a product or incorporated into an article, in accordance with paragraph (d) of this section, and quantities of research and development substances used solely for commercial purposes listed in paragraph (e) of this section, are not subject to the requirements of paragraphs (a), (b), and (c) of this section, once research and development activities have been completed.

(g) A person who manufactures a chemical substance in small quantities solely for research and development is not required to comply with the requirements of this section if the person's exclusive intention is to perform research and development activities solely for the purpose of determining

whether the substance can be used as a pesticide.

[51 FR 15102, Apr. 22, 1986, as amended at 87 FR 39763, July 5, 2022]

§ 720.38 Exemptions for test marketing.

(a) Any person may apply for an exemption to manufacture a new chemical substance for test marketing. EPA may grant the exemption if the person demonstrates that the chemical substance will not present an unreasonable risk to injury to health or the environment as a result of the test marketing.

(b) Persons applying for a test-marketing exemption should provide the following information:

(1) All existing data regarding health and environmental effects of the chemical substance, including physical/chemical properties or, in the absence of such data, a discussion of toxicity based on structure-activity relationships (SAR) and relevant data on chemical analogues.

(2) The maximum quantity of the chemical substance which the applicant will manufacture for test marketing.

(3) The maximum number of persons who may be provided the chemical substance during test marketing.

(4) The maximum number of persons who may be exposed to the chemical substance as a result of test marketing, including information regarding duration and route of such exposures.

(5) A description of the test-marketing activity, including its length and how it can be distinguished from full-scale commercial production and research and development.

(6) A fee payment identity number, as required in 40 CFR 700.45(g)(4).

(7) Any safety data sheet already developed for the chemical substance, including draft safety data sheets.

(c) In accordance with section 5(h)(6) of the Act, after EPA receives an application for exemption under this section, the Agency will file with the Office of the Federal Register a notice containing a summary of the information provided in the application, to the extent it has not been claimed confidential.

(d) No later than 45 days after EPA receives an application, the Agency will either approve or deny the application. Thereafter, EPA will publish a notice in the FEDERAL REGISTER explaining the reasons for approval or denial.

(e) In approving an application for exemption, EPA may impose any restrictions necessary to ensure that the substance will not present an unreasonable risk of injury to health and the environment as a result of test marketing.

(f) When applying for a test marketing exemption, persons are subject to fees in accordance with 40 CFR 700.45.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993; 83 FR 52719, Oct. 17, 2018; 87 FR 39763, July 5, 2022]

Subpart C—Notice Form

§ 720.40 General.

(a) *Use of the notice form; electronic submissions.* (1) Each person who is required by subpart B of this part to submit a notice must complete, sign, and submit a notice containing the information in the form and manner specified in this paragraph. The information submitted and all attachments (unless the attachment appears in the open scientific literature) must be in English. All information submitted must be true and correct.

(2) All notices must be submitted on EPA Form 7710–25. Notices, and any support documents related to these notices, may only be submitted in a manner set forth in this paragraph.

(i) *Submission via CDX.* TSCA section 5 notices and any related support documents must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices must be generated and completed on EPA Form 7710–25 using e-PMN software.

(ii) You can access the e-PMN software as follows:

(A) *Website.* Go to EPA's TSCA New Chemicals Program website at *http://www.epa.gov/oppt/newchems* and follow the appropriate links.

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

(C) *E-mail. HelpDesk@epacdx.net.*

(b) *When to submit a notice.* Each person who is required to submit a notice must submit the notice at least 90 calendar days before manufacture of the new chemical substance for commercial purposes begins.

(c) *Where to submit a notice or support documents.* For submitting notices or support documents via CDX, use the e-PMN software.

(d) *General notice requirements.* (1) Each person who submits a notice must provide the information described in § 720.45 and specified on the notice form, to the extent such information is known to or reasonably ascertainable by the person. In accordance with § 720.50, the notice must also include any test data in the person's possession or control, and descriptions of other data which are known to or reasonably ascertainable by the person and which concern the health and environmental effects of the new chemical substance.

(2) If information is claimed as confidential pursuant to § 720.80, a person who submits a notice to EPA in the manner set forth in § 720.40(a)(2)(i), (ii), or (iii) must also provide EPA with a sanitized copy.

(e) *Agency or joint submissions.* (1) A manufacturer (including importer) may designate an agent to assist in submitting the notice. If so, only the manufacturer (including importer), and not the agent, signs the certification on the form.

(2) A manufacturer may authorize another person, (e.g., a supplier or a toll manufacturer) to report some of the information required in the notice to EPA on its behalf. The manufacturer should indicate in a cover letter accompanying the notice which information will be supplied by another person and must identify that other person as a joint submitter where indicated on their notice form. The other person supplying information (i.e., the joint submitter) may submit the information to EPA using either the notice form or a Letter of Support, except that if the joint submitter is not incorporated, licensed, or doing business in the United States, the joint submitter must submit the information to EPA in a Letter of Support only, not in a notice form. The joint submitter must indicate in the notice or Letter of Support the identity of the manufacturer. Any person who submits a notice form or Letter of Support for a joint submission must sign and certify the notice form or Letter of Support.

(3) Only the Authorized Official (AO) of a submitting company can certify initial notices and submit all TSCA section 5 documents.

(i) An AO can authorize other persons to be non-certifying AOs who may conduct all section 5 business on behalf of the submitting company except for certifying and submitting initial notices to EPA via CDX.

(ii) An AO may grant access to a support registrant to edit section 5 documents.

(f) *New information.* During the applicable review period, if the submitter possesses, controls, or knows of new information that materially adds to or changes the information included in the notice, the submitter must submit that information to EPA within ten days of receiving the new information, but no later than five days before the end of the applicable review period. The new information must be submitted electronically to EPA via CDX and must clearly identify the submitter and the notice to which the new information is related. If the new information becomes available during the last five days of the applicable review period, the submitter must immediately inform its EPA contact for that notice by telephone or e-mail and submit the new information electronically to EPA via CDX.

(g) *Chemical substances subject to a section 4 test rule.* (1) Except as provided in paragraph (g)(3) of this section, if (i) A person intends to manufacture a new chemical substance which is subject to the notification requirements of this part, and (ii) The chemical substance is subject to a test rule promulgated under section 4 of the Act before the notice is submitted, section 5(b)(1) of the Act requires the person to submit the test data required by the testing rule with the notice. The person must submit the data in the form and manner specified in the test rule and in accordance with § 720.50. If the person does not submit the test data, the submission is incomplete and EPA will follow the procedures in § 720.65.

(2) If EPA has granted the submitter an exemption under section 4(c) of the Act from the requirement to conduct tests and submit data, the submitter may not submit a notice until EPA receives the test data.

(3) If EPA has granted the submitter an exemption under section 4(c) of the Act and if another person previously has submitted the test data to EPA, the exempted person may either submit the test data or provide the following information as part of the notice:

(i) The name, title, and address of the person who submitted the test data to EPA.

(ii) The date the test data were submitted to EPA.

(iii) A citation for the test rule.

(iv) A description of the exemption and a reference identifying it.

(h) *Chemical substances subject to a section 5(b)(4) rule.* (1) If a person (i) intends to manufacture a new chemical substance which is subject to the notification requirements of this part and which is subject to a rule issued under section 5(b)(4) of the Act; and (ii) is not required by a rule issued under section 4 of the Act to submit test data for the substance before the submission of a notice, the person must submit to EPA data described in paragraph (h)(2) of this section at the time the notice is submitted.

(2) Data submitted under paragraph (h)(1) of this section must be data which the person submitting the notice believes show that the manufacture, processing, distribution in commerce, use and disposal of the substance, or any combination of such activities, will not present an unreasonable risk of injury to health or the environment.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993; 60 FR 16309, Mar. 29, 1995; 75 FR 784, Jan. 6, 2010; 78 FR 72827, Dec. 4, 2013; 80 FR 42746, July 20, 2015; 87 FR 39763, July 5, 2022; 89 FR 102792, Dec. 18, 2024]

§ 720.45 Information that must be included in the notice form.

Each person who submits a notice must include the information specified in the notice form to the extent it is known to or reasonably ascertainable by the submitter. However, no person is required to include information which relates solely to exposure of human or ecological populations outside of the United States. The notice form requires the following information relating to the manufacture, processing, distribution in commerce, use, and disposal of the new chemical substance:

(a)(1) The specific chemical identity of the substance that the person intends to manufacture or import, which includes the following:

(i) The currently correct Chemical Abstracts (CA) name for the substance, based on the Ninth Collective Index (9CI) of CA nomenclature rules and conventions, and consistent with listings for similar substances in the Inventory. For each substance having a chemical composition that can be represented by a specific, complete chemical structure diagram (a Class 1 substance), a CA Index Name must be provided. For each chemical substance that cannot be fully represented by a complete, specific chemical structure diagram (a Class 2 substance), or if the substance is a polymer, a CA Index Name or CA Preferred Name must be provided (whichever is appropriate based on CA 9CI nomenclature rules and conventions). In addition, for a Class 2 substance, the notice must identify the immediate chemical precursors and reactants by specific chemical name and Chemical Abstracts Service Registry Number (CASRN), if the number is available. Tradenames or generic names of chemical precursors or reactants are not acceptable as substitutes for specific chemical names.

(ii) The currently correct CASRN for the substance if a CASRN already exists for the substance.

(iii) For a Class 1 substance and for any Class 2 substance for which a definite molecular formula is known or reasonably ascertainable, the correct molecular formula.

(iv) For a Class 1 substance, a complete, correct chemical structure diagram; for a Class 2 substance or polymer, a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.

(2) For a polymer, the submitter must also report the following:

(i) The specific chemical name and CASRN, if the number is available, of each monomer and other reactant used, at any weight percent, to manufacture the polymer. Tradenames or generic names of chemical reactants or monomers are not acceptable as substitutes for specific chemical names.

(ii) The typical percent by weight of each monomer and other reactant in the polymer (weight of the monomer or other reactant expressed as a percentage of the weight of the polymeric chemical substance manufactured), and the maximum residual amount of each monomer present in the polymer.

(iii) For monomers and other reactants used at 2 weight percent or less (based on the dry weight of the polymer manufactured), indicate on the PMN form any such monomers and other reactants that should be included as part of the polymer description on the Inventory, where the weight percent is based on either (A) the weight of monomer or other reactant actually charged to the reaction vessel, or (B) the minimum weight of monomer or other reactant required in theory to account for the actual weight of monomer or other reactant molecules or fragments chemically incorporated (chemically combined) in the polymeric substance manufactured.

(iv) For a determination that 2 weight percent or less of a monomer or other reactant is incorporated (chemically combined) in a polymeric substance manufactured, as specified in paragraphs (a)(2)(iii)(B) of this section, analytical data or appropriate theoretical calculations (if it can be documented that analytical measurement is not feasible or not necessary) to support this determination must be maintained at the site of manufacture or import of the polymer.

(v) Measured or estimated values of the minimum number-average molecular weight of the polymer and the amount of low molecular weight species below 500 and below 1,000 molecular weight, with a description of how the measured or estimated values were obtained.

(3) The person must use one of the following two methods to develop or obtain the specified chemical identity information reported under paragraphs (a) (1) and (2) of this section and must identify the method used in the notice:

(i) *Method 1.* Obtain the correct chemical identity information required by paragraphs (a) (1) and (2) of this section directly from the Chemical Abstracts Service (CAS), specifically from the CAS Registry Services Inventory Expert Service, prior to submitting a notice to EPA. A copy of the chemical identification report obtained from CAS must be submitted with the notice.

(ii) *Method 2.* Obtain the correct chemical identity information required by paragraphs (a) (1) and (2) from any source. The notice will be incomplete according to § 720.65(c)(1)(vi) if the person uses Method 2 and any chemical identity information is determined to be incorrect by EPA.

(4) If an importer submitting the notice cannot provide all the information specified in paragraphs (a)(1) and (2) of this section because it is claimed as confidential by the foreign supplier of the substance, the importer must have the foreign supplier follow the procedures in paragraph (a)(3) of this section and provide the correct chemical identity information specified in paragraphs (a)(1) and (2) of this section directly to EPA in a joint submission or as a letter of support to the notice, which clearly references the importer's notice and PMN User Fee Identification Number. The applicable review period will commence upon receipt of both the notice and the complete, correct information, in accordance with § 720.65.

(5) If a manufacturer cannot provide all the information specified in paragraphs (a)(1) and (2) of this section because the new chemical substance is manufactured using a reactant having a specific chemical identity claimed as confidential by its supplier, the manufacturer must submit a notice directly to EPA containing all the information known by the manufacturer about the chemical identity of the reported substance and its proprietary reactant. In addition, the manufacturer must ensure that the supplier of the confidential reactant submit a letter of support directly to EPA providing the specific chemical identity of the confidential reactant, including the CASRN, if

available, and the appropriate PMN or exemption number, if applicable. The letter of support must reference the manufacturer's name and PMN Fee Identification Number. The applicable review period will commence upon receipt of the notice, the letter of support, and the complete, correct information, in accordance with § 720.65.

(b) The impurities anticipated to be present in the substance by name, CAS Registry number, and weight percent of the total substance.

(c) Known synonyms or trade names of the new chemical substance.

(d) A description of the byproducts resulting from the manufacture, processing, use, and disposal of the new chemical substance.

(e) The estimated maximum amount to be manufactured during the first year of production and the estimated maximum amount to be manufactured during any 12-month period during the first three years of production.

(f)(1) A description of the intended category or categories of consumer or commercial use by function and application, which includes a description of the following:

(i) The estimated percent of production volume devoted to each category of use.

(ii) The percent of the new chemical substance in the formulation for each commercial or consumer use.

(iii) The types of products or articles that would incorporate the new chemical substance (*e.g.*, household cleaners, plastic articles).

(iv) Information related to the use of products or articles containing the new chemical substance by potentially exposed or susceptible subpopulations.

(v) How and where a product or article containing the new chemical substance would be used (*e.g.*, spray applied indoors, brushed on outdoor surfaces).

(vi) Consumption rates and frequency and duration of use of products or articles containing the new chemical substance.

(2) Using the applicable codes listed in Table 1 to paragraph (f)(2), submitters must designate the consumer and commercial product category or categories that best describe the consumer and commercial products in which the new chemical substance is intended or known to be used. When more than 10 codes apply to the consumer or commercial products in which the new chemical substance is intended or known to be used, submitters should only designate the 10 product categories that represent the highest proportion of the anticipated production volume.

TABLE 1 TO PARAGRAPH (f)(2)—CODES FOR REPORTING CONSUMER AND COMMERCIAL PRODUCT CATEGORIES

Code	Category
	Chemical Substances in Furnishing, Cleaning, Treatment Care Products
CC101	Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel.
CC102	Furniture & furnishings including plastic articles (soft); leather articles.
CC103	Furniture & furnishings including stone, plaster, cement, glass, and ceramic articles; metal articles; or rubber articles.
CC104	Leather conditioner.
CC105	Leather tanning, dye, finishing, impregnation, and care products.
CC106	Textile (fabric) dyes.
CC107	Textile finishing and impregnating/surface treatment products.
CC108	All-purpose foam spray cleaner.
CC109	All-purpose liquid cleaner/polish.
CC110	All-purpose liquid spray cleaner.
CC111	All-purpose waxes and polishes.
CC112	Appliance cleaners.
CC113	Drain and toilet cleaners (liquid).
CC114	Powder cleaners (floors).
CC115	Powder cleaners (porcelain).
CC116	Dishwashing detergent (liquid/gel).
CC117	Dishwashing detergent (unit dose/granule).
CC118	Dishwashing detergent liquid (hand-wash).
CC119	Dry cleaning and associated products.
CC120	Fabric enhancers.

TABLE 1 TO PARAGRAPH (f)(2)—CODES FOR REPORTING CONSUMER AND COMMERCIAL PRODUCT CATEGORIES—Continued

Code	Category
CC121	Laundry detergent (unit-dose/granule).
CC122	Laundry detergent (liquid).
CC123	Stain removers.
CC124	Ion exchangers.
CC125	Liquid water treatment products.
CC126	Solid/Powder water treatment products.
CC127	Liquid body soap.
CC128	Liquid hand soap.
CC129	Solid bar soap.
CC130	Air fresheners for motor vehicles.
CC131	Continuous action air fresheners.
CC132	Instant action air fresheners.
CC133	Anti-static spray.
CC134	Apparel finishing, and impregnating/surface treatment products.
CC135	Insect repellent treatment.
CC136	Pre-market waxes, stains, and polishes applied to footwear.
CC137	Post-market waxes, and polishes applied to footwear (shoe polish).
CC138	Waterproofing and water-resistant sprays.
	Chemical Substances in Construction, Paint, Electrical, and Metal Products
CC201	Fillers and putties.
CC202	Hot-melt adhesives.
CC203	One-component caulks.
CC204	Solder.
CC205	Single-component glues and adhesives.
CC206	Two-component caulks.
CC207	Two-component glues and adhesives.
CC208	Adhesive/Caulk removers.
CC209	Aerosol spray paints.
CC210	Lacquers, stains, varnishes, and floor finishes.
CC211	Paint strippers/removers.
CC212	Powder coatings.
CC213	Radiation curable coatings.
CC214	Solvent-based paint.
CC215	Thinners.
CC216	Water-based paint.
CC217	Construction and building materials covering large surface areas, including wood articles.
CC218	Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass, and ceramic articles.
CC219	Machinery, mechanical appliances, electrical/electronic articles.
CC220	Other machinery, mechanical appliances, electronic/electronic articles.
CC221	Construction and building materials covering large surface areas, including metal articles.
CC222	Electrical batteries and accumulators.
	Chemical Substances in Packaging, Paper, Plastic, Toys, Hobby Products
CC301	Packaging (excluding food packaging), including paper articles.
CC302	Other articles with routine direct contact during normal use, including paper articles.
CC303	Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft).
CC304	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard).
CC305	Toys intended for children's use (and child dedicated articles), including fabrics, textiles, and apparel; or plastic articles (hard).
CC306	Adhesives applied at elevated temperatures.
CC307	Cement/concrete.
CC308	Crafting glue.
CC309	Crafting paint (applied to body).
CC310	Crafting paint (applied to craft).
CC311	Fixatives and finishing spray coatings.
CC312	Modelling clay.
CC313	Correction fluid/tape.
CC314	Inks in writing equipment (liquid).
CC315	Inks used for stamps.
CC316	Toner/Printer cartridge.
CC317	Liquid photographic processing solutions.
	Chemical Substances in Automotive, Fuel, Agriculture, Outdoor Use Products
CC401	Exterior car washes and soaps.

TABLE 1 TO PARAGRAPH (f)(2)—CODES FOR REPORTING CONSUMER AND COMMERCIAL PRODUCT CATEGORIES—Continued

Code	Category
CC402	Exterior car waxes, polishes, and coatings.
CC403	Interior car care.
CC404	Touch up auto paint.
CC405	Degreasers.
CC406	Liquid lubricants and greases.
CC407	Paste lubricants and greases.
CC408	Spray lubricants and greases.
CC409	Anti-freeze liquids.
CC410	De-icing liquids.
CC411	De-icing solids.
CC412	Lock deicers/releasers.
CC413	Cooking and heating fuels.
CC414	Fuel additives.
CC415	Vehicular or appliance fuels.
CC416	Explosive materials.
CC417	Agricultural non-pesticidal products.
CC418	Lawn and garden care products.
Chemical Substances in Products not Described by Other Codes	
CC980	Other (specify).
CC990	Non-TSCA use.

(g) For sites controlled by the submitter:

(1) The identity and address of each site where the new chemical substance will be manufactured, processed, or used.

(2) A process description of each manufacture, processing, and use operation which includes a diagram of the major unit operations and chemical conversions; indication of whether batch or continuous manufacturing or processing occurs at the site, and the amount manufactured or processed per batch or per day if continuous and per year; the identity, approximate weight per batch or per day for continuous production, and entry point of all starting materials and feedstocks (including reactants, solvents, catalysts, etc.); the identity, approximate weight per batch or per day for continuous production, and entry point of all products, recycle streams, and wastes, including frequency of any equipment cleaning; the type of interim storage and transport containers used; and the points of release of the new chemical substance numbered. If the new chemical substance is released to two media at the same step in the process, assign a second number for the second medium.

(3) Worker exposure information for each worker activity anticipated or known to occur during manufacture, processing, or use of the new chemical substance, including worker exposure information from exempt manufacture or related use of the new chemical substance under § 720.30. This information includes:

(i) A description of each worker activity.

(ii) Type of potential worker exposure (*e.g.*, dermal, inhalation).

(iii) Protective equipment in place, if any, including a description of the kind of gloves, protective clothing, goggles, or respirator that limit worker exposure.

(iv) Engineering controls in place, if any.

(v) Physical form of the new chemical substance to which workers may be exposed and moisture content if physical form is solid.

(vi) The percent of new chemical substance in formulation at time of worker exposure.

(vii) The number of workers reasonably likely to be exposed.

(viii) The duration of activities.

(4) Information on known or anticipated release of the new chemical substance to the environment, including releases from the exempt manufacture or related use of the new chemical substance under § 720.30. This information

includes the type of release (*e.g.*, transport, interim storage, disposal, equipment cleaning), the quantity of the new chemical substance released directly to the environment, the quantity of the new chemical substance released into control technology, the quantity of the new chemical substance released to the environment after control technology, the media of release, the type of control technology used, and the following additional information based on the type of release:

(i) For equipment cleaning releases, frequency of equipment cleaning and what is used to clean the equipment.

(ii) For transport and storage releases, how the new chemical substance or product containing the new chemical substance is transported from the site and stored, whether dedicated containers are used, whether the cleaning and disposal of the containers is under the submitter's control, the container cleaning method, the frequency of container cleaning, and the amount of release per container cleaning.

(iii) For releases into air, Clean Air Act operating permit numbers, a description of any Leak Detection and Repair program in accordance with 40 CFR parts 60, 61, 63, 65, 264 or 265 (related to the monitoring and management of fugitive releases) the site has implemented, and the type of air pollution control technologies used at the site to treat the stack releases that will contain the new chemical substance.

(iv) For releases into water, the National Pollutant Discharge Elimination System (NPDES) permit number(s), outfall numbers, the name(s) of the waterbody into which the release occurs, and other destination(s) into which the release occurs.

(v) For releases into wastewater treatment plants, the name(s) of the publicly owned treatment works (POTW) or privately owned treatment works into which the release occurs and the corresponding NPDES permit number(s), the type of wastewater treatment technology or technologies employed, and a description of the known or expected treatment efficiency.

(h) For sites not controlled by the submitter:

(1) The identity and address of each site where the new chemical substance will be manufactured, processed, or used.

(2) A description of each type of processing and use operation involving the new chemical substance, including identification of the estimated number of processing or use sites; a process description of each operation which includes a diagram of the major unit operations and chemical conversions; the identity, approximate weight per batch or per day for continuous production, and entry point of all starting materials and feedstocks (including reactants, solvents, catalysts, etc.); the identity, approximate weight per batch or per day for continuous production, and entry point of all products, recycle streams, and wastes, including frequency of any equipment cleaning; the type of interim storage and transport containers used; and the points of release of the new chemical substance numbered. If the new chemical substance is released to two media at the same step in the process, assign a second number for the second medium.

(3) Worker exposure information for each worker activity anticipated or known to occur during manufacture, processing, or use of the new chemical substance, including worker exposure information from exempt manufacture or related use of the new chemical substance under § 720.30. This information includes:

(i) A description of each worker activity.

(ii) Type of potential worker exposure (*e.g.*, dermal, inhalation).

(iii) Protective equipment in place, if any, including a description of the kind of gloves, protective clothing, goggles, or respirator that limit worker exposure, if any.

(iv) Engineering controls in place if any.

(v) Physical form of the new chemical substance to which workers may be exposed and moisture content if physical form is solid.

(vi) The percent of the new chemical substance in formulation at time of worker exposure.

(vii) The number of workers reasonably likely to be exposed.

(viii) The duration of activities.

(4) Information on known or anticipated release of the new chemical substance to the environment, including releases from the exempt manufacture or related use of the new chemical substance under §720.30. This information includes the type of release (*e.g.,* transport, interim storage, disposal, equipment cleaning), the quantity of the new chemical substance released directly to the environment, the quantity of the new chemical substance released into control technology, the quantity of the new chemical substance released to the environment after control technology, the media of release, the type of control technology used, and the following additional information based on the type of release:

(i) For equipment cleaning releases, frequency of equipment cleaning and what is used to clean the equipment.

(ii) For transport and storage releases, how the new chemical substance or product containing the new chemical substance will be transported from the site and stored, whether dedicated containers are used, whether the cleaning and disposal of the containers is under the submitter's control, the container cleaning method, the frequency of container cleaning, and the amount of release of the new chemical substance per container cleaning.

(iii) For releases into air, Clean Air Act operating permit numbers, a description of any Leak Detection and Repair program in accordance with 40 CFR parts 60, 61, 63, 65, 264 or 265 (related to the monitoring and management of fugitive releases) the site has implemented, and the type of air pollution control technologies used at the site to treat the stack releases that will contain the new chemical substance.

(iv) For releases into water, the National Pollutant Discharge Elimination System (NPDES) permit number(s), outfall numbers, the name(s) of the waterbody into which the release occurs, and other destination(s) into which the release occurs.

(v) For releases into wastewater treatment plants, the name(s) of the publicly owned treatment works (POTW) or privately owned treatment works into which the release occurs and the corresponding NPDES permit number(s), the type of wastewater treatment technology or technologies employed, and a description of the known or expected treatment efficiency.

(i) Any safety data sheet already developed for the new chemical substance, including draft safety data sheets.

(j) The physical and chemical properties and environmental fate characteristics of the new chemical substance, which include the following:

(1) For physical and chemical properties, such information includes boiling point, sublimation, density/relative density, dissociation constant, explodability, flammability, melting point, octanol/water partition coefficient, particle size distribution, particle size distribution analysis (*i.e.*, analysis method and data used to develop the particle size distribution), the physical state of the neat substance, pH, solubility, vapor pressure, volatilization from water, volatilization from soil, spectra, UV–VIS absorption data, and surface tension.

(2) For environmental fate characteristics, such information includes hydrolysis, photolysis, aerobic and anaerobic biodegradation, atmospheric oxidation half-lives, Henry's law constant, adsorption/desorption coefficient, bioaccumulation or bioconcentration factor, Incineration Removal Efficiency (Destruction and Removal Efficiencies or DREs), and Sewage Treatment (WWTP) Removals.

(k) Information about pollution prevention efforts, such as using alternative fuel sources, reducing the use of water and chemical inputs, modifying a production process to produce less waste, or implementing water and energy conservation practices, or substituting for riskier existing products. Inclusion of this information is optional.

[48 FR 21742, May 13, 1983, as amended at 60 FR 16310, Mar. 29, 1995; 83 FR 52719, Oct. 17, 2018; 87 FR 39763, July 5, 2022; 89 FR 102792, Dec. 18, 2024]

§ 720.50 Submission of test data and other data concerning the health and environmental effects of a substance.

(a) *Test data on the new chemical substance in the possession or control of the submitter.* (1) Except as provided in paragraph (d) of this section, each notice must contain all test data in the submitter's possession or control which are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance or any mixture or article containing the new chemical substance, or any combination of such activities. This includes test data concerning the new chemical substance in a pure, technical grade, or formulated form.

(2) A full report or standard literature citation must be submitted for the following types of test data:

(i) Health effects data.

(ii) Ecological effects data.

(iii) Physical and chemical properties data.

(iv) Environmental fate characteristics.

(v) Monitoring data and other test data related to human exposure to or environmental release of the chemical substance.

(3)(i) If the data do not appear in the open scientific literature, the submitter must provide a full report. A full report includes the experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data.

(ii) If the data appear in the open scientific literature, the submitter need only provide a standard literature citation. A standard literature citation includes author, title, periodical name, date of publication, volume, and page numbers.

(4)(i) If a study, report, or test is incomplete when a person submits a notice, the submitter must identify the nature and purpose of the study; name and address of the laboratory developing the data; progress to date; types of data collected; significant preliminary results; and anticipated completion date.

(ii) If a test or experiment is completed before the applicable review period ends, the person must submit the study, report, or test data electronically to EPA via CDX, as specified in paragraph (a)(3)(i) of this section, within ten days of receiving it, but no later than five days before the end of the review period. If the test or experiment is completed during the last five days of the review period, the submitter must inform its EPA contact for that notice by telephone or e-mail prior to the end of the review period and submit the study, report, or test data electronically to EPA via CDX.

(5) For test data in the submitter's possession or control which are not listed in paragraph (a)(2) of this section, a person is not required to submit a complete report. The person must submit a summary of the data. If EPA so requests, the person must submit a full report within ten days of the request, but no later than five days before the end of the review period.

(6) All test data described by paragraph (a) are subject to these requirements, regardless of their age, quality, or results.

(b) *Other data concerning the health and environmental effects of the new chemical substance that are known to or reasonably ascertainable by the submitter.* (1) Except as provided in paragraph (d) of this section, any person who submits a notice must describe the following data, including any data from a health and safety study, if the data are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance, of any mixture or article containing the new chemical substance, or of any combination of such activities:

(i) Any data, other than test data, in the submitter's possession or control.

(ii) Any data, including test data, which are not in the submitter's possession or control, but which are known to or reasonably ascertainable by the submitter. For the purposes of this section, data are known to or reasonably ascertainable by the submitter

if the data are known to any of its employees or other agents who are associated with the research and development, test marketing, or commercial marketing of the substance.

(2) Data that must be described include data concerning the new chemical substance in a pure, technical grade, or formulated form.

(3) The description of data reported under this paragraph must include:

(i) If the data appear in the open scientific literature, a standard literature citation, which includes the author, title, periodical name, date of publication, volume, and pages.

(ii) If the data are not contained in the open scientific literature, a description of the type of data and summary of the results, if available, and the names and addresses of persons the submitter believes may have possession or control of the data.

(4) All data described by this paragraph are subject to these requirements, regardless of their age, quality, or results; and regardless of whether they are complete at the time the notice is submitted.

(c) *Other information.* A person may submit other information, not otherwise required in this section, to facilitate EPA's review of the notice.

(d) *Data that need not be submitted*—(1) *Data previously submitted to EPA.* (i) A person need not submit any data previously submitted to EPA with no claims of confidentiality if the notice includes the office or person to whom the data were submitted, the date of submission, and, if appropriate, a standard literature citation as specified in paragraph (a)(3)(ii) of this section.

(ii) For data previously submitted to EPA with a claim of confidentiality, the person must resubmit the data with the notice and any claim of confidentiality, under § 720.80.

(2) *Efficacy data.* This part does not require submission of any data related solely to product efficacy. This does not exempt a person from submitting any of the data specified in paragraph (a), (b), or (c) of this section.

(3) *Non-U.S. exposure data.* This part does not require submission of any data which relates only to exposure of humans or the environment outside the United States. This does not exclude nonexposure data such as data on health effects (including epidemiological studies), ecological effects, physical and chemical properties, or environmental fate characteristics.

[48 FR 21742, May 13, 1983, as amended at 51 FR 15102, Apr. 22, 1986; 89 FR 102795, Dec. 18, 2024]

§ 720.57 Imports.

(a) Except as otherwise provided in this section, the provisions of this subpart C apply to each person who submits a notice for a new chemical substance which he or she intends to import for a commercial purpose. In addition, each importer must comply with this section.

(b) EPA will hold the principal importer, or the importer that EPA determines must submit the notice when there is no principal importer under § 720.22(b)(2), liable for complying with this part, for completing the notice form and for the completeness and truthfulness of all information which it submits.

[48 FR 21742, May 13, 1983, as amended at 87 FR 39764, July 5, 2022]

Subpart D—Disposition of Notices

§ 720.60 General.

This subpart establishes procedures that EPA will follow in reviewing notices.

§ 720.62 Notice that notification is not required.

When EPA receives a notice, EPA will review it to determine whether the chemical substance is subject to the requirements of this part. If EPA determines that the chemical substance is not subject to these requirements, EPA will notify the submitter that section 5 of the Act does not prevent the manufacture or import of the substance and that the submission is not a notice under this part.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993]

§ 720.65 Acknowledgement of receipt of a notice; errors in the notice; incomplete submissions; and false and misleading statements.

(a) *Notification to the submitter.* (1) EPA will acknowledge receipt of each notice by sending a letter via CDX or U.S. mail to the submitter that identifies the premanufacture notice number assigned to the new chemical substance and date on which the applicable review period begins as described in paragraph (a)(2) of this section.

(2) Before EPA sends an acknowledgement of receipt of a notice pursuant to paragraph (a)(1) of this section, EPA will conduct a pre-screen of the notice, typically taking 2–3 days and according to the criteria under paragraphs (b)(1) and (c)(1) of this section.

(i) If EPA concludes that the notice contains errors warranting remedy or is incomplete, EPA will notify the submitter according to paragraph (d)(3) of this section. The applicable review period will not begin. Once the submitter corrects the errors or incomplete submission according to the requirements provided by EPA and re-submits the notice to EPA, EPA will follow the procedures of paragraph (a)(2) of this section.

(ii) If EPA does not identify errors or determine the notice to be incomplete during screening, EPA will notify the submitter according to paragraph (a)(1) of this section. The applicable review period will begin on the date EPA received the complete notice.

(b) *Errors in the notice.* (1) Within 30 days of receipt of the notice, EPA may request that the submitter remedy errors in the notice. The following are examples of such errors:

(i) Typographical errors that cause data to be misleading or answers to any questions to be unclear.

(ii) Contradictory information.

(iii) Ambiguous statements or information.

(2) The applicable review period does not begin for notices containing errors that EPA asks the submitter to remedy until corrections are made following the procedures of paragraph (d) of this section.

(c) *Incomplete submissions.* (1) A submission is not complete, and the applicable review period does not begin, if:

(i) The wrong person submits the notice form.

(ii) The submitter does not sign the notice form.

(iii) Some or all of the information in the notice or the attachments are not in English, except for published scientific literature.

(iv) The submitter does not submit the notice in the manner set forth in § 720.40(a)(2).

(v) The submitter does not provide information that is required by section 5(d)(1)(B) and (C) of the Act and § 720.50.

(vi) The submitter does not provide information required by § 720.45 or indicate that it is not known to or reasonably ascertainable by the submitter.

(vii) The submitter does not submit a second copy of the submission with all confidential information deleted for the public file, as required by § 703.5(c).

(viii) The submitter does not include any information required by section 5(b)(1) of the Act and pursuant to a rule promulgated under section 4 of the Act, as required by § 720.40(g).

(ix) The submitter does not submit data which the submitter believes show that the chemical substance will not present an unreasonable risk of injury to health or the environment, if EPA has listed the chemical substance under section 5(b)(4) of the Act, as required in § 720.40(h).

(x) The submitter does not include an identifying number and a payment identity number as required by § 700.45(e)(3).

(2) The submission may be declared incomplete if at any time during the applicable review period the submitter submits additional or revised information without demonstrating to EPA's satisfaction that the additional or revised information in the amended notice was not known to or reasonably ascertainable by the submitter at the time of initial notice submission (*e.g.*, new information as described in § 720.40(f) or information from testing in progress at the time of the original submission, as described in § 720.50(a)(4)), unless it relates to administrative or non-substantive amendments (*e.g.*, changing the technical point of contact) or amendments made at the request of EPA.

(d) *Corrections to errors in the notice or incomplete submissions.* (1) If EPA receives an incomplete submission or seeks remedy of errors identified in a notice, EPA will notify the submitter within 30 days of receipt that the submission contains errors or is incomplete and that the applicable review period will not begin until EPA receives a correct and complete notice.

(2) If EPA obtains additional information during the applicable review period that indicates the original submission was incomplete, EPA may declare the submission incomplete within 30 days after EPA obtains the additional information and so notify the submitter.

(3) The notification that a submission contains errors or is incomplete under paragraph (d)(1) or (2) of this section will include:

(i) A statement of the basis of EPA's determination that the submission contains errors or is incomplete.

(ii) The requirements for correcting the errors or incomplete submission.

(iii) Information on procedures under paragraph (d)(4) of this section for filing objections to the determination or requesting modification of the requirements for completing the submission.

(4) Within ten days after receipt of notification by EPA that a submission contains errors or is incomplete, the submitter may file written objections requesting that EPA accept the submission as a complete notice or modify the requirements necessary to complete the submission.

(5) EPA will consider the objections filed by the submitter and determine:

(i) Whether the submission was complete or incomplete, or whether to modify the requirements for completing the submission. EPA will notify the submitter in writing of EPA's response within ten days of receiving the objections.

(ii) If EPA determines, in response to the objection, that the submission was complete, the applicable review period will be deemed suspended on the date EPA declared the notice incomplete and will resume on the date that the notice is declared complete. The submitter need not correct the notice as EPA originally requested. If EPA can complete its review within 90 days from the date of the original submission, EPA may inform the submitter that the running of the review period will resume on the date EPA originally declared it incomplete.

(iii) If EPA modifies the requirements for completing the submission or affirms its original determination that the submission contains errors or is incomplete, or if no objections are filed, the applicable review period will begin (or if previously begun, will restart at Day 1) when EPA receives a complete notice.

(e) *Materially false or misleading statements.* If EPA discovers at any time that a person submitted materially false or misleading statements in the notice, EPA may find that the notice was incomplete from the date it was submitted and take any other appropriate action.

[48 FR 21742, May 13, 1983, as amended at 75 FR 785, Jan. 6, 2010; 89 FR 102796, Dec. 18, 2024]

§ 720.70 Notice in the Federal Register.

(a) *Filing notice of receipt.* In accordance with section 5(d)(2) of the Act, after EPA has received a complete notice, EPA will file a notice of receipt with the Office of the Federal Register including the information specified in paragraph (b) of this section.

(b) *Contents of notice.* (1) In the public interest, the specific chemical identity listed in the notice will be published in the FEDERAL REGISTER unless the submitter has claimed chemical identity confidential. If the submitter claims confidentiality, a generic name will be published in accordance with § 720.85(a)(3).

(2) The categories of use of the new chemical substance will be published as reported in the notice unless this information is claimed confidential. If confidentiality is claimed, the generic information which is submitted under § 720.87(b) will be published.

(3) For test data submitted in accordance with § 720.40(g), a summary of the data received will be published.

(4) The submitter's identity will be published, unless the submitter has claimed it confidential.

[48 FR 21742, May 13, 1983, as amended at 89 FR 102797, Dec. 18, 2024]

§ 720.75 Applicable review period and determination.

(a) *Length of applicable review period.* The applicable review period specified in section 5(a) of the Act runs for 90 days from the date EPA receives a complete notice, or the date EPA determines the notice is complete under § 720.65(d), unless the Agency extends the applicable review period under section 5(c) of the Act and paragraph (c) of this section.

(b) *Suspension of the running of the applicable review period.* (1) A submitter may voluntarily suspend the running of the applicable review period if EPA agrees. If EPA does not agree, the review period will continue to run, and EPA will notify the submitter. A submitter may request a suspension at any time during the applicable review period. The suspension must be for a specified period of time.

(2) *Requests for suspensions.* (i) A request for a suspension of 30 days or less may be made orally, including by telephone, or in writing, including by e-mail, to the submitter's EPA contact for that notice. Any request for a suspension exceeding 30 days must be submitted in the manner set forth in paragraph (b)(2)(ii) of this section. The running of the applicable review period will be suspended upon approval of the oral or written request by EPA.

(ii) Requests for suspensions exceeding 30 days must be submitted electronically to EPA via CDX using e-PMN software. Requests for suspensions of 30 days or less may also be submitted electronically to EPA via CDX using e-PMN software. See § 720.40(a)(2)(ii) for information on how to access the e-PMN software. The running of the applicable review period will be suspended upon approval of the request submitted electronically to EPA via CDX using e-PMN software by EPA.

(c) *Extension of applicable review period.* (1) At any time during the applicable review period, EPA may determine that good cause exists to extend the applicable review period specified in paragraph (a) of this section.

(2) If EPA makes such a determination, EPA will:

(i) Notify the submitter that EPA is extending the applicable review period for a specified length of time, and state the reasons for the extension.

(ii) Issue a notice for publication in the FEDERAL REGISTER which states that EPA is extending the applicable review period and gives the reasons for the extension.

(3) The initial extension may be for a period of up to 90 days. If the initial extension is for less than 90 days, EPA may make additional extensions. However, the total period of extensions may not exceed 90 days for any notice.

(4) The following are examples of situations in which EPA may find that good cause exists for extending the applicable review period:

(i) EPA has reviewed the notice and determined that there is a significant possibility that the chemical substance will be regulated under section 5(e) or section 5(f) of the Act, but EPA is unable to initiate regulatory action within the initial 90-day period.

(ii) EPA has reviewed the submission and is seeking additional information.

(iii) EPA has received significant additional information during the applicable review period, which was not known to or reasonably ascertainable by the submitter at the time of initial notice submission.

(iv) The submitter has failed to correct a notice after receiving EPA's request under § 720.65(b).

(d) *Determinations.* (1) Within the applicable review period, EPA will make one of the following five determinations, as set forth in section 5(a)(3) of the Act:

(i) The chemical substance presents an unreasonable risk of injury to health or the environment, as set forth in section 5(a)(3)(A) of the Act.

(ii) Information available to EPA is insufficient to permit a reasoned evaluation of the health and the environmental effects of the relevant chemical substance, as set forth in section 5(a)(3)(B)(i) of the Act.

(iii) In the absence of sufficient information to permit EPA to make such an evaluation, the chemical substance may present an unreasonable risk of injury to health or the environment, as set forth in section 5(a)(3)(B)(ii)(I) of the Act.

(iv) The chemical substance is or will be produced in substantial quantities,

and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance, as set forth in section 5(a)(3)(B)(ii)(II) of the Act.

(v) The chemical substance is not likely to present an unreasonable risk of injury to health or the environment, as set forth in section 5(a)(3)(C) of the Act.

(2) EPA will take the following actions required in association with the determination:

(i) For determinations described in paragraph (d)(1)(i) of this section, EPA will issue the submitter an order to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or any combination of such activities, to the extent necessary to protect against an unreasonable risk of injury to health or the environment, as set forth in section 5(f) of the Act, or will issue a proposed rule under section 6(a) of the Act, as set forth in section 5(f) of the Act.

(ii) For determinations described in paragraphs (d)(1)(ii), (iii), or (iv) of this section, EPA will issue the submitter an order to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance, or any combination of such activities, to the extent necessary to protect against an unreasonable risk of injury to health or the environment, as set forth in section 5(e) of the Act. EPA may issue an order under section 5(e) of the Act that requires certain testing to be conducted and presented to EPA after the applicable review period has concluded.

(iii) For determinations described in paragraph (d)(1)(v) of this section, EPA will issue the submitter a document containing EPA's final determination and will submit for publication in the FEDERAL REGISTER a statement of the finding, as set forth in section 5(g) of the Act. Upon EPA's issuance of the determination document, the submitter may commence the manufacture of the chemical substance without waiting for the end of the applicable review period.

(3) EPA may modify or revoke the prohibitions and limitations in an order issued under paragraph (d)(2)(i) or (ii) of this section after the applicable review period has ended if EPA receives additional testing, studies, reports, or other information that EPA determines, upon review, demonstrate that such prohibitions or limitations are no longer necessary to protect against an unreasonable risk of injury to health or the environment. Where such information demonstrates that the prohibitions or limitations of the order are not sufficient to protect against an unreasonable risk of injury to health or the environment, EPA may modify the order or take other action, as appropriate, to the extent necessary to protect against such risk.

(4) No person submitting a notice in response to the requirements of this part may manufacture a chemical substance subject to this part until EPA has issued a determination in accordance with paragraph (d)(1) of this section and taken the associated action required under paragraph (d)(2) of this section.

(e) *Withdrawal of a notice by the submitter.* (1)(i) A submitter may withdraw a notice during the applicable review period by submitting a statement of withdrawal in a manner set forth in this paragraph. The withdrawal is effective upon receipt by EPA of the CDX submission.

(ii) *Submission of withdrawal notices.* EPA will accept statements of withdrawal only if submitted in accordance with this paragraph. Statements of withdrawal must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See § 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

(2) If a manufacturer (including importer) which withdrew a notice later resubmits a notice for the same chemical substance, a new applicable review period begins.

[48 FR 21742, May 13, 1983, as amended at 53 FR 12523, Apr. 15, 1988; 58 FR 34204, June 23, 1993; 60 FR 34464, July 3, 1995; 71 FR 33641, June 12, 2006; 75 FR 786, Jan. 6, 2010; 78 FR 72827, Dec. 4, 2013; 80 FR 42746, July 20, 2015; 89 FR 102797, Dec. 18, 2024]

§ 720.78 Recordkeeping.

(a) Any person who submits a notice under this part must retain documentation of information in the notice, including (1) other data, as defined in § 720.50(b), in the submitter's possession or control; and (2) records of production volume for the first three years of production or import, the date of commencement of manufacture or import, and documentation of this information. This information must be retained for five years from the date of commencement of manufacture of import.

(b)(1) Persons who manufacture a chemical substance under § 720.36 must retain the following records:

(i) Copies of, or citations to, information reviewed and evaluated under § 720.36(b)(1) to determine the need to make any notification of risk.

(ii) Documentation of the nature and method of notification under § 720.36(c)(1) including copies of any labels or written notices used.

(iii) Documentation of prudent laboratory practices used instead of notification and evaluation under § 720.36(b)(2).

(iv) The names and addresses of any persons other than the manufacturer or importer to whom the substance is distributed, the identity of the substance to the extent known, the amount distributed, and copies of the notifications required under § 720.36(c)(2). These records are not required when substances are distributed as impurities or incorporated into an article, in accordance with paragraph (d) of this section.

(2) A person who manufactures a chemical substance under § 720.36 and who manufactures the substance in quantities greater than 100 kilograms per year must retain records of the identity of the substance to the extent known, the production volume of the substance, and the person's disposition of the substance. The person is not required to maintain records of the disposition of products containing the substance as an impurity or of articles incorporating the substances.

(3) Records under this paragraph must be retained for 5 years after they are developed.

(c) Any person who obtains a test-marketing exemption under this part must retain documentation of information in the application and documentation of compliance with any restrictions imposed by EPA when it granted the application. This information must be retained for five years from the final date of manufacture under the exemption.

[48 FR 21742, May 13, 1983; 48 FR 33872, July 26, 1983, as amended at 51 FR 15102, Apr. 22, 1986; 58 FR 34204, June 23, 1993; 87 FR 39764, July 5, 2022]

Subpart E—Confidentiality and Public Access to Information

§ 720.80 General provisions.

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

[88 FR 37172, June 7, 2023]

§ 720.87 Categories or proposed categories of uses of a new chemical substance.

(a) A person who submits information to EPA under this part on the categories or proposed categories of use of a new chemical substance may assert a claim of confidentiality for this information.

(b) A submitter that asserts such a claim must:

(1) Report the categories or proposed categories of use of the chemical substance.

(2) Provide, in nonconfidential form, a description of the uses that is only as generic as necessary to protect the confidential business information. The generic use description will be included in the FEDERAL REGISTER notice described in § 720.70.

(c) The person must submit the information required by paragraph (b) of this section in the manner specified in the notice form.

§ 720.95 Public file.

All information submitted with a notice, including any health and safety study and other supporting documentation, will become part of the public file for that notice, unless such materials are claimed confidential in accordance with procedures in 40 CFR 703.5. In addition, EPA may add materials to the public file, subject to subpart E of this

part. Publicly available materials are available at the docket addresses in §700.17(b)(1) and (2) of this subchapter and on EPA's website.

[88 FR 37172, June 7, 2023]

Subpart F—Commencement of Manufacture or Import

§ 720.102 Notice of commencement of manufacture.

(a) *Applicability.* Any person who commences the manufacture of a new chemical substance for a nonexempt commercial purpose for which that person previously submitted a section 5(a) notice under this part must submit a notice of commencement of manufacture.

(b) *When to report.* (1) If manufacture for commercial purposes begins on or after the effective date of this rule, the submitter must submit the notice to EPA on, or no later than 30 calendar days, after the first day of such manufacture.

(2) If manufacture for commercial purposes began or will begin before the effective date of this rule, the submitter must submit the notice by the effective date of this rule.

(c) *Information to be reported on form.* (1) The notice must be submitted on EPA Form 7710–56, which is available as part of EPA's e-PMN software. See §720.40(a)(2)(iv) for information on how to obtain e-PMN software. The form must be signed and dated by an Authorized Official (AO). All information specified on the form must be provided. The notice must contain the following information:

(i) The specific chemical identity of the PMN substance.

(ii) A generic chemical name (if the chemical identity is claimed as confidential by the submitter).

(iii) The premanufacture notice (PMN) number assigned by EPA.

(iv) The date of commencement for the submitter's manufacture for a nonexempt commercial purpose (indicating whether the substance was initially manufactured in the United States or imported). The date of commencement is the date of completion of non-exempt manufacture of the first amount (batch, drum, etc.) of new chemical substance identified in the submitter's PMN. For importers, the date of commencement is the date the new chemical substance clears United States customs.

(v) The name and address of the submitter.

(vi) The name of the authorized official.

(vii) The name and telephone number of a technical contact in the United States.

(viii) The address of the site where commencement of manufacture occurred.

(ix) Clear indications of whether the chemical identity, submitter identity, and/or other information are claimed as confidential by the submitter.

(2) If the submitter claims any information on the form as confidential, the claim must be asserted and substantiated in accordance with the requirements described in 40 CFR part 703 and must be submitted via EPA Form 7710–56. If the submitter wants the chemical identity to be listed on the confidential portion of the TSCA Inventory, the chemical identity must be claimed as confidential and the submitter must also follow the certification, substantiation, and generic name requirements described 40 CFR part 703 and paragraphs (e) and (f) of this section. Otherwise, EPA will list the specific chemical identity on the public TSCA Inventory. Submitters who did not claim the chemical identity, submitter identity, or other information to be confidential in the PMN cannot claim this information as confidential in the notice of commencement.

(d)(1) *Where to submit.* All notices of commencement must be submitted to EPA on EPA Form 7710–56. Notices may only be submitted in a manner set forth in this paragraph.

(2) *Submission of notice of commencement.* EPA will accept notices of commencement only if submitted in accordance with this paragraph. All notices of commencement must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices of commencement must be generated and completed using e-PMN software. See §720.40(a)(2)(ii) for information on how to obtain e-PMN software.

(e) *Confidentiality.* (1) Any person who asserts a confidentiality claim for chemical identity in a Notice of Commencement submitted under this section must:

(i) Comply with generic name requirements described in 40 CFR part 703 and as specified in paragraph (f) of this section.

(ii) Agree that EPA may disclose to a person with a *bona fide* intent to manufacture or import the chemical substance the fact that the particular chemical substance is included on the confidential TSCA Inventory for purposes of notification under section 5(a)(1)(A) of the Act.

(iii) Have available for the particular chemical substance, and agree to furnish to EPA upon request:

(A) An elemental analysis.

(B) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances), or an infrared spectrum of the particular chemical substance, or if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the chemical substance.

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

(f) *Generic name.* If a submitter asserts a claim of confidentiality for chemical identity in a notice of commencement, they must provide a structurally descriptive generic name.

(1) Generic names must:

(i) Be structurally descriptive (e.g., not a trade name);

(ii) Describe the chemical structure of the chemical substance as specifically as practicable while protecting only those features of the chemical structure that are claimed as confidential and disclosure of which would likely cause substantial harm to the competitive position of the person—the generic name should generally only obscure one structural feature, but in any case, should conceal only the feature(s) necessary to avoid a likelihood of substantial competitive harm to the submitter; and

(iii) Be consistent with guidance on the determination of structurally descriptive generic names, developed in accordance with TSCA section 14(c)(4)(A) (e.g., Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under TSCA; available at *https://www.epa.gov/tsca-inventory/guidance-creating-generic-names-confidential-chemical-substance-identity-reporting*).

(2) Generic names will be reviewed by EPA at the time of submission.

(i) If EPA concludes that a proposed generic name meets the criteria in paragraph (f)(1) of this section, EPA will include that generic name in the public TSCA Inventory listing for that substance.

(ii) If the proposed generic name does not meet the criteria in paragraph (f)(1) of this section, EPA will notify the submitter concerning the deficiency via CDX, as described in 40 CFR 703.5(f). EPA will provide 10 business days to correct the deficiency and provide an alternative generic name that would be acceptable to EPA. If the alternative generic name proposed by EPA is acceptable to the submitter (or if the submitter does not respond within the 10-day period), EPA will place that alternative generic name on the public TSCA Inventory. If the alternative generic name proposed by EPA is not acceptable to the submitter, the submitter must submit a revised generic name that meets the criteria in paragraph (f)(1) of this section and an explanation of how EPA's proposed generic name reveals confidential information. If EPA concludes that the submitter's revised generic name also does not meet the criteria in paragraph (f)(1) of this section, EPA will hold the notice of commencement for a period of up to 10 business days. Reporting requirements will not be considered to have been met and the substance will not be added to the TSCA Inventory during this period. If the submission remains deficient after this 10-day period, EPA will proceed with CBI review of the chemical identity claim and will likely deny the claim.

[48 FR 21742, May 13, 1983, as amended at 48 FR 41140, Sept. 13, 1983; 51 FR 15103, Apr. 22, 1986; 53 FR 12523, Apr. 15, 1988; 60 FR 16311, Mar. 29, 1995; 60 FR 34464, July 3, 1995; 65 FR 39304, June 26, 2000; 71 FR 33641, June 12, 2006; 75 FR 786, Jan. 6, 2010; 78 FR 72827, Dec. 4, 2013; 87 FR 39764, July 5, 2022; 88 FR 37172, June 7, 2023]

Subpart G—Compliance and Inspections

§ 720.120 Compliance.

(a) Failure to comply with any provision of this part is a violation of section 15 of the Act (15 U.S.C 2614).

(b) A person who manufactures a new chemical substance before a notice is submitted and the notice review period expires is in violation of section 15 of the Act even if that person was not required to submit the notice under § 720.22.

(c) 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 this rule is a violation of section 15 of the Act (15 U.S.C. 2614).

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

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

(f) 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 rule may be subject to penalties calculated as if they never filed their notices.

(g) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this rule or act to seize any chemical substance manufactured or processed in violation of this rule or take other actions under the authority of section 7 of this Act (15 U.S.C. 2606) or section 17 or this Act (15 U.S.C. 2616).

[48 FR 21742, May 13, 1983, as amended at 87 FR 39764, July 5, 2022]

§ 720.122 Inspections.

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

PART 721—SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

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721.50 Applicability.
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Subpart D—Expedited Process for Issuing Significant New Use Rules for Selected Chemical Substances and Limitation or Revocation of Selected Significant New Use Rules

721.160 Notification requirements for new chemical substances subject to section 5(e) orders.
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Subpart E—Significant New Uses for Specific Chemical Substances

721.225 2-Chloro-N-methyl-N-substituted acetamide (generic name).
721.267 N-[2-[(substituted dinitrophenyl)azo]diallylamino-4-substituted phenyl] acetamide (generic name).