Keller & Heckman

khlaw.com
202.434.4100

Keller and Heckman LLP
1001 G Street, NW
Suite 500 West
Washington, DC 20001

Writer's Direct Access
David B. Fischer
(202) 434-4224
fischer@khlaw.com

November 11, 2022

Michael Regan, Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460
Regan.Michael@epa.gov

Re: Petition for Rulemaking Pursuant to Section 553 of the Administrative Procedure Act Concerning Revisions to the Premanufacture Notice Regulations Under Section 5 of the Toxic Substances Control Act

Dear Administrator Regan:

On behalf of a coalition of chemical companies with significant business interest in the manufacture and use of new chemicals and new uses of existing chemicals ("the Coalition"), we hereby petition the U.S. Environmental Protection Agency ("EPA"), pursuant to section 553 of the Administrative Procedure Act ("APA"), to amend 40 C.F.R. Part 720 ("Part 720") regulations governing Premanufacture Notices ("PMNs") under Section 5 of the Toxic Substances Control Act ("TSCA").

The Coalition's proposed changes to Part 720 are outlined below and provided in Appendix A, enclosed herein. These changes not only reflect the 2016, Frank R. Lautenberg Chemical Safety for the 21st Century Act,[1] but offer concrete regulatory improvements to substantively address the ongoing, unduly time-consuming process by which EPA reviews PMNs. EPA recognizes the current challenges facing the New Chemicals Division within the Office of Chemical Safety and Pollution Prevention and has taken noteworthy programmatic steps to streamline the new chemical review process for at least some categories of new chemical notices, including biofuel PMNs[2] and mixed metal oxide PMNs[3]. But absent significant changes to the regulations themselves to facilitate an efficient process to review all new chemical substances, Coalition members will continue to face

[1] Pub. L. No. 114-182 (2016).
[2] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/integrated-approach-biofuel
[3] https://www.epa.gov/newsreleases/epa-announces-innovative-effort-bring-new-chemicals-used-electric-vehicle

avoidable roadblocks and delays in bringing new, innovative, and sustainable chemistries to the marketplace.

TSCA requires any company planning to manufacture (including import) a new chemical substance for a commercial purpose to submit a PMN to EPA for approval.[4] EPA has 90-180 days thereafter to review the PMN and determine the new chemical substance's effects on human health and/or the environment.[5] Due in part to the manner in which EPA conducts new chemical reviews, EPA has not been able to complete its review in 90 days or even 180 days, often taking a year or more to evaluate a PMN.[6] As a result, some manufacturers have opted to abandon the U.S. marketplace by not filing PMNs. Other manufacturers are increasingly relying on exemptions, such as the low-volume exemption, but processing these exemptions also exceeds EPA's review timelines.

To address these ongoing challenges that frustrate efforts to commercialize innovative and sustainable chemistries, the Coalition requests that EPA amend Part 720 as delineated in Appendix A and briefly summarized below.

The Coalition's proposed changes to Part 720 will:

- Provide the PMN submitter with the option to administratively appeal a risk determination, which shall be reviewed de novo by three EPA senior scientists within 60 days of receipt and determined by a simple majority vote.
- Require EPA to conduct reviews of PMNs in a fit for purpose manner, in which the review is commensurate with the specific circumstances applicable to the new chemical substance, and to conduct reviews consistent with the risk characterization TCCR principles of transparency, clarity, consistency, and reasonableness as described in EPA's Risk Characterization Handbook, December 2000.
- Limit the amount of time EPA may extend the notice review period, require EPA to reimburse the submitter 50% of the notice fee if the review period extension does not fall under the good cause exemption, reset the review period if the submitter substantially amends the original PMN submission, and allow a submitter to extend the suspension period for more than 90 days only for good cause;
- Require EPA to rely on the data provided by the submitter unless EPA can demonstrate that such data does not represent the best available science;
- Place greater emphasis on the Central Data Exchange (CDX) to allow for more accessible and efficient communication between PMN submitters and EPA;
- Require EPA to review new chemical submissions in the order in which they are submitted to EPA, unless the submission qualifies for expedited review as described in the proposed Part 720 amendments;

[4] 40 C.F.R. §720.22
[5] 15 U.S.C. §2604(a)(1)(B); 15 U.S.C. §2604(c)
[6] EPA, *Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs) Table* (November 3, 2022) https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/premanufacture-notices-pmns-and

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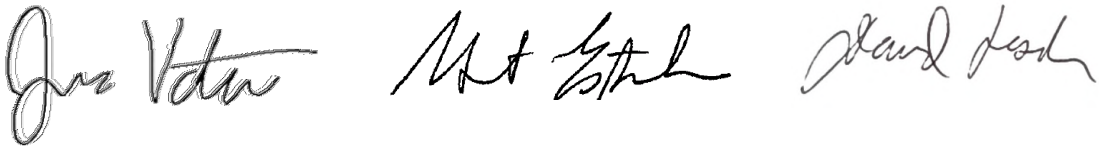
- Require EPA to provide a brief written statement identifying the basis for each determination, including the identification of foreseeable uses that were the basis for any determination under proposed §720.60(c)(i) or (iii);
- When evaluating unreasonable risk, require EPA to reach a determination based on certain probabilities, ensure that EPA does not render unreasonable risk determinations based on the worst-case scenarios involving unreasonable assumptions, and provide EPA with alternative options to section 5(e) Orders;
- Require EPA to notify a submitter of errors in the notice or that the submission is incomplete within 15 days of receipt;
- Describe what constitutes a major amendment to a PMN and present options for the submitter to take if EPA designates the amendment as "major;" and
- Require EPA to generally grant pre-submission meetings requested by the submitter. EPA shall address issues raised by the submitter no later than five business days after such meeting.

The Coalition requests that EPA promptly propose amendments to Part 720 consistent with Appendix A. On behalf of the Coalition, we look forward to EPA's response to this petition. Should you have any questions regarding this submission, please contact David Fischer at fischer@khlaw.com. Thank you for your consideration.

Respectfully Submitted,



James Votaw, Herb Estreicher, and David Fischer
Keller and Heckman LLP
1001 G Street NW. Suite 500
Washington, DC 20001

On behalf of the Coalition

cc: Jeffrey Prieto, General Counsel, U.S. Environmental Protection Agency
Michal Freedhoff, Assistant Administrator, OCSPP, U.S. Environmental Protection Agency

Enclosure:
Appendix A

APPENDIX A

PART 720—PREMANUFACTURE NOTIFICATION

Contents

Subpart G—Compliance and Inspections

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 and importers under section 5 of the Toxic Substances Control Act, 15 U.S.C. 2604. This part applies to microorganisms only to the extent provided by part 725 of this chapter. The rule defines the persons and chemical substances subject to the reporting requirements, prescribes the contents of section 5 notices, and establishes procedures for submitting notices. The rule also establishes EPA policy regarding claims of confidentiality for, and public disclosure of, various categories of information submitted in connection with section 5 notices. In carrying out this part, EPA decisions based on science shall adhere to the scientific standards and weight of scientific evidence approach of TSCA sections 26(h) and (i), respectively.

Commented [A1]: This new language reflects the science standards of amended TSCA section 26.

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

§720.3 Definitions.

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

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

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

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

(c) *Article* means a manufactured item:

(1) Which is formed to a specific shape or design during manufacture;

(2) Which has end use function(s) dependent in whole or in part upon its shape or design during end use; and

(3) Which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as

described in §720.30(h)(5), except that fluids and particles are not considered articles regardless of shape or design.

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

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

(1) Any mixture.

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

(3) Tobacco or any tobacco product.

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

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

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

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

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

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

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

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

(k) *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.

(l) *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 subpart C of 19 CFR part 144. (See “principal importer.”)

(m) *Impurity* means a chemical substance which is unintentionally present with another chemical substance.

(n) *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.

(o) *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.

(p) *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.

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

(r) *Manufacture or import for commercial purposes* means:

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

(i) For commercial distribution, including for test marketing.

(ii) For use by the manufacturer, including use for product research and development or as an intermediate.

(2) The term also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. Byproducts and impurities without separate commercial value are nonetheless produced for the purpose of obtaining a commercial advantage, since they are part of the manufacture of a chemical substance for commercial purposes. [See 720.30(g) and (h)]

Commented [A2]: This reference links to the section that addresses the circumstances in which chemicals (including byproducts and impurities) are not subject of TSCA notification requirements.

(s) *Manufacture solely for export* means to manufacture or import 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 or importer, 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.

(t) *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.

(u) *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.

(v) *New chemical substance* means any chemical substance which is not included on the Inventory.

(w) *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.

(x) *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.

(y) *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.

(z) *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.

(aa) *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.

(bb) *Processor* means any person who processes a chemical substance or mixture.

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

(dd) *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.

(ee) *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.

(ff) *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.

(gg) *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.

(hh) *United States*, when used in the geographic sense, means all of the States.

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

(jj) *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.

(kk) *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)).

(ll) *Conditions of Use* means the circumstances, as determined by EPA, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

(mm) *Reasonably Foreseen Conditions of Use* means the circumstances, not intended by the submitter, under which a reasonably knowledgeable person likely to manufacture, process, use or dispose

Commented [A3]: This new definition provides boundaries as to what conditions of use are reasonably foreseen.

of the new chemical substance, and exercising good judgment, would be expected to manufacture, process, distribute in commerce or dispose of the new chemical substance. This term does not include any misuse. Uses that are uneconomic, technically impracticable, or present obvious risks are not reasonably foreseeable uses. The factual basis for any determination of a Reasonably Foreseen Conditions of Use shall be reflected in EPA's determination.

Commented [A4]: These new definitions reflect amended TSCA.

[48 FR 21742, May 13, 1983, as amended at 51 FR 15101, Apr. 22, 1986; 75 FR 784, Jan. 6, 2010; 80 FR 42745, July 20, 2015]

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 at least 90 days before manufacture or import unless the substance is excluded under §720.30.

Commented [A5]: This addition reflects amended TSCA section 5(a)(1)(B)(i)

(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(e).

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

[1]A new chemical substance that is manufactured or imported 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.

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

(d) Any new chemical substance which will be manufactured or imported 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 or imported 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 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 or imported 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]

§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 or imported only in small quantities solely for research and development.

(2) The manufacturer or importer 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 or importer 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 or importer 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 or importer 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 non-production 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 or importer 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 or importer has reason to believe may be associated with the substance, as determined under paragraph (b)(1) of this section.

(2) If the manufacturer or importer distributes a chemical substance manufactured or imported under this section to persons not in its employ, the manufacturer or importer 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 or importer.

(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 or imports 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]

§720.38 Exemptions for test marketing.

(a) Any person may apply for an exemption to manufacture or import 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 or import 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).

(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]

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. The CDX shall allow for timely communication between EPA and the submitter or the submitter's designee regarding the status of the submission throughout the entire review period. Communications between the submitter and EPA should serve to advance EPA's timely review of the new chemical substance. Non-CBI information provided to the submitter via CDX shall include, but not limited to, analogs and models relied upon by EPA; the conditions of use EPA has identified are relevant to the submission; and reports or assessments developed by EPA pertaining to the submission. The submitter shall have an opportunity to provide timely feedback to EPA regarding the information provided to the submitter by EPA pertaining to the submission.

Commented [A6]: EPA Form 7710-25 should be updated to ensure that more than one individual can have access to CDX regarding the submission.

Commented [A7]: This new paragraph is aimed at ensuring that CDX is used as a vehicle for timely and efficient communication between both the submitter and EPA throughout the PMN review period.

(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 or import 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 or importer 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 or importer 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 or importer. 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 notice review period, if the submitter possesses, controls, or knows of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the notice, the submitter must submit that information via CDX, per paragraph (a)(2)(i) of this section,to the address listed on the notice form or via CDX within ten days of receiving the new information, but no later than five days before the end of the notice review period. The new submission 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 notice review period, the submitter must~~

Commented [A8]: This paragraph has been moved to section 720.60 regarding disposition of notices.

~~immediately inform its EPA contract for that notice by telephone~~ and or via CDX ~~per paragraph (2)(a) of this section~~.

(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 or import 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 or import 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]

§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 statutory review process will commence upon receipt of both the notice and the complete, correct information.

(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 CAS number, 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 statutory review period will commence upon receipt of both the notice and the letter of support.

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

(f) A description of intended categories of use by function and application, the estimated percent of production volume devoted to each category of use, and the percent of the new substance in the formulation for each commercial or consumer use.

(g) For sites controlled by the submitter:

(1) The identity of sites where the new 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, the identity and entry point of all feedstocks, and the points of release of the new chemical substance.

(3) Worker exposure information, including worker activities, physical form of the new substance to which workers may be exposed, the number of workers, and the duration of activities.

(4) Information on release of the new substance to the environment, including the quantity and media of release and type of control technology used.

(h) For sites not controlled by the submitter, 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, situations in which worker exposure to and/or environmental release of the new chemical substance will occur, the number of workers exposed and the duration of exposure, and controls which limit worker exposure and environmental release.

[48 FR 21742, May 13, 1983, as amended at 60 FR 16310, Mar. 29, 1995; 83 FR 52719, Oct. 17, 2018]

§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 notice review period ends, the person must submit the study, report, or test to the address listed on the notice form or 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 immediately inform its EPA contact for that notice by telephone.

(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) ~~[Reserved]~~Analog data. A submitter may submit any relevant data pertaining to an analog chemical that is structurally similar to the new chemical substance and which will facilitate the review of the new chemical substance. EPA shall use the analog information provided by the submitter unless EPA can demonstrate to the submitter that the best available science supports the use of another analog. If the analog identity is CBI, EPA shall provide to the submitter redacted copies of studies, reports or other information on the analog EPA relies upon to ~~clearly~~ demonstrate that EPA's choice of an analog represents the best available science.

(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.

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

(5) Use of data. In conducting reviews of new chemical substances, and to the extent feasible, EPA shall rely on data rather than models; models shall not replace data, unless EPA can demonstrate why the use of models in place of data represents the best available science.

(i) Data provided to EPA by the submitter shall be relied upon by EPA unless EPA can demonstrate that it does not represent the best available science.

(ii) To the extent EPA relies on conservative assumptions to assess either hazard or exposure during the review of a new chemical substance, such conservative assumptions shall be grounded in the TCCR principles referred to in §720.60(a).

[48 FR 21742, May 13, 1983, as amended at 51 FR 15102, Apr. 22, 1986]

Commented [A9]: This new paragraph makes clear that EPA must rely on the analog information provided by the submitter unless EPA can demonstrate that another analog represents the best available science.

Commented [A10]: This new paragraph makes clear that data provided by the submitter should be relied upon rather than models, unless EPA can demonstrate that models represent the best available science. This paragraph also recognizes that EPA relies on conservative assumptions, but those assumptions must comport with the TCCR principles within the Risk Characterization Handbook, referred to in section 720.60(a).

§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.

Subpart D—Disposition of Notices

§720.60 General.

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

(a) EPA shall conduct reviews of new chemical substances in a fit for purpose manner by which EPA tailors risk assessment components to be commensurate with the conditions of use specific and relevant to the chemical substance undergoing review. Reviews of chemical substances shall be consistent with the risk characterization TCCR principles of transparency, clarity, consistency, and reasonableness as described in EPA's Risk Characterization Handbook, December 2000. EPA shall ensure that EPA employees and EPA contractors who are engaged in reviewing new chemical substances possess the requisite expertise and knowledge to proficiently conduct reviews. Reviewers shall include, but not be limited to, certified industrial hygienists and risk assessors with industry experience, if feasible. At a minimum, EPA shall provide public access via the Internet to all contractor training manuals, procedures and other related information contractors rely upon to perform new chemical reviews. In conducting reviews of any new chemical substance EPA staff and contractors shall presume compliance with applicable legal standards, unless there is clear evidence to the contrary.

(~~a~~b) EPA must conduct a review of the notice, make a determination and take the required actions associated with the determination within the applicable review period. Generally, submissions will be reviewed in the order in which they are submitted, unless the submission qualifies for ~~-~~expedited review as described in paragraph (d~~e~~).

(~~b~~c) EPA shall review the notice and determine that:

(i) the new chemical substance or significant new use presents an unreasonable risk of injury to human health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use,

(ii) the information on the new chemical substance or significant new use is insufficient to make a reasoned evaluation of the health and environmental effects,

(iii) in the absence of sufficient information to permit EPA to evaluate the new chemical substance, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use,

Commented [A11]: This new paragraph mandates that reviews of new chemical substances must be "fit for purpose," in which the review is commensurate with the specific circumstances applicable to the new chemical substance. Reviews also must adhere to the principles of transparency, clarity, consistency, and reasonableness as described in the EPA Risk Characterization Handbook, December 2000. In addition, EPA must ensure that EPA staff and contractors conducting new chemical reviews possess the necessary skills and knowledge to proficiently conduct those review. Training manuals and other relevant information relied upon by contractors performing reviews must be publicly accessible via the internet, but may be provided to the public by other means as well.

Commented [A12]: This new paragraph requires new chemical review submissions to be reviewed in the order in which they are submitted to EPA. Under this provision, there is no ability for a review to occur out of order, unless that submission qualifies for expedited review as described in new paragraph (d).

Commented [A13]: This new language reflects amended TSCA section 5(a)(3)(A).

Commented [A14]: This new language reflects amended TSCA section 5(a)(3)(B)(i).

Commented [A15]: This new language reflects amended TSCA section 5(a)(3)(B)(ii)(I).

(iv) the new 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, or

(~~iv~~) the new chemical substance or significant new use is not likely to present an unreasonable risk of injury to human health or the environment without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use,

(d~~e~~) EPA may designate categories of submissions that are subject to expedited review. Categories of submissions shall include, but not limited to, those submissions that comport with the Sustainable Futures Program. -EPA shall render a determination on a new chemical substance undergoing expedited review within ~~60~~45 days of EPA initiating its review. For expedited reviews, EPA shall generate a single report that provides a summary of how EPA conducted its assessment and made its determination.

(e) Each determination under paragraph (c) shall be accompanied by a brief written statement identifying the basis for the determination, including the identification of foreseeable uses that were the basis for any determination under subparagraph (c)(i) or (iii). A preliminary determination shall be communicated to the submitter 45 days from the date the review period commences -and in advance of a final determination giving the submitter an opportunity to review and comment within 15 days of receipt of the preliminary determination.

f) *New information.* During the notice review period, if the submitter possesses, controls, or knows of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the notice, the submitter must submit that information via CDX, per paragraph §720.40 (a)(2)(i), within ten days of receiving the new information, but no later than five days before the end of the notice review period. The new submission 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 notice review period, the submitter must immediately inform its EPA contact for that notice by telephone and via CDX per paragraph § 720.40 (a)(2)(i).

(~~f~~g) Evaluating Unreasonable Risk.

(i) In determining under paragraph (c)(v) whether a chemical substance is unlikely to present an unreasonable risk, the probability of an unreasonable risk materializing under the conditions of use must be less likely than not. In determining under paragraph (c)(iii) whether a chemical substance may present an unreasonable risk, the probability of an unreasonable risk materializing under the conditions of use must be more likely than not. In determining under paragraph (c)(i) whether a chemical substance presents an unreasonable risk, the probability of an unreasonable risk materializing under the conditions of use must be a reasonable certainty.

(ii) EPA shall not make risk determinations under paragraph (c) using worst case scenarios involving unreasonable assumptions. EPA shall take into consideration the effect of representations concerning the conditions of use described in a PMN or SNUN, applicable laws and regulations, including the reasonably anticipated effect of future laws and regulations (including SNURs and Part 704 sentinel notification rules), the expected time frame in which any identified unreasonable risk is reasonably likely to arise under the conditions of use, reasonable assumptions of potential environmental releases of the chemical substance, and ~~,~~any ~~the~~ health risks created by proposed PPE.

Commented [A16]: This new language reflects amended TSCA section 5(a)(3)(B)(ii)(II).

Commented [A17]: This new language reflects amended TSCA section 5(a)(3)(C).

Commented [A18]: This new paragraph mandates that new chemical submissions that fall within the Sustainable Futures Program receive expedited review; determinations are to be rendered within 45 days of submission. EPA may designate other categories for expedited review.

Commented [A19]: This new paragraph describes the information to accompany a determination made under paragraph (c). EPA must make a preliminary determination on the chemical substance within 45 days of having initiated EPA's review of the chemical substance.

Commented [A20]: This new paragraph attaches probabilities to each unreasonable risk determination of paragraph (c).

Commented [A21]: This new paragraph makes clear that EPA should not evaluate unreasonable risk based on worst case scenarios involving unreasonable assumptions. Instead, this paragraph sets forth other considerations that EPA should take into account.

(iii) EPA is not bound to take actions required by section 5(e) of the Act until it makes a final determination for a chemical substance under paragraph (c) of this section. Before making a final determination, EPA may make a preliminary determination under paragraph (c) and, in its discretion, take actions or receive additional information that may change the reasonably anticipated conditions of use and make its final determination based on the revised conditions of use.

§720.61 Actions on Determinations.

(a) If EPA makes a final affirmative determination each determination under paragraph (c) shall be accompanied by a brief written statement identifying the basis for the unreasonable risk determination, including the identification of foreseeable uses that were the basis for any determination under subparagraph (c)(i) or (iii).

(b) If the Administrator makes an affirmative finding under (c)(ii), (iii) or (iv), the Administrator shall, to the extent necessary to protect against an unreasonable risk under the conditions of use, issue an Order, to take effect at the expiration of the applicable review period, to prohibit or limit the manufacture processing distribution in commerce, use or disposal of such substance or to prohibit or limit any combination ~~i~~of such activities. The Administrator shall not be obligated to issue an ~~o~~Order where, notwithstanding a determination under (c)(ii), (iii) or (iv), an ~~o~~Order issued to the submitter is, in the EPA's discretion, ~~is~~ not necessary to protect against an unreasonable risk under the reasonably anticipated conditions of use, including circumstances where the unreasonable risk may be adequately and timely addressed by a significant new use rule, sentinel reporting rule, or other means.

(c) Absent good cause, an Order issued under section 5(e) of the Act shall terminate when the O~~o~~rder is no longer necessary to protect against the unreasonable risk under the conditions of use that was the basis for the O~~o~~rder, including where such unreasonable ~~the potential~~ risk is addressed by a significant new use rule applicable to the Submitter.

(d) If the Administrator makes an affirmative finding under (c)(ii), (iii) or (iv), and determines to address the identified unreasonable risk with a significant new use rule, the notice submitter is obligated to comply with the manner of manufacture, processing and use described in its PMN until such time as the SNUR is issued. EPA may accept PMN amendments at any time to conform the PMN to expected SNUR terms.

§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*. 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 review period begins. The review period will begin on the date the notice is received by the Office of Pollution Prevention and Toxics Document Control Officer. The

Commented [A22]: This new paragraph provides EPA with alternative actions EPA may take other than TSCA section 5 (e) Orders. These actions would be based on a preliminary determination under paragraph (c) of section 720.60.

Commented [A23]: This new paragraph requires EPA to provide a written explanation for an unreasonable risk determination under paragraph (c). Based on this determination and accompanying written explanation, a Submitter may pursue an administrative appeal pursuant to section 720.71.

Commented [A24]: These new paragraphs bound the circumstances under which an Order may be issued and when such an Order terminates.

Commented [A25]: This new paragraph makes the PMN terms binding on the submitter until an intended SNUR is issued, thus potentially avoiding the need for Orders for issues of concern both (1) in the PMN and (2) not intended by submitter, but reasonably foreseeable to EPA.

acknowledgment does not constitute a finding by EPA that the notice, as submitted, is in compliance with this part.

(b) *Errors in the notice.* (1) Within 15 ~~30~~ days of receipt of the notice, EPA shall ~~may~~ request that the submitter remedy errors in the notice. The following are examples of such errors:

Commented [A26]: This new language shortens the time for EPA to alert the submitter of errors in the submission that require correction.

(i) Failure to date the notice form.

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

(iii) Contradictory information.

(iv) Ambiguous statements or information.

(2) In the request to correct the notice, EPA will explain the action which the submitter must take to correct the notice.

(3) If the submitter fails to correct the notice within 15 days of receipt of the request, EPA may extend the notice period under section (5)(c) of the Act, in accordance with §720.75(c).

(c) *Incomplete submissions.* (1) A submission is not complete, and the notification 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 on the notice form and 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 §720.80(b)(2).

(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 40 CFR 700.45(e)(3).

(xi) The submitter does not provide a description of any health and safety study concerning the PMN in progress at time of the PMN submission in CDX.

(2)(i) If EPA receives an incomplete submission, the Director, or his or her delegate, will notify the submitter within 15~~30~~ days of receipt that the submission is incomplete and that the notice review period will not begin until EPA receives a complete notice.

(ii) If EPA obtains additional information during the notice review period that indicates the original submission was incomplete, the Director, or his or her delegate, may declare the submission incomplete within 15~~30~~ days after EPA obtains the additional information and so notify the submitter.

(3) The notification that a submission is incomplete under paragraph (c)(2) (i) or (ii) of this section will include:

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

(ii) The requirements for correcting the incomplete submission.

(iii) Information on procedures under paragraph (c)(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 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)(i) EPA will consider the objections filed by the submitter. The Director, or his or her delegate, will determine 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 the Director, or his or her delegate, determines, in response to the objection, that the submission was complete, the notice 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, the Director, or his or her delegate, may inform the submitter that the running of the review period will resume on the date EPA originally declared it incomplete.

(iii) If the Director, or his or her delegate, modifies the requirements for completing the submission or concurs with EPA's original determination, the notice review period will begin when EPA receives a complete notice.

(d) *Materially false or misleading statements.* If EPA discovers at any time that 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]

Commented [A27]: This new language makes clear that the submitter must provide EPA with a description of any health and safety study ongoing, relevant to the PMN submission, but not yet completed at the time of the PMN submission via CDX.

Commented [A28]: The new, shorter time period mirrors the change in paragraph (b).

§720.70 Notice in the Federal Register.

(a) *Filing of* FEDERAL REGISTER *notice.* In accordance with section 5(d)(2) of the Act, after EPA receives a notice, EPA will file with the Office of the Federal Register a notice 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) A list of information ~~data~~ submitted in accordance with §720.50(a) will be published. In addition, for test data submitted in accordance with §720.40(g), a summary of the data will be published.

Commented [A29]: This change reflects amended TSCA.

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

§720.75 Notice review period.

(a) *Length of notice review period.* The notice review period specified in section 5(a) of the Act runs for 90 days from the date the Document Control Officer for the Office of Pollution Prevention and Toxics receives a complete notice, or the date EPA determines the notice is complete under §720.65(c), unless the Agency extends the period under section 5(c) of TSCA and paragraph (c) of this section. ~~.~~EPA may for good cause extend the review period for additional periods not to exceed in the aggregate 90 days.

Commented [A30]: This new language caps the amount of time EPA may extend the review period.

(i) If notice is submitted on a weekend or Federal holiday, Day 1 of review period starts on the following work day.

Commented [A31]: This language clarifies when the first day of the review period commences.

(ii) Review period resets to Day 1 if the submitter substantially amends the original submission after EPA has initiated review. Any extension of review periods for any submission shall not impact the timely review of any other submission by any submitter.

Commented [A32]: This new paragraph resets the review period if the submitter substantially amends the original submission. This paragraph also clarifies that changes to the review period for one submission should not impact the review of any other submission.

(b) *Suspension of the running of the notice review period.* (1) A submitter may voluntarily suspend the running of the notice review period if the Director or his or her delegate agrees. If the Director 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 notice review period. The suspension must be for a specified period of time and shall not exceed 90 days, unless good cause can be shown for greater exceedance.

Commented [A33]: This new language allows a submitter to extend the suspension period for a period greater than 90 days but only for good cause.

(2)~~(i) *Oral R*~~*equests.* A request for a suspension shall be made via CDX using e-PMN software. ~~of 15 days or less may be made orally, including by telephone, to the submitter's EPA contact for that notice. Any request for a suspension exceeding 15 days must be submitted in the manner set forth in paragraph (b)(2)(ii) of this section. The running of the notice review period will be suspended upon approval of the oral request by the Director or her or his delegate.~~

Commented [A34]: This new language requires submitters to use the CDX to request a suspension.

~~(ii) *Written requests.* Requests for suspensions exceeding 15 days must be submitted electronically to EPA via CDX using e-PMN software. Requests for suspensions of 15 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 notice review period will be suspended upon approval of the written request by the Director or her or his delegate.

(c) *Extension of notice review period.* (1) At any time during the notice review period, EPA may determine that good cause exists to extend the notice review period specified in paragraph (a) of this section. If EPA extends the review period ~~the total period of extensions exceeds 90 days~~ for any given notice and (4) (i) – (iv) do not apply, EPA shall reimburse the submitter 50% of the notice fee paid by the submitter.

Commented [A35]: This new language requires EPA to reimburse the submitter 50% of the notice fee if the review period extension does not fall under the good cause exemption as described in paragraph (4).

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

(i) Notify the submitter that EPA is extending the notice 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 notice 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 subject to paragraph (a). ~~However, the total period of extensions may not exceed 90 days for any notice. If the total period of extensions exceeds 90 days for any given notice and (4) (i) – (iv) do not apply, EPA shall reimburse the submitter 50% of the notice fee paid by the submitter.~~

Commented [A36]: This new language clarifies that the total aggregate extensions requested by the EPA shall be no greater than 90 days.

(4) The following are examples of situations in which EPA may find that good cause exists for extending the notice 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 that is necessary for EPA to complete its review.

Commented [A37]: This language clarifies that additional information sought by EPA must be necessary for EPA to complete the review.

(iii) EPA has received significant additional information during the notice review period.

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

(d) *Notice of expiration of notice review period.* EPA will notify the submitter that the notice review period has expired or that EPA has completed its review of the notice. Expiration of the review period does not constitute EPA approval or certification of the new chemical substance, and does not mean that EPA may not take regulatory action against the substance in the future. Submitter may not proceed to manufacture or import of the chemical substance until EPA has made one of the determinations in 720.60.

Commented [A38]: This new language reflects amended TSCA.

(e) *Withdrawal of a notice by the submitter.* (1)(i) A submitter may withdraw a notice during the notice 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 notice review period begins.

(f) Constructive withdrawal. (1) EPA will deem a submitter to have constructively withdrawn the notice if the submitter fails to provide a response to any EPA request within 30 days of EPA having sent the request, (2) Notwithstanding (1), a submitter's response received by EPA after 30 days shall be deemed to be timely submitted if the submitter made a good faith effort to respond within 30 days.

(2i) EPA shall provide notification to submitter that the submitter's notice is constructively withdrawn and will be closed out in CDX.

§720.76 Major Amendments to Notices

(a) Major amendments are those that would result in EPA substantially revising either risk assessment or risk management actions and prevent EPA from making a determination within the applicable review period.

(b) If EPA informs the submitter that a submission is deemed a major amendment to the original submission, the submitter shall take one of the following actions: (1) accept amendment as new notice subject to a new TSCA fee for section 5 activity under §700.45 and reset of review period to Day 1, (2) accept EPA determination based on information submitted with original notice, or (3) voluntarily withdraw the original submission.

§720.77 Pre and Post Submission Meetings

(a) Meetings between the submitter and EPA serve to advance EPA's review of the new chemical substance. Generally, EPA will grant a presubmission meeting request by the submitter. In requesting a meeting with EPA via CDX, the submitter shall indicate the issues for discussion.

(b) During the meeting or no later than five business days after the meeting, EPA shall to the extent practicable, and consistent with the TCCR principles as described in EPA's Risk Characterization Handbook, address the issues raised by the submitter and clearly convey to the submitter the anticipated data needs identified by EPA to facilitate EPA's review of the submission.

(c) All discussions during the meeting shall be made of record.

(a)(d) Post submission meeting requests via CDX will be granted by EPA if EPA reasonably believes a meeting will advance the disposition of the submission. A post submission meeting shall be conducted pursuant to paragraph (a).

[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]

Commented [A39]: These new paragraphs make clear that failure of a submitter to respond to any EPA request within 30 days will constitute constructive withdrawal, and unless the submitter can show a good faith effort to respond within 30 days, the submitter's notice will be closed out in CDX.

Commented [A40]: This new paragraph describes the nature of an amendment deemed to represent a major amendment, and if so designated by EPA, presents three options that the submitter of the major amendment shall choose from.

Commented [A41]: This new paragraph makes clear that presubmission meetings requested by the submitter generally will be granted by EPA, and that EPA shall address the issues raised by the submitter no later than five business days after the meeting, and consistent with the TCCR principles.

§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 or import 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 or imports a chemical substance under §720.36 and who manufactures or imports 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 or import under the exemption.

§720.79 Administrative Appeal

A submitter who disagrees with an EPA determination pursuant to 720.60 (c) (i) – (v), may appeal such determination to the Senior Science Advisor (SSA) or comparable scientist within the Office of Chemical Safety and Pollution Prevention. The appeal shall be filed via CDX within 15 days of EPA's determination and shall provide the scientific rationale for the submitter's disagreement, to the extent practicable and the rationale for an alternative determination. The SSA shall review the basis for the appeal within 15 days of receipt to ensure its completeness and shall promptly convene a panel of three EPA senior scientists who can objectively conduct a *de novo* review of the new chemical substance considering all the information provided by the submitter and EPA, and based on a simple majority vote, render a determination pursuant to 720.60 (c) (i) – (v) within 60 days of receipt of the submitter's appeal.

Commented [A42]: This new paragraph provides the submitter with the option of administratively appealing an EPA determination. The review of the determination shall be *de novo* and conducted by three EPA senior scientists who can objectively render a determination based on a simple majority vote within 60 days of receipt of the appeal.

([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]

Subpart E—Confidentiality and Public Access to Information

§720.80 General provisions.

(a) A person may assert a claim of confidentiality for any information which he or she submits to EPA under this part.

(b) Any claim of confidentiality must accompany the information when it is submitted to EPA.

(1)(i) For information submitted on the notice form, the claim(s) must be asserted on the form in the manner prescribed on the notice form.

(ii) When a person submits information in an attachment, the claim(s) must be asserted in the attachment as described on the notice form.

(2) If any information is claimed as confidential, the person must submit, in addition to the copies specified by §720.40, a sanitized copy of the notice form (or electronic submission) and any attachments.

(i) The notice and attachments must be complete. The submitter must designate that information which is claimed as confidential in the manner prescribed on the notice form, via EPA's e-PMN software. See §720.40(a)(2)(iv) for information on how to obtain e-PMN software.

(ii) The sanitized copy must be complete except that all information claimed as confidential in the original must be deleted. EPA will place this sanitized copy in the public file.

(iii) If the person does not provide the sanitized copy, or information in a health and safety study (except information claimed as confidential in accordance with §720.90), the submission will be deemed incomplete and the notice review period will not begin until EPA receives the sanitized copy or the health and safety study information is included, in accordance with §720.65(c)(1)(vii).

(c) EPA will disclose information that is subject to a claim of confidentiality asserted under this section only to the extent permitted by the Act, this subpart, and part 2 of this title.

(d) If a notice submitter does not assert a claim of confidentiality for information at the time it is submitted to EPA, EPA may make the information public and place it in the public file without further notice to the submitter.

[48 FR 21742, May 13, 1983, as amended at 58 FR 34204, June 23, 1993; 60 FR 16311, Mar. 29, 1995; 75 FR 786, Jan. 6, 2010]

§720.85 Chemical identity.

(a) *Claims applicable to the period prior to commencement of manufacture or import.* (1)(i) A person who submits information to EPA under this part may assert a claim of confidentiality for the chemical identity of the new chemical substance. This claim will apply only to the period prior to the commencement of manufacture or import for commercial purposes. A submitter may assert this claim only if the submitter

believes that public disclosure prior to commencement of manufacture or import of the fact that anyone intends to manufacture or import the specific chemical substance for commercial purposes would reveal confidential business information.

(ii) If the notice includes a health and safety study concerning the new chemical substance and if the claim for confidentiality with respect to the chemical identity is denied in accordance with §720.90(c), EPA will deny a claim asserted under this paragraph.

(2) Any person who asserts a claim of confidentiality for chemical identity under this paragraph must provide one of the following items at the time the notice is submitted:

(i) The generic name which was accepted by EPA in the prenotice consultation conducted under paragraph (a)(3) of this section.

(ii) One generic name that is only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. The name should reveal the specific chemical identity to the maximum extent possible. The generic name will be subject to EPA review and approval at the time a notice of commencement is submitted.

(3)(i) Any person who intends to assert a claim of confidentiality for the chemical identity of a new chemical substance may seek a determination by EPA of an appropriate generic name for the substance before submitting a notice. For this purpose, the person should submit to EPA:

(A) The chemical identity of the substance.

(B) A proposed generic name(s) which in only as generic as necessary to protect the confidential chemical identity of the new chemical substance. The name(s) should reveal the chemical identity of the substance to the maximum extent possible.

(ii) Within 30 days, EPA will inform the submitter either that one of the proposed generic names is adequate or that none is adequate and further consultation is necessary.

(4) If a submitter claims chemical identity to be confidential under this paragraph, and if the submitter complies with paragraph (a)(2) of this section, EPA will issue for publication in the FEDERAL REGISTER notice described in §720.70 the generic name proposed by the submitter or one agreed upon by EPA and the submitter.

(b) *Claims applicable to the period after commencement of manufacture or import.* (1) Any claim of confidentiality under paragraph (a) of this section is applicable only until the substance is manufactured or imported for commercial purposes and becomes eligible for inclusion on the Inventory. To maintain the confidential status of the chemical identity when the substance is added to the Inventory, a submitter must reassert the confidentiality claim and substantiate the claim in the notice of commencement of manufacture required under §720.102. A submitter may not claim the chemical i~~n~~dentity confidential for the period after commencement of manufacture or import unless the submitter claimed the chemical identity confidential for the period prior to commencement of manufacture or import under paragraph (a) of this section.

(2)(i) A person who believes that public disclosure of the fact that anyone man<u>u</u>factures or imports the new chemical substance for commercial purposes would reveal confidential business information may assert a claim of confidentiality under this paragraph.

(ii) If the notice includes a health and safety study concerning the new chemical substance, and if the claim for confidentiality with respect to the chemical identity is denied in accordance with §720.90(c), EPA will deny a claim asserted under this paragraph.

(3) Any person who asserts a confidentiality claim for chemical identity must:

(i) Comply with the requirements of paragraph (a)(3) of this section regarding submission of a generic name.

(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 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.

(iv) Provide a detailed written substantiation of the claim, by answering the following questions:

(A) What harmful effects to your competitive position, if any, do you think would result if EPA publishes on the Inventory the identity of the chemical substance? How could a competitor use such information given the fact that the identity of the substance otherwise would appear on the Inventory of chemical substances with no link between the substance and your company or industry? How substantial would the harmful effects of disclosure be? What is the casual relationship between the disclosure and the harmful effects?

(B) For what period of time should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

(C) Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential for purposes of the Inventory?

(D) Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know it is being manufactured on imported for a commercial purpose by anyone?

(E) Is the fact that someone is manufacturing or importing this chemical substance for commercial purposes available to the public, e.g., in technical journals or other publications; in libraries; or in State, local, or Federal agency public files?

(F) What measures have you taken to prevent undesired disclosure of the fact that you are manufacturing or importing this substance for a commercial purpose?

(G) To what extent has the fact that you are manufacturing or importing this chemical substance for a commercial purpose been disclosed to others? What precautions have you taken in regard to these disclosures? Has this information been disclosed to the public or to competitors?

(H) In what form does this particular chemical substance leave the site of manufacture, e.g., as part of a product; in an effluent or emission stream? If so, what measures have you taken to guard against discovery of its identity?

(I) If the chemical substance leaves the site of manufacture in a product that is available to either the public or your competitors, can they identify the substance by analyzing the product?

(J) For what purpose do you manufacture or import the substance?

(K) Has EPA, another Federal agency, or any Federal court made any pertinent confidentiality determinations regarding this chemical substance? If so, copies of such determinations must be included in the substantiation.

(L) If the notice includes a health and safety study concerning the new chemical substance, the submitter must also answer the questions in §720.90(b)(2).

(4) If the submitter does not meet the requirements of this paragraph, EPA will deny the claim of confidentiality.

(5)(i) EPA will publish a generic name on the public Inventory if:

(A) The submitter asserts a claim of confidentiality in accordance with this paragraph.

(B) No claim for confidentiality of the specific chemical identity as part of a health and safety study has been denied in accordance with part 2 of this title or §720.90.

(ii) Publication of a generic name on the public Inventory does not create a category for purposes of the Inventory. Any person who has a *bona fide* intent to manufacture or import a chemical substance which is described by a generic name on the public Inventory may submit an inquiry to EPA under §720.25(b) to determine whether the particular chemical substance is included on the confidential Inventory.

(iii) Upon receipt of a request described in §720.25(b), EPA may require the submitter which originally asserted confidentiality for a chemical substance to submit to EPA the information listed in paragraph (b)(3)(iii) of this section.

(iv) Failure to submit any of the information required under paragraph (b)(3)(iii) of this section within ten days of a request by EPA under this paragraph is a waiver of the original submitter's confidentiality claim. In this event, EPA may place the specific chemical identity on the public Inventory without further notice to the original submitter.

(6) If a submitter asserts a claim of confidentiality under this paragraph, EPA will examine the generic chemical name proposed by the submitter.

(i) If EPA determines that the generic name proposed by the submitter is only as generic as necessary to protect the confidential identity of the particular chemical substance, EPA will place that generic name on the public Inventory.

(ii) If EPA determines that the generic name proposed by the submitter is more generic than necessary to protect the confidential identity, EPA will propose in writing, for review by the submitter, an alternative generic name that will reveal the chemical identity of the chemical substance to the maximum extent possible.

(iii) If the generic name proposed by EPA is acceptable to the submitter, EPA will place that generic name on the public Inventory.

(iv) If the generic name proposed by EPA is not acceptable to the submitter, the submitter must explain in detail why disclosure of that generic name would reveal confidential business information and propose another generic name which is only as generic as necessary to protect the confidential identity. If EPA does not receive a response from the submitter within 30 days after the submitter receives the proposed name, EPA will place EPA's chosen generic name on the public Inventory. If the submitter does provide the information requested, EPA will review the response. If the submitter's proposed generic name is acceptable, EPA will publish that generic name on the public Inventory. If the submitter's proposed generic name is not acceptable, EPA will notify the submitter of EPA's choice of a generic name. Thirty days after this notification, EPA will place the chosen generic name on the public Inventory.

§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.

§720.90 Data from health and safety studies.

(a) *Information other than specific chemical identity.* Except as provided in paragraph (b) of this section, EPA will deny any claim of confidentiality with respect to information included in a health and safety study, unless the information would disclose confidential business information concerning:

(1) Processes used in the manufacture or processing of a chemical substance or mixture.

(2) In the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture.

(3) Information which is not in any way related to the effects of a substance on human health or the environment, such as the name of the submitting company, cost or other financial data, product development or marketing plans, and advertising plans, for which the person submits a claim of confidentiality in accordance with §720.80.

(b) *Specific chemical identity*—(1) *Claims applicable to period prior to commencement of manufacture.* A claim of confidentiality for the period prior to commencement of manufacture or import for the chemical identity of a chemical substance for which a health and safety study was submitted must be asserted in conjunction with a claim asserted under §720.85(a).

(2) *Claims applicable to period after commencement of manufacture or import for commercial purposes.* To maintain the confidential status of the chemical identity of a chemical substance for which a health and safety study was submitted after commencement of manufacture or import, the claim must be reasserted and substantiated in conjunction with a claim under §720.85(b). In addition to the questions set forth in §720.85(b)(3)(iv) of this part, the submitter must answer the following questions:

(i) Would disclosure of the chemical identity disclose processes used in the manufacture or processing of a chemical substance or mixture? Describe how this would occur. In responding to the question in §720.85(b)(3)(iv)(A), explain what harmful competitive effects would occur from disclosure of this process information.

(ii) Would disclosure of the chemical identity disclose the portion of a mixture comprised by any of the substances in the mixture? Describe how this would occur. In responding to the question in §720.85(b)(3)(iv)(A), explain what harmful competitive effects would occur from disclosure of this information.

(iii) Do you assert that disclosure of the chemical identity is not necessary to interpret any of the health and safety studies you have submitted? If so, explain how a less specific identity would be sufficient to interpret the studies.

(c) *Denial of confidentiality claim.* EPA will deny a claim of confidentiality for chemical identity under paragraph (b) of this section, unless:

(1) The information would disclose processes used in the manufacture or processing of a chemical substance or mixture.

(2) In the case of a mixture, the information would disclose the portion of the mixture comprised by any of the substances in the mixture.

(3) The specific chemical identity is not necessary to interpret a health and safety study.

(d) *Use of generic names.* When EPA discloses a health and safety study containing a specific chemical identity, which the submitter has claimed confidential, and if the Agency has not denied the claim under paragraph (c) of this section, EPA will identify the chemical substance by the generic name selected under §720.85.

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

§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 addition, EPA may add materials to the public file, subject to subpart E of this part. Publicall~~l~~y available docket materials are available at the addresses in §700.17(b)(1) and (2) of this chapter.

[48 FR 21742, May 13, 1983, as amended at 53 FR 12523, Apr. 15, 1988; 60 FR 16311, Mar. 29, 1995; 60 FR 34464, July 3, 1995; 77 FR 46292, Aug. 3, 2012]

Subpart F—Commencement of Manufacture or Import

§720.102 Notice of commencement of manufacture or import.

(a) *Applicability.* Any person who commences the manufacture or import 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 or import.

(b) *When to report.* (1) If manufacture or import 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 or import.

(2) If manufacture or import 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 or import for a non-exempt 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 the chemical identity confidential, and wants the identity to be listed on the confidential portion of the Inventory, the claim must be reasserted and substantiated in accordance with §720.85(b). Otherwise, EPA will list the specific chemical identity on the public 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.

[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]

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 or imports 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.

Commented [A43]: This deletion reflects amended TSCA.

(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).

§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.