Title 40 —Protection of Environment
Chapter I —Environmental Protection Agency
Subchapter R —Toxic Substances Control Act
Part 723 —Premanufacture Notification Exemptions
Subpart B —Specific Exemptions

Authority: 15 U.S.C. 2604.

§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

(a) ***Purpose and scope.***

(1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A)(i) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of:

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

(i) Submit a notice of intent to manufacture 30 days before manufacture begins, as required under paragraph (e) of this section.

(ii) Comply with all other provisions of this section.

(3) This section does not apply to microorganisms subject to part 725 of this chapter.

(b) ***Definitions.*** The following definitions apply to this subpart.

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

(2) ***Consumer*** means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

(3) ***Environment*** has the same meaning as in section 3 of the Act (15 U.S.C. 2602).

(4) ***Environmental transformation product*** means any chemical substance resulting from the action of environmental processes on a parent compound that changes the molecular identity of the parent compound.

(5) ***Metabolite*** means a chemical entity produced by one or more enzymatic or nonenzymatic reactions as a result of exposure of an organism to a chemical substance.

(6) ***Serious acute effects*** means human disease processes or other adverse effects that have short latency periods for development, result from short-term exposure, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(7) ***Serious chronic effects*** means human disease processes or other adverse effects that have long latency periods for development, result from long-term exposure, are long-term illnesses, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

(8) ***Significant environmental effects*** means:

(i) Any irreversible damage to biological, commercial, or agricultural resources of importance to society;

(ii) Any reversible damage to biological, commercial, or agricultural resources of importance to society if the damage persists beyond a single generation of the damaged resource or beyond a single year; or

(iii) Any known or reasonably anticipated loss of members of an endangered or threatened species. Endangered or threatened species are those species identified as such by the Secretary of the Interior in accordance with the Endangered Species Act, as amended (16 U.S.C. 1531).

(9) ***Site*** means a contiguous property unit. Property divided only by a public right-of-way is one site. There may be more than one manufacturing plant on a single site.

(10) The terms *byproduct, EPA, importer, impurity, known to or reasonably ascertainable, manufacture, manufacturer, new chemical substance, person, possession or control, and test data* have the same meanings as in § 720.3 of this chapter.

(11) ***PFAS* or *per- and poly-fluoroalkyl substance*** means a chemical substance that contains at least one of these three structures:

(i) R-(CF2)-CF(R')R", where both the CF2 and CF moieties are saturated carbons;

(ii) R-CF2OCF2-R', where R and R' can either be F, O, or saturated carbons; or

(iii) CF3C(CF3)R'R", where R' and R" can either be F or saturated carbons.

(12) ***PBT chemical substance*** means a chemical substance possessing characteristics of persistence (P) in the environment, accumulation in biological organisms (bioaccumulation (B)), and toxicity (T) resulting in potential risks to humans and ecosystems. For more information on EPA's Policy on new chemical substances that are PBTs, see EPA's 1999 policy statement (64 FR 60194, November 4, 1999 (FRL-6097-7)).

(c) ***Exemption categories.*** Except as provided in paragraph (d) of this section, this exemption applies to:

(1) Any manufacturer of a new chemical substance manufactured in quantities of 10,000 kilograms or less per year under the terms of this exemption.

(2) Any manufacturer of a new chemical substance satisfying all of the following low environmental release and low human exposure eligibility criteria:

(i) ***Consumers and the general population.*** For exposure of consumers and the general population to the new chemical substance during all manufacturing, processing, distribution in commerce, use, and disposal of the substance:

(A) No dermal exposure.

(B) No inhalation exposure (except as described in paragraph (c)(2)(iv) of this section.

(C) Exposure in drinking water no greater than a 1 milligram per year (estimated average dosage resulting from drinking water exposure in streams from the maximum allowable concentration level from ambient surface water releases established under paragraph (c)(2)(iii) of this section or a higher concentration authorized by EPA under paragraph (c)(2)(iii) of this section).

(ii) ***Workers.*** For exposure of workers to the new chemical substance during all manufacturing, processing, distribution in commerce, use and disposal of the substance:

(A) No dermal exposure (this criterion is met if adequate dermal exposure controls are used in accordance with applicable EPA guidance).

(B) No inhalation exposure (this criterion is considered to be met if adequate inhalation exposure controls are used in accordance with applicable EPA guidance).

(iii) ***Ambient surface water.*** For ambient surface water releases, no releases resulting in surface water concentrations above 1 part per billion, calculated using the methods prescribed in §§ 721.90 and 721.91, unless EPA has approved a higher surface water concentration supported by relevant and scientifically valid data submitted to EPA in a notice under paragraph (e) of this section on the substance or a close structural analogue of the substance which demonstrates that the new substance will not present an unreasonable risk of injury to aquatic species or human health at the higher concentration.

(iv) ***Incineration.*** For ambient air releases from incineration, no releases of the new chemical substance above 1 microgram per cubic meter maximum annual average concentration, calculated using the formula:

> (kg/day of release after treatment) multiplied by (number of release days per year) multiplied by (9.68×10^{-6}) micrograms per cubic meter.

(v) ***Land or groundwater.*** For releases to land or groundwater, no releases to groundwater, to land, or to a landfill unless the manufacturer has demonstrated to EPA's satisfaction in a notice under paragraph (e) of this section that the new substance has negligible groundwater migration potential.

(d) ***Chemical substances that cannot be manufactured under this exemption.*** A new chemical substance cannot be manufactured under this section, notwithstanding satisfaction of the criterion of paragraph (c)(1) or (2) of this section, if EPA determines, in accordance with paragraph (g) of this section, that the substance, any reasonably anticipated metabolites, environmental transformation products, or byproducts of the substance, or any reasonably anticipated impurities in the substance, under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance:

(1) May cause:

(i) Serious acute (lethal or sublethal) effects;

(ii) Serious chronic (including carcinogenic and teratogenic) effects; or

(ii) Significant environmental effects.

(2) Or is:

(i) A PFAS.

(ii) A PBT chemical substance with anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms.

(e) ***Exemption notice.***

(1) A manufacturer applying for an exemption under either paragraph (c)(1) or (c)(2) of this section must submit an exemption notice to EPA at least 30 days before manufacture of the new chemical substance begins. Exemption notices and modifications must be submitted to EPA on EPA Form No. 7710-25 via CDX using e-PMN software in the manner set forth in this paragraph. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software. Notices and any related support documents, must be generated and completed (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

(2) The notice shall contain the information described below, pursuant to the referenced provisions of § 720.45.

(i) Manufacturer identity.

(ii) Chemical identity (§ 720.45(a)).

(iii) Impurities (§ 720.45(b)).

(iv) Known synonyms or trade names (§ 720.45(c)).

(v) Byproducts (§ 720.45(d)).

(vi) Production volume (§ 720.45(e)).

(A) Manufacturers submitting an exemption application under paragraph (c)(1) of this section will be assumed to be manufacturing at an annual production volume of 10,000 kilograms. Manufacturers who intend to manufacture an exempted substance at annual volumes of less than 10,000 kilograms and wish EPA to conduct its risk assessment based upon such lesser annual production level rather than a 10,000-kilograms level, may so specify by writing the lesser annual production volume in the appropriate box on the PMN form and marking the adjacent binding option box. Manufacturers who opt to specify annual production levels below 10,000 kilograms and who mark the production volume binding option box shall not manufacture more than the specific annual amount of the exempted substance unless a new exemption notice for a higher (up to 10,000 kgs) manufacturing volume is submitted and approved pursuant to this section.

(B) Manufacturers submitting an exemption under paragraph (c)(2) of this section shall list the estimated maximum amount to be manufactured during the first year of production and the estimated maximum amount to be manufactured during any 12-month period during the first 3 years of production.

(vii) Description of intended categories of use (§ 720.45(f)).

(viii) For manufacturer-controlled sites, the manufacturer shall supply identity of manufacturing sites, process descriptions, and worker exposure and environmental release information (§ 720.45(g)); for sites not controlled by the manufacturer, processing and use operation descriptions, estimated number of processing and use sites, and worker exposure/environmental release information (§ 720.45(h)). A manufacturer applying for an exemption under paragraph (c)(1) of this section need not provide information on worker exposure and environmental release referenced in paragraphs (e)(2)(viii) of this section if such information is

not known or not readily available to the manufacturer. To assist in reporting this information, manufacturers may obtain a copy of EPA's Guidance for Reporting Occupational Exposure and Environmental Release Information under 40 CFR 723.50, available from the Environmental Assistance Division at the address listed in paragraph (e)(1) of this section. Where worker exposure and environmental release information is not supplied by the manufacturer, EPA will generally apply "bounding estimates" (i.e., exposure estimates higher than those incurred by persons in the population with the highest exposure) to account for uncertainties in actual exposure and release scenarios.

(ix) Type and category of notice. The manufacturer must clearly indicate on the first page of the PMN form that the submission is a "TSCA section 5(h)(4) exemption notice," and must indicate whether the notice is being submitted under paragraph (c)(1) or (c)(2) of this section. Manufacturers of chemical substances that qualify for an exemption under both paragraph (c)(1) and (c)(2) of this section may apply for either exemption, but not both.

(x) Test data (§ 720.50).

(xi) Certification. In addition to the certifications required in EPA form 7710-25, the following certifications shall be included in notices under this section. The manufacturer must certify that:

(A) The manufacturer intends to manufacture the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of this section.

(B) The manufacturer is familiar with the terms of this section and will comply with those terms.

(C) The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

(D) For substances manufactured under paragraph (c)(1) of this section, the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30-day review period.

(xii) Sanitized copy of notice.

(A) The manufacturer must make all claims of confidentiality in accordance with paragraph (l) of this section. If any information is claimed confidential, the manufacturer must submit a second copy of the notice, with all information claimed as confidential deleted, in accordance with paragraph (l)(3) of this section.

(B) If the manufacturer does not provide the second copy, the submission will be considered incomplete.

(xiii) Safety Data Sheet (§ 720.45(i)).

(xiv) Physical and chemical properties and environmental fate characteristics (§ 720.45(j)).

(3) ***Incomplete notices.*** EPA will conduct a pre-screen of the notice, typically taking 2-3 days and according to the criteria under paragraph (e)(2) of this section. If EPA concludes that the notice is incomplete, EPA will notify the submitter and the review period will not begin. Once the submitter corrects the errors or incomplete submission according to the requirements provided by EPA and re-

submits the notice to EPA, the review period will begin. If EPA does not identify errors or determine the notice to be incomplete during screening, the review period will begin on the date EPA received the complete notice.

(f) ***Multiple exemption holders.***

(1) A manufacturer who intends to manufacture a substance for which an exemption under this section was previously approved may apply for an exemption under paragraph (c)(1) or (c)(2) of this section; however, EPA will not approve any subsequent exemption application under paragraph (c)(1) of this section unless it can determine that the potential human exposure to, and environmental release of, the new chemical substance at the higher aggregate production volume will not present an unreasonable risk of injury to human health or the environment.

(2)

(i) If EPA proposes to deny an exemption application for a substance for which another manufacturer currently holds an exemption, and that proposed denial is based exclusively on the cumulative human exposure or environmental release of the substance which precludes the EPA from determining that the subsequent applicant's activities will not present an unreasonable risk of injury to human health or the environment, the EPA will notify the first exemption holder that it must, within 21 days of its receipt of EPA's notice, either:

(A) Provide a new certification that it has commenced, or that it will commence, manufacture of the new chemical substance under this section within 1 year of the expiration of its exemption review period; or

(B) Withdraw its exemption for the new chemical substance.

(ii) If the first exemption holder does not respond to the EPA's notice under paragraph (f)(2)(i) of this section within the prescribed time period, EPA shall issue a notice of ineligibility to the first exemption holder under the provisions of paragraph (h)(2) of this section.

(g) ***Review period.***

(1) EPA will review the notice submitted under paragraph (e) of this section to determine whether manufacture of the new chemical substance is eligible for the exemption. The review period will run for 30 days from the date EPA receives a complete notice. To provide additional time to address any unresolved issues concerning an exemption application, the exemption applicant may, at any time during the review period, request a suspension of the review period pursuant to the provisions of § 720.75(b) of this chapter.

(2) No person submitting a notice under paragraph (e) of this section may manufacture the new chemical substance until EPA notifies the submitter that the new chemical substance meets the terms of this section.

(h) ***Notice of ineligibility*** —

(1) ***During the review period.*** If the EPA determines during the review period that manufacture of the new chemical substance does not meet the terms of this section or that there are issues concerning toxicity or exposure that require further review which cannot be accomplished within the 30-day review period, EPA will notify the manufacturer by telephone that the substance is not eligible. This telephone notification will subsequently be confirmed by certified letter that identifies the reasons

for the ineligibility determination. The manufacturer may not begin manufacture of the new chemical substance without complying with section 5(a)(1) of the Act or submitting a new notice under paragraph (e) of this section that satisfies EPA's concerns.

(2) ***After the review period.***

(i)

(A) If at any time after the review period specified in paragraph (g) of this section the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention ("the Assistant Administrator") makes a preliminary determination that manufacture of the new chemical substance does not meet the terms of this section, the Assistant Administrator will notify the manufacturer by certified letter that EPA believes that the new chemical substance does not meet the terms of the section.

(B) The manufacturer may continue to manufacture, process, distribute in commerce, and use the substance after receiving the notice under paragraph (h)(2)(i)(A) of this section if the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time of the notification and if the manufacturer submits objections or an explanation under paragraph (h)(2)(ii) of this section. Manufacturers not manufacturing, processing, distributing in commerce, or using the substance at the time of the notification may not begin manufacture until EPA makes its final determination under paragraph (h)(2)(iii) of this section.

(ii) A manufacturer who has received notice under paragraph (h)(2)(i)(A) of this section may submit, within 15 days of receipt of written notification, detailed objections to the determination or an explanation of its diligence and good faith efforts in attempting to comply with the terms of this section.

(iii) The Assistant Administrator will consider any objections or explanation submitted under paragraph (h)(2)(ii) of this section and will make a final determination. The Assistant Administrator will notify the manufacturer of the final determination by telephone within 15 days of receipt of the objections or explanation, and subsequently by certified letter.

(iv) If the Assistant Administrator determines that manufacture of the new chemical substance meets the terms of this section, the manufacturer may continue or resume manufacture, processing, distribution in commerce, and use in accordance with the terms of this section.

(v) If the Agency determines that manufacture of the new chemical substance does not meet the terms of this section and that the manufacturer did not act with due diligence and in good faith to meet the terms of this section, the manufacturer must cease any continuing manufacture, processing, distribution in commerce, and use of the new chemical substance within 7 days of the written notification under paragraph (h)(2)(iii) of this section. The manufacturer may not resume manufacture, processing, distribution in commerce, and use of the new chemical substance until it submits a notice under section 5(a)(1) of the Act and part 720 of this chapter and EPA has made one of the five determinations as set forth in section 5(a)(3) of the Act and taken the action required in association with that determination.

(vi) If the Assistant Administrator determines that manufacture of the new chemical substance does not meet the terms of this section and that the manufacturer acted with due diligence and in good faith to meet the terms of this section, the manufacturer may continue manufacture, processing, distribution in commerce, and use of the new chemical substance if:

(A) It was actually manufacturing, processing, distributing in commerce, or using the chemical substance at the time it received the notification specified in paragraph (h)(2)(i)(A) of this section.

(B) It submits a notice on the new chemical substance under section 5(a)(1) of the Act and part 720 of this chapter within 15 days of receipt of the written notification under paragraph (h)(2)(iii) of this section. Such manufacture, processing, distribution in commerce, and use may continue unless EPA takes action under section 5(e) or 5(f) of the Act.

(3) Action under this paragraph does not preclude action under sections 7, 15, 16, or 17 of the Act.

(i) ***Additional information.*** If the manufacturer of a new chemical substance under the terms of this exemption obtains test data or other information indicating that the new chemical substance may not qualify under terms of this section, the manufacturer must submit these data or information to EPA within 15 working days of receipt of the information. If, during the notice review period specified in paragraph (g) of this section, the submitter obtains possession, control, or knowledge 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 to EPA within ten days of receiving the new information, but no later than five days before the end of the applicable review period. The new information must be submitted electronically to EPA via CDX and must clearly identify the submitter and the exemption notice to which the new information is related. If the new information becomes available during the last 5 days of the notice review period, the submitter must immediately inform its EPA contact for that notice by telephone or e-mail and submit the new information electronically to EPA via CDX.

(j) ***Changes in manufacturing site, use, human exposure and environmental release controls, and certain manufacturing volumes.***

(1) Except as provided in paragraph (j)(6) of this section, chemical substances manufactured under this section must be manufactured at the site or sites described, for the uses described, and under the human exposure and environmental release controls described in the exemption notice under paragraph (e) of this section.

(2) Where the manufacturer lists a specific physical form in which the new chemical substance will be manufactured, processed, and/or used, the manufacturer must continue manufacturing, processing, and/or using the new chemical substance in either the same physical form described in the notice under paragraph (e), or in a physical form which will not increase the human exposure to or environmental release of the new chemical substance over those exposures or releases resulting from the specified physical form (e.g., a manufacturer which specifies that the new chemical substance will be produced in a non-volatile liquid form generally may not change to a respirable powder form).

(3) The annual production volume of chemical substances manufactured under paragraph (c)(1) of this section for which the manufacturer designated a binding annual production volume pursuant to paragraph (e)(2)(vi) of this section must not exceed that designated volume.

(4) Any person who manufactures a new chemical substance under paragraph (c)(1) or (c)(2) of this section must comply with the provisions of this section, including submission of a new notice under paragraph (e) of this section, before:

(i) Manufacturing the new chemical substance at a site that was not approved in a previous exemption notice for the substance, except as provided in paragraph (j)(6) of this section.

(ii) Manufacturing the new chemical substance for a use that was not approved in a previous exemption notice for the substance.

(iii) Manufacturing the new chemical substance without employing the human exposure and environmental release controls approved in a previous exemption notice for the substance.

(iv) Manufacturing the new chemical substance in a physical form different than that physical form approved in a previous exemption notice for the substance and which form may increase the human exposure to, or environmental release of, the new chemical substance over those exposures or releases resulting from the physical form approved in the previous notice.

(v) Manufacturing the chemical substance in annual production volumes above any volume designated by the manufacturer as binding under paragraph (e)(2)(vi) of this section in a previous exemption notice for the substance.

(5) In an exemption notice informing EPA of a change in site, use, or worker protection, or environmental release controls, the manufacturer is not required to provide all of the same information submitted to EPA in a previous exemption notice for that chemical substance. The new exemption notice, however, must indicate the identity of the new chemical substance; the manufacturer's name; the name and telephone number of a technical contact; and location of the new site, new worker protection or environmental release controls, and new use information. The notice must also include the EPA-designated exemption number assigned to the previous notice and a new certification by the manufacturer, as described in paragraph (e)(2)(xi) of this section.

(6)

(i) A manufacturer may, without submitting a new notice, manufacture the new chemical substance at a site not listed in its exemption application under the following conditions:

(A) the magnitude, frequency, and duration of exposure of individual workers to the new chemical substance at the new manufacturing site is equal to, or less than, the magnitude, frequency, and duration of exposure of the individual workers to the new chemical substance at the manufacturing site for which the EPA performed its original risk-assessment pursuant to the original exemption notice; and

(B) Either

(1) at the new manufacturing site, the manufacturer does not release to surface waters any of the new chemical substance, or any waste streams containing the new chemical substance; or

(2) at the new manufacturing site, the manufacturer maintains surface water concentrations of the chemical substance, resulting from direct or indirect discharges from the manufacturing site, at or below 1 part per billion, or at or below an alternative concentration level approved by the Agency in writing or under the procedures described in paragraph (c)(2)(iii) of this section, using the water concentration calculation method described at §§ 721.90 and 721.91.

(ii) The manufacturer shall notify EPA of any new manufacturing site no later than 30 days after the commencement of manufacture of the new chemical substance under the exemption at the new manufacturing site as follows:

(A) The notification must contain the EPA-designated exemption number to which the notification applies, manufacturer identity, the street address of the new manufacturing site, the date on which manufacture commenced at the new site, the name and telephone number of a technical contact at the new site, any claim of confidentiality, and a statement that the notification is an amendment to the original exemption application under the terms of this section.

(B) The notification must be submitted electronically to EPA via CDX as a support document to the original notification. Prior to submission to EPA via CDX, such notices must be generated and completed using the e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to access the e-PMN software.

(k) ***Customer notification.***

(1) Manufacturers of new chemical substances described in paragraphs (c)(1) and (c)(2) of this section must notify processors and industrial users that the substance can be used only for the uses specified in the exemption notice at paragraph (e) of this section. The manufacturer must also inform processors and industrial users of any controls specified in the exemption notice. The manufacturer may notify processors and industrial users by means of a container labeling system, written notification, or any other method that adequately informs them of use restrictions or controls.

(2) A manufacturer of a new chemical substance described in paragraph (c)(2) of this section may distribute the chemical substance only to other persons who agree in writing to not further distribute the substance until it has been reacted, incorporated into an article, or otherwise rendered into a physical form or state in which environmental releases and human exposures above the eligibility criteria in paragraph (c)(2) of this section are not likely to occur.

(3) If the manufacturer learns that a direct or indirect customer is processing or using the new substance in violation of use restrictions or without imposing prescribed worker protection or environmental release controls, the manufacturer must cease distribution of the substance to the customer or the customer's supplier immediately unless the manufacturer is able to document each of the following:

(i) That the manufacturer has, within 5 working days, notified the customer in writing that the customer has failed to comply with the conditions specified in this section and the exemption notice under paragraph (e) of this section.

(ii) That, within 15 working days of notifying the customer of the noncompliance, the manufacturer received from the customer, in writing, a statement of assurance that the customer is aware of the terms of this section and the exemption notice and will comply with those terms.

(4) If, after receiving a statement of assurance from a customer under paragraph (k)(3)(ii) of this section, the manufacturer obtains knowledge that the customer has again failed to comply with any of the conditions specified in this section or the exemption notice, the manufacturer shall cease supplying the new chemical substance to that customer and shall report the failure to comply to EPA within 15 days of obtaining this knowledge. Within 30 days of its receipt of the report, EPA will notify the manufacturer whether, and under what conditions, distribution of the chemical substance to the customer may resume.

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

(m) ***Exemptions granted under superseded regulations.*** Manufacturers holding exemptions granted under the superseded requirements of this section (as in effect on May 26, 1995) shall either continue to comply with those requirements (including the production volume limit) or apply for a new exemption pursuant to this section. EPA will not accept requests to amend exemptions granted under the superseded requirements; manufacturers wishing to amend such exemptions must submit a new exemption under paragraph (e) of this section. If a new exemption for a new chemical substance is granted under this exemption to the manufacturer holding an exemption under the superseded requirements, the exemption under the superseded requirements for such substance shall be void.

(n) ***Recordkeeping.***

(1) A manufacturer of a new chemical substance under paragraph (c) of this section must maintain the records described in this paragraph at the manufacturing site or site of importation for a period of 5 years after their preparation.

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

(i) Records of annual production volume and import volume.

(ii) Records documenting compliance with the applicable requirements and restrictions of paragraphs (c), (e), (f), (h), (i), (j), and (k) of this section.

(3) Any person who manufactures a new chemical substance under the terms of this section must, upon request of a duly designated representative of EPA, permit such person at all reasonable times to have access to and to copy records kept under paragraph (n)(2) of this section.

(4) The manufacturer must submit the records listed in paragraph (n)(2) of this section to EPA upon request. Manufacturers must provide these records within 15 working days of receipt of such request.

(o) ***Compliance.***

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

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

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

(4) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section, or act to seize any chemical substance manufactured or processed in violation of this section, or take other action under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 1616).

(p) ***Subject to a significant new use rule or listed on TSCA Inventory.*** If a significant new use rule is proposed or finalized in part 721 of this chapter for a chemical substance described by a generic chemical name or if the specific chemical identity of a chemical substance is listed on the confidential portion of the TSCA Inventory, EPA may make reasonable efforts to notify any persons who may also manufacture the same chemical substance under the terms of this section. A disclosure to a person with an approved exemption under this section that the chemical substance is subject to a proposed or final rule in part 721 of this chapter or is listed on the confidential portion of the TSCA Inventory will not be considered public

disclosure of confidential business information under section 14 of the Act. The notification will inform manufacturers subject to the terms of this section that the chemical substance is subject to a proposed or final significant new use rule under section 5(a)(2) of the Act or is listed on the TSCA Inventory, and identify the proposed or final section in subpart E of part 721 of this chapter that pertains to the chemical substance or the generic name for that substance listed on the public portion of the TSCA Inventory, as applicable.

[60 FR 16346, Mar. 29, 1995, as amended at 60 FR 34465, July 3, 1995; 62 FR 17932, Apr. 11, 1997; 64 FR 31989, June 15, 1999; 71 FR 33642, June 12, 2006; 75 FR 787, Jan. 6, 2010; 77 FR 46292, Aug. 3, 2012; 78 FR 72828, Dec. 4, 2013; 80 FR 42746, July 20, 2015; 87 FR 39769, July 5, 2022; 88 FR 37173, June 7, 2023; 89 FR 102798, Dec. 18, 2024]

Editorial Note: At 89 FR 102798, Dec. 18, 2024, § 723.50 was amended in part by revising paragraph (a)(1). However, the set-out text included revised text for the introductory paragraph of (a)(1), and not the subparagraphs.