TABLE 1—EPA-APPROVED NON-REGULATORY AND QUASI-REGULATORY MEASURES—Continued

[Excluding certain resolutions and statutes, which are listed in tables 2 and 3, respectively][1]

Name of SIP provision	Applicable geographic or nonattainment area or title/subject	State submittal date	EPA approval date	Explanation
*	*	*	*	*

[1] Table 1 is divided into three parts: Clean Air Act Section 110(a)(2) State Implementation Plan Elements (excluding Part D Elements and Plans), Part D Elements and Plans (other than for the Metropolitan Phoenix or Tucson Areas), and Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas.

* * * * *

■ 3. Section 52.145 is amended by adding paragraph (o) to read as follows:

§ 52.145 Visibility protection.

* * * * *

(o) *Disapproval.* On August 15, 2022, the Arizona Department of Environmental Quality submitted the ''State Implementation Plan Revision: Regional Haze Program (2018–2028).''

(1) The following portions of the ''State Implementation Plan Revision: Regional Haze Program (2018–2028)'' are disapproved because they do not meet the applicable requirements of Clean Air Act sections 169A and 169B and the Regional Haze Rule in 40 CFR 51.301 through 51.308.

(i) Chapters 2, 6.1, 6.2, 6.3, 7, 8, 9, and 10;

(ii) Appendices B, C, D, E, F, G, H, I, J, and L.

■ 4. Section 52.147 is amended by adding paragraph (f) to read as follows:

§ 52.147 Interstate transport.

* * * * *

(f) *Disapproval.* The SIPs submitted on December 11, 2015 and September 24, 2018 do not meet the requirements of Clean Air Act section 110(a)(2)(D)(i)(II) (interfere with measures in any other state to protect visibility, only) for the 2012 $PM_{2.5}$ NAAQS and the 2015 ozone NAAQS, respectively.

[FR Doc. 2024–29508 Filed 12–17–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 68, 372, 703, 720, 721, 723, 725, and 761

[EPA–HQ–OPPT–2022–0902; FRL–7906–02–OCSPP]

RIN 2070–AK65

Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is amending the new chemicals procedural regulations under the Toxic Substances Control Act (TSCA). These amendments align the regulatory text with the amendments to TSCA's new chemicals review provisions contained in the Frank R. Lautenberg Chemical Safety for the 21st Century Act, enacted on June 22, 2016, will improve the efficiency of EPA's review processes, and update the regulations based on existing policies and experience implementing the New Chemicals Program. This final rule includes amendments that will increase the quality of information initially submitted in new chemicals notices and improve the Agency's processes for timely, effective completion of individual risk assessments and the new chemicals review process overall. EPA is also finalizing several amendments to the regulations for low volume exemptions (LVEs) and low release and exposure exemptions (LoREXs), which will require EPA approval of an exemption notice prior to commencement of manufacture, make per- and polyfluoroalkyl substances (PFAS) categorically ineligible for these exemptions, and provide that certain persistent, bioaccumulative, toxic (PBT) chemical substances are ineligible for these exemptions.

DATES: This final rule is effective January 17, 2025.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2022–0902, is available online at *https://www.regulations.gov*. Additional instructions for visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Tyler Lloyd, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–4016; e-mail address: *lloyd.tyler@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you intend to manufacture a new chemical substance, or manufacture or process a chemical substance for a significant new use. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Chemical Manufacturers (NAICS code 325).
- Petroleum and Coal Products (NAICS code 324).
- Merchant Wholesalers, Nondurable Goods (NAICS code 424).

This list details the types of entities that EPA is aware could potentially be regulated by this action. Other types of entities not listed could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria found in 40 CFR 720.22, 721.5, 723.50, and 725.1. If you have questions regarding the applicability of this action, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

EPA is promulgating this rule pursuant to its authority in TSCA section 5 (15 U.S.C. 2604). Section 5(a)(1) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2604(a)(1), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act of 2016 (Pub. L. 114–182) (herein referred to as the ''2016 Lautenberg

Amendments''), provides that no person, as defined at 40 CFR 720.3, may manufacture (which includes import under TSCA) a new chemical substance or manufacture or process a chemical substance for a use which EPA has determined is a significant new use, unless at least 90 days prior to such manufacture or processing that person submits a notice to EPA containing the information required by TSCA section 5(d). EPA must conduct a review of the notice, make one of five possible determinations pertaining to the likelihood of unreasonable risk of injury to health or the environment, and take any actions required as a result of that determination, all within the applicable review period. The submitted notice must include the information described in TSCA section 5(d)(1): insofar as known to the submitter or reasonably ascertainable, information described in certain provisions of TSCA section 8(a)(2) (*e.g.,* chemical identity, use, and exposure information); in the form and manner prescribed by EPA, information in the possession or control of the submitter related to the health or environmental effects of the chemical substance; and a description of any other information concerning the environmental and health effects of the chemical substance, insofar as known to the submitter or reasonably ascertainable.

C. What action is the Agency taking?

EPA is promulgating amendments to the procedural regulations at 40 CFR parts 720, 721, and 725 to align with the requirements in TSCA section 5, as amended by the 2016 Lautenberg Amendments, and to make additional updates. EPA is amending the regulations to specify that EPA must make a determination on each Pre-Manufacture Notice (PMN), Significant New Use Notice (SNUN), and Microbial Commercial Activity Notice (MCAN) received before the submitter may commence manufacturing or processing of the chemical substance that is the subject of the notice, and to list the five possible determinations and the actions required in association with those determinations. In addition, EPA is finalizing amendments that will clarify the level of detail expected for the information that a submitter is required to include in a PMN, SNUN, or exemption notice in order for the notice to be considered complete. EPA is also finalizing amendments to the procedures for reviewing PMNs and SNUNs; specifically, procedures for addressing PMNs and SNUNs that have errors or are incomplete or that are amended during the applicable review period. Additionally, EPA is finalizing several amendments to the regulations at 40 CFR 723.50 for LVEs and LoREXs. These amendments would require EPA approval of an exemption notice before the submitter may commence manufacture, allow EPA to inform an LVE or LoREX holder when the chemical substance that is the subject of the exemption becomes subject to a significant new use rule (SNUR) under TSCA and the chemical identity is confidential, make PFAS categorically ineligible for these exemptions, and make certain PBTs ineligible for these exemptions. Finally, EPA is amending the regulations pertaining to suspensions for all TSCA section 5 notices to allow submitters to request suspensions for up to 30 days via oral or e-mail request. This final rule takes into consideration comments received on the proposed rule (88 FR 34100, May 26, 2023 (FRL–7906–01–OCSPP)). Details on the final rule requirements, including modifications from the proposal, are explained in Unit III.

D. Why is the Agency taking this action?

Under amended TSCA, EPA must review all notices submitted under TSCA section 5(a)(1) and make a determination pertaining to the risks of new chemical substances or significant new uses of chemical substances described in such notices before they can proceed to the marketplace. Before the 2016 Lautenberg Amendments, TSCA allowed the PMN or SNUN submitter to commence manufacturing or processing upon expiration of the review period unless EPA made an affirmative finding of unreasonable risk. Under amended TSCA, EPA must review all notices submitted under TSCA section 5(a)(1) and make a determination pertaining to the risks of every new chemical substance or significant new use of a chemical substance described in such notices before they can proceed to the marketplace. To reflect and better meet these requirements, EPA is amending the procedural regulations codified at 40 CFR parts 720, 721, and 725 and making additional updates based on existing policies or lessons learned from administering the New Chemicals Program since TSCA was amended in 2016.

EPA is also finalizing amendments that will clarify the information that is required to be included in PMNs, SNUNs, and exemption notices to reduce the need to redo all or part of the risk assessment (''rework'') due to late submissions of information. This action is expected to reduce rework of risk assessments by minimizing requests from submitters to amend their PMNs, SNUNs, or exemption notices with additional information after the review period has commenced. The Agency is also finalizing amendments to make clear the procedures that will be employed if submitters amend their PMNs or SNUNs during the applicable review period.

EPA is amending the regulations for LVEs and LoREXs so that submitters may not commence manufacture until EPA has issued a decision for the exemption notice, to better ensure that manufacture under LVEs and LoREXs will not present an unreasonable risk. Additionally, EPA is promulgating amendments that allow the Agency to notify submitters if a chemical substance for which they hold an LVE or LoREX is or becomes subject to a proposed or final SNUR and the chemical identity is confidential, so that chemical manufacturers are made aware that they may be subject to additional TSCA requirements. EPA is also finalizing amendments to make PFAS categorically ineligible for an LVE or LoREX, which would ensure that all new PFAS are reviewed through the full PMN process. In addition, EPA is making certain PBTs ineligible for these exemptions, to better manage risks associated with PBT chemical substances that have anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms.

Lastly, EPA is promulgating amendments that will allow informal (oral or e-mail) requests for review period suspensions of up to 30 days to reduce the number of repeated requests for 15-day suspensions, because EPA believes that e-mail may be more expedient than oral communication for many submitters.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the costs and benefits of this rulemaking and provided an Economic Analysis (EA) of the potential impacts associated with this rule, titled ''Economic Analysis for the Final Rule: Updates to New Chemicals Regulations under the Toxic Substances Control Act'' (Ref. 1), which is available in the docket and briefly summarized here. The benefits of the rule include increased efficiency in both the submission and review processes for notices submitted through the PMN form. The changes under this rule would clarify the information requirements on the PMN form in the Agency's Central Data Exchange (CDX) to make more transparent the level of detail that EPA needs in order to make

a reasoned evaluation. As submitters provide more complete information in their initial submissions, the changes under this rule are expected to reduce the frequency with which PMNs, SNUNs, and exemption notices are amended with additional information and the amount of rework of risk assessments that the Agency conducts following such amendments.

In addition, the more detailed and comprehensive 90-day review afforded to PMNs allows EPA to make a more informed hazard determination for PFAS, leading to improvement in the expected outcome of these decisions. More informed decision making about a PFAS's potential risks is likely to result in a reduction in the cost of risk-based decision making about the PFAS, and an improvement in the expected outcome of the decisions.

As a result of the changes presented in this rule, the total annual burden to industry is expected to decrease by approximately 4,528 hours, while total annual costs to industry submitters are expected to have a net increase of approximately $203,150. The Agency is expected to experience an annual cost savings of approximately $1,117,132.

II. Background

A. What did EPA propose?

On May 26, 2023 (88 FR 34100; FRL–7906–01–OCSPP), EPA proposed amendments intended to align the regulatory text with the amendments to TSCA's new chemicals review provisions contained in the 2016 Lautenberg Amendments, to improve the efficiency of EPA's review processes, and update the regulations based on existing policies and experience implementing the New Chemicals Program. Additionally, the proposal included amendments that would reduce the need to redo all or part of a risk assessment by improving information initially submitted in new chemicals notices, which should also help reduce the length of time that new chemicals notices are under review. EPA also proposed several amendments to the regulations for LVEs and LoREXs, which included requiring EPA approval of an exemption notice prior to commencement of manufacture, making PFAS categorically ineligible for these exemptions, and providing that certain PBT chemical substances would be made ineligible for these exemptions, consistent with EPA's 1999 PBT policy. Lastly, the proposal included amendments related to the suspension of the review period.

B. How did the 2016 Lautenberg Amendments change TSCA section 5?

As enacted in 1976, TSCA provided EPA with authority to require reporting, recordkeeping, and testing, and to issue restrictions relating to chemical substances and/or mixtures. TSCA section 5(a)(1) required that a person submit to EPA a notice at least 90 days before commencing manufacture of a new chemical substance or manufacture or processing of a chemical substance for a use which EPA determined to be a significant new use. Under the 1976 law, EPA was not obligated to make a determination or finding regarding unreasonable risk for each notice submitted under TSCA section 5(a)(1). EPA's obligations with respect to making determinations on notices submitted under TSCA section 5(a)(1) fundamentally changed with the passage of the 2016 Lautenberg Amendments. The 2016 Lautenberg Amendments added a new paragraph to TSCA at section 5(a)(3) titled ''Review and Determination,'' under which EPA must review and make one of five determinations pertaining to the likelihood of risk on all notices received under TSCA section 5(a)(1), which include PMNs, SNUNs and MCANs, within the applicable review period. EPA's obligation to take action after making a determination on a notice submitted under TSCA section 5(a)(1) also changed with the passage of the 2016 Lautenberg Amendments.

The 2016 Lautenberg Amendments require EPA to review each notice submitted under TSCA section 5(a)(1), make a determination on that notice, and take the action required in association with that determination within the applicable review period. Under TSCA section 5(i)(3), the ''applicable review period'' means 90 days from the date EPA receives a notice under TSCA section 5(a)(1), or up to 180 days from that date if EPA extends the applicable review period according to the provisions in TSCA section 5(c). The 2016 Lautenberg Amendments also added a new paragraph at TSCA section 5(a)(4) explaining that a failure by EPA to render a determination within the applicable review period would not relieve EPA of any requirement to make such determination, but would, with certain exceptions, result in a fee refund to the notice submitter.

TSCA section 5(h) was not significantly amended by the 2016 Lautenberg Amendments. TSCA section 5(h) provides EPA the authority to exempt a person from certain TSCA section 5 requirements under certain situations. EPA developed the current LVE and LoREX regulations in 1995 pursuant to TSCA section 5(h)(4) (60 FR 16336, March 29, 1995). See Unit II. of the May 26, 2023, proposed rule (88 FR 34100) for further discussion of the 2016 Lautenberg Amendments.

C. How are the new chemicals regulations structured?

EPA's regulations related to TSCA section 5 are codified in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR). They include:

- Regulations pertaining to PMNs, which are codified at 40 CFR part 720;
- Regulations pertaining to SNUNs, which are codified at 40 CFR part 721;
- Regulations pertaining to certain exemptions, which are codified at 40 CFR part 723; and
- Regulations pertaining to MCANs and microorganism-related exemptions, which are codified at 40 CFR part 725.

The information requirements codified for PMNs in 40 CFR 720.45 generally also apply to SNUNs under 40 CFR part 721 (see 40 CFR 721.1(c) and 721.25(a), which cross-reference 40 CFR part 720) and to LVEs and LoREXs submitted under 40 CFR 723.50 (see 40 CFR 723.50(e)(2), which cross-references 40 CFR 720.45). As a result, the amendments to the requirements in 40 CFR 720.45 apply to PMNs and also to SNUNs, LVEs, and LoREXs. The review procedures for PMNs codified in 40 CFR part 720 generally also apply to SNUNs under 40 CFR part 721 (see 40 CFR 721.25(c)) but not to exemptions under 40 CFR part 723, so the amendments to the part 720 review procedures promulgated by this action apply to PMNs and SNUNs but not to such exemptions. Neither the information requirements nor the review procedures in 40 CFR part 720 apply to MCANs or microorganism-related exemptions under 40 CFR part 725, so EPA is also finalizing certain amendments to the MCAN and microorganism-related exemption regulations at 40 CFR part 725.

D. Did EPA receive public comments on the proposed rule?

EPA received 51 public comments on the proposed rule. Commenters included potentially affected businesses, trade associations, environmental and public health advocacy groups, unions, and other Federal agencies. In this preamble, EPA has responded to many of the significant comments on the proposed rule; however, the more comprehensive version of EPA's response to comments for this rulemaking can be found in the Response to Comments document (Ref.

2). The Response to Comments document summarizes all the comments relevant to the proposal and EPA's response to those comments. In the Response to Comments document, EPA also discusses any changes to and clarifications from the proposed rule made in this final rule.

III. Overview of the Final Rule

This final rule is based on the May 26, 2023, proposed rule (88 FR 34100) and in consideration of the public comments received on the proposed rule.

A. Amendments To Conform Regulations to 2016 Lautenberg Amendments

EPA is amending the PMN procedural regulations at 40 CFR part 720 to align them with the notice review and determination requirements in TSCA section 5, as amended by the 2016 Lautenberg Amendments. These procedural regulations also generally apply to SNUNs under 40 CFR part 721 (see 40 CFR 721.1(c) and 721.25(c)). EPA is also promulgating similar changes to the MCAN procedural regulations at 40 CFR part 725 to align them with the same notice review and determination requirements added by the 2016 Lautenberg Amendments. EPA has been implementing the amended statutory requirements but, prior to this rulemaking, had not yet codified these updates into the new chemicals procedural regulations. The amendments specify that EPA must make a determination on each PMN, SNUN, and MCAN received before the submitter may commence manufacturing (which includes importing) or processing and lists the five possible determinations and the actions required in association with those determinations. EPA is also adding definitions for new terms and to update existing terminology introduced by the 2016 Lautenberg Amendments.

1. Commencement of Manufacture or Processing

As proposed, EPA is finalizing amendments at 40 CFR 720.75(d) by removing outdated language allowing the submitter to commence manufacture of a chemical substance when the review period expires and adding new language specifying that EPA must issue a determination and take any required action on each PMN before manufacture may commence. EPA is also finalizing an amendment to 40 CFR 721.25(d) to state that any person submitting a SNUN shall not manufacture or process a chemical substance for a significant new use until EPA has issued a determination with respect to the significant new use and taken the actions required in association with that determination. Likewise, EPA is finalizing an amendment at 40 CFR 725.170(b) and (c) by removing similar outdated language allowing the submitter to commence manufacture of a new microorganism or manufacture or processing of a microorganism for a significant new use when the review period expires and adding new language specifying that EPA must issue a determination and take any required action on each MCAN before manufacture or processing may commence.

Some comments on the proposal challenged the EPA's description of how the New Chemicals Program operated prior to the passage of the 2016 Lautenberg Amendments and suggested that the 2016 Lautenberg Amendments had only minor impacts on the Program. EPA disagrees with these comments, as prior to the 2016 Lautenberg Amendments, EPA was not required to conduct a review of and issue a determination for every notice. Following the 2016 Lautenberg Amendments, EPA must review all notices submitted under TSCA section 5(a)(1) and make a determination pertaining to the risks of a new chemical or significant new use of an existing chemical before it is allowed into the marketplace. For a detailed response to these and other comments, please see the Response to Comments document (Ref. 2).

2. Required Determinations and Associated Actions

As proposed, EPA is finalizing amendments at 40 CFR 720.75(d) and 725.170 by listing the five possible determinations that EPA must make for each PMN, SNUN, or MCAN it receives. EPA is also finalizing amendments to 40 CFR 720.75(d) and 725.170(b) to describe the actions that EPA must take in association with its determination for a PMN, SNUN, or MCAN. EPA is codifying those actions, which EPA has been implementing, as applicable, for every PMN, SNUN, and MCAN since the 2016 Lautenberg Amendments, to be clear about EPA's review process to the public.

After EPA issues an order under TSCA section 5(e) or (f) and the applicable review period concludes, the submitter may submit studies, tests, reports, or other additional information. If EPA concludes from an assessment of the additional information that one or more of the prohibitions or limitations contained in the order are no longer necessary to protect against an unreasonable risk of injury to health or the environment, EPA may modify or revoke the prohibitions or limitations of the order. If EPA determines that none of the order terms are warranted after assessment of the additional information, EPA may revoke all the requirements of the order.

Several comments on the proposed rule asserted that EPA not only has the authority to revoke or lessen restrictions in an order after it has been issued, but also can and must strengthen protections in an order based on new information received on a chemical substance that demonstrates the order is insufficient to protect against unreasonable risk. The commenters further urged EPA to clarify that an order may be modified based on new information obtained from any source, not solely the submitter. EPA agrees with these commenters and a detailed response is available in the Response to Comments document (Ref. 2). Upon consideration of these comments, EPA is modifying the proposed amendments at 40 CFR 720.75(d)(3) and 725.170(b)(3) to clarify that new information may be received from any source, and to add that where such information demonstrates that the prohibitions or limitations of the order are not sufficient to protect against an unreasonable risk of injury to health or the environment, EPA may modify the order or take other action, as appropriate, to the extent necessary to protect against such risk.

3. Other Updates

As proposed, EPA is finalizing amendments to the regulation that will replace the undefined terms ''notice period,'' ''notification period,'' ''statutory review period,'' and ''notice review period'' with the term ''applicable review period'' throughout 40 CFR part 720 to conform to the new terminology in TSCA section 5 added by the 2016 Lautenberg Amendments. EPA is also finalizing an amendment to add, as proposed, a definition for ''applicable review period'' to 40 CFR 720.3, which EPA would define as the period starting on the date EPA receives a complete notice under section 5(a)(1) of the Act and ending 90 days after that date or on such date as is provided for in sections 5(b)(1) or 5(c) of the Act. In response to the proposed amendment adding a definition for ''applicable review period,'' commenters expressed difficulty in determining what EPA considers to be a complete notice and requested that the Agency clearly define what constitutes a notice that is ''complete.'' EPA considers a complete notice to be a notice that meets all the procedural requirements indicated in 720.65(c)(1) (*e.g.* a notice that includes

a company signature, is submitted via CDX, includes a second copy of the submission with all confidential information deleted, includes the payment identity number, etc.) and includes all required information that is known to or reasonably ascertainable by the submitter, as described in 720.45 and 720.50. A submission that fails to meet the statutory information requirements is incomplete, and EPA is justified in refusing to review the notice until the information is received. In the Response to Comments document (Ref. 2), EPA discusses in more detail the longstanding definition of ''known to or reasonably ascertainable by'' and its application in specific contexts.

After considering the comments, EPA is finalizing an amendment to add a definition for ''potentially exposed or susceptible subpopulation'' (PESS) to 40 CFR 720.3. For this rule, EPA is defining ''potentially exposed or susceptible subpopulation'' as proposed and using the same definition that was proposed and finalized as part of the rulemaking entitled ''Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act (TSCA)'' (89 FR 37028, May 3, 2024 (FRL–8529–02–OCSPP)).

As a primary matter, the inclusion of ''overburdened communities'' in the list of example subpopulations in this definition is not itself a determination. Rather, it is an example of a subpopulation that EPA may identify as a PESS in future risk assessments, and it is reflective of the reality that, in addition to groups like children and pregnant women, there are communities of people that may experience disproportionate environmental risks from chemicals due to greater exposure or susceptibility to environmental and health harms.

EPA proposed to add a regulatory definition of PESS that includes the term ''overburdened communities'' in the list of example subpopulations. This term, which is an addition to the examples provided in the statutory definition of PESS at TSCA section 3(12), reflects the Agency's understanding and acknowledgment that a chemical substance may disproportionately expose and/or may disproportionately impact communities already experiencing disproportionate and adverse human health or environmental burdens. Such disproportionality can be as a result of greater exposure or vulnerability to environmental hazards, lack of opportunity for public participation, or other factors. Increased exposure or vulnerability may be attributable to an accumulation of negative or lack of positive environmental, health, economic, or social conditions within these populations or places. The term describes situations where multiple factors, including both environmental and socio-economic stressors, may act cumulatively to impact health and the environment and contribute to persistent environmental health disparities. These situations may apply to communities with environmental justice concerns.

While some commenters on the proposed rule objected to the inclusion of ''overburdened communities,'' EPA believes that it is appropriate to include ''overburdened communities'' as an example subpopulation in the definition of PESS. Congress' inclusion of ''such as'' in the statutory definition provides EPA with clear discretion to go beyond the statute's list of examples. EPA further disagrees that this addition is substantively changing the criteria for identification of PESS (i.e., greater exposure or susceptibility and greater risk than general population).

EPA does not believe it is necessary to define ''overburdened communities'' as part of this rule. In the same way that EPA considers whether children or workers or the elderly are a PESS in the context of a specific risk assessment, EPA will look to whether ''overburdened communities'' may become subject to exposure or could be more susceptible than the general population. EPA does not intend for this term to be confined to a location or geographic proximity but would use reasonably available information for each new chemical substance or significant new use to determine the inclusion of specific communities. Those who could potentially experience ''greater exposure'' could include individuals or communities that would experience higher levels of exposure to a chemical substance due to geography (e.g., fenceline communities in close proximity to facilities that could emit air pollutants or living near potential effluent releases to water), unique exposure pathways that differ from those of the general population (e.g., Tribal communities where reliance on subsistence fishing may result in increased exposure via ingestion), and/or aggregate exposure via multiple conditions of use (e.g., a worker potentially exposed to the chemical substance who also lives in close proximity to the facility that may also release the chemical substance through air emissions).

In making these additions to 40 CFR 720.3, EPA is also revising the overall format used to list the definitions in 40 CFR 720.3, by removing the designations for each definition and adopting the alphabetical listing approach consistent with the recommendation of the Office of the Federal Register (OFR). See page 2–27 of the OFR's Document Drafting Handbook, August 2018 Edition (Revision 2.1, dated October 2023), *https://www.archives.gov/federal-register/write/ddh/*. Specifically, EPA is using the revise and republish instructions in the regulatory text of this final rule to reflect the addition of the two definitions and the adoption of the recommended undesignated alphabetical listing format for this definition section. This change also requires corresponding technical corrections to the citation in several other regulations. The existing definitions and these other regulations are otherwise unchanged. Conforming edits to remove the designations for the definitions in 40 CFR 720.3 are being made to 40 CFR 68.115, 372.38, 703.3, and 761.3.

EPA is also promulgating an update to 40 CFR 720.70(b) by revising paragraph (b)(3). Some commenters opposed EPA's proposal to remove the regulatory-only requirement in 40 CFR 720.70(b)(3) to publish a list of test data submitted in accordance with 40 CFR 720.50(a) in the TSCA section 5(d)(2) notice of receipt. EPA disagrees with these comments. As EPA explained in the preamble to the proposed rule (88 FR 34100, May 26, 2023), the Agency believes that its objective of providing such information to the public is now better achieved through ChemView than through publication in the **Federal Register.** Through ChemView, the Agency currently makes the section 5 notice, including test data submitted with it, publicly available generally within 5 business days of receipt, subject to confidentiality protections. EPA is finalizing the change to 720.70(b)(3) as proposed. For additional response to the comments received on the amendments to 40 CFR 720.70(b)(3), see the Response to Comments document (Ref. 2).

B. Amendments Related to Notice Information Requirements

EPA is promulgating amendments to the notice information requirements at 40 CFR 720.45, as well as corresponding changes to the PMN form in CDX, to clarify the level of detail expected for information that must be submitted to EPA in PMN, SNUN, and certain exemption notices. EPA is finalizing these amendments largely as proposed, with most changes representing minor clarifications to the proposed regulatory text in response to the comments.

1. Background

A notice submitted under TSCA section 5(a)(1) must include the information described in TSCA section 5(d)(1): (1) insofar as known to the submitter or reasonably ascertainable, information described in certain provisions of TSCA section 8(a)(2); (2) in the form and manner prescribed by EPA, information in the possession or control of the submitter related to the health or environmental effects of any manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or any article containing such substance; and (3) a description of any other information concerning the environmental and health effects of the chemical substance, insofar as known to the submitter or reasonably ascertainable. EPA has promulgated regulations detailing these information requirements in 40 CFR 720.45 and 720.50.

EPA has developed an application form in CDX to collect such information from submitters. The user guide for CDX is listed in the references section of this final rule and can be found in the docket (Ref. 3). This form is prescribed by EPA for submission of PMNs, SNUNs, LVEs, LoREXs, and test marketing exemption (TME) applications. In this preamble, EPA refers to the form as the ''PMN form'' for simplicity, but the changes outlined in this section would impact the other types of notices that use the same form (*i.e.,* PMNs, SNUNs, LVEs, LoREXs, and TMEs).

EPA has observed that most section 5 notices do not contain all required information at the level of detail that EPA needs to perform refined risk assessments. As described in the preamble of the proposed rule, these deficiencies frequently result in EPA using conservative assumptions in its risk assessments due to lack of available data, which can create delays in the timeline for case completion, particularly when submitters provide information to EPA late in a case's review in response to risk estimates stemming from the lack of available data. In recent years, EPA has issued guidance documents (Ref. 3 and 4), established pre-screen processes for incoming cases, and conducted outreach efforts (Ref. 5) to make clearer to submitters the level of detail necessary for timely review of their chemicals, as well as to minimize the need for costly rework of case assessment materials. EPA believes that amending the notice information requirements at 40 CFR 720.45 to specify the level of detail needed, as well as building that additional detail into the CDX user interface, will help submitters provide more detailed section 5 notices and help to minimize the need for EPA to use default values and conservative assumptions in its risk assessments due to the lack of available data. Therefore, EPA is finalizing the amendments to the notice information requirements at 40 CFR 720.45 as well as the corresponding changes to the PMN form in CDX largely as described in the proposed rule.

2. Changes to 40 CFR 720.45, 40 CFR 720.50, and the PMN Form

EPA is amending 40 CFR 720.45 and the PMN form in CDX to clarify the information requirements for a notice. Specifically, EPA is adding details to certain information requirements already contained in 40 CFR 720.45. EPA is also adding additional reporting fields to the PMN form to reflect these details. In this action, EPA is adding these details as separate, unique information requirements in 40 CFR 720.45 and making corresponding changes to the PMN form to clarify the level of detail needed for EPA's review of section 5 notices and to ensure that the fields in the PMN form are consistent with the regulations. In some cases, information requested in the PMN form is not clearly required in the 720.45 regulations, so EPA is adding those details to 40 CFR 720.45 to ensure that the regulations and PMN form are as consistent as possible. Although EPA is finalizing these amendments largely as they were described in the proposed rule, changes, mostly to improve clarity, have been made to some amendments in response to comments received by EPA. In response to comments, EPA is also finalizing additional amendments to the regulations at 720.45 and 720.50, as well as to the PMN form in CDX, that further add clarity and better align the PMN form with the regulations. See Ref. 6, which includes tables that detail the changes that are being made to 40 CFR 720.45, 720.50, and the CDX interface per this final rule. Additionally, EPA has amended 40 CFR 723.50(e) to update a cross-reference to 40 CFR 720.45 based on the amendments made in this rule.

Consistent with TSCA section 5(d)(1), for all information requirements under 40 CFR 720.45, submitters are only required to provide information to the extent that it is known to or reasonably ascertainable by the submitter, as defined at 40 CFR 720.3. Under the amendments to 40 CFR 720.45, a submitter is required to include in the PMN form the detailed information finalized in this action, along with all other information already required, to the extent the information is known to or reasonably ascertainable by the submitter. This is an important point because a submitter may not know or be able to reasonably ascertain certain details about the chemical substance that is the subject of the notice, such as details about manufacturing, processing, or use sites not controlled by the submitter. In those situations, EPA will make conservative assumptions and use default values for any information that is not known to or reasonably ascertainable by the submitter and therefore not provided in the PMN form.

Based on a public comment, EPA is adding language to 720.50(c) to clarify that submitters can submit additional information not otherwise required by 720.50(a)–(b) to facilitate EPA's review of the notice.

a. Physical and Chemical Properties and Environmental Fate Characteristics

The first set of detailed information requirements that EPA is adding to 40 CFR 720.45 concerns the physical and chemical properties and environmental fate characteristics of the chemical substance (see Table 1 in Ref. 6). Currently, if submitters have physical-chemical or environmental fate test data, they must provide the test data or a standard literature citation in accordance with 720.50(a)(2)–(3). EPA collects physical and chemical properties test data required by 40 CFR 720.50, ''Submission of test data and other data concerning the health and environmental effects of a substance,'' in two ways. First, the CDX user interface prompts the submitter to attach relevant documents, such as test data, to the PMN form using an attachment function. Second, the PMN form includes a CDX user interface screen with form fields for physical and chemical properties available for completion via a pick list. Data provided in the PMN form via CDX may be pulled from the test data provided by submitters per 720.50(a)(2)–(3), or the data can be submitted as standalone information for which submitters do not have underlying test data. EPA believes that the information requirements in 40 CFR 720.45 should reflect the PMN form fields. EPA is therefore adding relevant physical and chemical properties information requirements in a new provision at 40 CFR 720.45(j)(1) that are already specified within the PMN form. Submitters must submit physical-chemical and environmental fate information in the corresponding PMN form fields in accordance with new paragraph 720.45(j), which is added as described in the proposed rule.

EPA is also adding several information requirements to 40 CFR 720.45(j)(1) that are not already specified within the PMN form for physical and chemical properties. Specifically, EPA is requiring that data on surface tension and ultraviolet–visible (UV–VIS) absorption, as well as any particle size distribution analysis, be submitted as part of the PMN form, to the extent it is known to or reasonably ascertainable by the submitter. One commenter requested that EPA clarify the language outlined in the proposed rule for the particle size distribution analysis data requirement to make it clear that it includes both the analysis method as well as any data used to develop the particle size distribution value, a suggestion that EPA is incorporating in this final rule. Two commenters requested that EPA include several amendments to the nanomaterial morphology requirements outlined in the proposed rule, recommendations that EPA considers to be overly prescriptive and as such is declining to finalize. Additionally, after considering these comments, EPA anticipates that the proposed requirements at 40 CFR 720.45(j)(1) for information on aspect ratio, thickness, and number of layers or walls for nanomaterials are likely to be applicable only to a narrow subset of nanomaterials. Because this information would not be relevant to most nanomaterials, EPA will not include the proposed nanomaterial data requirements in the final regulations. For all other amendments to 40 CFR 720.45(j), as was proposed in the May 2023 proposed rule, EPA will also add fields for attaching associated data on the physical and chemical properties screen of the PMN form.

As proposed, EPA is also adding information requirements for the environmental fate characteristics of the chemical substance (see Table 1 in Ref. 6) to 40 CFR 720.45(j)(2). Environmental fate characteristics test data are already required by 40 CFR 720.50; however, this provision does not describe in detail what these relevant characteristics include. In addition, this information is already collected by EPA as attachments to the PMN form; however, fields for environmental fate characteristics are not yet included on the CDX user interface screen pick list. EPA is thus adding the relevant environmental fate characteristics to the information requirements at 40 CFR 720.45(j)(2) and form fields to the PMN form by expanding the pick list.

b. Categories of Use

The next set of changes that EPA is finalizing at 40 CFR 720.45 relates to the categories of use of the chemical substance (see Table 2 in Ref. 6). The requirements being finalized include detailed information on commercial and consumer uses, which already have form fields in the PMN form in CDX. Although the regulations at 40 CFR 720.45(f) previously required 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, certain details on commercial and consumer uses were not specified. The added information requirements include the types of products or articles that would incorporate the new chemical substance (*e.g.,* household cleaners, plastic articles), how and where a product or article incorporating the new chemical substance would be used (*e.g.,* spray applied indoors, brushed on outdoor surfaces), consumption rates and frequency and duration of use for products or articles containing the new chemical substance, and information related to the use of products or articles containing the new chemical substance by potentially exposed or susceptible subpopulations. Additionally, EPA is finalizing at 40 CFR 720.45(f) a requirement to designate applicable consumer and commercial product categories using Organization for Economic Co-operation and Development (OECD)-based functional use codes, which would create consistency with TSCA section 8(a) Chemical Data Reporting (CDR) requirements in 40 CFR part 711. EPA is finalizing corresponding changes to the PMN form fields in CDX for this data element. EPA is also finalizing amendments to 40 CFR 721.25 to ensure that submitters of SNUNs include in their notice both a description of the intended categories of use, as required by 40 CFR 720.45(f)(1), and of all known categories of use, to the extent known to or reasonably ascertainable by the submitter. Such categories of use may include uses that are ongoing and not subject to a significant new use rule (SNUR). Such information is valuable for EPA in determining necessary regulatory action should potential risks be identified during review of a SNUN. In the final rule, this provision appears in a new paragraph (e) of 40 CFR 721.25 rather than as an addition to paragraph (c), and the text was rephrased slightly for clarification. One commenter requested that EPA include a provision at 40 CFR 720.45(f) that would require submitters with chemicals having more than 10 intended uses to designate codes only for the 10 uses that represent the largest proportion of the anticipated production volume of the chemical, a suggestion that EPA is finalizing. EPA, however, will still require submitters to identify in the free form text field of the PMN form all intended or known uses of the chemical substance.

c. Details Concerning Manufacture, Processing, and Use

The third set of information requirements that EPA is finalizing at 40 CFR 720.45 is information related to where and how the chemical substance will be manufactured, processed, or used. These requirements apply to sites controlled by submitters as well as sites controlled by others, and although the information requirements that EPA is finalizing are similar for both, different types of activities often occur at submitter-controlled sites versus those at sites controlled by others (*e.g.,* manufacturing versus processing). Moreover, activities at sites controlled by others are typically not as well characterized by submitters compared to descriptions of the submitters' own activities, since in many cases the identity and number of sites controlled by others is unknown to and not reasonably ascertainable by the submitters when a notice is submitted. As such, some slight differences exist in the requirements EPA is finalizing for information related to sites controlled by submitters versus sites controlled by others. See Ref. 6 for more details.

Both for sites controlled by submitters and for sites controlled by others, EPA is adding information requirements for site addresses (see Table 3 and Table 5 in Ref. 6). For submitter-controlled sites, EPA is also adding requirements for a description of whether a particular chemical substance is manufactured or processed via batch or continuous production, as well as the amount of the chemical substance manufactured or processed in each batch and/or timeframe (see Tables 3, 4, and 5 in Ref. 6). These information requirements already have a corresponding form field in the PMN form in CDX because they are each covered by the existing information requirements in 40 CFR 720.45(g)(1) and (2) and (h) for a process description of operations at such sites. Since these information requirements were not specified in the regulations, EPA is finalizing them at 40 CFR 720.45(g)(1) and (2) for sites controlled by the submitter and 40 CFR

720.45(h)(1) and (2) for sites not controlled by the submitter.

EPA is also adding requirements for detailed information about the process diagram or description for each site controlled by the submitter (see Table 4 in Ref. 6) and for each site not controlled by the submitter (see Table 5 in Ref. 6). These data elements were previously required but not expressly included in the list of required data elements in 40 CFR 720.45. They include descriptions of the identity, approximate weight per batch or per day for continuous production, and entry point of all starting materials and feedstocks; the identity, approximate weight per batch or per day for continuous production, and entry point of all products, recycle streams, and wastes, including frequency of any equipment cleaning; the type of containers used for interim storage and transport of the chemical substance; and identification, by number, of any points of release. EPA is finalizing requirements for this information at 40 CFR 720.45(g)(2) and (h)(2) and in new fields in the PMN form to clarify the level of detail needed and to ensure that the regulations and PMN form are consistent.

One commenter noted that an existing data requirement related to manufacturing, processing, use, and disposal of chemical substances subject to section 5 notification is ambiguous in its scope. 40 CFR 720.45(d) requires submitters to describe any byproducts resulting from the manufacture, processing, use, and disposal of a chemical substance, and the commenter requested that EPA clarify whether its definition of byproduct includes ''degradation products''. In the Response to Comments document (Ref. 2), EPA notes that byproducts are distinct from degradants and that information on degradants is required under the information requirements outlined in 720.45(j)(2).

d. Worker Exposure

EPA is also finalizing requirements for details about the possible worker exposures at each site controlled by the submitter (see Table 6 in Ref. 6), and at each site not controlled by the submitter (see Table 7 in Ref. 6). These requirements include types of potential worker exposure (*e.g.,* dermal, inhalation), descriptions of any protective equipment and engineering controls in place, the moisture content of the chemical substance (if a solid), and the percentage of the chemical substance in the formulation at the time of exposure. In addition, for sites controlled by others, these requirements also include worker activities and descriptions of the physical form of the chemical substance (consistent with information requirements for sites controlled by the submitter). Although these details are already covered by the existing information requirements in 40 CFR 720.45(g)(3) and (h) regarding worker exposure information, and some already have a corresponding form field in the PMN form in CDX, EPA is finalizing them as separate, unique information requirements at 40 CFR 720.45(g)(3) and (h)(3) and in new fields in the PMN form to clarify the level of detail needed and to ensure that the regulations and PMN form are consistent. One commenter requested that EPA revise the proposed text at 40 CFR 720.45(g)(3) and (h)(3) to clarify that the worker exposure information required in 40 CFR 720.45(g)(3)(ii)-(viii) and (h)(3)(ii)-(viii) pertains to each worker activity occurring during the manufacturing, processing, and use of the chemical substance, as identified pursuant to 720.45(g)(3)(i) and 720.45(h)(3)(i). EPA has incorporated this suggestion in the final rule because it provides additional clarity to submitters.

Several commenters made requests related to worker exposure that, if accepted by EPA, would affect the structure of and level of detail contained in the PMN form in CDX. For example, one commenter requested that EPA allow submitters to assign a ''Letter of Activity'' (a field in CDX to link specific worker activities to operations described in the corresponding manufacturing diagram) to activities at submitter-controlled sites; the option to assign a Letter of Activity already exists for activities at sites controlled by others. Another commenter requested that EPA include in the PMN form dropdown options for ''Worker Activity'' and ''Worker Category'' for sites controlled by others—dropdown options that currently exist for submitter-controlled sites in the PMN form. EPA is finalizing all of the aforementioned suggestions by making corresponding changes to the CDX interface. EPA, however, also received several additional suggestions related to worker exposures that EPA is choosing not to adopt. More information on the comments received relating to worker exposure and EPA's responses can be found in the Response to Comments document (Ref. 2).

Additionally, EPA is finalizing proposed amendments to 40 CFR 720.45(g)(3) and (h)(3) to ensure that submitters include worker exposure information from exempt manufacture or related use of the chemical substance under 40 CFR 720.30 (*e.g.,* manufacture of the chemical substance under the byproduct or impurity exemptions) at each site where the chemical substance will be manufactured, processed, or used, if known or reasonably ascertainable. However, to avoid any confusion occasioned by the abbreviated, non-exhaustive list of exemption examples that appeared in a parenthetical in the proposed regulatory text, the final rule does not include the proposed parenthetical and streamlines the text by simply cross-referencing 40 CFR 720.30.

e. Environmental Releases

EPA is finalizing information requirements concerning the potential environmental releases at each site controlled by the submitter (see Table 8 in Ref. 6) and at each site not controlled by the submitter (see Table 9 in Ref. 6). EPA is requiring descriptions of the type of release (*e.g.,* transport, interim storage, disposal, equipment cleaning), as well as the amount of the chemical substance released directly to the environment or into a control technology. EPA is finalizing an amendment to require a description of the amount of the chemical substance released to the environment after use of a control technology. EPA is also requiring for equipment cleaning releases a description of the frequency of equipment cleaning and what is used to clean equipment. EPA is also requiring for transport and storage releases a description of how the chemical substance or the product containing the chemical substance is transported from the site and stored, as well as information about the containers used. For releases into air, EPA is requiring Clean Air Act operating permit numbers and a description of any Leak Detection and Repair program the site has implemented; one commenter requested that EPA amend the language for this data element to require a description of the type of control technology used to treat stack air releases, which EPA is finalizing. For releases into water, EPA is requiring National Pollutant Discharge Elimination System (NPDES) permit numbers and information on the waterbodies and other destinations into which the release occurs; one commenter requested that EPA also require a description of any outfall numbers associated with the known points of release associated with the NPDES permit number(s), a suggestion that EPA is finalizing. For releases into wastewater treatment plants, EPA is requiring information on the publicly owned treatment works (POTW) into which the release occurs. For the

requirement concerning information on POTW, one commenter requested that EPA amend this data requirement to also specifically request information concerning privately owned treatment works to which releases might occur, the type of wastewater technology employed at any treatment facilities, and the known or estimated treatment efficiency at these facilities—all of which are suggestions that EPA is finalizing. In addition, for sites controlled by others, these requirements also include a description of the media of release consistent with the requirement for sites controlled by the submitter.

Although each of these detailed data elements are already covered by the existing information requirements in 40 CFR 720.45(g)(4) and (h) regarding environmental releases, and some already have a corresponding form field in the PMN form in CDX, EPA is finalizing them as separate, unique information requirements at 40 CFR 720.45(g)(4) and (h)(4) and in new fields in the PMN form to clarify the level of detail needed and to ensure that the regulations and PMN form are consistent.

EPA is finalizing amendments to 40 CFR 720.45(g) and (h) to make their formatting and the information required in both consistent. EPA recognizes that a submitter may not possess such information about sites not controlled by the submitter. As mentioned elsewhere in this preamble and in the Response to Comments document (Ref. 2), submitters are only required to supply information that is known to or reasonably ascertainable by them, as defined at 40 CFR 720.3.

Additionally, EPA is finalizing amendments to 40 CFR 720.45(g)(4) and 720.45(h)(4) to ensure that submitters include environmental release information from exempt manufacture or related use of the chemical substances under 40 CFR 720.30 (*e.g.,* manufacture of the chemical substance under the byproduct or impurity exemptions) at each site where the chemical substance will be manufactured, processed, or used, if known or reasonably ascertainable. However, to avoid any confusion occasioned by the abbreviated, non-exhaustive list of exemption examples that appeared in a parenthetical in the proposed regulatory text, the final rule does not include the proposed parenthetical and streamlines the text by simply cross-referencing 40 CFR 720.30.

f. Pollution Prevention Information

Lastly, EPA is adding optional pollution prevention information at 40 CFR 720.45(k) as proposed. The PMN form in CDX currently includes an optional text field and attachment function for submitters who wish to provide pollution prevention information about the chemical substance, such as information about using alternative fuel sources, reducing the use of water and chemical inputs, modifying a production process to produce less waste, implementing water and energy conservation practices, or substituting for riskier existing products.

3. Other Modifications to the PMN Form in CDX

In addition to the amendments intended to clarify the information requirements for a notice and the corresponding changes to the PMN form in CDX outlined in Unit III.B.1. and 2., EPA is also adding statements with accompanying check boxes to certain screens of the PMN form (such as when transitioning between the various worksheets completed by the submitter) that indicate that information fields can only be left blank if such information is not known to or reasonably ascertainable by the submitter. Additionally, a statement would warn the submitter of the potential consequences of leaving the field blank and later amending the field. If a field is left blank, EPA generally follows the scientifically informed approach to make conservative assumptions and use appropriate default values when assessing risk, which could result in more stringent risk management requirements than might be directed if data were provided showing such assumptions or default values were not necessary to use. If a field that has been left blank is later amended during the review process, EPA may declare the original submission incomplete (see Unit III.C.3. for a more detailed discussion on notice amendments indicating that the original submission was incomplete). Several commenters expressed concerns about the potential burden posed by the inclusion of these check boxes in the CDX workflow, concerns with which EPA disagrees. While the inclusion of check boxes might require submitters to spend slightly more time preparing the PMN form for their section 5 notices, EPA believes that the improved quality of submissions resulting from this, and the other changes being finalized to the CDX environment, will save submitters, as well as EPA, more time, and resources in the long run. This check box approach does not have a corresponding regulatory change, as it is consistent with the existing requirements to provide all information that is known to or reasonably ascertainable by the submitter and EPA's longstanding practice to use conservative assumptions and default values in the absence of information. The ICR document accompanying this final rule describes the potential modifications to each screen of the PMN form (Ref. 7).

Some commenters made requests related to the CDX enhancements outlined in the proposed rule that EPA is addressing in this final rule. First, two commenters requested that EPA include in the enhancements to the CDX interface an option for submitters to, if data are not provided for a particular data element, explain why this information is not known or reasonably ascertainable, a suggestion that EPA will incorporate. Another commenter requested that EPA allow submitters to access a ''beta version'' of the enhanced CDX environment before rolling out the changes to the broader CDX environment. EPA will make efforts to do so and plans to share more information with stakeholders via outreach once this final rule is published. The CDX enhancements described in this rulemaking will not be finalized upon publication or effective date of the final rule. The enhancements will take time to develop, and EPA will make the updated CDX interface reflecting these changes publicly available as soon as resources allow. However, submitters are currently able to include all information for the newly specified data elements described in this preamble and the amended regulatory text as generic attachments in the current CDX workflow. EPA will share additional guidance and conduct outreach with stakeholders prior to the rollout of the changes to CDX and will work to extend flexibility to submitters in the event that issues arise related to discrepancies between the regulations and the PMN form before the CDX enhancements can be implemented.

C. Amendments Related To Pre-Screen, Incomplete Submissions, Correcting Errors, and New Information

EPA is finalizing amendments to the regulations regarding how EPA acknowledges the receipt of a notice to account for EPA's pre-screen process and to clarify the start of the applicable review period, particularly when a notice contains errors or is incomplete. EPA is also finalizing amendments to align the process for correcting errors in

the notice with the existing process for incomplete submissions. EPA is further clarifying that an initial notice submission may later be deemed incomplete if the submitter submits additional information at any time during the review period that was known to or reasonably ascertainable by the submitter at the time of initial notice submission. Finally, EPA is promulgating amendments that clarify that new information about a chemical substance under EPA review must be submitted electronically via CDX and that certain notification to EPA of new information may be made by e-mail.

1. Pre-Screening Procedures

EPA is finalizing amendments to 40 CFR 720.65(a) to codify the pre-screen process that EPA conducts prior to moving forward to the risk assessment process. The new language would clarify, for purposes of transparency, EPA's current pre-screen practice as described in Unit III.C.1 of the proposed rule preamble. EPA is also finalizing an amendment to 40 CFR 720.70 to clarify that a notice of receipt will be published in the **Federal Register** after EPA receives a complete notice, rather than merely receiving the notice, to accommodate the pre-screening procedures. Additionally, based on public comments, EPA is amending 40 CFR 723.50(e)(3) to add a description of current pre-screen procedures and update/clarify the process for completing an incomplete LVE or LoREX notice, which will better align with similar changes made to 40 CFR 720.65 and with existing electronic submission requirements.

One comment on the proposal asserted that EPA should include in section 5 prescreen a review of all CBI claims for consistency with sections 14(b) and (c) of TSCA and treat any submission that includes a CBI claim that appears to be inconsistent with the requirements of these sections as ''erroneous or incomplete.'' EPA disagrees with these comments as assuring that every CBI claim is consistent with section 14(b) and (c) of TSCA would require a substantive review of each claim, which is well beyond the CBI review requirements described in TSCA section 14(g). For a more detailed response regarding CBI review during pre-screen, please see the Response to Comments document (Ref. 2).

2. Correcting Errors in Notices

As proposed, EPA is finalizing amendments at 40 CFR 720.65(a) and (b) to state that if EPA receives a notice with errors and EPA requests (as part of the pre-screen process or, at latest, within 30 days of receipt of the notice) that the submitter remedy such errors, the applicable review period will not begin until EPA receives a corrected notice. This will align the process for correcting errors with the current process in 40 CFR 720.65 for correcting an incomplete notice.

3. Notice Amendments Indicating Original Notice was Incomplete

EPA is finalizing amendments at 40 CFR 720.65(c)(2) and to 40 CFR 720.65(c)(5)(iii) (moved to 720.65(d)(5)(iii)), to clearly communicate and clarify that EPA may deem an original notice incomplete, and restart the review period at Day 1, if a submitter provides required information during the applicable review period without demonstrating that it was not known to or reasonably ascertainable by the submitter at the time of the initial notice submission. Additionally, EPA is updating the reference to 40 CFR 720.80(b)(2) at 40 CFR 720.65(c)(vii) to instead point to 40 CFR 703.5(c) because the 2023 CBI rule (88 FR 37155, June 7, 2023) moved the language that was previously at 720.80(b)(2) to a new section at 40 CFR 703.5.

As stated in the proposal for this rule (88 FR 34100, May 26, 2023), EPA is changing the longstanding practice of accepting amendments that contain required information that was known or reasonably ascertainable at the time of the original submission and then accepting a request to suspend the review period under 40 CFR 720.75(b).

As explained in Unit II.B., the 2016 Lautenberg Amendments impose additional obligations on EPA. EPA believes that exercising its discretionary authority under the existing regulations to declare an original submission incomplete and restart the applicable review period upon submission of the complete notice (e.g., when an amendment is submitted that makes a notice complete) is appropriate in order for EPA to efficiently meet current statutory requirements. Several comments on the proposed rule objected to these amendments, stating that submitters often are prompted to generate new or additional information during the review period to rebut unforeseen or conservative assumptions made by EPA. To address this comment and assist with efficient review, EPA is also amending the notice information requirements at 40 CFR 720.45 to specify the level of detail needed to perform refined risk assessments, as well as building that additional detail into the CDX user interface, which is detailed in Unit III.B of both the proposed rule (88 FR 34100, May 26, 2023) and this final rule. By specifying more detailed information requirements in 40 CFR 720.45 and data fields in the CDX user interface, EPA should receive more complete submissions upfront and help to minimize the need for EPA to use default values and conservative assumptions in its risk assessment due to a lack of available data. The Agency, however, reiterates that the submitter is required to provide all required information that is known or reasonably ascertainable at the time of the initial submission and not in reaction to risk assessment findings. Submitters must provide all information required by 40 CFR 720.45 and 720.50 upfront to satisfy the requirement of submitting a complete notice.

In response to the proposal, EPA received a comment asking that the Agency provide submitters with an opportunity to explain why information submitted as part of an amendment should not result in restarting the applicable review period. Under the amendment to 40 CFR 720.65(c)(2) being finalized in this action, the submitter of additional or revised information during the review period must demonstrate to EPA's satisfaction that the information was not known to or reasonably ascertainable by the submitter at the time of the original submission to preclude an EPA determination that the original notice was incomplete. Amendments to a notice that will not be considered as amendments indicating that the original notice was incomplete are: (1) Amendments based on new data (as described at 40 CFR 720.40(f) and 720.50(a)(4)); (2) Administrative, non-substantive amendments (*e.g.,* submitter contact information); and (3) Amendments made at the request of EPA. EPA, however, will take case-by-case facts into consideration when determining whether a late submission of information indicates that a notice was incomplete when originally submitted. If a submitter disagrees with EPA's determination that the original notice submission was incomplete, the submitter may object according to the existing procedures at 40 CFR 720.65(c)(4) and (5), as amended in this final rule, which updates and moves these provisions to 40 CFR 720.65(d)(4) and (5).

As explained in the proposed rule, a notice submitted under TSCA section 5(a)(1) is statutorily required to include the information described in TSCA section 5(d)(1) insofar as it is known to the submitter or reasonably ascertainable. In response to various procedural amendments proposed in

this rulemaking, EPA received comments asking the Agency to further define ''known to or reasonably ascertainable by'' beyond the current definition at 40 CFR 720.3. While EPA understands and recognizes the desire to have a more explicitly defined list of criteria or more detailed definition of ''known to or reasonably ascertainable by,'' EPA believes that it is not possible to define ''known to or reasonably ascertainable by'' more explicitly—as was stated in the 1983 final rule entitled ''Premanufacture Notification; Premanufacture Notice Requirements and Review Procedures'' (Ref. 8) and restated in the May 2023 proposed rule (88 FR 34100). EPA has not, in this rulemaking, proposed or finalized any amendment to or undertaken any substantive reconsideration, reexamination, or reinterpretation of the existing definition at 40 CFR 720.3. That said, to assist submitters, EPA has provided additional discussion and examples as to what is meant by ''known to or reasonably ascertainable by'' in the Response to Comments document (Ref. 2).

4. Notifying EPA of the Receipt of New Information on a Chemical Substance Under Review

EPA is finalizing amendments to 40 CFR 720.40(f), 40 CFR 720.50(a)(4)(ii), and 40 CFR 723.50(i) to clarify that new information about a chemical substance under EPA review must be submitted electronically via CDX, consistent with the general electronic submission requirements in 40 CFR 720.40(a). In addition, when submitters receive new information within five days of the end of the review period, EPA is amending the regulations to allow submitters to notify EPA by e-mail of the receipt of new information. Although the regulatory text in 40 CFR 720.40(f) and 40 CFR 723.50(i) are similar, the regulatory text provided along with the proposed rule erroneously showed only the proposed changes to 40 CFR 720.40(f) and did not show proposed changes to 40 CFR 723.50(i). This was an oversight and the regulatory text accompanying this final rule consistently amends both 40 CFR 720.40(f) and 40 CFR 723.50(i).

D. Amendments to Low Volume Exemptions and Low Release and Exposure Exemptions

EPA is promulgating several amendments to the current LVE and LoREX regulations. Specifically, EPA is finalizing amendments so that: (1) submitters may not commence manufacture until EPA has approved the LVE or LoREX notice; (2) EPA may proactively inform LVE and LoREX holders if the chemical substance that is the subject of the LVE or LoREX becomes subject to a SNUR and the chemical identity is CBI, or if it is listed on the confidential portion of the TSCA Inventory; (3) PFAS are categorically ineligible for these exemptions; and (4) certain PBT chemical substances are ineligible for these exemptions.

LVE and LoREX regulations are promulgated under the statutory authority of TSCA section 5(h)(4), 15 U.S.C. 2604(h)(4), which provides that EPA may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of TSCA section 5 if EPA determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, ''will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by [EPA] under the conditions of use.''

1. Amendments to Expiration of LVE and LoREX Review Period

EPA is finalizing, as proposed, amendments to the LVE and LoREX regulations at 40 CFR 723.50(g) to require a notification of approval of an LVE or LoREX from EPA prior to commencement of manufacture of the chemical substance under the exemption. Prior to the promulgation of this amendment, 40 CFR 723.50(g)(2) provided that the submitter may begin manufacture of a chemical substance under an LVE or LoREX upon expiration of the 30-day review period if EPA had taken no action. As described in Unit III.A., EPA is also amending the regulations that allow submitters to begin manufacture or processing of chemical substances for which a PMN, MCAN, or SNUN was submitted upon expiration of the review period, so that those regulations would require a determination from EPA prior to commencement of manufacture or processing of such substances. As discussed in Unit III.A., these changes to 40 CFR 720.75, 721.25(d), and 725.170 are being made to conform those regulations to the 2016 Lautenberg Amendments. EPA is finalizing similar amendments to the LVE and LoREX regulations at 40 CFR 723.50 to align with the amendments to the PMN, SNUN, and MCAN regulations and with the statutory framework and to better ensure that chemical substances manufactured under LVEs and LoREXs will not present an unreasonable risk.

2. Notification of LVE and LoREX Holders if the Chemical Substance is Subject to a SNUR or Listed on the Confidential Portion of the TSCA Inventory

EPA is finalizing amendments to 40 CFR 723.50 to allow EPA to inform an LVE or LoREX holder whenever the chemical substance that is the subject of that LVE or LoREX becomes subject to a proposed or final SNUR that describes the chemical substance by a generic chemical name due to a confidentiality claim for its specific chemical identity. This amendment would, as a courtesy, help inform LVE and LoREX holders of regulatory requirements that they may have otherwise been unable to determine on their own without submitting an inquiry to EPA (also known as a *bona fide* notice) pursuant to 40 CFR 721.11. In the proposed rule (88 FR 34100, May 26, 2023), EPA stated that the Agency did not intend to proactively inform current LVE and LoREX holders about SNURs that predate this rule and that EPA would only start the practice of notifying LVE and LoREX holders subject to this amendment after the date of the final rule. However, upon consideration of public comments in support of notifying current exemption holders of preexisting SNURs, EPA intends, subject to availability of resources, to notify current LVE and LoREX holders about preexisting SNURs that describe the chemical substance by a generic chemical name. Given current resource constraints, however, EPA is unable to provide a timeline for when it will begin and complete this notification effort. A lack of receipt of this courtesy notice that a chemical substance is subject to a SNUR does not excuse chemical manufactures and processors from complying with any existing regulations. LVE and LoREX holders who wish to determine whether their chemical substance is subject to a SNUR may always submit an inquiry to EPA (also known as a *bona fide* notice) pursuant to 40 CFR 721.11.

In response to public comments, in addition to notifying LVE and LoREX holders when they are subject to a SNUR, EPA also intends, subject to availability of resources, to begin notifying LVE or LoREX submitters if a substance is added to the confidential portion of the TSCA Inventory as a result of filings by a different submitter that claimed the specific chemical identity of the substance as confidential. As of February 7, 2024, more than 460 LVEs and LoREXs that were granted by EPA pertain to chemical substances that are now listed on the TSCA Inventory.

Once on the Inventory, a chemical substance may be subject to additional requirements under TSCA. Of the more than 390 chemical substances covered by these LVE and LoREX, approximately 125 are on the confidential portion of the TSCA Inventory. Without notice by EPA or by submitting a *bona fide* notice, a submitter is unlikely to know their substance is listed on the confidential portion of the Inventory, unless they also submitted the PMN and subsequent Notice of Commencement that led to the Inventory listing of the substance. While EPA intends to begin providing notice to exemption holders whose chemical substance now appears on the confidential portion of the TSCA Inventory, EPA does not intend to provide notice to those who hold granted LVEs or LoREXs pertaining to chemical substances whose specific chemical identities are added to the public portion of the TSCA Inventory due to the additional resources this would require and to the fact this information is publicly available.

In response to public comment, EPA affirms that once a chemical substance is added to the Inventory, an LVE or LoREX (or any other exemption from PMN requirements) is no longer necessary to manufacture the chemical substance and thus any approved LVE or LoREX is no longer binding on the manufacturer. The premanufacture notice requirements of TSCA section 5(a)(1), the relevant statutory exemption authority at TSCA section 5(h)(4), and the LVE/LoREX regulations at 40 CFR 723.50 all apply to manufacturers of new chemical substances, yet a chemical substance is no longer a ''new chemical substance'' as defined in TSCA section 3(11) once it is added to the Inventory. While EPA intends to begin providing notice to LVE and LoREX submitters once their substance is listed on the confidential portion of the Inventory, EPA does not intend to formally revoke these exemptions under the process described in 40 CFR 723.50(h)(2), as that process pertains to new chemical substances for which manufacture is not otherwise permitted in the absence of a PMN or applicable exemption.

The amendments to the regulations at 40 CFR 723.50 establish that a granted LVE or LoREX notice demonstrates a *bona fide* intent to manufacture the substance, such that a disclosure to an LVE or LoREX holder that the substance is the subject of a proposed or final rule under Part 721 or similarly that the substance is on the confidential portion of the TSCA Inventory will not be considered public disclosure of confidential business information under section 14 of the Act. EPA is not amending the procedures in 40 CFR 723.50(l) for asserting and protecting confidential business information.

3. Making PFAS Categorically Ineligible for LVEs and LoREXs

EPA is finalizing amendments to limit the scope of the LVE and LoREX exemptions that were first promulgated in accordance with TSCA 5(h)(4) in 1985 and 1995 respectively (50 FR 16477 (April 26, 1985) and 60 FR 16346 (March 29, 1995)). TSCA 5(h)(4) allows, but does not require, the Administrator to exempt the manufacturer of any new chemical substance from all or part of the requirements of TSCA section 5 in certain circumstances. The statute does not specify any circumstances under which the Administrator would be required to provide an exemption and EPA's action here is consistent with its authority under 5(h)(4) to create and/or define the scope of exemptions. These amendments make PFAS categorically ineligible for LVEs and LoREXs going forward, using a structural definition of PFAS for purposes of the LVE and LoREX regulations. Upon the effective date of this rule, any LVE or LoREX notice for a PFAS that is submitted to the Agency will be denied upon receipt without substantive review. This includes any chemical substance where any of the reasonably anticipated metabolites, environmental transformation products, byproducts, or reasonably anticipated impurities are a PFAS. Persons who wish to manufacture a PFAS not on the TSCA Inventory will be required to submit a PMN at least 90 days prior to commencing manufacture for a non-exempt commercial purpose. The definition for PFAS that EPA is finalizing is aligned with the recently finalized TSCA section 8(a)(7) rule (88 FR 70516, October 11, 2023) and the Inactive PFAS SNUR (89 FR 1822, January 11, 2024). Although PFAS would no longer be eligible for LVE or LoREX, there may be case-specific circumstances where a use of a new PFAS or a new use of an existing PFAS may be needed by a federal agency to meet its mission or is required in order to meet another critical need. EPA will work with other federal agencies to expedite review of such cases. Furthermore, EPA recognizes the critical role that many new chemicals play, including some PFAS, in the manufacture of semiconductors. The new chemicals program now prioritizes notices for chemicals used in sectors supported by the Creating Helpful Incentives to Produce Semiconductors (CHIPS) and Science Act and the Inflation Reduction Act's (IRA) climate goals. Since beginning the process of prioritizing CHIPS and Science Act and IRA related chemicals, EPA now reviews these new chemicals in a third of the time compared to other sectors. The Agency believes these key sectors are important to growing new jobs as part of the Biden-Harris Administration's domestic manufacturing initiatives. For some new chemicals needed by the semiconductor sector, such as photo-acid generators, EPA's multi-year collaborative effort with the sector has resulted in a regulatory pathway for dozens of these chemicals, and recent submittals have had review timeframes of under 90 days.

As noted in the proposed rule, EPA's New Chemicals Program began implementing a new policy for reviewing and managing LVE notices for PFAS in April 2021. In an April 27, 2021, press release announcing the new PFAS LVE policy (Ref. 9), the Agency stated that ''[g]iven the complexity of PFAS chemistry, potential health effects, and their longevity and persistence in the environment, an LVE notice for a PFAS is unlikely to be eligible for this kind of exemption under the regulations.'' Since 2021, EPA has reviewed 8 LVE notices for PFAS, which were each reviewed on a case-by-case basis. Each of the 8 PFAS were determined to be ineligible for an LVE due to the risks identified and/or an inability to complete the review in 30 days as a result of the complexities of the review or uncertainties in the assessment. EPA has never received or approved any PFAS LoREX notices.

Each of the 8 PFAS that were the subject of LVE notices reviewed since 2021, or the reasonably anticipated metabolites and environmental transformation products of those PFAS, was determined to be a PBT chemical substance. In 5 of the 8 cases, however, the PBT designation included noted uncertainties for each of the substances reviewed. If EPA is unable to score a characteristic (*e.g.,* B ''unknown'' for bioaccumulation), the characteristic is still considered to be potentially a 2 or higher for the purposes of identifying potential PBTs (Ref. 10). In many cases, additional uncertainties were identified for the potential routes of exposure, which included exposures to workers, the general population, a potentially exposed or susceptible subpopulation (*e.g.,* consumers, infants), or the environment. PFAS present a challenge for EPA to evaluate because there is often insufficient information to quantify the risk they may pose and consequently make effective decisions

about how to regulate them (Ref. 11). As currently described in the regulations, EPA may determine that a new chemical substance is ineligible for an LVE or LoREX if there are issues concerning toxicity or exposure that require further review which cannot be accomplished within the 30-day review period. EPA notes that the shortened 30-day review period for LVEs and LoREX is one of the major benefits of these exemptions as it allows companies to introduce new chemical substances more quickly into commerce. The 30-day review period provides a screen for EPA to identify any new chemical substances with issues that require more detailed and comprehensive review and analysis, such as that available in a full PMN review. See 60 FR 16336. Given the shortened 30-day review of an LVE along with the inability to require testing or impose additional restrictions under a section 5(e) or 5(f) order, EPA was unable to address those uncertainties which would be necessary to conclude that the substance would not present an unreasonable risk. Since all of the 8 PFAS that were the subject of LVE notices were deemed ineligible for the exemption, the submitters were required to submit a PMN if they wanted to move forward with the manufacture of the new chemical substances.

For the purpose of making PFAS ineligible for LVEs and LoREXs, EPA is defining ''PFAS'' using a structural definition. In this rule, EPA defines PFAS to mean a chemical substance that contains at least one of these three structures:

(1) R-(CF2)-CF(R′)R″, where both the CF2 and CF moieties are saturated carbons;

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

(3) CF3C(CF3)R′R″, where R′ and R″ can either be F or saturated carbons.

Manufacturers of substances that do not meet this structural definition and of substances where any of the reasonably anticipated metabolites, environmental transformation products, byproducts, or reasonably anticipated impurities do not meet this structural definition remain eligible to submit an LVE or LoREX notice.

In opposition to these amendments, EPA received comments asserting that because PFAS are a broad category of chemicals, any proposed regulatory action on PFAS should not group PFAS into a single category. Comments also asserted that there was no scientific basis or risk-based evidence for making PFAS ineligible for LVEs and LoREXs. EPA agrees with the comments that PFAS are a broad category of chemical substances with common toxicological properties, exposures, or uses, and notes that the assessment and management of these substances for regulatory purposes should generally be done on a case-by-case basis or as groups of substances with common toxicological properties, exposures, or uses. Furthermore, EPA believes that any assessment of PFAS should be done in line with the scientific standards, weight of scientific evidence, and consideration of any reasonably available information as outlined in section 26 of TSCA. The amendment to make PFAS ineligible for LVEs and LoREXs, however, is not based on an assessment of all PFAS or any PFAS and does not impose risk management restrictions on any PFAS substance. The decision to make PFAS ineligible for LVEs and LoREXs is not a determination of risk for all or any PFAS. While the current state of science and EPA's understanding of PFAS has motivated the decision to make all PFAS ineligible for LVEs and LoREXs, these amendments are not based on EPA findings that particular PFAS chemicals, or all chemicals qualifying as PFAS under this rule, may present unreasonable risks of injury to human health or the environment under the conditions of use due to levels of hazards and exposures identified and evaluated by EPA. Rather, due to the scientific complexities or uncertainties associated with assessing PFAS and the lack of data on most PFAS with regards to toxicity and exposure to human health and the environment, EPA expects in most cases to be unable to determine pursuant to TSCA section 5(h)(4) that a PFAS ''will not present an unreasonable risk'' under the conditions of use within the 30-day review period provided for LVE and LoREX notices. This action is a procedural action based on EPA's experience administering TSCA and reviewing LVEs for PFAS.

Additionally, making PFAS ineligible for the LVE and LoREX exemptions may in fact reduce burden in many instances by avoiding the submission and review of LVEs that are ultimately denied and required to be resubmitted and reviewed anew through the PMN review process. Furthermore, the New Chemicals Program developed the PFAS Framework to help ensure that the Program effectively and efficiently reviews and makes appropriate decisions on new PFAS or significant new uses of existing PFAS reviewed through PMNs and SNUNs. The PFAS Framework will guide EPA's review of PFAS under TSCA section 5, ensuring consistency and efficiency in its review of incoming submissions while advancing the Agency's goals to ensure protection of public health and the environment. Please see the Response to Comments document that accompanies this rule for a more detailed discussion of and response to the comments received on the amendments to make PFAS categorically ineligible for LVEs and LoREXs (Ref. 2).

The definition for PFAS promulgated at 40 CFR 723.50 does not include substances that only have a single fluorinated carbon or unsaturated fluorinated moieties (*e.g.,* fluorinated aromatic rings and olefins), which are more susceptible to chemical transformation than their saturated counterparts, and therefore less likely to persist in the environment. These potentially degradable substances, if submitted to EPA in a LVE or LoREX notice, would still be evaluated by EPA and a decision made to either deny or grant the exemption.

The three-part structural definition for PFAS includes fluoropolymers. Fluoropolymers are made using fluorinated monomers, and often fluorinated processing aides, which contributes to the release of PFAS. In addition, the disposal of fluoropolymers may also result in PFAS releases. EPA has been concerned about potential risks of fluoropolymers for more than a decade. On January 27, 2010 (75 FR 4295, 1/27/2010), EPA amended the 'polymer exemption rule,' to exclude from eligibility polymers containing as an integral part of their composition, except as impurities, certain perfluoroalkyl moieties consisting of a CF3- or longer chain length. EPA issued this amendment because, based on information at the time, EPA could no longer conclude that these polymers will not present an unreasonable risk to human health or the environment under the terms of the polymer exemption rule, which is the determination necessary to support an exemption under section 5(h)(4) of TSCA. While some comments stated that fluoropolymers are safe, there remains debate on the toxicity of fluoropolymers especially when considering their entire life cycle (Ref. 12). EPA's decision to include fluoropolymers as part of the amendment to make PFAS ineligible for LVEs and LoREXs, however, was not based on hazard, exposure, or risk. Fluoropolymers are no less complicated to review than nonpolymeric PFAS, and the Agency expects it would need the longer 90-day review for a PMN.

At the time of finalizing this rulemaking, EPA is not revoking previously granted LVEs for PFAS. EPA, however, may take future action on a case-by-case basis to revoke previously

granted LVEs for PFAS, which would be done in accordance with the existing regulations at 40 CFR 723.50(h)(2). EPA believes that the revocation of any existing LVE should be done on a case-by-case basis. While there are well identified hazards for many PFAS and PFAS studies have repeatedly found harm to human health, EPA has not determined that PFAS as an entire category of chemical substances do not meet the ''will not present unreasonable risk of injury to health or the environment'' standard of TSCA section 5(h)(4). As noted previously, EPA's decision to make future PFAS ineligible for LVEs is not based on hazard or risk but is instead based on EPA's experience administering TSCA and reviewing LVEs for PFAS (please see the Response to Comments document for a more detailed discussion (Ref. 2)).

As EPA continues to consider previously granted PFAS LVEs, EPA will take into consideration the concerns raised about the potential impacts to domestic semiconductor and electric vehicle industry, national defense, or other critical applications. The Biden-Harris Administration is committed to restoring U.S. leadership in semiconductor and electric vehicle manufacturing, supporting good-paying jobs across those supply chains, and advancing U.S. economic and national security. EPA's Framework for Addressing New PFAS and New Uses of PFAS (PFAS Framework) (Ref. 10) outlines EPA's planned approach when reviewing new PFAS and new uses of existing PFAS. The application of the PFAS Framework will help ensure that new PFAS won't harm human health and the environment and allows that certain PFAS be used when exposures and releases can be mitigated, which is critical for important sectors like semiconductors. Under the framework, EPA expects that some PBT PFAS will not result in worker, general population or consumer exposure and are not expected to result in releases to the environment, such as when PFAS are used in a closed system with occupational protections as is generally the practice in the manufacture of some semiconductors and other electronic components. Additionally, EPA continues to work cooperatively with companies who wish to voluntarily withdraw previously granted LVEs for PFAS. As of April 1, 2024, 56 LVEs have been withdrawn through EPA's PFAS Low Volume Exemption Stewardship Program.

4. Codifying EPA's Policy Concerning PBT Chemicals and LVEs and LoREXs

EPA is finalizing amendments to 40 CFR 723.50(d) that would codify EPA's long-standing practice that, whenever EPA identifies a chemical substance under LVE or LoREX review (or any reasonably anticipated metabolites, environmental transformation products, or byproducts of the substance, or any reasonably anticipated impurities in the substance) as PBT with anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms, that substance would be ineligible for the LVE or LoREX. As noted in Unit III.D.3., the LVE and LoREX exemptions were first promulgated in accordance with TSCA section 5(h)(4) in 1985 and 1995 respectively (50 FR 16477, April 26, 1985 (FRL–2742–1) and 60 FR 16346, March 29, 1995 (FRL–4923–1)). TSCA section 5(h)(4) allows, but does not require, the Administrator to exempt the manufacturer of any new chemical substance from all or part of the requirements of TSCA section 5 in certain circumstances. The statute does not specify any circumstances under which the Administrator would be required to provide an exemption and EPA's action here is consistent with both its long-standing practice and with its authority under TSCA section 5(h)(4) to create and/or define the scope of exemptions.

On November 4, 1999, EPA issued its policy statement identifying a category for PBT new chemical substances (Ref. 13). The 1999 policy statement formally acknowledged PBT chemical substances as a category based on shared characteristics to facilitate premanufacture assessment and regulation. In response to the proposed amendment to the LVE and LoREX regulations, EPA received comment asserting that the Agency cannot categorically make all PBT chemicals ineligible for LVEs and LoREXs. EPA did not propose to categorically make all PBT chemicals ineligible for LVEs and LoREXs and is not doing so in this final rule. Rather, EPA proposed and is finalizing amendments to 40 CFR 723.50(d) to codify that whenever EPA identifies a chemical substance under LVE or LoREX review (or any reasonably anticipated metabolites, environmental transformation products, or byproducts of the substance, or any reasonably anticipated impurities in the substance) as PBT with anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms, that substance would be ineligible for the LVE or LoREX. In order to effectuate these amendments for individual exemption notices, EPA would first need to review the exemption notice to determine if the substance is a PBT and then review the environmental releases and exposures to humans or environmental organisms to determine if releases and exposures are expected. Only after EPA has reviewed the hazards and exposures, will EPA make a decision to either grant or deny an LVE or LoREX for a PBT chemical substance.

Based on EPA's experience administering LVEs and LoREXs, EPA expects that most exemptions for PBT chemical substances will not be granted. However, EPA agrees that there are instances where PBT chemical substances can be managed under an exemption. EPA may receive an exemption notice for a PBT chemical substance that will not result in worker, general population, or consumer exposure and that is not expected to result in releases to the environment, such as chemical substances used in a closed system to make semiconductors or other electronic components. In such a negligible exposure and environmental release scenario where worker exposure is fully mitigated and general population exposures are not expected, if EPA has sufficient information on the substance and the conditions of use to ensure that such PBT chemical substances can be disposed of properly and no consumer exposure is expected, EPA generally expects to grant the exemption.

EPA is defining ''PBT chemical substance'' for purposes of 40 CFR 723.50 as ''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 PBT, see EPA's 1999 policy statement (64 FR 60194; November 4, 1999).''

E. Amendments Related to Suspensions of the Review Period

As proposed, EPA is finalizing amendments to 40 CFR 720.75(b)(2) to allow PMN, SNUN, LVE, and LoREX submitters to request a suspension of the notice review period for up to 30 days orally or in writing, including by e-mail, without the need for a formal, written request submitted to EPA via CDX using e-PMN software. EPA is similarly finalizing amendments to 40 CFR 725.54(c) to permit MCAN submitters to request suspensions for up

to 30 days orally or in writing, including by e-mail, without the need for a formal, written request submitted to EPA via CDX using e-PMN software. Some comments to the proposal took issue with increasing the number of suspension days made through oral or e-mail communication from 15 to 30 days. These comments suggested such an amendment would result in less frequent communication from EPA regarding the status of a new chemical review. EPA disagrees with these comments, as the amendments would allow the submitter to request *up to* a 30-day suspension through oral or e-mail communication; however, submitters will still be allowed to suspend the review period for a shorter amount of time if preferred. For a more detailed response to the comments regarding the amendments relating to suspensions of the review period, please see the Response to Comments document (Ref. 2).

F. Severability

As explained in this preamble, EPA is finalizing several different types of amendments in this rule, including amendments related to: commencement of manufacture or processing; required determinations and associated actions; terminology and definitions; notice information requirements; pre-screening procedures; correcting errors in notices; incomplete notices; notification of the receipt of new information; expiration of the LVE and LoREX review period; notification of LVE and LoREX holders regarding certain other actions involving their chemical substance; PFAS ineligibility for LVE and LoREX exemptions; certain PBT ineligibility for LVE and LoREX exemptions; and suspensions of the review period. Each type of amendment functions independently, serves a discrete purpose, and is intended to be severable from the other amendments. In the event of litigation staying, remanding, or invalidating a portion of EPA's amendments in this rule, EPA intends to preserve all other amendments in this rule to the fullest extent possible. For example, the amendment to the LVE and LoREX regulations making PFAS ineligible for such exemptions functions independently from the amendment to those regulations making certain PBTs ineligible for the exemptions, such that if either ineligibility provision were stayed or invalidated, it would have no effect on the other, and EPA intends that the other would remain effective. Similarly, any stay or invalidation of the amendment making PFAS ineligible for the LVE and LoREX exemptions would have no effect on amendments related to incomplete notices, and vice versa. These specific examples are not intended to be exhaustive, but rather illustrative of scenarios that reflect EPA's overarching intent that each type of amendment be severable.

Furthermore, within the broader category of amendments to notice information requirements, the rule includes a number of discrete amendments pertaining to different types of information. Each of these specific amendments to notice information requirements functions independently and is intended to be severable from the others. As an example, if amended information requirements regarding the categories of use of the chemical substance were to be stayed or invalidated, it would have no effect on amended information requirements regarding worker exposure, and vice versa.

The limited circumstance in which severability is not intended is where a single type of amendment involved changes to multiple paragraphs or sections of the regulations. For example, in cases where EPA is finalizing the same or similar amendment in multiple parts of the CFR for conformity (e.g., where an amendment to part 721, 723, or 725 is intended merely to conform to the same or similar amendment in part 720), severability is not intended between those provisions. In addition, were the amendment making PFAS ineligible for LVE and LoREX exemptions to be invalidated, the related amendment defining PFAS for purposes of that ineligibility provision would no longer be necessary or helpful. However, EPA does intend severability in the inverse scenario: if the definition of PFAS were stayed or invalidated, EPA intends severability of all other amendments, including the amendment making PFAS ineligible for LVEs and LoREX.

IV. References

The following is a listing of the documents that are specifically referenced in this **Federal Register** notice. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Economic Analysis for the Final Rule: Updates to New Chemicals Regulations under the Toxic Substances Control Act. December 2024.
2. EPA. Response to Comments on the Proposed Rule Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA). December 2024.
3. EPA. Central Data Exchange Online User Guide. Accessible at: *https://cdx.epa.gov/About/UserGuide.*
4. EPA. Points to Consider When Preparing TSCA New Chemical Notification. OMB Control No.: 2070–0012. June 2018. Accessible at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/points-consider-when-preparing-tsca.*
5. EPA. TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Rework. Accessible at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-new-chemical-engineering.*
6. EPA. Tables Detailing the Final Amendments to Add Details to 40 CFR 720.45 Reporting Requirements and Enhancements to the CDX Reporting Form. December 2024.
7. EPA. Supporting Statement for an Information Collection Request (ICR) Under the Paperwork Reduction Act (PRA); TSCA Section 5 Premanufacture Review of New Chemical Substances and Significant New Use Rules for New and Existing Chemical Substances (Revision); EPA ICR No. 1188.15; OMB Control No. 2070–0038]. December 2024.
8. EPA. Premanufacture Notification; Premanufacture Notice Requirements and Review Procedures; Final Rule. **Federal Register.** 48 FR 21722; May 13, 1983 (TSH–FRL 2998–5).
9. EPA. Press Release: EPA Announces Changes to Prevent Unsafe New PFAS from Entering the Market. April 27, 2021.
10. EPA. Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs). June 2023.
11. Executive Office of the President of the United States. Per- and Polyfluoroalkyl Substances Report. March 2023.
12. Lohmann, Rainer, *et al.* Are fluoropolymers really of low concern for human and environmental health and separate from other PFAS? Environmental science & technology 54.20 (2020): 12820–12828.
13. EPA. Policy Statement on Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. **Federal Register.** (64 FR 60194, November 4, 1999) (FRL–6097–7).

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Orders 12866: Regulatory Planning and Review and 14094: Modernizing Regulatory Review

This action is a ''significant regulatory action'' as defined in Executive Order

12866, as amended by Executive Order 14094 (88 FR 21879, April 11, 2023). Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. The EPA prepared an economic analysis of the potential impacts associated with this action. This analysis, ''Economic Analysis for the Final Rule: Updates to New Chemicals Regulations under the Toxic Substances Control Act'' (Ref. 1), is also available in the docket.

B. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted to OMB for review and approval under the PRA (44 U.S.C. 3501 *et seq.*). The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR No. 1188.15 (Ref. 7). This ICR represents a revision to the currently approved ICR that covers the information collection activities contained in the existing regulations. The Economic Analysis covers the incremental changes from this action. You can find copies of the Economic Analysis and ICR in the docket, and the ICR is briefly summarized here.

Respondents/affected entities: Certain chemical manufacturers (including importers) and processors (see Unit I.A.).

Respondent's obligation to respond: Mandatory under TSCA section 5.

Estimated number of respondents: 560.

Frequency of response: On occasion.

Total estimated incremental burden: Estimates show that this rule will decrease existing approved ICR burden by 4,528 hours per year. Burden is defined at 5 CFR 1320.3(b).

Total estimated incremental cost: Estimates show that this rule will increase existing approved ICR costs by $203,150 per year. This includes $0 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

EPA did not receive any comments on the ICR revision that was posted with the proposed rule. EPA prepared a Response to Comments document (Ref. 2) that summarizes all the comments relevant to the proposal, including comments affecting the Agency's burden estimates related to the rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The Agency's basis is briefly summarized here and is detailed in the Economic Analysis (Ref. 1).

The majority of firms that submit a TSCA section 5 notice will realize either no change or a decrease in costs associated with form submission. However, EPA expects that firms that submit LVE notices for PFAS will incur an estimated cost of approximately $61,049 per notice due to the greater burden and non-labor costs associated with submitting a PMN form. EPA estimates that 98 percent of small firms (184 firms) will have cost impacts of less than 1 percent of revenues, less than 1 percent (1 firm) will have cost impacts between 1 and 3 percent of revenues, and 1 percent (2 firms) will have cost impacts greater than 3 percent of revenues.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million (adjusted annually for inflation) or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. EPA has concluded that this action imposes no enforceable duty on any state, local or Tribal governments because, based on EPA's experience with reviewing TSCA section 5 actions, state, local and Tribal governments have not been impacted and EPA does not have any reasons to believe that any state, local, or Tribal government would engage in the activities such that they would be impacted by this rulemaking.

In addition, given that the estimated incremental cost on the private sector is expected to be less than $50,000 (Ref. 1), EPA has concluded that this rulemaking is not expected to result in expenditures by the private sector of $183 million or more in any one year ($100 million in 1995$ adjusted for inflation using the CDP implicit price deflator).

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–201 of the Executive Order. Therefore, this action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk. Since this action does not concern human health risks, EPA's Policy on Children's Health also does not apply. This procedural rule would align the implementing regulations codified at 40 CFR parts 720, 721, and 725 with amended TSCA and make additional updates based on existing policies or lessons learned from administering the New Chemicals Program since TSCA was amended in 2016.

Although this procedural rule itself would not directly affect the level of protection provided to human health or the environment, EPA expects that the rule would improve the Agency's consideration of risks to children—in furtherance of EPA's Policy on Children's Health—and other PESS. In turn, EPA anticipates that the amendments would help better inform the Agency's determinations for each new chemical substance or significant new use for which it received a notice under TSCA section 5(a)(1), pertaining to the likelihood of unreasonable risk to human health or the environment under known, intended or reasonably foreseen conditions of use. EPA uses an integrated approach that draws on knowledge and experience across disciplinary and organizational lines to

identify and evaluate concerns regarding health and environmental effects, and exposure and release.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards under the NTTAA section 12(d), 15 U.S.C. 272.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

EPA believes that this type of action does not concern human health or environmental conditions and therefore cannot be evaluated with respect to potentially disproportionate and adverse effects on communities with environmental justice concerns in accordance with Executive Orders 12898 (59 FR 7629, February 16, 1994) and 14096 (88 FR 25251, April 26, 2023). This action is procedural in nature. Therefore, EPA believes that it is not practicable to assess whether the human health or environmental conditions that exist prior to this action result in disproportionate and adverse effects on communities with environmental justice concerns. Although this action does not concern human health or environmental conditions, EPA identifies and addresses environmental justice concerns by finalizing, among other things, the regulatory definition of PESS to include overburdened communities, the Agency believes that this action would assist EPA and others in determining the potential exposures, hazards and risks to overburdened communities associated with the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substances and significant new uses of chemical substances subject to this rulemaking. EPA anticipates that the inclusion of overburdened communities among the PESS considered in the Agency's review of a TSCA section 5 submission would also enable the Agency, if necessary, to design appropriate future risk management actions to address an unreasonable risk that the Agency may determine is presented by that chemical substance and to consider how such risk management actions would affect communities with environmental justice concerns.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 68

Administrative practice and procedure, Air pollution control, Chemicals, Environmental protection, Hazardous substances.

40 CFR Part 372

Environmental protection, Reporting and recordkeeping requirements, Toxic substances.

40 CFR Part 703

Chemicals, Confidential business information, Environmental protection, Exports, Hazardous substances, Imports, Reporting and recordkeeping requirements.

40 CFR Parts 720, 721, 723, and 725

Environmental protection, Chemicals, Hazardous materials, Reporting and recordkeeping requirements.

Dated: December 3, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, for the reasons set forth in the preamble, 40 CFR chapter I is amended as follows:

PART 68—CHEMICAL ACCIDENT PREVENTION PROVISIONS

■ 1. The authority citation for part 68 continues to read as follows:

Authority: 42 U.S.C. 7412(r), 7601(a)(1), 7661–7661f.

§ 68.115 Threshold determination.

■ 2. Amend § 68.115(b)(5) by revising the citation ''§ 720.3(ee)'' to read ''§ 720.3.''

PART 372—TOXIC CHEMICAL RELEASE REPORTING: COMMUNITY RIGHT-TO-KNOW

■ 3. The authority citation for part 372 continues to read as follows:

Authority: 42 U.S.C. 11023 and 11048.

§ 372.38 Exemptions.

■ 4. Amend § 372.38(d) by revising the citation ''§ 720.3(ee)'' to read ''§ 720.3.''

PART 703—CONFIDENTIALITY CLAIMS

■ 5. The authority citation for part 703 continues to read as follows:

Authority: 15 U.S.C. 2613.

§ 703.3 Definitions.

■ 6. Amend § 703.3 by:
■ a. Revising in the introductory text the citation ''§ 720.3(ff)'' to read ''§ 720.3;''
■ b. Revising in the definition for ''*Health and safety study*'' the citation ''§ 720.3(k)'' to read ''§ 720.3.''

PART 720—PREMANUFACTURE NOTIFICATION

■ 7. The authority citation for part 720 continues to read as follows:

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

§ 720.1 Scope.

■ 8. Amend § 720.1 by removing the phrase ''The rule'' and adding in its place the phrase ''This part'' wherever it appears.

■ 9. Revise and republish § 720.3 to read as follows:

§ 720.3 Definitions.

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

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

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

Article means a manufactured item:

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

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

(3) Which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 720.30(h)(5), except that fluids and particles are not considered articles regardless of shape or design.

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

Byproduct material, source material, and *special nuclear material* have the

meanings contained in the Atomic Energy Act of 1954, 42 U.S.C. 2014 *et seq.* and the regulations issued under it.

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

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

(1) Any mixture;

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

(3) Tobacco or any tobacco product;

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

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

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

Commerce means trade, traffic, transportation, or other commerce:

(1) Between a place in a State and any place outside of such State; or

(2) Which affects trade, traffic, transportation, or commerce between a place in a State and any place outside of such State.

Cosmetic, device, drug, food, and *food additive* have the meanings contained in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.,* and the regulations issued under it. In addition, the term ''food'' includes poultry and poultry products, as defined in the Poultry Products Inspection Act, 21 U.S.C. 453 *et seq.;* meats and meat food products, as defined in the Federal Meat Inspection Act, 21 U.S.C. 60 *et seq.;* and eggs and egg products, as defined in the Egg Products Inspection Act, 21 U.S.C. 1033 *et seq.*

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

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

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

EPA means the U.S. Environmental Protection Agency.

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

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

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

(2) Examples include:

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

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

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

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

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

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

(1) The consignee.

(2) The importer of record.

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

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

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

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

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

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

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

Manufacture for commercial purposes means:

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

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

they are part of the manufacture of a chemical substance for commercial purposes.

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

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

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

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

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

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

Mixture means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except ''mixture'' does include:

(1) Any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined, and if all of the chemical substances comprising the combination are not new chemical substances; and

(2) Hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water, so long as the nonhydrated form is itself not a new chemical substance.

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

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

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

Pesticide has the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.* and the regulations issued under it.

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

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

(i) Associated with research, development, test marketing, or commercial marketing of the chemical substance in question.

(ii) Reasonably likely to have such data.

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

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

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

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

(1) In the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or

(2) As part of a mixture or article containing the chemical substance or mixture.

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

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

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

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

Technically qualified individual means a person or persons:

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

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

(3) Who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting a research and development activity.

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

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

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

§ 720.30 [Amended]

■ 10. Amend § 720.30 by revising the citations ''§ 720.3(e)'' in paragraph (a) and ''720.3(u)'' in paragraph (b) to both read ''§ 720.3.''

■ 11. Amend § 720.40 by revising paragraph (f) to read as follows:

§ 720.40 General.

* * * * *

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

* * * * *

■ 12. Amend § 720.45 by:

■ a. Revising paragraphs (a)(4) and (5), and (f) through (h); and

■ b. Adding paragraphs (j) and (k).

The revisions and additions read as follows:

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

* * * * *

(a) * * *

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

(5) If a manufacturer cannot provide all the information specified in paragraphs (a)(1) and (2) of this section because the new chemical substance is manufactured using a reactant having a specific chemical identity claimed as confidential by its supplier, the manufacturer must submit a notice directly to EPA containing all the information known by the manufacturer about the chemical identity of the reported substance and its proprietary reactant. In addition, the manufacturer must ensure that the supplier of the confidential reactant submit a letter of support directly to EPA providing the specific chemical identity of the confidential reactant, including the CASRN, if available, and the appropriate PMN or exemption number, if applicable. The letter of support must reference the manufacturer's name and PMN Fee Identification Number. The applicable review period will commence upon receipt of the notice, the letter of support, and the complete, correct information, in accordance with § 720.65.

* * * * *

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

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

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

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

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

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

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

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

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

Code	Category
Chemical Substances in Furnishing, Cleaning, Treatment Care Products	
CC101	Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel.
CC102	Furniture & furnishings including plastic articles (soft); leather articles.
CC103	Furniture & furnishings including stone, plaster, cement, glass, and ceramic articles; metal articles; or rubber articles.
CC104	Leather conditioner.
CC105	Leather tanning, dye, finishing, impregnation, and care products.

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

Code	Category
CC106	Textile (fabric) dyes.
CC107	Textile finishing and impregnating/surface treatment products.
CC108	All-purpose foam spray cleaner.
CC109	All-purpose liquid cleaner/polish.
CC110	All-purpose liquid spray cleaner.
CC111	All-purpose waxes and polishes.
CC112	Appliance cleaners.
CC113	Drain and toilet cleaners (liquid).
CC114	Powder cleaners (floors).
CC115	Powder cleaners (porcelain).
CC116	Dishwashing detergent (liquid/gel).
CC117	Dishwashing detergent (unit dose/granule).
CC118	Dishwashing detergent liquid (hand-wash).
CC119	Dry cleaning and associated products.
CC120	Fabric enhancers.
CC121	Laundry detergent (unit-dose/granule).
CC122	Laundry detergent (liquid).
CC123	Stain removers.
CC124	Ion exchangers.
CC125	Liquid water treatment products.
CC126	Solid/Powder water treatment products.
CC127	Liquid body soap.
CC128	Liquid hand soap.
CC129	Solid bar soap.
CC130	Air fresheners for motor vehicles.
CC131	Continuous action air fresheners.
CC132	Instant action air fresheners.
CC133	Anti-static spray.
CC134	Apparel finishing, and impregnating/surface treatment products.
CC135	Insect repellent treatment.
CC136	Pre-market waxes, stains, and polishes applied to footwear.
CC137	Post-market waxes, and polishes applied to footwear (shoe polish).
CC138	Waterproofing and water-resistant sprays.
Chemical Substances in Construction, Paint, Electrical, and Metal Products	
CC201	Fillers and putties.
CC202	Hot-melt adhesives.
CC203	One-component caulks.
CC204	Solder.
CC205	Single-component glues and adhesives.
CC206	Two-component caulks.
CC207	Two-component glues and adhesives.
CC208	Adhesive/Caulk removers.
CC209	Aerosol spray paints.
CC210	Lacquers, stains, varnishes, and floor finishes.
CC211	Paint strippers/removers.
CC212	Powder coatings.
CC213	Radiation curable coatings.
CC214	Solvent-based paint.
CC215	Thinners.
CC216	Water-based paint.
CC217	Construction and building materials covering large surface areas, including wood articles.
CC218	Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass, and ceramic articles.
CC219	Machinery, mechanical appliances, electrical/electronic articles.
CC220	Other machinery, mechanical appliances, electronic/electronic articles.
CC221	Construction and building materials covering large surface areas, including metal articles.
CC222	Electrical batteries and accumulators.
Chemical Substances in Packaging, Paper, Plastic, Toys, Hobby Products	
CC301	Packaging (excluding food packaging), including paper articles.
CC302	Other articles with routine direct contact during normal use, including paper articles.
CC303	Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft).
CC304	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard).
CC305	Toys intended for children's use (and child dedicated articles), including fabrics, textiles, and apparel; or plastic articles (hard).
CC306	Adhesives applied at elevated temperatures.
CC307	Cement/concrete.
CC308	Crafting glue.
CC309	Crafting paint (applied to body).

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

Code	Category
CC310	Crafting paint (applied to craft).
CC311	Fixatives and finishing spray coatings.
CC312	Modelling clay.
CC313	Correction fluid/tape.
CC314	Inks in writing equipment (liquid).
CC315	Inks used for stamps.
CC316	Toner/Printer cartridge.
CC317	Liquid photographic processing solutions.
Chemical Substances in Automotive, Fuel, Agriculture, Outdoor Use Products	
CC401	Exterior car washes and soaps.
CC402	Exterior car waxes, polishes, and coatings.
CC403	Interior car care.
CC404	Touch up auto paint.
CC405	Degreasers.
CC406	Liquid lubricants and greases.
CC407	Paste lubricants and greases.
CC408	Spray lubricants and greases.
CC409	Anti-freeze liquids.
CC410	De-icing liquids.
CC411	De-icing solids.
CC412	Lock deicers/releasers.
CC413	Cooking and heating fuels.
CC414	Fuel additives.
CC415	Vehicular or appliance fuels.
CC416	Explosive materials.
CC417	Agricultural non-pesticidal products.
CC418	Lawn and garden care products.
Chemical Substances in Products not Described by Other Codes	
CC980	Other (specify).
CC990	Non-TSCA use.

(g) For sites controlled by the submitter:

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

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

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

(i) A description of each worker activity.

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

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

(iv) Engineering controls in place, if any.

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

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

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

(viii) The duration of activities.

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

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

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

frequency of container cleaning, and the amount of release per container cleaning.

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

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

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

(h) For sites not controlled by the submitter:

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

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

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

(i) A description of each worker activity.

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

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

(iv) Engineering controls in place if any.

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

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

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

(viii) The duration of activities.

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

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

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

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

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

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

* * * * *

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

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

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

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

■ 13. Amend § 720.50 by revising paragraphs (a)(4)(ii) and adding paragraph (c) to read as follows:

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

(a) * * *

(4) * * *

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

* * * * *

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

* * * * *

■ 14. Revise § 720.65 to read as follows:

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

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

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

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

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

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

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

(ii) Contradictory information.

(iii) Ambiguous statements or information.

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

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

(i) The wrong person submits the notice form.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

may inform the submitter that the running of the review period will resume on the date EPA originally declared it incomplete.

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

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

■ 15. Amend § 720.70 by revising paragraphs (a) and (b)(3) to read as follows:

§ 720.70 Notice in the Federal Register.

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

(b) * * *

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

* * * * *

■ 16. Amend § 720.75 by:

■ a. Revising the section heading;

■ b. Removing the phrase ''notice review period'' and adding in its place the phrase ''applicable review period,'' wherever it appears; and

■ c. Revising paragraphs (a), (b), (c)(4) introductory text, (c)(4)(iii), and (d).

The revisions read as follows:

§ 720.75 Applicable review period and determination.

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

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

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

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

(c) * * *

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

* * * * *

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

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

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

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

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

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

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

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

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

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

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

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

appropriate, to the extent necessary to protect against such risk.

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

* * * * *

PART 721—SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

■ 17. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 18. Amend § 721.25 by:
■ a. Revising paragraph (d); and
■ b. Adding paragraph (e).

The revisions and additions read as follows:

§ 721.25 Notice requirements and procedures.

* * * * *

(d) Any person submitting a significant new use notice in response to the requirements of this part shall not manufacture or process a chemical substance identified in subpart E of this part for a significant new use until EPA has issued a determination with respect to the significant new use and taken the actions required in association with that determination in accordance with the procedures for new chemical substances at § 720.75(d) of this chapter.

(e) When submitting a significant new use notice, in addition to providing a description of the intended categories of consumer or commercial use by function and application as required by § 720.45(f)(1) of this chapter, the submitter must also provide, to the extent known to or reasonably ascertainable by the submitter, a description of known categories of consumer or commercial use by function and application.

■ 19. Amend §§ 721.10647(a)(1), 721.10844(a)(1), 721.10929(a)(1), 721.11149(a)(1), 721.11179(a)(1), 721.11361(a)(1)(iii), and 721.11712(a)(1) by revising the citation ''720.3(c)'' to read ''720.3.''

■ 20. Amend § 721.11777(b) by revising the citations ''720.3(w)'' and ''720.3(d)'' to read ''720.3.''

PART 723–PREMANUFACTURE NOTIFICATION EXEMPTIONS

■ 21. The authority citation for part 723 continues to read as follows:

Authority: 15 U.S.C. 2604.

■ 22. Amend § 723.50 by:
■ a. Revising paragraphs (a)(1);
■ b. Adding paragraphs (b)(11) and (12);
■ c. Revising paragraphs (d);
■ d. Adding paragraphs (e)(2)(xiv);
■ e. Revising paragraphs (e)(3), (g), (h)(2)(v), and (i); and
■ f. Adding paragraph and (p).

The revisions and additions read as follows:

§ 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) * * *

(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:

* * * * *

(b) * * *

(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)).

* * * * *

(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) * * *

(2) * * *

(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.

* * * * *

(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) * * *

(2) * * *

(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.

* * * * *

(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.

* * * * *

(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.

PART 725–REPORTING REQUIREMENTS AND REVIEW PROCESSES FOR MICROORGANISMS

■ 23. The authority citation for part 725 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, 2613, and 2625.

■ 24. Amend § 725.8(c)(1) by revising the citation ''720.3(e)'' to read ''720.3.''

■ 25. Amend § 725.54 by revising paragraphs (b)(1), (c) and (d) to read as follows:

§ 725.54 Suspension of the review period.

* * * * *

(b)(1) *Request for suspension.* A request for suspension may only be submitted in a manner set forth in this paragraph. The request for suspension also may be made orally, including by telephone, or in writing, including by e-mail, to the submitter's EPA contact for that notice, subject to paragraph (c) of this section.

* * * * *

(c) An oral or written request for suspension may be granted by EPA for a maximum of 30 days only. Requests for longer suspension must only be submitted in the manner set forth in paragraph (b)(2) of this section.

(d) If the submitter has not made a previous oral or written request, the running of the applicable review period is suspended as of the date of receipt of the CDX submission by EPA.

■ 26. Amend § 725.60 by revising paragraph (a)(1) to read as follows:

§ 725.60 Withdrawal of submission by the submitter.

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

* * * * *

■ 27. Amend § 725.170 by:

■ a. Revising paragraphs (a) and (b); and

■ b. Removing paragraph (c).

The revisions read as follows.

§ 725.170 EPA review of the MCAN.

* * * * *

(a) *Length of the review period.* The MCAN review period specified in section 5(a) of the Act runs for 90 days from the date EPA receives a complete MCAN, or the date EPA determines the MCAN is complete under § 725.33, unless the Agency extends the period under section 5(c) of the Act and § 725.56.

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

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

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

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

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

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

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

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

(ii) For determinations described in paragraphs (b)(1)(ii), (iii), or (iv), EPA will issue the submitter an order to prohibit or limit the manufacture, processing, distribution in commerce,

use, or disposal of the microorganism, or any combination of such activities, to the extent necessary to protect against an unreasonable risk of injury to health or the environment, as set forth in section 5(e) of the Act. EPA may issue an order under section 5(e) of the Act that requires certain testing to be conducted and presented to EPA after the applicable review period has concluded.

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

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

(4) No person submitting an MCAN in response to the requirements of this subpart may manufacture a microorganism subject to this subpart until EPA has issued a determination in accordance with paragraph (b)(1) of this section and taken the associated action required under paragraph (b)(2) of this section.

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PART 761—POLYCHLORINATED BIPHENYLS (PCBs) MANUFACTURING, PROCESSING, DISTRIBUTION IN COMMERCE, AND USE PROHIBITIONS

■ 28. The authority citation for part 761 continues to read as follows:

Authority: 15 U.S.C. 2605, 2607, 2611, 2614, and 2616.

■ 29. In § 761.3 amend the definition for ''Importer'' by removing the citation ''§ 720.3(l)'' and adding in its place ''§ 720.3.''

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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 37

[Docket No. DOT–OST–2024–0090]

RIN 2105–AF05

Transportation for Individuals With Disabilities; Adoption of Accessibility Standards for Pedestrian Facilities in the Public Right-of-Way

AGENCY: Office of the Secretary (OST), U.S. Department of Transportation (DOT or the Department).

ACTION: Final rule.

SUMMARY: The Department of Transportation (DOT or the Department) is amending its Americans with Disabilities Act regulations to adopt, without modification, the Architectural and Transportation Barriers Compliance Board's Accessibility Guidelines for Pedestrian Facilities in the Public Right-of-Way (PROWAG) as DOT's regulatory standards for new construction and alterations of transit stops in the public right-of-way.

DATES: This rule is effective January 17, 2025.

FOR FURTHER INFORMATION CONTACT: For general questions, Holly Ceasar-Fox, Office of the General Counsel, U.S. Department of Transportation, (202) 366–7420, *holly.ceasarfox@dot.gov.* For legal questions related to PROWAG, James T. Esselman, Office of Chief Counsel, Federal Highway Administration, (202) 366–6181, *james.esselman@dot.gov.* For legal questions related to transit, Diane Alexander, Office of Chief Counsel, Federal Transit Administration, (202) 366–3101, *diane.alexander@dot.gov.* For questions related to intercity or high-speed rail, Linda Martin, Federal Railroad Administration, Office of Chief Counsel, 202–689–9408, *Linda.Martin@dot.gov.*

Electronic Access and Filing: This document, the notice of proposed rulemaking (NPRM), all comments received, and all background material may be viewed online at *www.regulations.gov* using the docket number listed above. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *www.federalregister.gov* and the Government Publishing Office's website at *www.GovInfo.gov.*

SUPPLEMENTARY INFORMATION: The Americans with Disabilities Act (ADA) directs the Architectural and Transportation Barriers Compliance Board (U.S. Access Board, or the Board) to issue minimum guidelines for accessible design to guide the U.S. Department of Justice (DOJ) and the U.S. Department of Transportation (DOT) in the development of ADA accessibility standards. *See* 42 U.S.C. 12204(a). On August 8, 2023, the Board issued its final rule on Public Rights-of-Way Accessibility Guidelines (PROWAG). (88 FR 53604).

Title II of the ADA sets forth accessibility requirements applicable to public entities. Under Title II, Part B, DOT is authorized to implement the ADA relating to nondiscrimination in the provision of public transportation services. *See* 42 U.S.C. 12149(a). The ADA directs DOT to adopt standards for accessible public transportation facilities that are ''consistent with'' final minimum accessibility guidelines issued by the Board. *Id.* at section 12149(b). Similarly, Title III of the ADA directs DOT to adopt regulations implementing the transportation provisions of Title III, applicable to private entities that provide specified public transportation services and provides that any standards adopted under such regulations must be ''consistent with'' final minimum accessibility guidelines adopted by the Access Board. *Id.* at sections 12186(a), (c).

Under these authorities, DOT issued a notice of proposed rulemaking (NPRM) to adopt the PROWAG into DOT's ADA regulations on August 22, 2024 (89 FR 67922). The NPRM proposed to adopt the entirety of the PROWAG into DOT's ADA regulations but noted that DOT's independent regulatory authority under the ADA extends only to the accessibility of public transportation facilities. *See* 42 U.S.C. 12149(a), 12186(a), (c). As a result, the NPRM proposed that in adopting the PROWAG into DOT's ADA regulations, DOT will apply only those provisions applicable to new construction and alterations of transit stops in the public right-of-way. PROWAG R210 requires transit stops and transit shelters to comply with technical requirements set forth in PROWAG R309. Elements required to be accessible under PROWAG R309 include the boarding and alighting area