PRE-PUBLICATION NOTICE

On May 16, 2023, Michal Freedhoff, the EPA Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, signed the following document:

Action:	**Proposed Rule**
Title:	**Updates to New Chemicals Regulations under the Toxic Substances Control Act (TSCA)**
FRL #:	**7906-01-OCSPP**
Docket ID #:	**EPA-HQ-OPPT-2022-0902**

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Once the official version of this document is published in the *Federal Register*, this version will be removed from the Internet and replaced with a link to the official version. At that time, you will also be able to access the on-line docket for this *Federal Register* document at http://www.regulations.gov.

For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 720, 721, 723, and 725

[EPA-HQ-OPPT-2022-0902; FRL-7906-01-OCSPP]

RIN 2070-AK65

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The United States Environmental Protection Agency (EPA) is proposing amendments to the new chemicals procedural regulations under the Toxic Substances Control Act (TSCA). These amendments are intended to 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, improve the efficiency of EPA's review processes, and update the regulations based on existing policies and experience implementing the New Chemicals Program. The proposal includes amendments that would reduce the need to redo all or part of the 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 is also proposing several amendments to the regulations for low volume exemptions (LVEs) and low release and exposure exemptions (LoREXs), which include requiring EPA approval of an exemption notice prior to commencement of manufacture, making per- and polyfluoroalkyl substances (PFAS) categorically ineligible for these exemptions, and providing that certain persistent, bioaccumulative, toxic (PBT) chemical substances are ineligible for these exemptions, consistent with EPA's 1999 PBT policy.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE

OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2022-0902 through the Federal eRulemaking Portal at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or 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; email 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; email 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 Industry 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).

If you have any 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?

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 (Pu b. 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. EPA is issuing this proposed rule under TSCA section 5, 15 U.S.C. 2604.

C. What action is the Agency taking?

When EPA receives a premanufacture notice (PMN), significant new use notice (SNUN), or microbial commercial activity notice (MCAN), the Agency is required to assess the risk associated with the new chemical substance or significant new use that is the subject of the notice under the conditions of use and make a determination for the chemical substance pertaining to the likelihood of such risk. Under TSCA, the term "chemical substance" includes microorganisms. To improve the effectiveness and efficiency of these reviews, EPA is proposing to amend 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. In particular, EPA is proposing to amend the regulations to specify that EPA must make a determination on each PMN, SNUN, and 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 proposing to 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 proposing 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 proposing to make several amendments to the regulations at 40 CFR 723.50 for low volume exemptions (LVEs) and low release and exposure exemptions (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 perfluoroalkyl and polyfluoroalkyl substances (PFAS) categorically ineligible for these exemptions, and codify

EPA's use of the 1999 PBT policy for these exemptions by making certain PBTs ineligible for these exemptions. Finally, EPA is proposing to amend 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.

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 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 chemical substances described in such notices before they can proceed to the marketplace. To reflect and better meet these requirements, EPA is proposing to align the procedural regulations codified at 40 CFR parts 720 and 725 with amended TSCA and to make additional updates based on existing policies or lessons learned from administering the New Chemicals Program since TSCA was amended in 2016.

EPA is also proposing to clarify the information that is required to be included in PMNs, SNUNs, and exemption notices and to clarify EPA review procedures to make the review process more efficient, promote more complete submissions, and reduce the need to redo all or part of the risk assessment ("re-work") due to late submissions of information that delay EPA review of PMNs, SNUNs, and exemption notices. In order to continue to meet amended TSCA's requirement for the Agency to make determinations for all PMNs and SNUNs within an

applicable review period of 90 days from receipt (or up to 180 days with an extension), EPA needs to identify and implement efficiencies in the PMN and SNUN review process, ensure notices are complete and reduce re-work of risk assessments. This action, if finalized, is expected to reduce re-work 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 proposing to clarify the procedures that will be employed if submitters amend their PMNs or SNUNs during the applicable review period.

EPA is also proposing to amend 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 proposing amendments that would allow the Agency to notify submitters if a chemical substance for which they hold an LVE or LoREX 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 proposing 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 proposing to codify EPA's 1999 PBT policy by making certain PBTs ineligible for these exemptions.

Lastly, EPA is proposing to 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, and 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 potential incremental impacts of this rulemaking in an economic

analysis (EA), titled "Economic Analysis for the Proposed Rule: Updates to New Chemicals Regulations under the Toxic Substances Control Act" (Ref. 1), which is available in the docket, discussed in Unit IV, 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 proposed 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 proposed rule are expected to reduce the frequency with which PMNs, SNUNs, and exemption notices are amended with additional information and the amount of re-work of risk assessments that the Agency conducts following such amendments.

As a result of the changes presented in this proposed rule, the total annual burden to industry is expected to decrease by approximately 4,518 hours, while total annual costs to industry submitters are expected to have a net increase of $45,120. The Agency is expected to experience an annual cost savings of approximately $923,280.

F. What should I consider as I prepare my comments for EPA?

1. Submitting CBI.

Do not submit CBI to EPA through *https://www.regulations.gov* or email. If you wish to include CBI in your comment, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments.

When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets*.

II. Background

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. TSCA section 5(e) provided that EPA could issue a proposed order to regulate a chemical substance for which a notice was submitted under TSCA section 5(a)(1) if it determined that: (1) the information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance, and (2) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance may present an unreasonable risk of injury to health or the environment in the absence of sufficient information, or the chemical substance is or will be produced in substantial quantities and may either enter the environment in substantial quantities or result in significant or substantial human exposure. Further, TSCA section 5(f) required EPA to issue a proposed rule or proposed order to regulate the chemical substance, or to seek an injunction to prohibit the manufacture, processing, or distribution in commerce of the chemical substance, if it found that there is a reasonable basis to conclude that the chemical substance presents or will present an unreasonable risk of injury to health or the environment.

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). However, if EPA decided to take action under TSCA section 5(e) or 5(f), TSCA required EPA to do so within 90

days of receiving the notice (or up to 180 days if EPA extended the notice period pursuant to TSCA section 5(c)). If EPA did not take action during that time, manufacturing or processing of the chemical substance could commence.

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 a determination 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 and lists five types of risk determinations available to EPA.

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. Under amended TSCA, EPA is required to issue an order pursuant to TSCA section 5(e) when it makes a determination under TSCA section 5(a)(3)(B) that: (1) the information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance or significant new use; (2) in the absence of sufficient information, the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA; or (3) the chemical substance is or will be produced in substantial quantities and may either enter the environment in substantial quantities or result in significant or substantial human exposure. EPA must issue an order to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance to the extent necessary to protect against an unreasonable risk of injury to

health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA under the conditions of use.

Furthermore, TSCA section 5(f) requires EPA to issue either an order or a proposed rule under TSCA section 6(a) when EPA makes a determination under TSCA section 5(a)(3)(A) that a chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA under the conditions of use. If EPA issues an order under TSCA sections 5(e) or 5(f), it must do so no later than 45 days before the expiration of the applicable review period.

Lastly, when EPA makes a determination under TSCA section 5(a)(3)(C) that a chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA under the conditions of use, EPA must publish a statement of its finding in the *Federal Register* according to TSCA section 5(g).

In summary, 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). TSCA section 5(c) allows EPA to extend the original 90-day review period by up to another 90 days for good cause and requires the reasons for the extension to be published in the *Federal Register*. The 2016

Lautenberg Amendments also added 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, such as if the person will manufacture the chemical substance for test marketing purposes, in small quantities for scientific experimentation, or under other conditions that 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. EPA developed the LVE and LoREX regulations in 1995 pursuant to TSCA section 5(h)(4) (60 FR 16336, March 29, 1995).

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 related 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-references 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 proposed amendments to

the requirements in 40 CFR 720.45 would 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 proposed in this action would apply to PMNs and also to 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 proposing amendments to the MCAN and microorganism-related exemption regulations at 40 CFR part 725.

III. Summary of Proposed Rule

A. Amendments to Conform Regulations to 2016 Lautenberg Amendments

EPA is proposing changes to 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 proposing 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 has not yet codified these updates into the new chemicals procedural regulations. The Agency is now proposing to amend the regulations to 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 to list the five possible determinations and the actions required in association with those determinations. EPA is also proposing to add definitions for new terms and to update existing terminology introduced by the 2016 Lautenberg Amendments.

1. Commencement of manufacture or processing.

Prior to the passage of the 2016 Lautenberg Amendments, TSCA did not require EPA to make a risk determination on each notice submitted under TSCA section 5(a)(1). Rather, TSCA required the submission of a notice at least 90 days before manufacturing a new chemical substance, or manufacturing or processing a chemical substance for a significant new use. If EPA did not take any regulatory action on a notice, the submitter could commence the manufacturing or processing after 90 days (or up to 180 days if EPA extended the notice period pursuant to TSCA section 5(c)). Promulgated in 1983, the PMN procedural regulation at 40 CFR 720.75(d) reflects that prior statutory provision and states that "in the absence of regulatory action by EPA under section 5(e), 5(f), or 6(a) of the Act, the submitter may manufacture or import the chemical substance even if the submitter has not received notice of expiration [of the review period]." A similar provision was promulgated in the MCAN procedural regulations in 1997 at 40 CFR 725.170(b) and (c).

The 2016 Lautenberg Amendments changed the requirements of TSCA section 5(a) by adding section 5(a)(1)(B)(ii) and (a)(3), which require EPA to conduct a review of each notice submitted under TSCA section 5(a)(1), make a determination on the notice, and take the action required in association with that determination before a submitter can commence the manufacture of a new chemical substance or the manufacture or processing of a chemical substance for a significant new use. Since amended TSCA went into effect, EPA has been implementing the new law by making a determination and taking any required action on each PMN, SNUN, and MCAN received. However, the outdated regulatory text at 40 CFR 720.75(d) and 725.170(b) and (c) is still in place, even though it has been superseded by the amendments to the statute.

Therefore, in this action, EPA is proposing to amend 40 CFR 720.75(d) by removing the 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 proposing to amend 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 proposing to amend 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 may commence.

2. Required determinations and associated actions.

As previously described, the 2016 Lautenberg Amendments added a new paragraph at TSCA section 5(a)(3) titled "Review and Determination," which lists the five possible determinations that EPA may make on a notice. To improve clarity and help inform the regulated community about EPA's statutory obligations under TSCA section 5(a)(3), EPA is proposing to further amend 40 CFR 720.75(d) and 725.170 by listing the five possible determinations for each PMN, SNUN, or MCAN.

EPA is also proposing to add language 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 proposing to codify 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. The five possible determinations and associated actions are as follows:

• When EPA makes a determination for a PMN, SNUN, or MCAN according to TSCA

section 5(a)(3)(C) that the new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA under the conditions of use, EPA issues a determination document to the submitter of the PMN, SNUN, or MCAN. The submitter may commence manufacturing or processing of the chemical substance once they receive the determination document. As required by TSCA section 5(g), EPA also submits for publication in the *Federal Register* a statement of the "not likely" finding.

• When EPA makes a determination for a PMN, SNUN, or MCAN according to TSCA section 5(a)(3)(B) that (1) the information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects of the new chemical substance or significant new use, (2) in the absence of sufficient information, the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA, or (3) the chemical substance is or will be produced in substantial quantities and may either enter the environment in substantial quantities or result in significant or substantial human exposure, EPA must issue an order pursuant to TSCA section 5(e). The order prohibits or limits the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA under the conditions of use. EPA may issue an order under TSCA section 5(e) that requires testing to be conducted and presented to EPA after the applicable review period has concluded.

• When EPA makes a determination for a PMN, MCAN, or SNUN according to TSCA section 5(a)(3)(A) that the chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA under the conditions of use, EPA must take one of the following actions described in TSCA section 5(f) to the extent necessary to protect against such risk: (1) issue an immediately effective proposed rule to limit the amount of such substance that may be manufactured, processed, or distributed in commerce or to impose other requirements described in TSCA section 6(a), or (2) issue an order to prohibit or limit the manufacture, processing or distribution in commerce of the substance, to take effect on the expiration of the applicable review period.

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. EPA is proposing amendments to 40 CFR 720.75(d) and 725.170 to state that EPA may modify or revoke the prohibitions and limitations in an order after the applicable review period has ended if the submitter submits to EPA 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. While the current regulations do not specify that EPA may modify or revoke the

prohibitions and limitations in an issued order, the proposed amendments at 40 CFR 720.75(d) and 725.170 would codify current practices. EPA believes that these existing processes and actions for modifying or revoking the prohibitions and limitations in an issued order fulfill the requirements of TSCA section 5, as amended by the 2016 Lautenberg Amendments.

3. Other updates.

EPA is proposing to replace the 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 proposing to add 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." This proposed definition is based on the TSCA section 5(i)(3) definition for "applicable review period."

EPA is also proposing to add a definition for "potentially exposed or susceptible subpopulation" to 40 CFR 720.3, a term added to TSCA by the 2016 Lautenberg Amendments. Based on the definition in TSCA section 3(12), EPA would define "potentially exposed or susceptible subpopulation" as "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."

EPA is also proposing to update 40 CFR 720.70(b) by revising paragraph (b)(3). The language in paragraph (b) describes the content of the document that EPA routinely publishes in the ***Federal Register*** under TSCA section 5(d)(2) to announce the receipt of PMNs submitted to EPA. Although not required by TSCA section 5(d)(2), the first sentence in 40 CFR 720.70(b)(3)

specifies that the document EPA publishes in the ***Federal Register*** pursuant to TSCA section 5(d)(2) will also include a list of data submitted with the PMN in accordance with 40 CFR 720.50(a). In proposing to establish this requirement in the original 40 CFR part 720 regulations, EPA described its objective as providing relevant information to the public in terms of the PMNs submitted and under review with EPA. See e.g., 44 FR 2242, 2253 (January 10, 1979). That transparency goal is now better achieved through other more efficient and effective mechanisms that negate the need to publish that information in the ***Federal Register***. Specifically, to provide streamlined access to information EPA receives and develops about chemicals, EPA has built and is constantly expanding content in an online searchable data base called ChemView (*https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/introduction-chemview*), and currently makes the PMN itself, including test data submitted with it, available on ChemView (subject to confidentiality claims) generally within 5 workdays of receipt. In addition, EPA is making the list of new chemical submissions received available in one place on our website to increase transparency and make information on new chemicals easier to find (see *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemical-notices-received-epa*). This approach was adopted several years ago to provide an alternative to searching individual Federal Register notices and dockets on *https://www.regulations.gov*. The links below provide a listing of the following types of new chemical submissions received. The lists on the website are updated on a regular basis and allow anyone to track the status of active new chemical cases by visiting our page on statistics for the new chemicals review program (*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review*).

B. Amendments Related to Notice Information Requirements

EPA is proposing changes to the notice information requirements at 40 CFR 720.45, as

well as corresponding changes to the reporting form in CDX, to clarify the level of detail expected for information that must be submitted to EPA in the PMN, SNUN, and certain exemption notices.

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 proposed rule and can be found in the docket (Ref. 2). 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 proposed 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 PMN, SNUN, and exemption notices do not contain all required information at the level of detail that EPA needs to perform refined, quantitative risk assessments. When a submission is lacking detail, EPA typically uses conservative assumptions and default values to ensure the assessment is protective of human health and the environment.

The Agency may make predictions using models concerning physical and chemical properties, environmental transport and partitioning, environmental fate, environmental toxicity, human health, engineering releases to the environment, and environmental concentrations—see the document titled "Points to Consider When Preparing TSCA New Chemical Notification" (Ref. 3) for more information on EPA's use of predictive models in the new chemical review process. EPA has repeatedly observed, however, that when submitters see the level of risk estimated by EPA using such conservative assumptions and default values, as well as the risk mitigation measures developed by EPA as a result, submitters often amend their initial notices to provide additional detailed information. In an effort to improve the accuracy of EPA's risk assessment, submitters often either provide information that was missing in their initial notice or clarify details about the manufacturing process. When EPA receives such information during the review process, EPA takes the information into consideration and may redo its risk assessments ("re-work") to factor in the additional information. This longstanding practice of submitters amending their initial notices to provide additional information after the beginning of the review period and EPA having to consider the information late in the review process results in re-work by EPA and diverts EPA attention from processing new notices. This creates delays in the review of notices generally.

EPA has previously worked to address the inefficiency of the review process associated with late submission of information by issuing several supplemental documents to aid submitters in providing all relevant information in the initial notice. EPA published a Points to Consider document in 2018 (Ref. 3) and provides a user guide and resource tab that are accessible within the CDX application and provide instructions on how to complete the submission (Ref. 2). To further address this issue, EPA began implementing a pre-screen process for notices in April 2020, which is detailed in Unit III.C. of this document. And in July 2022, the Agency launched

the TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Re-work that included a broad outreach effort to describe and discuss with stakeholders how the Agency evaluates data provided with notices and common issues that cause EPA to have to re-work risk assessments (Ref. 4).

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, would help submitters provide all relevant information in their initial notice submissions. EPA has observed that many data elements in notice submissions often lack the level of detail that EPA needs. EPA believes that specifying more detailed information requirements in 40 CFR 720.45 and data fields in the CDX user interface would promote more complete submissions upfront and help to minimize the need for EPA to use default values and conservative assumptions in its risk assessment. Therefore, EPA is proposing to amend the notice information requirements at 40 CFR 720.45, as well as implementing corresponding changes to the PMN form in CDX.

2. Proposed changes to 40 CFR 720.45 and the PMN Form.

EPA is proposing to amend 40 CFR 720.45 and the PMN form in CDX to clarify the information requirements for a notice. Specifically, EPA is proposing to add details to certain information requirements already contained in 40 CFR 720.45 and to add additional reporting fields to the PMN form to reflect these details. This detailed information is already required by the broader information requirements contained in 40 CFR 720.45 and 720.50 and is reflected in the CDX user interface. In this action, EPA is proposing to add these details as separate, unique information requirements in 40 CFR 720.45 and make corresponding changes to the PMN form to clarify the level of detail needed for EPA's review of a notice and to ensure that the fields in the PMN form are consistent with the regulations. In some cases, reporting fields for detailed

information are already included in the PMN form because they are covered by broader information requirements contained in 40 CFR 720.45 or 720.50. EPA is proposing to add those details to 40 CFR 720.45 so that the regulations and PMN form are consistent. See Ref. 5, which provides tables that list the detailed information requirements proposed to be added to 40 CFR 720.45 and indicate whether reporting fields for that information are already included in the PMN form.

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(p). Under the proposed changes to 40 CFR 720.45, a submitter would be required to include in the PMN form the detailed information proposed 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 out of the submitter's control. In those situations, EPA would make conservative assumptions and use conservative default values for any information that is not known to or reasonably ascertainable by the submitter and therefore not provided in the PMN form.

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). Submitters must also submit this information in the corresponding PMN form fields in accordance with the proposed changes to 720.45(j). 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.

a. Physical and chemical properties and environmental fate characteristics.

The first set of detailed information requirements that EPA is proposing to add to 40 CFR 720.45 is about the physical and chemical properties and environmental fate characteristics of the chemical substance (see Table 1 in Ref. 5). EPA currently 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. To ensure that the regulations are clear about what information fields are included in the PMN form itself, EPA believes that the information requirements in 40 CFR 720.45 should reflect the PMN form fields. EPA is therefore proposing to add 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.

EPA is proposing several information requirements at 40 CFR 720.45(j)(1) that are not already specified within the PMN form for physical and chemical properties. EPA is proposing to require in 40 CFR 720.45(j)(1) 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. Data on surface tension and UV-VIS absorption are not currently included on the pick list for physical and chemical properties in CDX, and their inclusion there as well as in the proposed regulations at 40 CFR 720.45(j)(1) will promote more complete submissions. The particle size distribution value is already a physical and chemical property that appears in the pick list on the CDX user interface screen, but it would improve EPA's ability to assess risk if the value were accompanied

by the analysis data used to develop the value. Additionally, EPA proposes to require at 40 CFR 720.45(j)(1) information for aspect ratio, thickness, and number of layers or walls for nanomaterials. Information requirements for nanomaterial morphology do not currently appear on the pick list for physical and chemical properties on the CDX user interface screen or in the regulations. Requiring data for these properties will allow EPA to offer additional clarity to submitters providing notices for nanomaterials, since submitters might otherwise omit such data. Therefore, EPA is proposing to add these requirements to the regulations at 40 CFR 720.45(j)(1) and to add fields for attaching associated data on the physical and chemical properties screen of the PMN form.

EPA also proposes to add information requirements for the environmental fate characteristics of the chemical substance (see Table 1 in Ref. 5) 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 proposing to add the relevant environmental fate characteristics to the information requirements at 40 CFR 720.45(j)(2) and to add form fields to the PMN form by expanding the pick list.

b. Categories of use.

The next set of information requirements that EPA is proposing to add to 40 CFR 720.45 relates to the categories of use of the chemical substance (see Table 2 in Ref. 5). The proposed requirements include detailed information on commercial and consumer uses, which already have form fields in the PMN form in CDX specifying in greater detail the broader information requirement in the regulations at 40 CFR 720.45(f) regarding categories of use. Although the

regulations at 40 CFR 720.45(f) currently require 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 specific information requirements for details on commercial and consumer uses are not yet specified. These 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. EPA is proposing to add these requirements to 720.45(f). Additionally, EPA is proposing to add to 40 CFR 720.45(f) a requirement to designate applicable consumer and commercial product categories using Organisation 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 also proposing corresponding changes to the PMN form fields in CDX.

c. Details concerning manufacture, processing, and use.

The third set of information requirements that EPA is proposing to add to 40 CFR 720.45 is information related to each site where 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 proposing are similar for both, different types of activities (*e.g.*, manufacturing versus processing) often occur at submitter-controlled sites versus those at sites controlled by others. 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 the submitters when a notice is submitted. As such, some slight differences exist in the requirements EPA is proposing for information related to sites controlled by submitters versus sites controlled by others.

For both sites controlled by submitters and sites controlled by others, EPA is proposing to add information requirements for site addresses (see Table 3 and Table 5 in Ref. 5). For submitter-controlled sites, EPA is also proposing to add requirements for 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 a given batch and/or timeframe (see Table 5 in Ref. 5). These proposed 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)-(2) and (h) for a process description of operations at such sites. Since these proposed information requirements are not yet specified in the regulations, EPA is proposing to add 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 proposing to add requirements for detailed information about the process diagram or description for each site controlled by the submitter (see Table 4 in Ref. 5) and for each site not controlled by the submitter (see Table 5 in Ref. 5). These requirements 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. Although these details are already covered by the existing information requirements in

40 CFR 720.45(g)(2) and (h) for a process description of operations at such sites, EPA is proposing to add them as separate, unique information requirements 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.

d. Worker exposure.

EPA is also proposing to add requirements for detailed information about the possible worker exposure at each site controlled by the submitter (see Table 6 in Ref. 5), and at each site not controlled by the submitter (see Table 7 in Ref. 5). 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. 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 proposing to add 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.

e. Environmental releases.

Finally, EPA is proposing to add detailed information requirements about the potential environmental releases at each site controlled by the submitter (see Table 8 in Ref. 5) and at each site not controlled by the submitter (see Table 9 in Ref. 5). These requirements include descriptions of the type of release (*e.g.*, transport, interim storage, disposal, equipment cleaning); the amount of the chemical substance released directly to the environment or into control

technology; the amount of the chemical substance released to the environment after control technology; for equipment cleaning releases, frequency of equipment cleaning and what is used to clean equipment; for transport and storage releases, how the chemical substance or the product containing the chemical substance is transported from the site and stored and information about the containers used; for releases into air, Clean Air Act operating permit numbers and a description of any Leak Detection and Repair program the site has implemented; for releases into water, National Pollutant Discharge Elimination System (NPDES) permit numbers and information on the navigable waterways and other destinations into which the release occurs; and for releases into wastewater treatment plants, information on the publicly owned treatment works (POTW) into which the release occurs. In addition, for sites controlled by others, these requirements also include a description of the media of release. Although each of these details 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 proposing to add 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.

If the information is not known to or reasonably ascertainable by the submitter for one or more sites, EPA makes conservative assumptions and uses default values to replace the missing information whether the site is controlled by the submitter or not. Therefore, EPA believes that the level of detail in the regulations for process description, worker exposure, and environmental release information for sites controlled by the submitter at 40 CFR 720.45(g) should mirror the level of detail in the regulations for process description, worker exposure, and environmental release information for sites not controlled by the submitter at 40 CFR 720.45(h). EPA is proposing to amend 40 CFR 720.45(g) and (h) to make them consistent. EPA recognizes that a

submitter may not possess such information about sites not controlled by the submitter. Submitters are only required to supply information that is known to or reasonably ascertainable by them as defined at 40 CFR 720.3(p).

Additionally, EPA is proposing clarifying amendments to 40 CFR 720.45(g)(3) and (4) and 720.45(h)(3) and (4) to ensure that submitters include worker exposure and environmental release information from exempt manufacture or related use of the chemical substances under 40 CFR 720.30 (*e.g.*, a chemical substance manufactured under the byproduct or impurity exemptions) at each site where the chemical substance will be manufactured, processed, or used, if known or reasonably ascertainable. EPA is also proposing clarifying amendments to 40 CFR 721.25(c) to ensure that submitters of SNUNs include in their notice both a description of the significant new use for which they are submitting a SNUN and of all other known or intended categories of use. 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.

f. Pollution prevention information.

Lastly, EPA is proposing to add optional pollution prevention information at 40 CFR 720.45(k). 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.

EPA estimates that the proposed amendments, which are intended to clarify the level of detail required for existing data requirements under 40 CFR 720.45 and 720.50, would have a very minor impact on submitter burden because they are largely reflected in existing fields in the

PMN form in CDX that submitters already are prompted to complete. Moreover, they are also already included in the Points to Consider document (Ref. 3) that submitters are encouraged to review before completing a notice. EPA's estimate of the burden impacts of these proposed information requirement amendments are presented in an Information Collection Request (ICR) document (Ref. 6), a copy of which is in the docket and is summarized in Unit VI.B.

EPA is seeking comment specifically on its burden estimate and on the general pros and cons of clarifying these information requirements in the regulations and making corresponding changes to the PMN form. EPA is also seeking comment from the public, including those who have submitted a notice to EPA in the past, on any information requirement details that are not clearly explained in the PMN form or the regulations.

3. Other modifications to the PMN Form in CDX.

In addition to the proposed amendments 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 considering 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. In other words, if a submitter leaves information fields blank, they would have to check a box on the screen to affirm that the information is not known to or reasonably ascertainable by the submitter before advancing to the next screen. 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 would make conservative assumptions and use conservative default values when assessing risk, which could result in more stringent risk management requirements. 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). This check box approach would 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 proposed rule describes the potential modifications to each screen of the PMN form (Ref. 6).

As an alternative to this check box approach, EPA considered adding automatic checks in CDX to make certain critical fields mandatory such that the user could not advance to the next screen in the PMN form or submit the form without entering information into the field. EPA does not favor this approach because information required on the PMN form is required to the extent it is known to or reasonably ascertainable by the submitter, and EPA understands that there may be situations where such information may not be known to or reasonably ascertainable by the submitter. EPA also considered adding a statement and check box to every screen in the PMN form that information in the form is required if it is known to or reasonably ascertainable by the submitter, and not just to certain screens as described above. EPA does not favor this approach because it would require significant resources to program such statements and check boxes on each screen. Furthermore, the PMN form is designed to allow users the flexibility of moving back and forth through the screens, skipping screens, and returning to previous screens as needed. EPA feels that implementing such check boxes on every screen may impede this flexibility and unnecessarily increase the burden of completing a PMN form. EPA seeks comment on these alternatives, as well as on whether there are other approaches to modifying the PMN form to encourage complete submission of data.

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

Information

EPA is proposing 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 proposing amendments to align the process for correcting errors in the notice with the existing process for incomplete submissions. EPA is also clarifying that a notice is not considered complete at the time of the initial notice submission 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 proposing amendments to 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. Background.

The first step that EPA takes after the receipt of a new chemicals notice before the risk assessment begins is to conduct a pre-screen of the notice, which typically takes 2-3 days. During the pre-screen process, EPA determines whether a notice is required for the chemical substance under TSCA. For example, EPA determines whether the chemical substance is already on the TSCA Chemical Substance Inventory (also called the "TSCA Inventory" or "Inventory"), not a "chemical substance" as defined in TSCA section 3(2), or will be manufactured solely for export. If EPA determines that a notice is not required, EPA notifies the submitter that they are not required to submit a notice under TSCA in order to proceed commercially. EPA rejects the notice, and an applicable review period does not begin. See 40 CFR 720.62.

During this pre-screen process, EPA also initiates a chemistry, engineering, and administrative screen of the notice. EPA chemists evaluate whether the chemical identity of the

new chemical substance is clear, the starting materials add up to the final chemical substance, and the chemical structure is consistent with the name. EPA engineers evaluate whether certain information is contained in the notice, such as complete site identification information, manufacturing process descriptions, and information on environmental releases and worker exposure for each site. EPA also evaluates whether any of the other conditions for incomplete submissions outlined in 40 CFR 720.65(c)(1) have been met, such as a failure to properly sanitize for CBI a second copy of the notice or the failure to submit the notice in English. Finally, EPA checks for other errors in the notice. See 40 CFR 720.65(b).

If EPA deems the notice complete after the pre-screen process, then the notice moves forward to the risk assessment process. If EPA does not deem the notice complete during the pre-screen period, EPA notifies the submitter that the notice is incomplete and explains the requirements for correcting the incomplete submission, per 40 CFR 720.65(c)(3). Once the submitter submits a complete notice according to the requirements previously provided by EPA, the applicable review period begins.

Currently, after EPA completes its risk assessment of a chemical substance, EPA reaches out to the submitter to explain the findings of the risk assessment and any proposed prohibitions or limitations on the manufacturing, processing, distribution in commerce, use, or disposal of the chemical substance. If the submitter disagrees with the potential risks identified in the risk assessment, the submitter may provide additional information intended to demonstrate that risks are lower than EPA estimated. The additional information may be detailed information on worker exposures or environmental releases that was missing from the initial notice submission, or it may be previously unsubmitted testing on the chemical substance to better characterize the potential risk that EPA identified in its assessment. These and other amendments could indicate that the original notice was incomplete if the additional information was known to or reasonably

ascertainable by the submitter at the time of the original submission. See 40 CFR 720.65(c)(1)(v) through (vi), (c)(2)(ii). If an original notice is later found to have been incomplete, EPA may restart the review period at Day 1 when additional information is submitted that then makes the notice complete.

Under its current practice, EPA may consider the additional information and, if warranted, conduct the risk assessment again to factor in the additional information. This is in line with EPA's longstanding objective to take into consideration reasonably available information and account for real-world conditions during manufacturing, processing, distribution, use, or disposal of a chemical substance. While this practice has the benefit of refining the risk assessments, it uses EPA resources inefficiently and adds significant time to the review process.

2. Pre-screening procedures.

EPA is proposing to amend 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. If through the pre-screen process EPA finds that the initial notice submission is complete, Day 1 of the applicable review period is the day the notice was received by EPA via CDX, consistent with the existing regulations at 40 CFR 720.75(a). If the pre-screen process finds that the initial submission is incomplete, the applicable review period will not begin until EPA receives a complete notice, consistent with the existing regulation at 40 CFR 720.65(c)(2)(i). After the pre-screen, EPA may still determine within 30 days of receipt of the submission, once the risk assessment is underway and the information submitted more thoroughly evaluated, that the notice is incomplete, as currently described at 40 CFR 720.65(c)(2)(i). However, it has been EPA's experience that the pre-screen process helps

minimize the number of submissions identified as incomplete or containing errors later in the review period. EPA is also proposing 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.

3. Correcting errors in notices.

EPA is proposing amendments to 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 proposed amendment will align the process for correcting errors with the current process for correcting an incomplete notice at 40 CFR 720.65(c)(2) through (5). The 1983 final rule that established the current process for correcting errors stated that "the submitter is under no obligation to make the correction, but failure to do so may cause EPA to extend the review period under section 5(c) of the Act." ((Ref. 7) (48 FR 21735, May 13, 1983). While the current regulations and the proposed amendment give EPA discretion to request remedy of errors, EPA now believes that if the Agency exercises that discretion to request that the submitter remedy an error, review of the notice should not move forward until the error is corrected. EPA does recognize that some errors may be minor and not require correction prior to EPA initiating review of the notice, such as easily recognized spelling errors or an incorrectly numbered list—EPA does not intend to request correction of such errors. EPA's notification to the submitter that a submission contains errors would include (i) a statement of the basis of EPA's determination that the submission contains errors, (ii) the requirements for correcting the errors, and (iii) information on procedures for filing objections to the determination or requesting modification of the requirements for completing the submission. Additionally, EPA is proposing an amendment to remove "failure to date the notice form" as an

example of an error because the electronic PMN form submitted through CDX automatically dates the notice upon submission and this error is no longer possible.

4. Notice amendments indicating original notice was incomplete.

If information required under 40 CFR 720.45 and 720.50 and specified in the PMN form is known to or reasonably ascertainable by a submitter, the submitter must report the information in the notice. EPA defines "known to or reasonably ascertainable by" at 40 CFR 720.3(p) to mean "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." This definition is not overly prescriptive and is based on a concept of reasonableness that is fact specific. Furthermore, the existing regulation at 40 CFR 720.65(c)(2)(ii) states that if EPA obtains additional information during the review period that indicates the original submission was incomplete, EPA may declare the submission incomplete. Accordingly, if a submitter amends their notice during the applicable review period to add information required under 40 CFR 720.45 or 720.50 that was known to or reasonably ascertainable by the submitter at the time of the original submission, EPA would have cause to declare that the original submission was incomplete. Because the applicable review period does not begin until a submission is complete, EPA can restart the applicable review period to Day 1 if a submission is later amended during the review period and such amendment demonstrates that the original submission was incomplete.

To date, EPA has generally not exercised its discretionary authority under section 720.65(c)(2)(ii) to declare original submissions incomplete when the Agency has received late submissions of information required by 40 CFR 720.45 or 720.50 that may have been known to or reasonably ascertainable by the submitter at the time of the original notice submission. Instead, EPA has considered the additional information and if applicable, conducted re-work on its risk assessments. To accomplish this re-work during the applicable review period, EPA has

generally granted a submitter's request for a suspension of the review period, per 40 CFR 720.75(b).

EPA intends to change this longstanding practice of accepting amendments that contain 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, and 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 is appropriate in order for EPA to efficiently meet current statutory requirements. Overall, amendments and re-work often lead to an inefficient use of EPA resources and a review timeline that is not predictable and/or reliable for all stakeholders. EPA would continue to accept amendments and, as necessary, refine risk assessments based on these amendments, but believes that the shift to restart the applicable review period would create a more transparent and predictable review process for submitters.

To clearly communicate this intended change in longstanding practice, EPA is proposing to amend 40 CFR 720.65(c) by adding a paragraph (2), which would state that a notice submission may be declared incomplete if the submitter submits additional or revised information at any time during the review period without demonstrating to EPA's satisfaction that such information was not known to or reasonably ascertainable by the submitter at the time of initial notice submission. Additionally, EPA is proposing an amendment at 40 CFR 720.65(d)(5)(iii) to clarify that if EPA obtains additional information during the review period that leads EPA to declare the initial notice submission incomplete, in accordance with 40 CFR 720.65(d)(2) (proposed to be redesignated from current 40 CFR 720.65(c)(2)(ii)), the applicable review period would restart at Day 1 upon receipt of the complete notice.

It is EPA's view that information on basic physical and chemical properties and on anticipated environmental releases or worker exposures at any sites controlled by the submitter, as required at 40 CFR 720.45, would be known to or reasonably ascertainable by the submitter at the time of the original submission. Furthermore, EPA believes that it is extremely unlikely that a submitter would neither know nor be able to reasonably ascertain such information at the time of the original submission, but could know or ascertain it 20 or 40 or 60 days after the original submission or at other times during the review period. In this action and with the amendment proposed at 40 CFR 720.65(c)(2), EPA is communicating to stakeholders that they must provide all information required by 40 CFR 720.45 and 720.50 upfront and submit a complete notice.

Based on its experience reviewing thousands of notices and amendments, EPA believes that it should be very uncommon for a submitter to amend their notice during the review period by adding information that they could not have known or reasonably ascertained at the time of the original submission, such as for new information as described at 40 CFR 720.40(f) or information from testing in progress at the time of the original submission, as described at 40 CFR 720.50(a)(4). Under the proposed amendment at 40 CFR 720.65(c)(2), the submitter of additional or revised information during the review period would have to 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. As a matter of policy, EPA believes that the only amendments to a notice that would not indicate 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, would 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) (proposed to be redesignated as 40 CFR 720.65(d)(4) and (5)). Amendments based on new data, administrative or non-substantive amendments, and amendments made at the request of EPA would not impact the completeness of a submission.

EPA offers the following example to illustrate the intended change to its longstanding practice: If a submitter leaves blank a field in the PMN form for information required under 40 CFR 720.45 to the extent it is known to or reasonably ascertainable by the submitter, EPA may use a conservative assumption or default factors in place of that information for the risk assessment and conclude that certain prohibitions or limitations on the chemical substance may be warranted. If after learning the findings of EPA's risk assessment, the submitter then amends its original notice in CDX by providing information in the field previously left blank, EPA would notify the submitter, according to the existing regulation at 40 CFR 720.65(c)(2)(ii) and (3) (proposed to be redesignated as 40 CFR 720.65(d)(2) and (3)), that the original submission was incomplete. The submitter may then file an objection to the determination that the original notice was incomplete, at which time they may seek to demonstrate that the additional or revised information was not known to or reasonably ascertainable by them at the time of initial notice submission. If in response to the objection, EPA determines the original notice 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. However, if EPA considers the objections and still determines that the original notice was incomplete, or if no objections are filed, EPA will restart the applicable review period and the new Day 1 will be the date the additional information that completed the notice was submitted to EPA.

EPA believes that the meaning of "known to or reasonable ascertainable by" described in

this preamble is generally consistent with EPA's original interpretation laid out in the 1983 final rule entitled "Premanufacture Notification; Premanufacture Notice Requirements and Review Procedures" (Ref. 7). That final rule states that "EPA believes that it is not possible to define 'known to or reasonably ascertainable' more explicitly"; "EPA believes that 'reasonably ascertainable' can be defined only on a case-by-case basis"; and "EPA generally can judge from the notice itself whether it includes information that is known to or reasonably ascertainable by the submitter" (Ref. 7 at page 21730). Further, that final rule provides an example of what would not be reasonably ascertainable to illustrate a rather high bar for information to qualify as not reasonably ascertainable: "Certainly, in most instances, data-gathering that is so costly as to preclude commercialization is not reasonable." (Ref. 7 at page 21730)

EPA is seeking comment on the proposed new provision at 40 CFR 720.65(c)(2) and proposed amendment to 40 CFR 720.65(c)(5)(iii) (proposed to be redesignated as 720.65(d)(5)(iii)), which clarify that EPA may deem an original notice incomplete, and restart the review period at Day 1 upon completion of the notice, 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. EPA is seeking comment on situations when this interpretation may not be appropriate.

5. Notifying EPA of the receipt of new information on a chemical substance under review.

EPA acknowledges that in some cases new information can become available about a chemical substance during the course of its review. When this occurs, submitters are required to inform EPA in writing and provide the new information within ten days of receiving the new information, but no later than five days before the end of the notice review period. 40 CFR 720.40(f) and 40 CFR 720.50(a)(4)(ii) address the requirements for informing EPA of receipt of new information (including a study, report, or test that is completed during the notice review

period), which require submitters to communicate receipt of new information to EPA via mail correspondence, or via telephone if the new information is received within five days of the end of the notice review period. EPA is proposing to amend 40 CFR 720.40(f) and 40 CFR 720.50(a)(4)(ii) 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 proposing to allow them to notify EPA by e-mail of the receipt of new information. E-mail communication would provide an alternative means of notifying EPA of the receipt of new information in the event that an EPA contact is unavailable to receive a phone call. While the submitter could use phone or e-mail to notify EPA of the receipt of new information, all new information would be submitted electronically to EPA via CDX. Additionally, e-mails should not contain CBI.

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

EPA is proposing several amendments to the current LVE and LoREX regulations. Specifically, EPA is proposing 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, (3) PFAS be categorically ineligible for these exemptions; and (4) the regulations codify the ineligibility for exemptions of certain PBTs as described in EPA's 1999 PBT policy (Ref. 8).

1. Amendments to expiration of LVE and LoREX review period.

By way of background, 40 CFR 723.50(a)(2)(i) currently requires that LVE and LoREX applicants submit a notice of intent to manufacture a chemical substance under an LVE or LoREX 30 days before commencing manufacture. 40 CFR 723.50(g)(1) provides that EPA will

review the LVE or LoREX notice to determine whether manufacture of the chemical substance is eligible for the exemption. 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." At present, 40 CFR 723.50(g)(2) provides 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 has taken no action. In practice, EPA would move to deny an LVE or LoREX notice at the end of the review period if it were not able to conclude by that time that the substance will not present unreasonable risk on the basis that there are issues concerning toxicity or exposure that require further review which cannot be accomplished within the 30-day review period. EPA's current practice when other delays occur during the review of an LVE is to agree to submitter requests to suspend the running of the review period while EPA completes its review and determines whether to approve or deny the exemption notice. See 40 CFR 723.50(g)(1).

Elsewhere in this rulemaking, EPA is proposing to amend 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 proposed changes to 40 CFR 720.75, 721.25(d), and 725.170 are intended to conform those regulations to the 2016 Lautenberg Amendments.

EPA is proposing similar amendments to the LVE and LoREX regulations at 40 CFR 723.50 to align with the proposed 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. Specifically, EPA is proposing to amend 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.

2. Notification of LVE and LoREX holders if the chemical substance is subject to a SNUR.

At present, when a chemical substance is reviewed via a PMN and becomes subject to a SNUR, confidentiality claims for the specific chemical identity in the PMN and reflected in the associated SNUR may, in the absence of submitting a *bona fide*, prevent holders of current LVEs and LoREXs for that same substance from being informed that the chemical substance is now subject to a SNUR. EPA is proposing to add language 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 proposed 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*) pursuant to 40 CFR 721.11. EPA is proposing to amend the regulations at 40 CFR 723.50 to 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 will not be considered public disclosure of confidential business information under section 14 of

the Act. EPA is not proposing in this rulemaking any revisions to the procedures in 40 CFR 723.50(l) for asserting and protecting confidential business information.

This amendment would also help inform certain LVE and LoREX holders that they may now or in the future become subject to chemical data reporting (CDR) requirements. The CDR requirements described at 40 CFR 711.8 differ for chemical substances subject to certain TSCA actions (*e.g.*, SNURs). The annual production volume threshold at which reporting is ordinarily required is 25,000 pounds, and as such LVE holders are generally exempt, and LoREX holders may be exempt, from such reporting even if their chemical substance has been added to the Inventory. However, if a chemical substance previously approved as an LVE or LoREX is later reviewed as a PMN and becomes subject to certain new actions under TSCA (such as a SNUR) as well as being added to the Inventory, the threshold for reporting is lowered to 2,500 pounds annually. This creates the potential for inadvertent non-compliance with CDR requirements by those LVE and LoREX holders.

EPA does not intend to proactively inform current LVE and LoREX holders about SNURs that predate this rule. EPA is seeking comment on its proposal to allow EPA to proactively 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. EPA would only start the practice of notifying LVE and LoREX holders subject to this proposed amendment after the date of the final rule.

3. Making PFAS categorically ineligible for LVEs and LoREXs.

EPA is proposing amendments to make PFAS categorically ineligible for LVEs and LoREXs going forward and proposing a structural definition of PFAS for purposes of the LVE and LoREX regulations. The Agency is proposing the same chemical structure definition for PFAS as the definition proposed in the recent rule entitled “Per- and Poly-fluoroalkyl Chemical

Substances Designated as Inactive on the TSCA Inventory; Significant New Use Rule" (known as the "Inactive PFAS SNUR") (88 FR 4937, January 26, 2023 (FRL-9655-01-OCSPP)).

In April 2021, EPA's New Chemicals Program began implementing a new policy for reviewing and managing LVE notices for PFAS. In the 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." Prior to the new policy, EPA had approved more than 600 LVE notices for PFAS—many of which were granted prior to the 2016 Lautenberg Amendments and were often intended to be substitutes for longer chain PFAS, *i.e.*, substances having a fluorinated carbon chain length of C8 or longer. (In the past, long-chain PFAS were generally thought to present greater risks to humans and the environment than shorter-chain PFAS). In June 2021, EPA launched the "PFAS LVE Stewardship Program" to encourage the voluntary withdrawal of the more than 600 previously granted PFAS LVEs. Under that program, an eligible company that wishes to participate is asked to submit a voluntary withdrawal of their LVE. As of April 2023, there are 45 PFAS LVEs that have been voluntarily withdrawn under the PFAS LVE Stewardship Program. EPA has not granted an LVE for a PFAS since May 2020. EPA has not ever received or approved any PFAS LoREX notices.

Under the current policy, manufacturers may still submit LVE and LoREX notices for PFAS, which EPA must review individually. The proposed amendments to the LVE and LoREX regulations would make PFAS categorically ineligible to be considered for these exemptions. Under the proposal, any LVE or LoREX notice for a PFAS that is submitted to the Agency would 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 would instead be required to submit a PMN at least 90 days prior to commencing manufacture for a non-exempt commercial purpose.

The LVE and LoREX are predicated on strict production volume or release/exposure limits, respectively, and notices are subject to an abbreviated 30-day review by EPA designed to serve as a procedural safeguard to screen out substances that pose potential risks, rather than the more detailed and comprehensive 90-day review afforded to PMNs. See 60 FR 16336, March 29, 1995 (FRL-4923-1). The existing LVE and LoREX regulations at 40 CFR 723.50(h)(1) provide that if EPA determines during the review period that manufacture of the new chemical substance does not meet the terms of the LVE or LoREX requirements or that there are issues concerning toxicity or exposure that require further review which cannot be accomplished within the 30-day review period, EPA will notify the manufacturer that the substance is not eligible for the exemption.

When EPA initially proposed and then finalized the LVE requirements, EPA considered compiling a list of chemical categories, based on structure, that would not be eligible for the exemption. See the proposed rule entitled "Premanufacture Notification; Proposed Exemption for Site-Limited Intermediate Chemical Substances and Chemical Substances Manufactured in Quantities of 10,000 Kg or Less Per Year" (47 FR 33896, 33907, August 4, 1982 (FRL-2105-1)); and the final rule entitled "Premanufacture Notification Exemption; Exemption for Chemical Substances Manufactured in Quantities of 1,000 Kg or Less Per Year" (50 FR 16477, 16483, April 26, 1985 (FRL-2742-1)). EPA did not adopt categorical exclusions at the time because EPA believed that identifying such categories upfront would be unnecessarily resource-consuming and would provide no more protection than that already provided by EPA's LVE notice review requirements (50 FR at 16483). Neither reason, however, is currently persuasive

for chemical substances that meet the proposed structural definition of PFAS. Under TSCA section 26(c), any action taken by EPA on a single chemical substance may also be taken with respect to a category of chemical substances, "the members of which are similar in molecular structure." Here, it is not difficult or resource-consuming to identify a category to exclude, as the substances that meet the PFAS structural definition share a similar structure and are appropriately addressed as a category in this action. EPA has also committed to "[b]uild the evidence base on individual PFAS" and "use its authorities to impose appropriate limitations on the introduction of new unsafe PFAS into commerce and will, as appropriate, use all available regulatory and permitting authorities to limit emissions and discharges from industrial facilities." (Ref. 10). Additionally, due to the scientific complexities 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. Reviewing all new PFAS as PMNs also will preserve EPA's authority to address information gaps when there is insufficient information on the chemical substance and further support the Agency's PFAS Strategic Roadmap, which lays out a whole-of-agency approach to addressing PFAS (see *https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024*).

Under the existing regulations at 40 CFR 723.50(h)(2), at any time after EPA approves an LVE or LoREX notice, EPA can determine that manufacture of the new chemical substance does not meet the exemption criteria. If the Agency does so, it would notify the manufacturer by certified letter that EPA believes that the new chemical substance does not meet the terms for the exemption. With these considerations in mind, EPA solicits comment on revoking previously granted LVEs for PFAS pursuant to the process set forth in 40 CFR 723.50(h)(2) and requiring

those who wish to continue manufacture to submit a PMN.

For the purpose of making PFAS ineligible for LVEs and LoREXs, EPA is proposing to define "PFAS" using a structural definition. EPA is proposing to define PFAS as 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

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 would remain eligible to submit an LVE or LoREX notice. The proposed chemical structure definition for PFAS is the same definition used for the Inactive PFAS SNUR (88 FR 4937, January 26, 2023).

EPA determined that a structural definition was most appropriate for this rule rather than developing a list of specifically identified substances. Since the substances that would be submitted in LVE or LoREX notices are new chemical substances, it is impractical to generate a comprehensive list of PFAS not on the TSCA Inventory that may be submitted in the future. Additionally, other TSCA requirements have relied on a structural definition when appropriate (*e.g.*, the long-chain perfluoroalkyl carboxylate (LCPFAC) SNUR defines covered substances using a structural definition (40 CFR 721.10536), and the polymer exemption from PMN requirements defines covered PFAS polymers using structural definitions (40 CFR 723.250)). Furthermore, other scientific and regulatory bodies such as the OECD (Ref. 11) have defined PFAS using various structural definitions. Thus, there is clear precedent for using a structural definition for TSCA rules and other actions addressing PFAS.

The proposed definition for PFAS 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 proposed three-part structural definition for PFAS includes fluoropolymers.

The first sub-structure (R-(CF2)-C(F)(R′)R″), where both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R′ or R″) can be hydrogen, has been the working definition of PFAS used by EPA's Office of Pollution Prevention and Toxics when identifying PFAS on the TSCA Inventory. For this rule, EPA has decided to expand the working definition to include two additional sub-structures.

The second sub-structure (R-CF2OCF2-R', where R and R' can either be F, O, or saturated carbons) aims to capture certain fluorinated ethers. Examples of substances that meet this sub-structure include, PFMOAA (CASRN 674-13-5) and other chemicals, with properties similar to hexafluoropropylene oxide (HFPO) dimer acid and its ammonium salt (known as "GenX chemicals"), that have been found in the Cape Fear River.

Finally, the third sub-structure (CF3C(CF3)R'R'', where R' and R" can either be F or saturated carbons) aims to capture fluorinated substances that are more branched and would not otherwise meet the first or second sub-structure definitions due to their non-adjacent carbons. Although these substances have carbons that are not fully fluorinated and that may be more susceptible to degradation and metabolism, highly fluorinated moieties of the substance are still likely to be persistent.

This proposed definition may not be identical to other definitions of PFAS used within EPA or by other organizations. The term "PFAS" has been used varyingly by many organizations for their distinct research and/or regulatory needs, and different definitions of the term "PFAS" may be appropriate for such purposes. The Agency notes that this perspective, that

different users may have distinct needs and that no single PFAS characterization or definition meets all needs, is shared by many other organizations, including OECD (see page 29, Ref. 11). EPA proposes that the above definition of "PFAS" is the most appropriate definition for the proposal to make PFAS ineligible for future LVEs and LoREXs and acknowledges that there may be other rules or programs that apply different definitions to meet their own needs.

4. PBT Chemicals and LVEs and LoREXs.

a. Background.

Currently, 40 CFR 723.50(d) describes certain criteria that EPA uses to determine the eligibility of chemical substances for manufacture under an LVE and LoREX. These criteria include the potential of a chemical substance to cause serious acute or chronic effects or significant environmental effects under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal. These criteria also extend to any reasonably anticipated metabolites, environmental transformation products, or byproducts of the chemical substance, as well as any reasonably anticipated impurities in the substance.

Although numerous factors can contribute to the potential of a particular chemical substance to cause serious acute or chronic effects or significant environmental effects as described in 40 CFR 723.50(d), chemical substances that are persistent, bioaccumulative, and toxic (PBT) are of special concern because: (1) their persistence in the environment increases the likelihood of exposure of biological systems to those chemicals; (2) their bioaccumulative potential increases the probability that they will move vertically through and become embedded in trophic chains; and (3) their persistence and bioaccumulation potential, coupled with toxicity concerns, can result in risk to biological systems. Once PBT chemicals are released into the environment, they are often difficult or impossible to remediate.

On November 4, 1999, EPA issued its policy statement (64 FR 60194) (Ref. 8)

identifying a category for PBT new chemical substances. The 1999 policy statement formally acknowledged PBT chemical substances as a category based on shared characteristics to facilitate premanufacture assessment and regulation. Furthermore, the PBT policy statement established EPA's current criteria for identifying PBT chemical substances for the New Chemicals Program, which involves using physical-chemical properties, as well as structural activity alerts, analogue data, and test data to quantify on a scale of 1 to 3 the potential for persistence (P), bioaccumulation (B), and toxicity (T) for a given new chemical substance. If a substance scores a 2 or above for all three characteristics, EPA considers the substance to be PBT. EPA emphasized in responses to comments received on the October 1998 draft policy released for public comment that the decision to identify and assess a new chemical substance as PBT would be based on the available data and would be made on a case-by-case basis.

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

At present, the exemption regulations at 40 CFR 723.50 do not expressly disqualify PBT chemical substances from eligibility for the LVE or LoREX. However, under TSCA section 5(h)(4), EPA may exempt a chemical substance from section 5 requirements upon application and by rule only if EPA determines the manufacture, processing, distribution in commerce, use, or disposal of the substance will not present an unreasonable risk. And as explained above, the regulations at 40 CFR 723.50(d) provide that chemical substances that may cause serious acute or chronic effects or significant environmental effects are not eligible for the LVE or LoREX. When exposure of the environment or biological organisms (including humans) to a PBT chemical is expected, one or more of the conditions above (*i.e.*, serious acute or chronic effects or significant environmental effects) is generally likely to occur, often making the PBT chemical ineligible for the exemptions. Whenever the potential for unreasonable exposures to a PBT chemical is identified during the review of an LVE or LoREX notice, EPA's longstanding policy

has been to deny the exemption notice. However, EPA's specific concerns for PBT chemicals as they relate to LVEs and LoREXs are not separately codified in the existing regulations at 40 CFR 723.50.

EPA is therefore proposing 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. The proposed amendments clarify that PBT chemicals with anticipated environmental releases and potentially unreasonable human or environmental organism exposures would be ineligible for the LVE or LoREX but would not prevent companies from submitting an exemption notice for a given substance. The finding that a substance is PBT would be made by EPA during the review of the notice. While EPA has offered generic guidance regarding how it determines the PBT status of chemical substances, the policies and science used to ascribe discrete scores (*i.e.*, 1-3) to the persistence, bioaccumulative potential, and toxicity of a particular chemical substance are based on the available data and made on a case-by-case basis. As such, a submitter may not be able to determine in advance of submitting an exemption notice if EPA would find the substance to be PBT. Although EPA is ultimately responsible for assessing whether chemical substances are potentially PBT, submitters who possess data indicating that their new chemical substances could be PBT and could be handled in such a way as to result in anticipated or unreasonable exposures may be less likely to expend the time and resources to submit an LVE or LoREX notice for EPA review of those substances if the outcome of the review would almost certainly be denial of the notice.

EPA is further proposing to define "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

EPA is proposing to amend 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 proposing to amend 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. EPA would continue to require that all requests for suspensions exceeding 30 days be submitted electronically to EPA via CDX using e-PMN software.

When the notice or exemption review period for a PMN, SNUN, LVE, or LoREX approaches its end, submitters may request that EPA suspend the running of the notice review period so that the review period does not expire (40 CFR 720.75(b); see also 40 CFR 721.25(c) and 723.50(g)(1), applying the 720.75(b) suspension procedures to SNUNs, LVEs, and LoREXs). The existing regulations at 720.75(b) specify that such requests can be made orally to EPA, so long as the length of the suspension does not exceed 15 days; suspensions exceeding 15 days must be submitted to EPA in writing via CDX using EPA's e-PMN software. At the submitter's request, EPA can suspend a notice review period until the review is complete and a decision has been made for the notice. Once a final decision is made, any remaining suspension

days are rescinded.

Currently, the regulations at 40 CFR 725.54, which pertain to the suspension of the review period for MCANs and exemptions related to microorganisms (*e.g.*, TSCA Environmental Release Applications (TERA) and Tier II submissions) mirror those at 720.75(b) for PMNs, SNUNs, LVEs, and LoREXs. As in 40 CFR 720.75(b), the language at 40 CFR 725.54 indicates that submitters may suspend a notice or exemption review period for up to 15 days via oral request, or for greater than 15 days via a formal, written request submitted to EPA via CDX using EPA's e-PMN software. Although suspensions occur less frequently during the reviews of notices and exemptions for microorganisms than during reviews for PMNs, SNUNs, LVEs, and LoREXs, submitters do occasionally request suspensions in order to develop additional information.

Given the relative ease and value of suspending a notice review period via informal oral request, most submitters who seek suspensions opt to suspend for 15 days whenever their case is nearing expiration of its review period to allow EPA to finalize its review. If a case is suspended, it is often suspended more than once, and submitters typically informally request multiple 15-day suspensions rather than requesting a longer suspension in writing via CDX. As such, EPA is proposing to allow for informal suspensions up to 30 days to reduce the number of repeated informal requests. Additionally, EPA believes that e-mail may be more expedient than oral communication for many submitters. Therefore, EPA is proposing amendments to allow submitters to request suspensions for up to 30 days either orally or via e-mail.

EPA is seeking comment on its proposal to increase the number of days permissible for suspensions not requiring a formal, written request submitted to EPA via CDX using e-PMN software. Specifically, EPA requests comment on its proposal to permit requests for suspensions up to 30 days to be communicated orally or via e-mail, and to update the relevant regulations

pertaining to suspension of microorganism-related submissions under 40 CFR 725.54 to mirror the proposed changes for suspension of PMNs, SNUNs, LVEs, and LoREXs. EPA is not considering, proposing, or requesting comment on any additional changes to the regulations regarding suspensions at this time.

IV. Economic Analysis

The estimated incremental impacts of this rulemaking are briefly summarized in this unit and the complete Economic Analysis (Ref. 1) is available in the docket. The proposed rule is expected primarily to affect two types of firms:

(1) Manufacturers of PFAS who would have submitted an LVE or LoREX in the baseline but would need to submit a PMN under the proposed rule due to the proposed amendment to make PFAS ineligible for the exemptions; and

(2) Firms submitting any TSCA section 5 notices through the PMN form (PMNs, SNUNs, LVEs, LoREXs, TMEs) that are expected to submit fewer amendments to their original submissions due to the amended procedural requirements of the proposed rule.

While the proposed rule includes additional amendments to the new chemicals regulations under TSCA, EPA expects that these additional amendments will not result in incremental burden or savings because they are largely already performed in the baseline.

As a result of this proposed rule, EPA expects that the average number of amendments per notice will decrease from 1.81 to 0.9, with a decrease in burden to EPA of 12 hours per avoided amendment. In addition, EPA expects that the 12 annual average of LVE submissions for PFAS will instead be submitted as PMNs. It is expected that individual submitters of PMNs will experience an overall decrease in burden of 13 hours with an associated decrease in cost of approximately $1,120 per notice.

Additionally, improvements in the submission process are expected to reduce

inefficiency in the Agency's review process. As a result of the changes under the proposed rule, it is expected that the cost to the Agency associated with reviewing PMNs, SNUNs, and exemption notices will decrease by ten percent. Therefore, it is expected that the Agency will experience an annual cost savings of approximately $923,280.

V. References

The following is a listing of the documents that are specifically referenced in this document. 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 Proposed Updates to New Chemicals Regulations under the Toxic Substances Control Act (TSCA). May 2023.

2. EPA. Central Data Exchange Online User Guide. Accessible at: *https://cdx.epa.gov/About/UserGuide*.

3. 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*.

4. EPA. TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Re-work. Accessible at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-new-chemical-engineering*.

5. EPA. Tables Detailing the Proposed Amendments to Add Details to 40 CFR Part 720.45 Reporting Requirements and Enhancements to the CDX Reporting Form. May 2023.

6. EPA. Supporting Statement for an Information Collection Request (ICR) Under the

Paperwork Reduction Act (PRA); Updates to New Chemicals Regulations under the Toxic Substances Control Act; Proposed Rule (RIN 2070-AK65); EPA ICR No. 2749.01; OMB Control No. 2070-[NEW]. May 2023.

7. EPA. Premanufacture Notification; Premanufacture Notice Requirements and Review Procedures; Final Rule. *Federal Register*. 48 FR 21722; May 13, 1983 (TSH-FRL 2998-5).

8. EPA. Policy Statement on Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. *Federal Register*. (64 FR 60194, November 4, 1999) (FRL-6097-7).

9. EPA. Press Release: EPA Announces Changes to Prevent Unsafe New PFAS from Entering the Market. April 27, 2021.

10. EPA. PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024. October 18, 2021. Accessed at: *https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf*.

11. OECD. Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance. July 9, 2021. Accessed at: *https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf*.

VI. 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 not a significant regulatory action as defined in Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023), and was therefore not subject to review under Executive Order 12866.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed 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. 2749.01 (Ref. 6). This ICR represents an amendment to the currently approved ICR that covers the information collection activities contained in the existing regulations, which are approved under OMB control number 2070-0012 (EPA ICR No. 574.15). Estimates presented in the ICR below reflect the minor incremental changes associated with the rule that are presented in the Economic Analysis (Ref. 1). EPA is proposing amendments to the new chemicals procedural regulations under TSCA. These amendments are intended to align the regulatory text with the amendments to TSCA's new chemicals review provisions and improve the efficiency of EPA's review processes and update the regulations based on existing policies and experience implementing the New Chemicals Program. You can find copies of the Economic Analysis and ICR in the docket, and the ICR is briefly summarized here.

Respondents/affected entities: Certain 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, *i.e.*, upon submission of a PMN, SNUN, LVE, LoREX, or MCAN.

Total estimated incremental burden: Estimates show that this proposed rule will decrease existing approved burden by 4,518 hours per year. Burden is defined at 5 CFR 1320.3(b).

Total estimated incremental cost: Estimates show that this proposed rule will increase existing approved costs by $45,120 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 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this rule. EPA will respond to any ICR-related comments in the final rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at *https://www.reginfo.gov/public/do/PRAMain*. Find this particular ICR by selecting "Currently under Review - Open for Public Comments" or by using the search function. OMB must receive comments no later than [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].

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 $45,863 per notice due to the greater burden and non-labor costs associated with submitting a PMN form. EPA estimates that 99 percent of small firms (185 firms) will have cost impacts of less than 1 percent of revenues, less than 1 percent (1 firms) 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 or more as described

in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments and the incremental cost on the private sector is estimated to be less than $50,000. Based on EPA's experience with reviewing actions under TSCA section 5, state, local, and tribal governments have not been impacted by these rulemakings, 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, based on the Economic Analysis prepared for this proposed rule (Ref. 1), EPA concludes that this rule is not expected to result in expenditures by the private sector of $100 million or more (when adjusted annually for inflation) in any one year. Accordingly, this rule is not subject to the requirements of UMRA sections 202, 203, or 205. The Economic Analysis (Ref. 1) for this action is summarized in Unit IV. and is available in the docket.

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 procedural regulations codified at 40 CFR parts 720 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 proposed 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 and has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs.

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

Executive Order 12898 (59 FR 7629, February 16, 1994) directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or Indigenous peoples) and low-income populations. 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 people of color, low-income populations and/or Indigenous peoples. By proposing, among other things, to include overburdened communities in the regulatory definition of PESS.

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 rule. 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.

List of Subjects in 40 CFR Parts 720, 721, 723, and 725

Environmental protection, Chemicals, Hazardous materials, Recordkeeping, and Reporting Requirements.

Dated: May 16, 2023.

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 720 -- PREMANUFACTURE NOTIFICATION

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

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

§ 720.1 Scope.

2. Amend § 720.1 by removing the phrase "The rule" and adding in its place the phrase "This part" everywhere it appears.

3. Amend § 720.3 by adding new paragraphs (ll) and (mm) to read as follows:

§ 720.3 Definitions.

* * * * *

(ll) *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.

(mm) *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.

* * * * *

4. 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 email and submit the new information electronically to EPA via CDX.

* * * * *

5. Amend § 720.45 by:

a. Revising paragraphs (a)(4) and (a)(5);

b. Revising paragraph (f) and adding a new Table 1 to paragraph (f)(2);

c. Revising paragraphs (g) and (h); and

d. 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 statutory review period will commence upon receipt of both the

notice and the complete, correct information, in accordance with § 720.65.

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

Table 1 to Paragraph (f)(2) - Codes for Reporting Consumer and Commercial Product Categories

Code	Category
Chemical Substances in Furnishing, Cleaning, Treatment Care Products	
CC101	Construction and building materials covering large surface areas including stone, plaster, cement, glass and ceramic articles; fabrics, textiles, and apparel
CC102	Furniture & furnishings including plastic articles (soft); leather articles
CC103	Furniture & furnishings including stone, plaster, cement, glass and ceramic articles; metal articles; or rubber articles
CC104	Leather conditioner
CC105	Leather tanning, dye, finishing, impregnation and care products
CC106	Textile (fabric) dyes
CC107	Textile finishing and impregnating/surface treatment products
CC108	All-purpose foam spray cleaner
CC109	All-purpose liquid cleaner/polish
CC110	All-purpose liquid spray cleaner
CC111	All-purpose waxes and polishes
CC112	Appliance cleaners
CC113	Drain and toilet cleaners (liquid)
CC114	Powder cleaners (floors)
CC115	Powder cleaners (porcelain)
CC116	Dishwashing detergent (liquid/gel)
CC117	Dishwashing detergent (unit dose/granule)
CC118	Dishwashing detergent liquid (hand-wash)
CC119	Dry cleaning and associated products
CC120	Fabric enhancers
CC121	Laundry detergent (unit-dose/granule)
CC122	Laundry detergent (liquid)
CC123	Stain removers
CC124	Ion exchangers
CC125	Liquid water treatment products
CC126	Solid/Powder water treatment products

CC127	Liquid body soap
CC128	Liquid hand soap
CC129	Solid bar soap
CC130	Air fresheners for motor vehicles
CC131	Continuous action air fresheners
CC132	Instant action air fresheners
CC133	Anti-static spray
CC134	Apparel finishing, and impregnating/surface treatment products
CC135	Insect repellent treatment
CC136	Pre-market waxes, stains, and polishes applied to footwear
CC137	Post-market waxes, and polishes applied to footwear (shoe polish)
CC138	Waterproofing and water-resistant sprays
Chemical Substances in Construction, Paint, Electrical, and Metal Products	
CC201	Fillers and putties
CC202	Hot-melt adhesives
CC203	One-component caulks
CC204	Solder
CC205	Single-component glues and adhesives
CC206	Two-component caulks
CC207	Two-component glues and adhesives
CC208	Adhesive/Caulk removers
CC209	Aerosol spray paints
CC210	Lacquers, stains, varnishes and floor finishes
CC211	Paint strippers/removers
CC212	Powder coatings
CC213	Radiation curable coatings
CC214	Solvent-based paint
CC215	Thinners
CC216	Water-based paint
CC217	Construction and building materials covering large surface areas, including wood articles
CC218	Construction and building materials covering large surface areas, including paper articles; metal articles; stone, plaster, cement, glass and ceramic articles
CC219	Machinery, mechanical appliances, electrical/electronic articles
CC220	Other machinery, mechanical appliances, electronic/electronic articles
CC221	Construction and building materials covering large surface areas, including metal articles
CC222	Electrical batteries and accumulators
Chemical Substances in Packaging, Paper, Plastic, Toys, Hobby Products	
CC301	Packaging (excluding food packaging), including paper articles
CC302	Other articles with routine direct contact during normal use, including paper articles
CC303	Packaging (excluding food packaging), including rubber articles; plastic articles (hard); plastic articles (soft)
CC304	Other articles with routine direct contact during normal use including rubber articles; plastic articles (hard)
CC305	Toys intended for children's use (and child dedicated articles), including fabrics,

	textiles, and apparel; or plastic articles (hard)
CC306	Adhesives applied at elevated temperatures
CC307	Cement/concrete
CC308	Crafting glue
CC309	Crafting paint (applied to body)
CC310	Crafting paint (applied to craft)
CC311	Fixatives and finishing spray coatings
CC312	Modelling clay
CC313	Correction fluid/tape
CC314	Inks in writing equipment (liquid)
CC315	Inks used for stamps
CC316	Toner/Printer cartridge
CC317	Liquid photographic processing solutions
Chemical Substances in Automotive, Fuel, Agriculture, Outdoor Use Products	
CC401	Exterior car washes and soaps
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 de-icers/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, including worker exposure information from exempt manufacture or related use of the new chemical substance under § 720.30 (*e.g.*, byproduct, impurity). This information includes:

(i) worker activities.

(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 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 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 (*e.g.*, byproduct, impurity). 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 and 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.

(iv) For releases into water, the National Pollutant Discharge Elimination System (NPDES) permit number(s), the name(s) of the navigable waterway(s) 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 work(s) (POTW) into which the release occurs and the corresponding NPDES permit number(s).

(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, including worker exposure information from exempt manufacture or related use of the new chemical substance under § 720.30 (*e.g.*, byproduct, impurity). This information includes:

(i) worker activities.

(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 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 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 (*e.g.*, byproduct, impurity). 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 of the new chemical substance per container cleaning.

(iii) For releases into air, Clean Air Act operating permit numbers and 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.

(iv) For releases into water, the National Pollutant Discharge Elimination System (NPDES) permit number(s), the name(s) of the navigable waterway(s) 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 work(s) (POTW) into which the release occurs and the corresponding NPDES permit number(s).

* * * * *

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

(1) For physical and chemical properties, such information includes boiling/sublimation temperature, density/relative density, dissociation constant, explodability, flammability, melting temperature, octanol/water partition coefficient, particle size distribution, particle size distribution analysis, 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. For nanomaterials, such information also includes aspect ratio, thickness, and number of layers or walls.

(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.

* * * * *

6. Amend § 720.50(a)(4)(ii) 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 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 electronically to EPA via CDX.

* * * * *

7. Amend § 720.65 by:

a. Revising paragraphs (a), (b) and (c);

b. Redesignating existing paragraph (d) to be paragraph (e); and

c. Adding a new paragraph (d).

The revisions and addition 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).

(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 it to EPA, EPA will follow the procedures of paragraph (a)(2).

(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 § 720.80(b)(2).

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

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

(x) The submitter does not include an identifying number and a payment identity number as required by 40 CFR 700.45(e)(3).

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

(ii) If 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.

* * * * *

8. Amend § 720.70 by revising paragraphs (a) and (b) 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.

* * * * *

9. Amend § 720.75 by:

a. Removing the section heading "Notice review period" and adding in its place "Applicable review period and determination;"

b. Removing the phrase "notice review period" as used throughout the section and adding in its place "applicable review period;"

c. Revising paragraphs (a), (b), (c)(4) and (d) to 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)(i) *Requests for suspension 30 days or less*. 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 greater than 30 days*. 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:

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

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

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

(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), 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 paragraph (d)(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 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) Following a determination described in paragraph (d)(1)(v), EPA will issue the submitter a document describing that 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, 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) after the applicable review period has ended if the submitter submits to EPA 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.

(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) and taken the associated action required under paragraph (d)(2) of this section.

* * * * *

PART 721 -- SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

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

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

11. Amend § 721.25 by revising paragraphs (c) and (d) to read as follows:

§ 721.25 Notice requirements and procedures.

* * * * *

(c) EPA will process the notice in accordance with the procedures of part 720 of this chapter, except to the extent they are inconsistent with this part. When submitting a SNUN the provision at 720.45(f)(1) is modified to require a description of both known and intended categories of consumer or commercial use by function and application.

(d) Any person submitting a significant new use notice in response to the requirements of this part 721 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.

* * * * *

PART 723 -- PREMANUFACTURE NOTIFICATION EXEMPTIONS

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

Authority: 15 U.S.C. 2604

13. Amend § 723.50 by:

a. Revising paragraph (a);

b. Adding paragraph (b)(11) and (b)(12);

c. Revising paragraphs (d), (g), and (h)(2)(v); and

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

* * * * *

(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 paragraphs (c)(1) or (c)(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.

* * * * *

(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)(v) If the Assistant Administrator 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.

* * * * *

(p) *Subject to a Significant New Use Rule*. If a significant new use rule is proposed or finalized in Part 721 for a chemical substance described by a generic chemical name, 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 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, and identify the proposed or final section in subpart E of Part 721 that pertains to the chemical substance.

* * * * *

PART 725 -- REPORTING REQUIREMENTS AND REVIEW PROCESSES FOR MICROORGANISMS

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

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

15. 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).

(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.

* * * * *

16. 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.

* * * * *

17. 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), 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 paragraph (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) For determinations described in paragraph (b)(1)(v), EPA will issue the submitter a document describing that 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, 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) after the applicable review period has closed if the submitter submits to EPA 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.

(4) No person submitting a 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) and taken any action as required under paragraph (b)(2) of this section.