

Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs)

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I. Introduction

The TSCA New Chemicals Program (New Chemicals Program)—consistent with the provisions of TSCA sections 5 and 2—regulates chemicals in a manner that promotes technological innovation while ensuring that chemicals are safe to humans and the environment. The New Chemicals Program functions as a "gatekeeper" that can identify, and, as appropriate, address, potential risks of a new chemical before it enters into commerce or before a significant new use of an existing chemical is commenced.

Per- and polyfluoroalkyl substances (PFAS) are of great public and governmental interest because of their widespread historic and current use in a variety of products such as cleaners, textiles, leather, paper and paints, plastics, and fire-fighting foams; their occurrence in the environment (e.g., in finished drinking water samples and in fish tissue); and the documented adverse human health and environmental effects associated with well-studied PFAS (e.g., perfluorooctanoic acid (PFOA), perfluorooctanesulfonic acid (PFOS), perfluorohexanoic acid (PFHxA), perfluorobutanoic acid (PFBA), and hexafluoropropylene oxide dimer acid (HFPO-DA) (GenX)).

The New Chemicals Program developed this framework ("PFAS Framework") to help ensure that the Program effectively and efficiently reviews and makes appropriate decisions on new PFAS or significant new uses of existing PFAS reviewed through premanufacture notices (PMNs) and significant new use notices (SNUNs^{1,2,3}). This framework was developed in light of the significant health concerns, widespread environmental exposures, and environmental persistence associated with most existing PFAS. Its implementation is generally

¹ Under section 5(a) of TSCA and 40 CFR part 721, if EPA promulgates a Significant New Use Rule (SNUR), a manufacturer or processor wishing to engage in a designated significant new use must submit a Significant New Use Notice (or "SNUN") to EPA at least 90 days before engaging in the significant new use. This notification provides EPA the opportunity to evaluate the significant new use and, if necessary to protect against unreasonable risk, take action to prohibit or limit the activity.

² EPA has proposed amendments to make new PFAS categorically ineligible for low volume exemptions (LVEs) or low release and exposure exemptions (LoREXs) under TSCA section 5 (88 FR 34100; May 25, 2023).

³ Photoacid generators (PAGs) are substances used primarily in the manufacture of semi-conductors. PFAS that are PAGs follow a separate, standardized process that includes testing requirements and risk mitigation.

expected to largely preclude intentional environmental releases or expected exposures of new PFAS or those associated with significant new uses of PFAS, while identifying appropriate risk mitigation (including banning manufacture if warranted) and required testing.

The PFAS Framework is an important element of the larger [EPA PFAS Strategic Roadmap](#), which conveys that “EPA will apply a rigorous review [...] process for new PFAS to ensure these substances are safe before they enter commerce.” The PFAS Framework will guide EPA’s review of PFAS under TSCA Section 5, ensuring consistency and efficiency in its review of incoming submissions while advancing the Agency’s goals to ensure protection of public health and the environment. The implementation of this PFAS Framework will also help, indirectly, to improve the body of knowledge on the effects and environmental impacts of PFAS, which in turn will help continuously improve the scientific foundation for effective risk management across the spectrum of PFAS chemistries.

II. Assessment of the Persistent, Bioaccumulative and Toxic (PBT) Properties and Exposure Potential for PFAS

A. Identifying PFAS

The first step in the PFAS Framework is to determine whether the substance under review (as a PMN or SNUN) falls into the chemical category definition of PFAS. For the purpose of this Framework, OPPT considers PFAS to include substances with alkyl and alkyl ether structures where all of the saturated carbons are fully fluorinated (i.e., perfluorinated) or chemical structures with a mixture of fully fluorinated, partially fluorinated, and/or non-fluorinated saturated carbons. The PFAS Framework uses the following definition for PFAS⁴:

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

- (i) $R-(CF_2)-CF(R')R''$, where both the CF_2 and CF moieties are saturated carbons;

⁴ EPA also previously proposed to define PFAS using the same chemical structure in the recent proposed Inactive Inventory PFAS SNUR (88 FR 4937; January 26, 2023) and the proposed rule that would, among other things, make new PFAS categorically ineligible for low volume exemptions (LVEs) or low release and exposure exemptions (LoREXs) (88 FR 34100; May 25, 2023).

(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.

Natural processes have been shown to break down PFAS that are precursor compounds (e.g., fluorotelomer alcohols) into other PFAS that may be more stable and deleterious to human health and the environment.⁵ In some cases, volatile PFAS are subject to long range atmospheric transport⁶ and can degrade into stable and bioaccumulative end products. For this reason, EPA not only considers the substance itself but also focuses on potential metabolites or degradants when reviewing a PFAS under TSCA section 5.

B. Evaluating Available Hazard Information and Determining PBT Status of PFAS

After EPA has concluded that the substance submitted as a PMN or SNUN is a PFAS and determined the key components of interest (e.g., the substance itself, or potential metabolites or degradants), EPA will begin reviewing all available data on the PFAS. The submitted PMN or SNUN must include all information in the possession or control of the submitter that can inform the evaluation of the human health or environmental effects of the chemical substance (insofar as known or reasonably ascertainable to the submitter). Often, however, EPA receives submissions for chemical substances that lack critical data on physical-chemical properties, fate, and toxicity. Early in the review process, EPA will consider whether the PFAS is a persistent, bioaccumulative and toxic (PBT⁷) chemical. To determine if a substance is a PBT chemical, EPA relies on the reasonably available data, which includes data submitted with the notice, appropriate analogue data, and/or supplementary information to support the PBT designation. EPA will make a PBT determination for submitted

⁵ H. Hamid, L.Y. Li, and J.R. Grace. 2020. Aerobic biotransformation of fluorotelomer compounds in landfill leachate-sediment. *Science of the Total Environment*. 713. <https://www.sciencedirect.com/science/article/pii/S0048969720300577?via%3Dihub>

⁶ A. Dreyer, I. Weinberg, C. Temme, and R. Ebinghaus. 2009. Polyfluorinated Compounds in the Atmosphere of the Atlantic and Southern Oceans: Evidence for a Global Distribution. *Environmental Science and Technology*. 43 (6507-6514).

⁷ On November 4, 1999, EPA issued its final policy statement ([64 FR 60194](#)) on a category for Persistent, Bioaccumulative and Toxic (PBT) new chemicals.

PFAS using a weight of evidence approach⁸ using data from either the specific new chemical substance or appropriate analogues and will consider testing needs where there is a lack of information. While there are thousands of different PFAS, only a small fraction has been well studied.

In the 1999 PBT policy statement (64 FR 60194) and the 2018 *Points to Consider* policy document⁹, EPA established criteria for identifying PBTs for the New Chemicals Program, which involves considering physical-chemical properties, as well as structural activity alerts, analogue data, and test data on the new chemical substance 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 compound scores a 2 or above for all three characteristics (i.e., P2B2T2), EPA considers the compound to be a PBT chemical. Additionally, if EPA is unable to score a characteristic (e.g., B “unknown” for bioaccumulation), the characteristic is still considered to be potentially a 2 or higher for the purposes of identifying potential PBTs. EPA identifies and assesses the PBT properties of new chemical substances on a case-by-case basis using the reasonably available data.

PBT chemicals are of particular concern because they continuously accumulate in the environment, humans, and environmental organisms over extended periods of time, leading to greater exposures and, potentially, toxic effects that may not be identified or accounted for using normal hazard/risk assessment methodology. Many of the well-studied PFAS are PBT chemicals with published reports that show increasing concentrations of PFAS in human blood over time.¹⁰ As such, determining whether a specific PFAS (including its metabolites or degradants) is/is not PBT is at the core of this framework. For each PFAS reviewed under TSCA section 5, the New Chemicals Program prepares reports to summarize the persistence, bioaccumulation, and

⁸ There is a large body of evidence that most PFAS are PBT chemicals. EPA New Chemicals Division has reviewed the following sources to support PBT determinations through the weight of the evidence approach, including observational data, standard OECD test results, public databases (i.e., ITRC), New Chemicals CBI data, peer-reviewed literature, OECD PFAS Fact Cards, and other sources.

⁹ Available at https://www.epa.gov/sites/default/files/2018-06/documents/points_to_consider_document_2018-06-19_resp_to_omb.pdf

¹⁰ NAS. 2022. *Guidance on PFAS Exposure, Testing and Clinical Follow-Up* <https://nap.nationalacademies.org/catalog/26156/guidance-on-pfas-exposure-testing-and-clinical-follow-up>

toxicity (both human health and ecological) scores for the substance(s), as well as identifying potential environmental releases and exposures.

C. Assessing Exposures for PFAS

As with any PBT chemical, when a PFAS (including its metabolites or degradants) is found to be a PBT chemical, there is potential exposure and risk not only to those who come into direct contact with the chemical substance in the workplace or through the use of the material but also to the general population because these chemicals persist and build up in the environment over time. Due to their persistence in the environment and bioaccumulation potential, small releases of PBT PFAS into the environment over time can contribute to considerable exposure and potential risk. EPA considers the intended conditions of use of the PFAS to determine if exposure is likely to a potentially exposed or susceptible subpopulation (e.g., consumers, workers), the general population, and/or the environment. For PFAS (including its metabolites or degradants) that are determined to be PBT, EPA typically will assess both environmental releases and worker exposures; understanding the expected sources of releases and worker exposures (and the possible effects of engineering or other controls in the workplace) is important for managing risks. For PBT PFAS, EPA will typically qualitatively consider the potential extent of exposures to the general population, consumers, and the environment, throughout the lifecycle of the PFAS, but not attempt to quantitatively assess them. Although it is possible to quantify exposures associated with the immediate release of a specific amount of a PBT PFAS, this would provide only a “snap-shot” of the exposure at one point in time and would not accurately reflect the overall environmental and human health risk posed by these chemicals because they persist and bioaccumulate over time.

If a PFAS is not found to be a PBT chemical, the chemical will go through the typical New Chemicals’ assessment process and EPA will conduct a quantitative risk assessment, where appropriate. For each PFAS reviewed, EPA’s assessment will consider the opportunities for exposure throughout the lifecycle of the PFAS. EPA generally expects that most PFAS will be PBT.

D. Risk Assessment Conclusions and Testing Recommendations for PFAS

When EPA receives a PMN or SNUN for a chemical substance that is determined to be a PFAS (the substance itself, or potential metabolites or degradants), the New Chemicals Program will coordinate with the National PFAS Testing Strategy Workgroup¹¹ implementing the National PFAS Testing Strategy. Where there are existing data, EPA's New Chemicals Program will draw on the existing body of knowledge, in combination with data submitted to EPA with the PMN or SNUN, to inform its hazard and risk assessment from the new PFAS or significant new uses of an existing PFAS.

If the PFAS is considered a PBT chemical, exposure pathways and receptors will be identified. Risk will be qualitatively evaluated due to factors associated with PBT PFAS that represent limitations to the standard New Chemicals Program risk calculation methods, including the known widespread background levels of PFAS present throughout both the environment and humans, as well as the highly persistent and bioaccumulative nature of most well-studied PFAS. If the PFAS is NOT considered a PBT chemical, it is expected to continue through the typical New Chemicals Program process of quantifying risk, where appropriate.

Where EPA finds that the information submitted with the notice, derived from the applicable category available from the National PFAS Testing Strategy, and otherwise reasonably available information do not provide sufficient information for EPA's New Chemicals Program to make a reasoned evaluation of the health and environmental effects of a PFAS under TSCA section 5 (including the extent to which the PFAS is a PBT), the New Chemicals Program expects to utilize its legal authority to require testing under section 5(e). The risk assessment may generate testing recommendations that EPA risk managers can include as part of risk management for the chemical substance. The testing results may reduce uncertainties in the assessment and inform potential refinements in risk management approaches for the chemical substance. Although the testing

¹¹ As announced on October 18, 2021, EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and Office of Research and Development (ORD) have collaborated to develop the [National PFAS Testing Strategy](#). The Strategy developed categories of PFAS based on information about similarities in structure, physical-chemical properties, and existing test data on the toxicity of PFAS (both publicly available and submitted to EPA under TSCA).

would be required because of the data insufficiencies identified by EPA with respect to the chemical substance under review, EPA recognizes that the test results may also help fill some of the data gaps in the PFAS categories of the PFAS Testing Strategy that lack toxicity data. The testing needs identified for PFAS through the New Chemicals Program may include information on physical chemical properties, environmental fate and effects, and human health effects.

III. Risk Management of PFAS

TSCA requires EPA to review each PMN and SNUN submission and make a finding pertaining to the risk of the new chemical substance or significant new use. The law sets forth five possible determinations with related actions. As part of the New Chemicals PFAS Framework, EPA has developed a risk management process that lays out general considerations with respect to PFAS uses and exposures, restrictions that may be included in 5(e) or 5(f) orders that are designed to address unreasonable risk to human health and the environment from manufacturing, processing, distribution, use, and disposal of PFAS, and considerations for testing. At a high level, the five possible determinations for any PMN or SNUN and the related actions are:

Determination	Related Action
In the absence of sufficient information to permit a reasoned evaluation of risk from the substance or significant new use, the substance or significant new use <u>may present</u> unreasonable risk	EPA must issue an order under section 5(e)
There is <u>insufficient information</u> to permit a reasoned evaluation of risk from the substance or significant new use	EPA must issue an order under section 5(e)
The substance or significant new use <u>presents</u> an unreasonable risk	EPA must take action under section 5(f)
The substance is or will be produced in substantial quantities and there may be significant or substantial human and/or environmental exposure (exposure based).	EPA must issue an order under section 5(e)
The substance or significant new use is <u>not likely</u> to present an unreasonable risk	EPA notifies submitter of its decision and publishes its finding in the <i>Federal Register</i>

Regardless of whether EPA determines that the new chemical substance or significant new use may present unreasonable risk – or determines that there is insufficient information to permit a reasoned evaluation of risk from the new chemical substance or the significant new use – or determines that there will be substantial quantities produced and there may be significant or substantial human and/or environmental exposure – the action required by EPA under TSCA is the same: The Agency must issue a section 5(e) order to protect against unreasonable risk to human health and the environment. The section 5(e) order may include testing requirements.

If EPA has measured data for the PFAS or the potential metabolites or degradants of the PFAS and these data indicate it is a PBT chemical and EPA expects exposures or releases, then the Agency may determine that the substance or significant new use presents unreasonable risk. If EPA determines that a substance or significant new use presents unreasonable risk, then the Agency must issue either an order under section 5(f) or an immediately-effective proposed rule under TSCA section 6(a) that will impose restrictions to protect against such risk. An order issued under section 5(f) applies to the PMN or SNUN submitter.¹² A rule under section 6(a) to impose restrictions necessary to protect against unreasonable risk would be applicable to all manufacturers, processors, or users of the chemical substance. However, if the finding is for a SNUN, the scope of the 6(a) rule would generally focus on the significant new use covered by the SNUN.

Given EPA's current understanding of PFAS, EPA believes that PBT PFAS are unlikely to receive a determination of "not likely" to present an unreasonable risk.

Where EPA makes a determination for a PBT PFAS that results in the need for testing and risk management measures under a section 5(e) order, the following sections describe EPA's general risk management approach for PBT PFAS under this Framework. In an effort to provide transparency, EPA describes

¹² EPA would typically issue a SNUR requiring all persons manufacturing or processing the chemical substance without the protections contained in this order to submit a SNUN for Agency review and possible action.

three scenarios that illustrate EPA's intended risk management as a function of the degree of expected exposures and environmental releases. However, EPA determines risk management on a case-by-case basis.

A. Negligible Exposure and Environmental Release Scenario: EPA determines with confidence that worker exposures will be sufficiently mitigated, and the PBT PFAS will be fully captured (with no environmental release above a negligible level judged by EPA not to be of concern) and disposed of in accordance with guidance from EPA's Office of Land and Emergency Management (OLEM), and the substance will not be used in consumer products (or there is no release or exposure from consumer-product use expected).

In this scenario, if complete physical-chemical property data on the substance is not already reasonably available to EPA, the Agency likely would require that only physical-chemical property testing of the PFAS be completed and submitted to EPA prior to manufacture. If EPA's review of the submitted physical-chemical property data does not result in increased concern about the substance, then in most cases, no further up-front testing would be required and manufacture could then commence with limitations as needed to sufficiently mitigate and monitor worker exposures and releases as required under a consent order.

If EPA's review of the submitted physical-chemical property data results in increased concern about the substance, EPA likely would require additional testing before manufacture could commence (e.g., toxicokinetic testing, human health toxicity, and/or environmental toxicity testing) and may require additional risk mitigation measures. The Agency is also considering orders that would impose additional protections if the new data demonstrate greater concern than EPA concluded based on the reasonably available data considered during review of the PMN or SNUN.

B. Low Exposure and Environmental Release Scenario: EPA determines that worker exposure cannot be sufficiently mitigated and/or environmental releases of the PBT PFAS remain at a level of concern despite the fact that the substance is largely captured. The PBT PFAS will be disposed of in accordance with guidance from EPA's OLEM, and the substance will not be used in consumer products (or there is no release or exposure from consumer-product use expected).

In this scenario, if complete physical-chemical property data on the substance is not already reasonably available to EPA, the Agency likely would require that both physical-chemical property testing and other testing

(e.g., toxicokinetic testing) be completed and submitted to EPA prior to manufacture. Depending on the result of EPA's review of the submitted data, either manufacture could then commence with limitations as needed to sufficiently mitigate exposures and releases, or additional testing (e.g., human health and/or environmental toxicity testing) would be required prior to commencing manufacture. If additional testing is required, then depending on the result of EPA's review of that additional test data, either manufacture could then commence with limitations as needed to eliminate exposures and further mitigate releases, or manufacture may be prohibited. The Agency is also considering orders that would impose additional protections if the new data demonstrate greater concern than EPA concluded based on the reasonably available data considered during review of the PMN or SNUN.

C. Expected Exposure and Environmental Release Scenario: EPA determines that release of the PBT PFAS to the environment is expected based on the intended use of the substance (e.g., release of the substance is essential to its use or unavoidable because of the nature of the use) or exposure to the PBT PFAS by consumers is expected based on the intended use.

In this scenario, EPA likely would require a full suite of testing be completed and submitted to EPA for review prior to manufacture. The extensive suite of required testing may include physical-chemical property testing, other testing such as toxicokinetic, and human health and/or environmental toxicity testing. Based on EPA's review of the submitted data, manufacture may be allowed to commence with limitations as needed to sufficiently mitigate exposures and releases, or manufacture may be prohibited if warranted. The Agency is also considering orders that would impose additional protections if the new data demonstrate greater concern than EPA concluded based on the reasonably available data considered during review of the PMN or SNUN.

D. Other Considerations for Risk Management

While the PFAS Framework describes how EPA currently intends to consider the assessment and management of PFAS submitted as a PMN or SNUN for review (including PFAS PMNs or SNUNs already under review and any that EPA receives in the future), it does not itself impose legally binding requirements on EPA or the regulated community. Under TSCA, EPA is required to consider each PFAS PMN or SNUN individually and

consider case-specific circumstances or information. For example, there may be case-specific circumstances where a use of a new PBT PFAS or a new use of an existing PBT PFAS may be needed by a federal agency to meet its mission or is required in order to meet another critical need. With the application of appropriate risk mitigation measures, EPA may allow some limited manufacture of a chemical substance while testing is ongoing if the Agency finds that allowing manufacture during this limited period would not present unreasonable risk.

E. Issuing SNURs for PFAS

Following any TSCA section 5(e) or 5(f) order that allows manufacture of a PFAS, EPA will issue a significant new use rule (SNUR) or modify an existing SNUR, since such orders are only binding on the original PMN or SNUN submitter for that substance. The issuance of a SNUR requires notice to EPA by any manufacturer, importer, or processor who wishes to manufacture or process the chemical substance for a significant new use. EPA would generally designate as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the section 5 order.

IV. Conclusion

Since early 2021, EPA has taken steps to ensure that new PFAS are subject to rigorous reviews and appropriate safeguards, including making changes to the policies and processes underpinning reviews and determinations on new chemicals to better align with the 2016 TSCA amendments. Current scientific research suggests that exposure to certain PFAS may lead to adverse health and environmental outcomes at exceedingly low concentrations, and that most PFAS are likely persistent and bioaccumulative chemicals. Once persistent and bioaccumulative chemicals are released into the environment, they are often difficult or impossible to remediate. As such, the New Chemicals PFAS Framework is designed to stop the environmental release of PBT PFAS at the source and eliminate unreasonable risks before any manufacturing activity can commence. Additionally, using our testing authority under TSCA Section 5, implementation of the PFAS Framework will

ensure that PFAS assessments are done using the best available information. It may also help advance the Agency's understanding of this large and diverse set of chemistries.