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

Public Webinar

September 6, 2023

Office of Chemical Safety and Pollution Prevention (OCSPP)
New Chemicals Division (NCD), Office of Pollution Prevention and Toxics (OPPT)

Webinar Overview

- Introduction
- Role of PFAS Framework
- Assessing PFAS Risks
  - Identify PFAS
  - Evaluate Hazard
  - PBT Status
  - Assessing Exposures
  - Potential Testing
  - Risk Assessment Report
- Risk Management
- Conclusion
- Questions

Introduction

- 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

Introduction (continued)

- There are 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)

Role of PFAS Framework

- The framework outlines EPA's planned approach when reviewing new PFAS and new uses of PFAS **to ensure that these chemicals & uses do not present unreasonable risk to human health and the environment.**
  - Provides consistency in the review approach and **predictability** and **transparency** of process.
- New PFAS present a challenge for EPA to evaluate because there is often insufficient information to precisely quantify the risk they may pose.
  - While work is underway under EPA's PFAS Testing Strategy to improve our understanding of risks posed by categories of PFAS, it will take some time for us to obtain all the data we need.
- However, well-studied PFAS (such as PFOA and PFOS) are known to persist and bioaccumulate (build-up) in the environment and therefore pose potential risks not only to those directly exposed during their manufacture and processing but also to the general population when products are used and disposed of. This framework will be used to assess PFAS to determine whether they are likely persistent, bioaccumulative and toxic (PBT) chemicals.
- The new PFAS framework strikes the balance between the New Chemical Division's roles in protecting human health and the environment and in fostering innovation.

PFAS Framework Step 1: Identify PFAS

- The PFAS Framework defines PFAS or per- and poly-fluoroalkyl substance as 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.
- EPA not only considers the substance itself but also focuses on potential metabolites or degradants when reviewing a PFAS under TSCA section 5
- If the substance is found to not be a PFAS, it will be reviewed through the typical New Chemicals Review Process
- Generally, if the substance is a PFAS but also a Photo Acid Generator (PAG), it will be reviewed through a standardized approach developed for PAGs

Step 2a: Evaluate Hazard

- After EPA has concluded that the substance 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 and its metabolites and degradants.
- While there are thousands of different PFAS, only a small fraction have been well studied
- The 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 citical data on physical-chemical properties, fate, and toxicity

Step 2b: Evaluate PBT Status

- Early in the review process, EPA will consider whether the PFAS is a persistent, bioaccumulative and toxic (PBT) chemical
- In the 1999 PBT policy statement (64 FR 60194) and the 2018 Points to Consider policy document, 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
- EPA identifies and assesses the PBT properties of new chemical substances on a case-by-case basis using the reasonably available data
- If the substance is found to not be a PBT, it will be reviewed through the typical New Chemicals Review Process

PFAS Framework and PBT Focus

- 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
- 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 determines the persistence, bioaccumulation, and toxicity (both human health and ecological) scores for the substance(s), as well as assessing potential environmental releases and exposures

Step 3: Assessing Exposures of PBT PFAS

- 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
  - Small releases of PBT PFAS into the environment over time can contribute to considerable exposure and potential risk
- EPA assesses 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 consider the potential extent of exposures to the general population, consumers, and the environment, for the lifecycle of the PFAS
- While 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

Step 4: Identify Potential Testing

- 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 review, the New Chemicals Program expects to utilize its legal authority to require testing under section 5(e)
- The risk assessment may identify 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
- 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

Step 5: Risk Assessment Findings

- Based on the identified hazards and exposures, EPA will qualitatively assess the risk of the PBT PFAS
  - For any non-PBT PFAS, EPA will identify hazards and exposures, and quantify risk
- A PFAS Framework risk assessment will take into account 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
- Risk findings and potential testing will be packaged into a final report, which will be used by EPA Risk Managers to make a risk determination and develop any necessary risk management

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
- At a high level, the five possible determinations for any PMN or SNUN and the related actions are:

Determination	Related Action
The substance or significant new use is not likely to present an unreasonable risk	EPA notifies submitter of its decision and publishes its finding in the Federal Register
There is insufficient information 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 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)
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 may present unreasonable risk	EPA must issue an order under section 5(e)
The substance or significant new use presents an unreasonable risk	EPA must take action under section 5(f)

Not Likely Determination

- Determination: "Not Likely"
  - The relevant 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 the Administrator under the conditions of use. TSCA §5(a)(3)(C)
- Outcome: The submitter may commence manufacture of the chemical substance or manufacture or processing for a significant new use
  - Section 5(g) – Statement on Administrator Finding
    - Commercialization of the chemical substance can commence after a "not likely to present" determination is made, notwithstanding any remaining portion of the review period
- 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

Insufficient Information Determination

- Determination: "Insufficient information"
  - The information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use. TSCA §5(a)(3)(B)(i)
- Outcome: The Administrator shall take the actions required under section 5(e)
  - Regulation under section 5(e): Regulation Pending the Development of Information
    - Section 5(e) order - Typically a consent order
    - Testing generally required before commercialization of the chemical substance can occur

Exposure-based Determination

- Determination: "Chemical substances produced in substantial quantities…" (i.e., the "exposure-based" finding)
  - Such 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. TSCA § 5(a)(3)(B)(ii)(II)
- Outcome: The Administrator shall take the actions required under section 5(e)
  - Regulation under section 5(e): Regulation Pending the Development of Information
    - Section 5(e) order - Typically a consent order
    - Commercialization with restrictions
    - Testing generally due at a specified point after commercialization of the chemical substance

May Present Determination

- Determination: “May present”
  - In the absence of sufficient information to permit the Administrator to make a reasoned evaluation of the health and environmental effects of the chemical substance, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator. TSCA § 5(a)(3)(B)(i)(I).

May Present Determination (continued)

- Outcome: The Administrator shall take the actions required under section 5(e)
  - Regulation under section 5(e): Regulation Pending the Development of Information
    - Section 5(e) order - Typically a consent order
    - Commercialization with restrictions
    - Testing may be required before commercialization and/or due at a specified point after commercialization of the chemical substance

Presents Determination

- Determination: "Presents an unreasonable risk"
  - The relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use. TSCA § 5(a)(3)(A)
- Outcome: The Administrator shall take the actions required under section 5(f)
  - Regulation under section 5(f) – Protection Against Unreasonable Risks
    - Section 5(f) order or section 6(a) proposed rule (immediately effective)
    - Restriction or prohibition of chemical substance
  - 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.

Risk Management Scenarios

Negligible Exposure and Environmental Release

- 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 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)

Negligible Exposure and Environmental Release (continued)

- Likely outcome:
  - 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., environmental fate/bioaccumulation testing, toxicokinetic testing, human health toxicity, and/or environmental toxicity testing) and may require additional risk mitigation measures
  - The Agency may also consider 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

Low Exposure and Environmental Release

- 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)

Low Exposure and Environmental Release (continued)

- Likely outcome:
  - 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., environmental fate/bioaccumulation testing, 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 may also consider 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

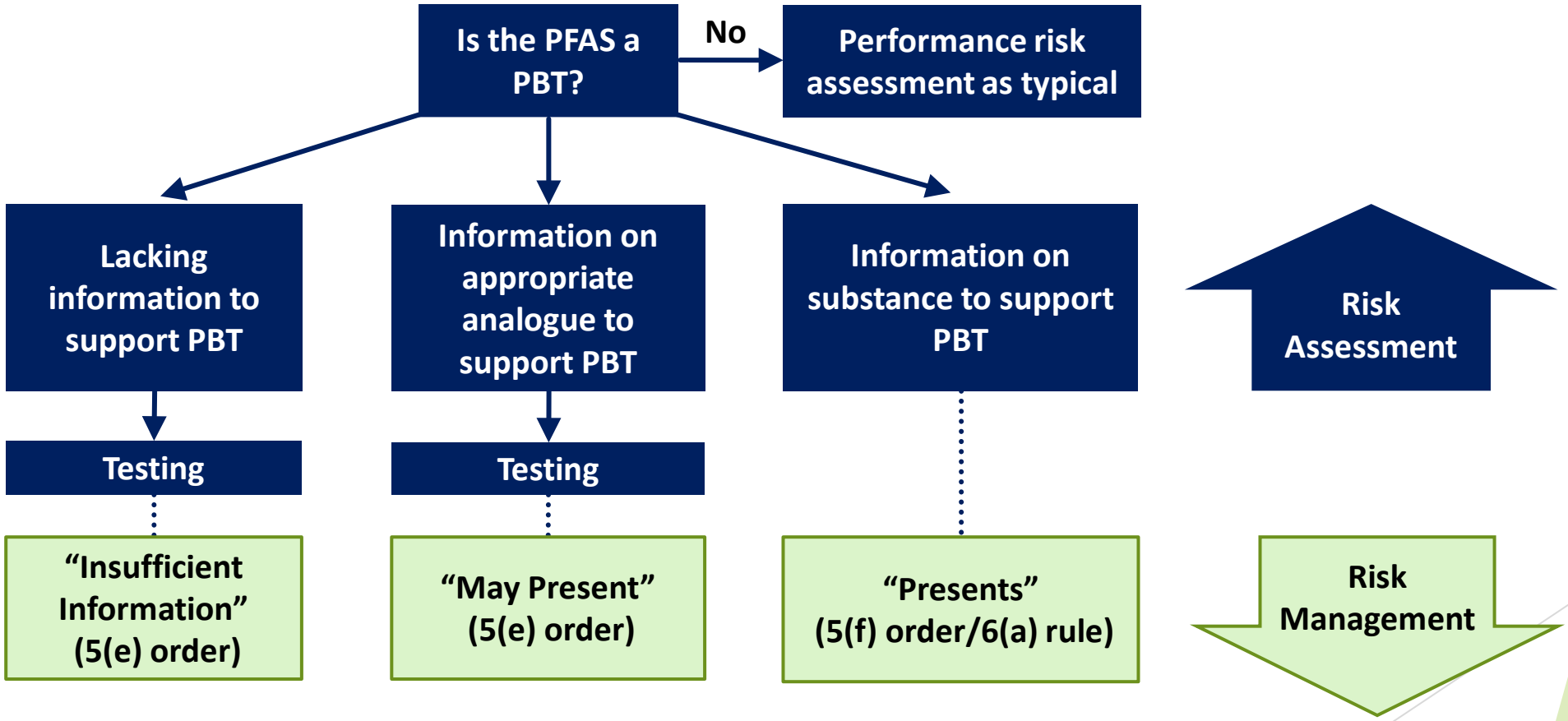
Expected Exposure and Environmental Release

- 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

Expected Exposure and Environmental Release (continued)

- Likely outcome:
  - 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 environmental fate/bioaccumulation, 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 may also consider 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

PFAS Framework – Risk Assessment (Including Hazard and Exposure) & Risk Determination



Issuing SNURs for PFAS—What is a SNUR?

- 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
- A SNUR is a Significant New Use Rule, issued under section 5(a)(2) of TSCA, that identifies a potential new use of a chemical as a "significant new use"
- If a chemical is the subject of a SNUR, anyone intending to manufacture, import, and/or process the chemical for a "significant new use" must notify EPA at least 90 days before commencing that new use by submitting a Significant New Use Notice (SNUN)
  - EPA must review the notice and make the same determinations for the significant new use as described earlier for PMNs
- A SNUR is a <u>not</u> a ban or restriction on the use of a chemical

Why are SNURs issued?

- To allow EPA to review the significant new use before it occurs, make an appropriate determination on the SNUN, and take any risk management actions as are required as a result of that determination
- EPA uses SNURs to examine new uses where the uses may create concerns by changing the exposure of people or the environment to those chemicals

SNURs - New Use Determination

- Considerations required by statute:
  - Projected volume of manufacturing and processing of a chemical substance
  - Extent to which a use changes the type/form of exposure of humans/environment to a chemical substance
  - Extent to which a use changes the magnitude and duration of exposure of humans/environment to a chemical substance
  - The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance
- No risk determination is required to issue a SNUR
- Uses of a chemical determined to be ongoing may not be subject to a SNUR

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

Question and Answer

Additional Resources

- **Points of Contact**
  - Shari Barash (barash.shari@epa.gov)
  - Tyler Lloyd (lloyd.tyler@epa.gov)
  - James Sanders (sanders.james@epa.gov)
  - Meg Victor (victor.meg@epa.gov)

- **Resources**
  - Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs)
  - Points to Consider When Preparing TSCA New Chemical Notifications
  - PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024
  - Policy Statement on a New Chemicals Category for Persistent, Bioaccumulative, and Toxic (PBT) Chemicals