



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

PFAS TSCA Workshop

February 15, 2024

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# Introduction (1)

- ▶ 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 (2)

- ▶ There are documented adverse human health and environmental effects associated with well-studied PFAS.
- ▶ The New Chemicals Program developed a “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).

# New Chemicals PFAS-Related Activities

- April 2021 - announced policy to deny new request for PFAS low volume exemptions (LVEs).
- July 2021 - launched its “PFAS LVE Stewardship Program.”
- May 2023 - proposed amendments to the new chemicals procedural regulations under TSCA, including proposal to make PFAS categorically ineligible for LVEs and low release and exposure exemptions (LoREXs).
- December 2022 and ongoing - Developing significant new use rules (SNURs) for approximately 150 PFAS that were subject to certain restrictions under Section 5 orders.
  - The new SNURs would extend the same requirements to all other manufacturers and processors of those 150 PFAS.
- June 2023 - released the **New Chemicals PFAS Framework**.

# Role of PFAS Framework (1)

- ▶ The framework outlines EPA's planned approach when reviewing new PFAS and new uses of PFAS **to ensure that these chemicals and new uses of these chemicals 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.

## Role of PFAS Framework (2)

- ▶ Well-studied PFAS (such as PFOA and PFOS) are known to persist and bioaccumulate 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.
- ▶ The Framework:
  - ▶ Will be used to assess new PFAS and significant new uses of PFAS to determine whether they are likely persistent, bioaccumulative and toxic (PBT) chemicals.
  - ▶ Focuses on PBT PFAS and the degree there are releases to the environment and expected exposure to workers and consumers.
  - ▶ 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 as 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;
  - ii.  $R-CF_2OCF_2-R'$ , where  $R$  and  $R'$  can either be  $F$ ,  $O$ , or saturated carbons; or
  - iii.  $CF_3C(CF_3)R'R''$ , 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 submission 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 it is 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.

# 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 PFAS 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 (1)

- ▶ 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.

## Step 3: Assessing Exposures of PBT PFAS (2)

- ▶ For PBT PFAS, EPA will also consider the potential extent of exposures to the general population, consumers, and the environment, for the lifecycle of the PFAS.
  - ▶ From manufacture, through processing, use, and disposal.
- ▶ 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.

# Step 4: Identify Potential Testing (1)

- ▶ Where EPA finds that the information submitted with the notice, derived from the applicable category available from the National PFAS Testing Strategy, and/or 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 4: Identify Potential Testing (2)

Depending on Outcome of Assessment:

- ▶ Physical Chemical Properties

- ▶ Water solubility, vapor pressure, boiling point, melting point, hydrolysis,  $K_{ow}$ ,  $K_{oc}$ , surface tension, micelle assembly and Henry's Law Constant

- ▶ Toxicokinetic Testing

- ▶ Dermal absorption (in vitro)
- ▶ Toxicokinetics in rats and mice

- ▶ Human Health Effects

- ▶ Genetic toxicity studies
- ▶ Combined repeat dose toxicity study with reproduction/developmental toxicity screening test in species with the longer half-life

- ▶ Environmental Fate and Effects

- ▶ Bioaccumulation studies
- ▶ Chronic ecotoxicity studies
- ▶ Avian reproduction study

# 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, the chemical will go through the typical New Chemicals' assessment process and EPA will conduct a quantitative risk assessment, where appropriate.
- ▶ 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; and
  - ▶ 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.

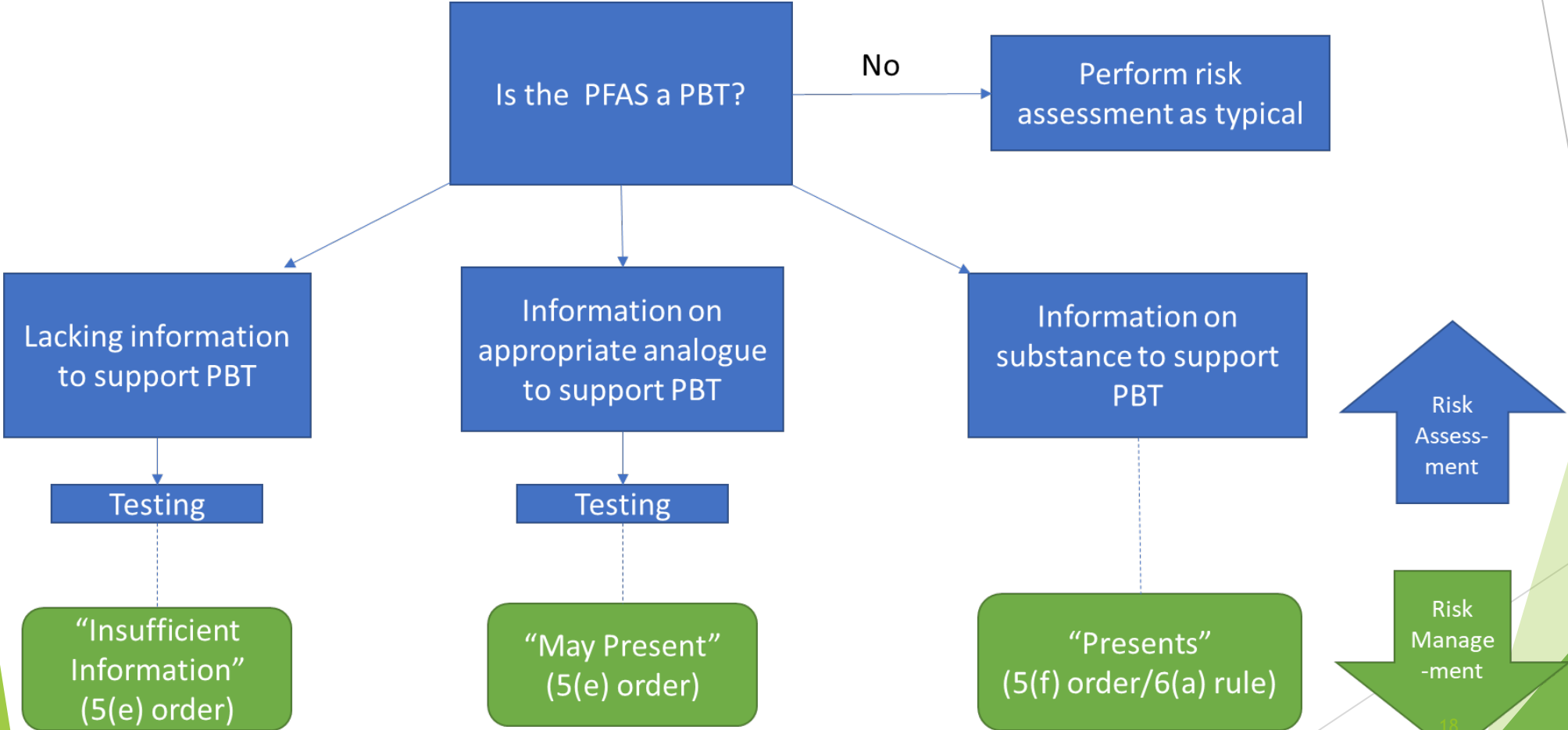


# Risk Management of PFAS

- ▶ 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 <u>not likely</u> to present an unreasonable risk	EPA notifies submitter of its decision and publishes its finding in the Federal Register
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 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 <u>may present</u> unreasonable risk	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) or issue rule on section 6(a)

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



# Use of TSCA Section 5(e) and 5(f) Orders and Significant New Use Rules (SNUR) for PFAS

- ▶ Where EPA makes a determination of “insufficient”, “may present”, or “exposure-based”, EPA will issue an order under section 5(e) that includes required testing, if applicable, as well as any risk mitigation requirements necessary to control the potential risks.
  - ▶ Typically done through a Consent Order signed by submitter and EPA.
- ▶ Where EPA makes a determination of “presents” unreasonable risk, EPA will issue an order under section 5(f) or a rule under TSCA section 6(a).
- ▶ Following any TSCA section 5(e) or 5(f) order that allows manufacture of a PFAS, EPA will issue a SNUR or modify an existing SNUR, since the orders are only binding on the original submitter for that substance.

# Summary of PFAS Framework Risk Management Scenarios

## Scenario A - “Negligible”

- ▶ PBT PFAS fully captured/negligible environmental release -e.g., all processes are fully enclosed
- ▶ Worker exposure fully mitigated - e.g., worker inhalation exposure is not expected (or is only negligible/non-quantifiable) under normal operations
- ▶ All waste is captured and disposed of in accordance with OLEM guidance
- ▶ No consumer exposures

## Scenario B - “Low”

- ▶ All cases that don’t fit into scenarios A or C
- ▶ No consumer exposures

## Scenario C - “Expected”

- ▶ Release is essential to the use (e.g., traditional fire-fighting foams) or unavoidable due to the nature of the use; or
- ▶ Consumer exposure expected based on intended use.

# Key Takeaways

- ▶ PFAS that can be manufactured, processed, used, and disposed of with negligible releases to the environment, where workers are fully protected, there are no expected consumer exposures, and wastes are disposed of properly, have less testing prior to manufacture.
- ▶ The more environmental releases and exposure expected, the more upfront testing the Framework includes.
- ▶ Providing more detailed information to EPA on environmental releases and exposures and the controls in place will speed review and reduce rework.
- ▶ In risk mitigation phase, submitters may be able to commit to increased worker protection and engineering controls that will allow them to move from a scenario with more upfront testing to one with less upfront testing, for more timely commencement of manufacturing.
- ▶ PFAS where releases are expected because they are essential to the use or where consumer exposure is expected, will have a full suite of upfront testing and, depending on test results, manufacture could be prohibited.
- ▶ PFAS-free alternatives are needed.

# Questions

# Additional Resources

## ▶ Point of Contact

- ▶ Shari Barash ([barash.shari@epa.gov](mailto:barash.shari@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](#)



# Pollution Prevention Approaches to Addressing PFAS

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# Pollution Prevention (P2)

Pollution Prevention is any practice that reduces, eliminates, or prevents pollution at its source before it is created.



P2 Programs implementing PFAS source reduction strategies:

- EPA's Environmentally Preferable Purchasing (EPP) Program
- EPA's Pollution Prevention Grants Program
- EPA's Safer Choice Program


# Addressing PFAS via Standards and Ecolabels

Federal agencies have been directed via Executive Order 14057 & the Federal Sustainability Plan to prioritize the purchase of products that do not contain PFAS.

## Private Sector Standard/Ecolabel Recommendations (not an exhaustive list)

Logo	Standard/Ecolabel Name	Product or Service Category(ies)	Product or Service Sub-category(ies)	Multi-Attribute or Single-Attribute	PFAS Criteria
	Cradle to Cradle Certified™ Product Standard	Construction; Office/Furniture	Adhesives; Carpet; Ceiling Tiles-Acoustical; Fiberboard, Gypsum Panels, and Wallboard; Flooring: Tile, Resilient, and Other Non-carpet; Furniture; Insulation; Interior Latex Paint; Other Miscellaneous Building Finishes	Multi-Attribute	Required: Under Version 4.0 of the Standard, PFAS are prohibited in certified products at all certification levels. If present as an impurity or minor additive, the level must be <1000ppm or <100 ppm in any homogeneous material by weight for products certified at Bronze and Gold levels, respectively. Some exemptions apply for specific materials or parts.
	Green Seal™ 53 Standard for Specialty Cleaning Products for Industrial and Institutional Use	Cafeteria	Commercial Dishwasher Detergent	Multi-Attribute	Required: Under the most recent standard editions, PFAS are prohibited in certified products. If present as a contaminant, the level must be below 100 ppm.

## EPA Ecolabel

Logo	Standard/Ecolabel Name	Product or Service Category(ies)	Product or Service Sub-category(ies)	Multi-Attribute or Single-Attribute	PFAS Criteria
	Safer Choice	Cafeteria; Custodial; Machine Shop Operations	Cleaners: Carpet, Glass, Multipurpose; Commercial Dishwasher Detergent; Floor Care; Hand Soap; Parts Wash Solution	Multi-Attribute	Required: EPA's Safer Choice program requires every ingredient used in a product to meet the stringent hazard criteria of the Safer Choice Standard for the product to be eligible for Safer Choice certification. PFAS are not allowed in certified products, as they do not meet the Safer Choice Standard.

# P2 Grantees Addressing PFAS

(not an exhaustive list)

## University of Illinois Urbana-Champaign

- Working with food service businesses (including restaurants, churches, soup kitchens, etc.) to increase the use of safer, more sustainable foodware by supporting purchasing programs for food contact materials that do not contain PFAS.

## University of Illinois Chicago

- Working with Minority-Serving Institutions and Black, Indigenous, People of Color (BIPOC)–led restaurants to transition to reusable and compostable food contact materials that do not contain PFAS.

## Vermont Department of Environmental Conservation

- Working with food processors to reduce PFAS and microplastics contamination in food and food waste recycling streams from food packaging.

## Missouri University of Science and Technology

- Identifying an environmentally friendly acid mist suppressant alternative to the discontinued fluorochemical reagent FC-1100, a PFAS that poses environmental issues in its production and application.