



Review Outcomes of New Chemical Substances under TSCA

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**Global Chem Conference
PMN Workshop
March 25, 2024**



Overview

- Background
- Types of Section 5 Determinations and Outcomes
- Consent Orders
- SNURS
- Exemptions



PMN (Premanufacture Notice), SNUN (Significant New Use Notice) and MCAN (Microbial Commercial Activity Notice) Notifications

- The TSCA New Chemicals program serves a "gatekeeper" role to help to manage potential risk to human health and environmental from chemicals new to the marketplace.
- TSCA section 5 requires that any person planning to manufacture or import a new chemical substance (i.e., a chemical not on the TSCA Inventory) submit notice to EPA prior to commencing that activity. This notice is known as a premanufacture notice (PMN).
- EPA is required to review these PMNs within 90 days, assess the potential risks to human health and the environment of the chemical, and make a decision.
- In order for a chemical to enter commerce, EPA must make an affirmative determination that the chemical is not likely to present unreasonable risks.
- Where potential risks are identified, EPA must take action to mitigate those risks before the chemical can enter commerce.

Determinations & Requisite Actions for PMNs

Presents an Unreasonable Risk

*Section 5(f) order or section 6(a) Rule: Restriction /prohibition of manufacturing, processing, or distribution or disposal

Not Likely to present an unreasonable risk

*May commence manufacture after the determination is made
*Section 5(g): Statement in the Federal Register

Information is insufficient to permit a reasoned evaluation of the risk

*Section 5(e) order: regulation pending development of more information

Insufficient information to permit a reasoned evaluation & **may present unreasonable risk**

*Section 5(e) order: regulation pending development of more information

Produced in **substantial quantities** and may reasonably be anticipated to enter the environment in substantial quantities or there may be significant or substantial human exposure

*Section 5(e) order



Section 5 Review and 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
 - Restriction or prohibition of chemical substance



Section 5 Review and Determination

- Determination: “May present an unreasonable risk”
 - 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).
- 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, if required, is generally due at a specified point after commercialization of the chemical substance, unless risks cannot be mitigated then testing needed before commercialization of the chemical substance



Section 5 Review and 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



Section 5 Review and Determination

- Determination: “Insufficient information available to permit a reasoned evaluation”
 - 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



Section 5 Review and Determination

- Determination: “Not Likely to Present an Unreasonable Risk”
 - 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 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)(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

5(e) Orders

- When potential risks are identified, EPA must take action to mitigate those risks before the chemical can enter commerce
- The action EPA typically takes is to issue a 5(e) consent order
- The typical determination is “may present an unreasonable risk”



Typical Order Terms

- No domestic manufacture
- May not manufacture in any manner that results in inhalation exposure
- Disposal by landfill or incineration only
- Water release restrictions
- Restrictions on air releases
- No consumer use

Typical Order Terms, continued

- Dermal personal protective equipment
- Respiratory personal protective equipment with specific assigned protection factors (APF)
 - use of a New Chemicals Exposure Limit as an alternative to the specific APF
- Dust or other engineering controls
- Hazard Communication Statements



What is a SNUR?

- 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 not a ban or restriction on the use of a chemical

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
- Ongoing uses of a chemical may not be subject to a SNUR

SNURs That Follow Section 5(e) Orders

- TSCA section 5(e) consent orders apply only to the notice submitter, so a SNUR is used to extend those restrictions to other manufacturers, importers, and processors
- TSCA requires that EPA consider promulgating a SNUR following a 5(e) order (TSCA section 5(f)(4))
 - Must promulgate SNUR corresponding to the 5(e) order or explain why not
- “5(e) SNURs” typically require notification for any use not conforming to the restrictions in the 5(e) order
- The exemptions and exclusions specific to the 5(e) order are also included in the SNURs



Exemptions from PMNs & MCANs

- Following is a discussion of exemptions and outcomes for the PMN and MCAN notifications previously discussed
- **Submission of Exemption Application Required:**
 - Low Volume ($\leq 10,000$ Kg/Yr) - 30 Day Review
 - Low Release/Exposure (LOREX) - 30 Day Review
 - Test Market Exemption (TME) - 45 Day Review
 - TSCA Experimental Release Application – 60 Day Review
 - Tier 2 Biotechnology Exemptions
 - For all exemption applications, EPA assesses whether the manufacture, processing, distribution in commerce, use or disposal of the substance **under anticipated conditions** will present an unreasonable risk to human health or the environment
- **Exemption Application Not Required for:**
 - R&D Chemicals
 - Exempted Polymers of Low Concern (only annual reporting)
 - Tier 1 Biotechnology Exemptions (only one time reporting)



Regulatory Options for Exemption Applications

- **Grant**

- An exemption is granted if the chemical substance meets the eligibility requirements for the exemption (i.e., will not present an unreasonable risk).
- Specific conditions/controls detailed in the application must be maintained throughout the duration of the exemption.

- **Deny**

- The chemical substance does not meet the eligibility requirements for the exemption.
- There are issues concerning toxicity or exposure that require further review which cannot be accomplished within the review period.



Thank You

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