

# Overview of New Chemicals Program under the Toxic Substances Control Act

AIHA Potomac Section Winter Virtual Professional Development  
Seminar

Cathy Fehrenbacher, CIH  
U.S. EPA, Office of Pollution Prevention and Toxics,  
February 28, 2022

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## Overview



- Background:
  - Toxic Substances Control Act (TSCA) Section 5
- New Chemical Reviews Under TSCA:
  - Risk Assessment
  - Risk Management
- Coordination with other Agencies
- Recent Developments
- Some COVID-related Resources

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## PMN (Premanufacture Notice)



- The TSCA New Chemicals program serves a "gatekeeper" role to help to manage potential risk to human health and environment from chemicals new to the marketplace.
- TSCA section 5 requires that any person planning to manufacture or import a non-exempt new chemical substance (i.e., a chemical not on the TSCA Inventory) notify EPA before beginning that activity. This notice is known as a premanufacture notice (PMN).
- EPA is generally required to review these PMNs within 90 days, assess the potential risks to human health and the environment of the chemical under the conditions of use, and to make an affirmative determination.
- Where the chemical substance presents or may present an unreasonable risk, EPA must take action to prevent those risks before the chemical can enter commerce.

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## Types of Notices and Exemptions



- **New chemical notices:** PMN (Premanufacture Notice), SNUN (Significant New Use Notice) and MCAN (Microbial Commercial Activity Notice) Notifications (90 day review)
- **Types of submissions eligible for exemption from PMN/MCAN (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 I and Tier 2 Biotechnology Exemptions
- **Exemption Application Not Required for:**
  - R&D Chemicals
  - Exempted Polymers of Low Concern (only one-time reporting required)

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## Information Manufacturers Must Submit



- Chemical Identity
- By-products and impurities
- Estimated production/import volume
- Proposed uses and amounts for each use
- Human exposure information
- Disposal methods and estimates of releases to the environment
- Existing test data in notifier's possession or control (or otherwise reasonably ascertainable) concerning human and environmental effects

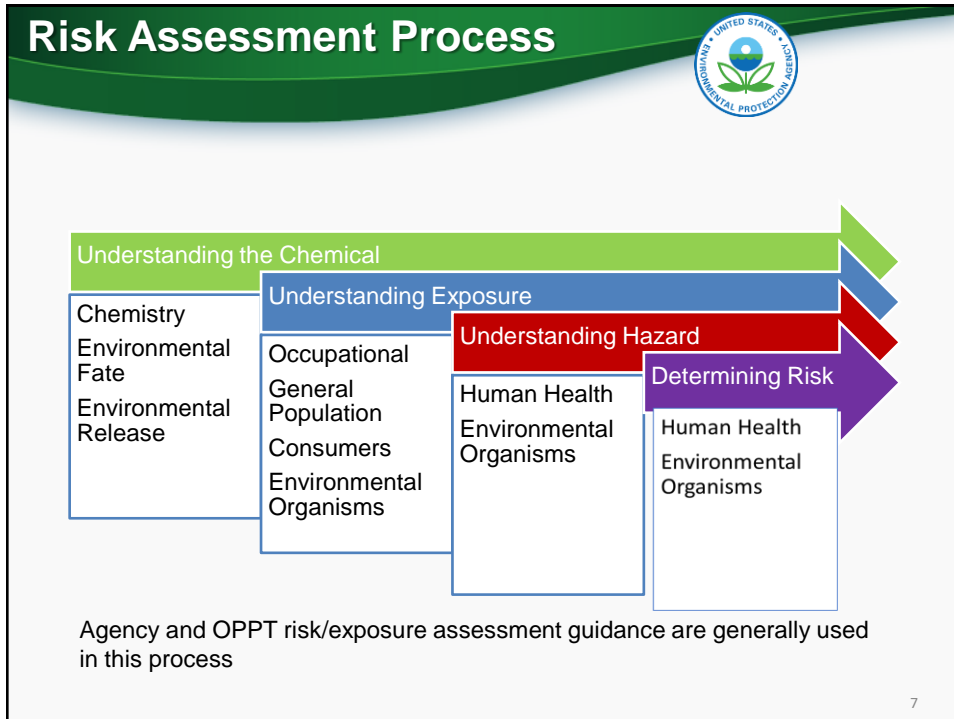
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## Risk Assessment Paradigm for New Chemicals




- Under TSCA, OPPT evaluates and regulates, as appropriate, the full life cycle of a chemical, i.e., manufacture (including import), processing, distribution in commerce, use and disposal
  - Risk assessments for a wide variety of industrial chemicals
  - Data availability/quality varies, but generally limited/incomplete

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## Overview of EPA Assessments



- TSCA requires new chemical manufacturers to submit studies or data in their possession or control or otherwise reasonably ascertainable (no minimum set of toxicity or fate studies must be performed)
- Risks from new chemical substances are considered throughout their product life-cycle
- Exposure review focuses on exposure to workers, site-specific assessment of environmental and general population exposure, and consumer exposure

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## Predictive Models in the Absence of Data



- OPPT uses reliable and relevant predictive models in the absence of data to support risk assessment of new chemicals
- Representative measured data obtained under realistic conditions are generally more accurate than modeled estimates and are needed to develop predictive models
- EPA's models and tools are intended to be used by **scientists and engineers** familiar with exposure assessment principles

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## Release and Exposure Information Hierarchy



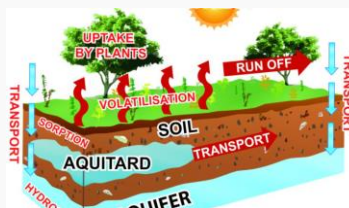
- Monitoring data for the chemical (personal and area)
- Monitoring data for a “surrogate chemical” (similar physical/chemical properties and handling)
- Mass balance or Generic scenario based on available information for specific industrial/commercial process or operation
- Models
  - Regulatory limits (release and worker exposure e.g. OSHA PELs for surrogate chemical or chemical present in same workplace as chemical)
  - Mathematical models
- Professional judgment

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## Chemistry & Environmental Fate and Transport



### Estimation Program Interface (EPI Suite)<sup>TM</sup>



## Occupational Exposure and Environmental Release



- Chemical Screening Tool for Exposures and Environmental Release (ChemSTEER)
- Generic Scenarios

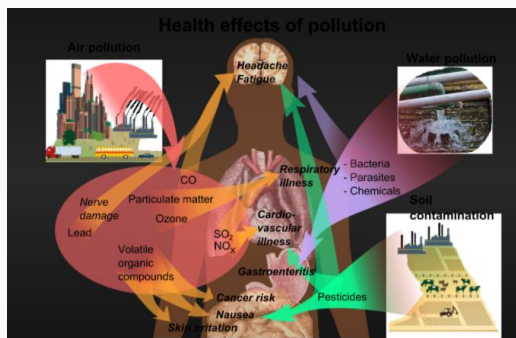
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## Consumer, General Population and Environmental Exposures



- Exposure Fate Assessment Screening Tool (EFAST)
- Consumer Exposure Model (CEM)
- Integrated Indoor-Outdoor Air Calculator (IIOAC)
- Internet Graphical Exposure Modeling System (IGEMS)
- Point Source Calculator (PSC)
- ReachScan (under development)

## Human Health Assessment



- Analogue Identification Methodology (AIM)
- Chemical Assessment Clustering Engine (ChemAce)
- Non-Cancer Screening Approaches for Health Effects
- Oncologic
- The Model Averaging for Dichotomous Benchmark Dose (MADr-BMD) Tool

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## Environmental Hazards



ECOSAR and  
relevant databases



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## Predictive Models in the Absence of Data



- For more information see [Predictive Models and Tools for Assessing Chemicals Under TSCA](#)



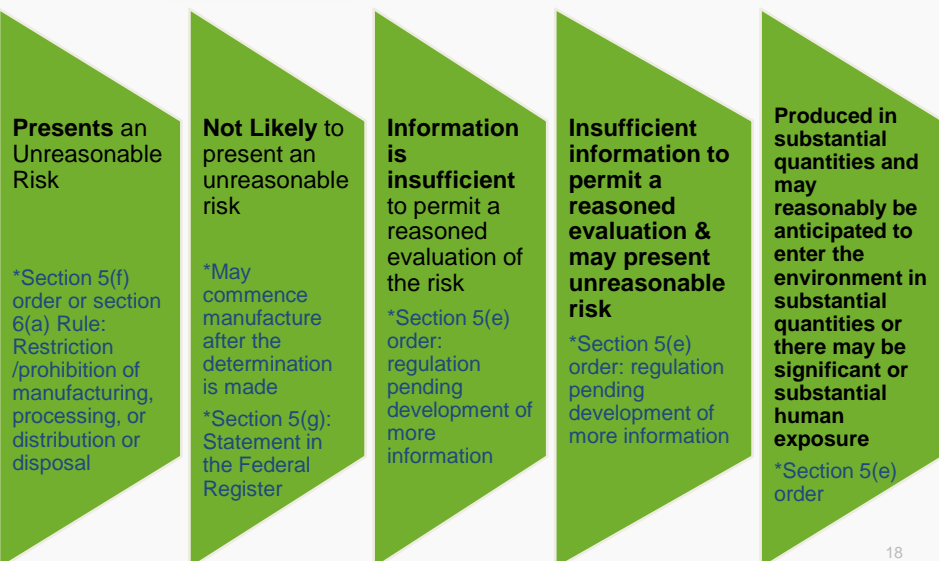
## The Risk Management Process



- After completion of the risk assessment, risk managers develop a path forward for each chemical
- EPA must make one of five affirmative findings in TSCA section 5(a)(3) before manufacturing/processing activity for the new chemical (or significant new use) can commence

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## Determinations & Requisite Actions for PMNs



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## Examples of Order Requirements



- Toxicity/environmental fate testing
- Manufacturing, processing, and use restrictions
- Distribution, transport, and disposal restrictions
- Restrictions on releases to water, air and/or land
- Use of specific engineering controls and/or worker personal protective equipment deemed adequate based on the assessed conditions of Use
- [New Chemical Exposure Limits \(NCELs\) for worker protection](#)
- Hazard communication language
- Recordkeeping

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## New Chemical Exposure Limits



- Modeled after Occupational Safety and Health Administration (OSHA) requirements
- Generally include:
  - Substance-specific New Chemical Exposure Limits
  - Performance criteria for sampling and analytical methods
  - Periodic monitoring
  - Respiratory protection
  - Recordkeeping
  - Automatic sunset if OSHA issues a PEL

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## New Chemical Exposure Limits, continued



- Generally extended to other manufacturers and processors through a SNUR
- [List of NCELS](#) is available

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## Hazard Communication



- Modeled after Occupational Safety and Health Administration (OSHA) requirements
- Uses Globally Harmonized System of Classification and Labeling of Chemicals
  - Defining hazards
  - Communication of standard language for labels and Safety Data Sheets (SDS)
- EPA may identify text to be included in the SDS (e.g., exposure limits, engineering controls, PPE, etc. to minimize exposures)

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## Coordination with Other Agencies



- Memorandum of Understanding with OSHA, January 2021
  - Framework for coordination and collaboration on new chemicals
  - Supports common goal of protecting workers from risks to chemicals
- Monthly OPPT coordination meetings with OSHA and NIOSH
- Coordination with other Agencies on New Approach Methodologies, etc.

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## Recent Developments



- [PFAS Low Volume Exemption Stewardship Program](#)
  - Builds on a 2016 program which resulted in voluntary withdrawal of more than half of the 82 long-chain PFAS LVEs targeted for withdrawal at the time
  - Initiated in April 2021; majority are shorter-chain PFAS LVEs
  - EPA will work cooperatively with companies to voluntarily withdraw previously granted low volume exemptions (LVEs) for per- and polyfluoroalkyl substances (PFAS)
  - About 12 LVEs have been voluntarily withdrawn thus far

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## Recent Developments, continued



- [Integrated Approach to Biofuel PMN Notices](#)
  - Dedicated team to collaborate on the review of premanufacture notices (PMNs) for biobased or waste-derived feedstocks used to make transportation fuel substitutes
  - Use the best available science while creating a consistent and efficient review process
  - Outreach and training for interested stakeholders in the biofuels sector

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## Some COVID-related Resources



- [EPA Coronavirus \(COVID-19\) Resources](#)
  - Disinfectants (List N)
  - Indoor air
  - COVID-19 Research
  - Water and wastewater
- [Organization for Economic Cooperation and Development \(OECD\) Coronavirus \(COVID-19\) Resources](#)

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