

# Overview of the New Chemicals Premanufacture Process

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# Toxic Substances Control Act (TSCA) - An Overview

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- Provides basic authority for chemicals in US
- TSCA provides broad authority to:
  - Gather information on new and existing chemical substances and mixtures
  - Require testing of certain chemicals
  - Screen and control new and existing chemicals
  - Control existing chemicals that present risk
  - Coordinate with other Federal and State agencies

# TSCA - An Overview

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- an “existing” chemical substance is on the TSCA Chemical Substances Inventory as being manufactured or imported in the U.S.
- a “new” chemical substance is one that does not appear on the TSCA Chemical Substances Inventory

# Section 5 of TSCA

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The Toxic Substances Control Act (TSCA), Section 5, requires a manufacturer or importer of a new chemical substance to submit a “premanufacture notice” (PMN) to EPA 90 days before the date of intended start of production or import of the subject chemical.

# Is Your Substance Subject to a PMN?

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- Intent to Manufacture (Import) for Commercial Purpose
- Not Excluded by Statute or Regulation
- Not on the TSCA Inventory
- Defined as Chemical or Microorganism

# Exclusions – By Statute

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- FOOD, FOOD ADDITIVES, DRUGS, COSMETICS OR DEVICES
- PESTICIDES
- TOBACCO AND TOBACCO PRODUCTS
- FIREARMS, NUCLEAR SOURCE MATERIALS

# Exclusions – By Regulation

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- MIXTURES
- BYPRODUCTS / IMPURITIES
- NON-ISOLATED INTERMEDIATES
- SUBSTANCES IMPORTED AS COMPONENTS OF AN ARTICLE

# Who Submits A PMN?

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- U.S. Manufacturer
- U.S. Principal Importer
- Manufacturer, Processor, or User of Excess R&D substance for Non-Exempt Commercial Purpose

# PMN Exemptions

	<b>Application</b>	<b>Time for Review</b>	<b>User Fee Costs</b>	<b>Results</b>	<b>Workload (EPA Resources)</b>
<b>Low Volume (Regulatory)</b>	EPA Form	30 days	None	Grant or Deny	New Chemicals Review Team
<b>Low Releases/ Low Exposure (Regulatory)</b>	EPA Form	30 days	None	Grant or Deny	New Chemicals Review Team
<b>Polymer (Regulatory)</b>	Postcard Notification	Must be submitted by 01/31 of the year subsequent to initial manufacture	None	Not Applicable	Notification Management of Postcards
<b>Research &amp; Development (Statutory)</b>	Record-Keeping (Industry)	Not Applicable	None	Submitter must meet definition	None
<b>Test Market (Statutory)</b>	EPA Form preferred	45 days	None	Grant or Deny	New Chemicals Review Team

# Since 1977...

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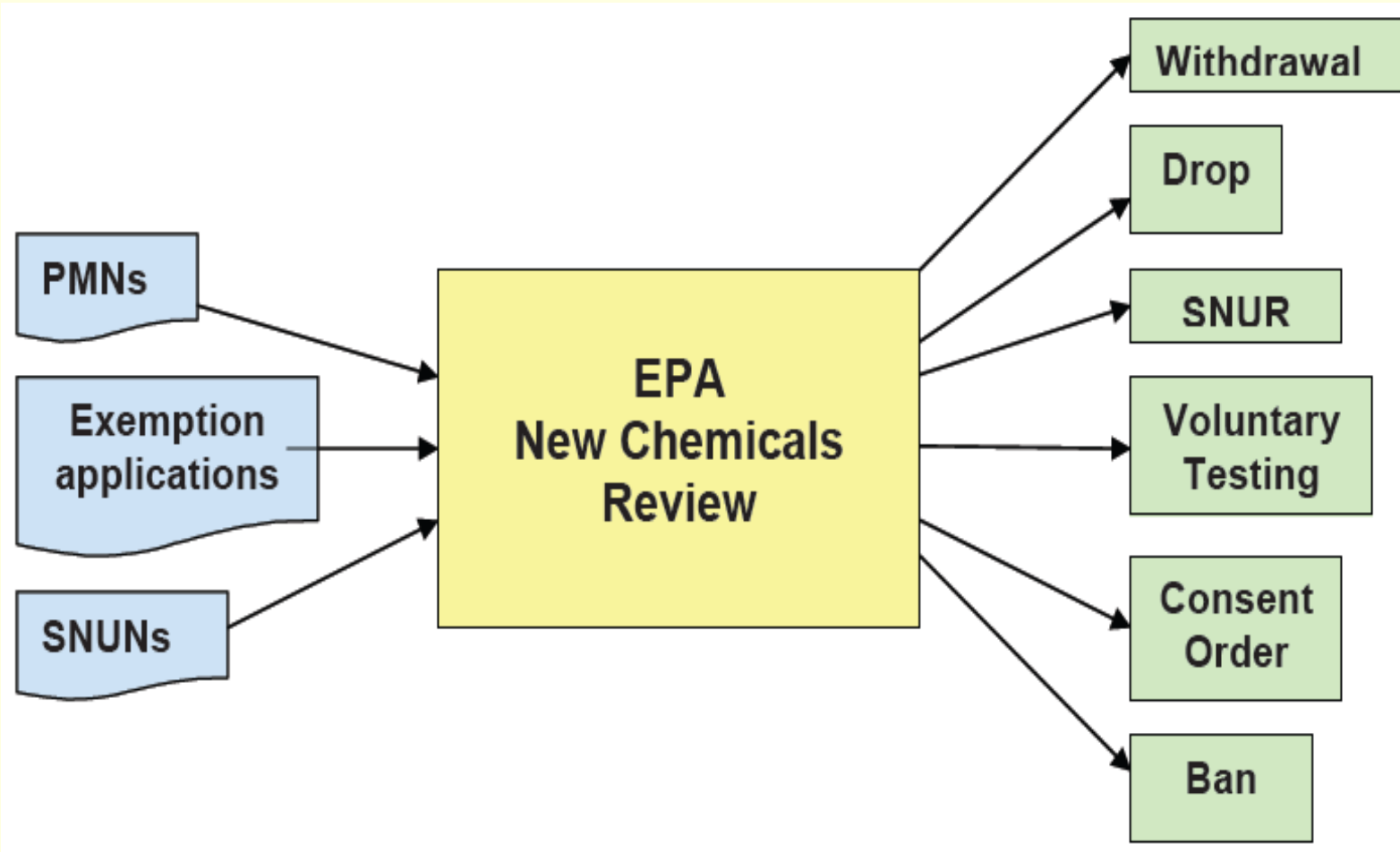
- Total PMN submissions  $\approx$  35,400
- Total PMN exemptions  $\approx$  13,000
- New chemicals added to the TSCA Inventory >21,000

# Information Required in Submissions

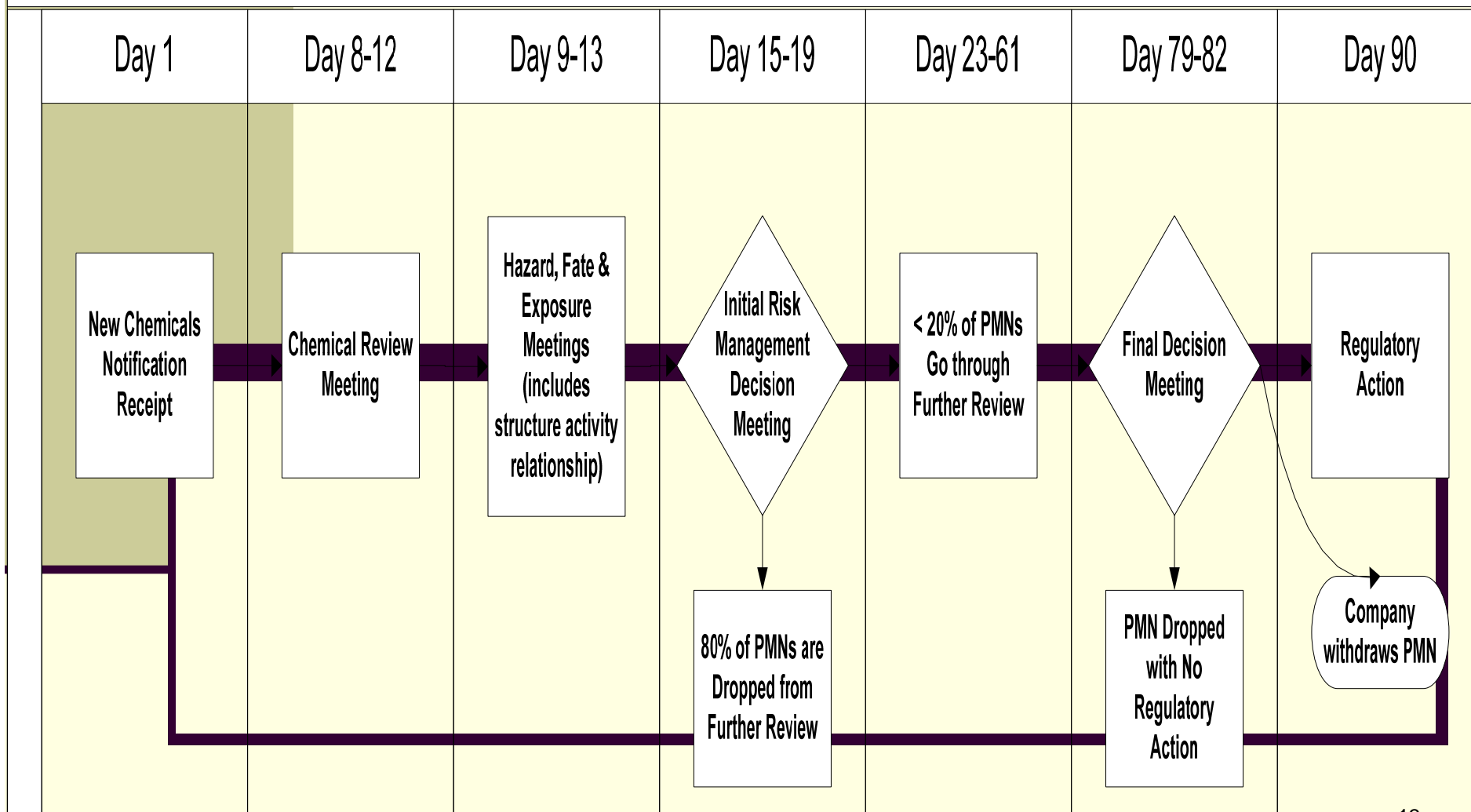
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- Chemical identity
- Byproducts
- Production/Import volume
- Description of uses
- Description of human exposure
- Description of disposal practices

# Inputs and Outputs of the New Chemicals Review Process



# New Chemicals Review Process



# Chemical Review and Search Strategy (CRSS) Meeting

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- Chemical Identity
- Structure/Nomenclature
- Analogs/Inventory Status
- Synthesis (includes byproducts and impurities)
- Physical/Chemical properties
- Pollution Prevention

# Structure Activity Team (SAT)

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- Screening level assessment of potential hazard to human health and the environment and environmental fate
- Hazard profile based on:
  - Physical and Chemical properties
  - Routes of absorption
  - PMN data
  - Structure activity relationship (SAR) analysis
  - Quantitative Structure Activity Relationship estimates
  - Persistent Bioaccumulative Toxic properties

# Exposure Assessment

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- Entire life-cycle of chemical
  - Workplace
  - Media for releases
- Quantification of releases and exposures
  - Physical and Chemical properties and environmental fate
  - Industrial practices
  - Use practices

# Focus Meeting

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- Risk management decision meeting by a multi-disciplinary group
- Reporting of hazard and exposure assessments (initial screen)
- Address “low concern” chemicals and chemical categories
- Determination of significant risk for categories, substantial production/significant and/or substantial exposure
- Make decisions on categories and exposure based actions or to initiate Standard Review

# Standard Review

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- Review and reporting beyond screening level
- Hazard and exposure assessments are in greater detail and depth
- Quantification of potential risk
- Economic analysis on use, substitutes, production volume, and benefits
- Risk management decision meeting

# Risk Assessment/Risk Management at Final Decision Meeting

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- Consider results of the detailed assessment
- Factor in hazard, exposure, risk, risk/benefit, alternatives, and regulatory history for related PMN cases, etc.
- Outcome
  - Final decisions are made on the 20% of PMN cases continued into this review, of these about  $\frac{1}{2}$  are dropped,  $\frac{1}{4}$  are withdrawn by submitter in face of regulatory action, and control measures are taken on remaining  $\frac{1}{4}$ .

# Notice of Commencement

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- Submit within 30 days of first manufacture
- Must be submitted by PMN submitter
- Substantiate CBI Claims



# Supplemental Information

# Possible Decisions

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- Drop from further review
- Drop with a concern letter
- Regulate:
  - Suspension, pending upfront testing (under section 5(e) authority)
  - Section 5(e) consent order – Risk-based and Exposure-based
  - Section 5(a)(2) significant new use rule (SNUR)
  - Section 5(f) action -> section 6 ban or rule
  - Unilateral section 5(e) order (ban, pending testing)

# “Drop” Decision

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A case is dropped from further review when it:

- Does not meet any of the exposure-based criteria
- Does not present an unreasonable risk to human health or the environment
- Does not present increased potential for risk from an increased production volume or other uses

# Drop with a Concern Letter

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- The notifier is informed by letter of potential hazard or risk.
- Data exist for structurally analogous substances.
- Small population may be affected and potential risk is controllable.
  - Standard industrial practices
  - PPE
  - Environmental controls

# Suspension, Pending Upfront Testing

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- There is insufficient information, and chemical substance may pose an unreasonable risk
- Risk from exposure or release cannot be controlled
- Testing or other information will provide a more informed risk assessment

# TSCA, Section 5(e) Consent Orders

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- The information . . . is insufficient . . . to permit a reasoned evaluation . . . such activities . . .
- May present an unreasonable risk of injury to health or the environment, or . . .
  - Will be produced in substantial quantities, and . . . enter the environment in substantial quantities or there . . . may be significant or substantial human exposure .

## 5(e) Risk-based Consent Order

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- There is insufficient information, and chemical substance may pose an unreasonable risk
- Risk from exposure or release can be controlled
- Manufacturing can commence under specific terms and conditions
- Testing or other information will provide a more informed risk assessment

# Potential Control Measures in 5(e) Orders

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## MAY INCLUDE:

**Testing**

**Protective Equipment Requirements**

**Worker Training Programs**

**Distribution/Use/Disposal Restrictions**

**Labels, MSDS, and Notification Letters**

**Restrictions on Releases to Water/Air**

**Recordkeeping Requirements**

**Production/Importation Volume Testing Trigger**

**New Chemical Exposure Limit (NCEL)**

**Product Stewardship Programs**

## 5(e) Exposure-based Consent Order

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- $PV \geq 100,000$  kg/yr
- There is insufficient information, and
  - (1) substantial environmental exposure or
  - (2) significant/substantial human exposure criteria are met.
- Manufacturing can commence.
- Testing or other information will provide a more informed hazard assessment.
- Testing is triggered at specified PV.

# Significant New Use Rules (SNURs)

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- “Section 5(e) SNUR” – extends consent order requirements to other manufacturers and processors
- “Non-section 5(e) SNUR” – provides that standard provisions would apply without use of 5(e) consent order
- Notice and Comment SNUR

# Additional Information

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- **New Chemicals Program**  
[www.epa.gov/oppt/newchems](http://www.epa.gov/oppt/newchems)
- **Policies**  
[www.epa.gov/oppt/newchems/pubs/policies.htm](http://www.epa.gov/oppt/newchems/pubs/policies.htm)
- **Guidance**  
[www.epa.gov/oppt/newchems/pubs/guideman.htm](http://www.epa.gov/oppt/newchems/pubs/guideman.htm)
- **International Trade Data System (ITDS) - Automated Commercial Environment (ACE)**  
[www.itds.gov/xp/itds/home.xml](http://www.itds.gov/xp/itds/home.xml)
- **EPA Agency-wide Import-Export Portal**  
[www.epa.gov/compliance/international/importexport.html](http://www.epa.gov/compliance/international/importexport.html)
- **OPPT TSCA Import-Export Website**  
[www.epa.gov/oppt/import-export/index.htm](http://www.epa.gov/oppt/import-export/index.htm)
- **TSCA Section 13 Import Checklist**  
[www.epa.gov/oppt/import-export/pubs/checklist.pdf](http://www.epa.gov/oppt/import-export/pubs/checklist.pdf)
- **Compliance Guide for Chemical Import Requirements of TSCA**  
[www.epa.gov/compliance/resources/publications/monitoring/tsca/importguid ejune2008.pdf](http://www.epa.gov/compliance/resources/publications/monitoring/tsca/importguid ejune2008.pdf)