



**EPA's New Chemical
Program
Under Section 5 of TSCA**

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TSCA Overview

- » TSCA, which became effective on Jan. 1, 1977, gives EPA broad authority to:
 - † gather data on health/safety and exposure for,
 - † require testing of, and
 - † control exposure to
- » “new” and “existing” industrial chemicals

TSCA Overview

- » Under most circumstances,
 - † an “existing” chemical substance is one that was reported for EPA’s initial TSCA Inventory as being already in U.S. commerce
 - † a “new” chemical substance is one that does not appear on EPA’s TSCA Inventory

TSCA Overview

» The following substances (as defined under other Federal laws) are not covered by TSCA:

† pesticides

† tobacco, tobacco products

† firearms and ammunition

† source, special, byproduct nuclear materials

† foods, food additives, drugs, medical devices, cosmetics

Section 5 of TSCA

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

Process Overview

- † **Designed to prevent health and/or environmental risks before they occur**
- † **Over 40,000 PMNs reviewed to date**
 - » Receive about 1,500 notices annually
- † **Various exemptions available**

PMN Exemptions

† **PMN Not Required**

- » R&D Chemicals
- » Polymers (annual reporting only)

† **Exemption Submission 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

Incoming Data Overview

No toxicity data requirements

- † **Regulatory decisions are often made in the absence of data**
 - » 50% of PMNs received contain no test data
- † **The majority of the submitted data pertains to human health**
- † **Minimal environmental effects/fate data submitted**

Required PMN Information

- † Chemical Identity/Structure
- † Description of Uses
- † Production/Importation Volume
- † Description of Byproducts
- † Description of Human Exposure
- † Description of Disposal Practices
- † Available Health/Environmental Effects
Test Data

90-day Review Process

- † Chemical Review/Search Strategy (CRSS) Meeting
 - » Day 8-12
- † Structure Activity Team (SAT) Meeting
 - » Day 9-13
- † Exposure/Release Profile developed
 - » Day 10-19
- † Focus Meeting
 - » Day 15-20
- † Standard Review
 - » Day 21-85

Chemical Review/Search Strategy (CRSS) Meeting

Establishes chemistry profile:

- † Chemical identity
- † Structure and Nomenclature
- † Structural analogs and Inventory Status
- † Notice completeness
- † Synthesis
- † Use/TSCA Jurisdiction
- † Physical-Chemical Properties

Structure Activity Team (SAT) Meeting

Utilizes:

- † SAR data
- † PMN data
- † CRSS data

Evaluates:

- † Health Effects
- † Environmental Effects
- † Environmental Fate

Establishes:

- † Health and Environmental HAZARD Potential

Chemical Categories

- † Currently 45 categories; routinely updated
- † Used to group chemicals with similar physical/chemical, structural toxicological properties for purposes of risk assessment and regulatory review
- † Provide testing recommendations
- † EPA needs relevant data to refine concerns

Significant Risk Guidelines

- † Cancer Risk
- † Non-Cancer Risks
- † Aquatic Organisms

Exposure and Release Profile

Profile of exposure and releases from manufacture, processing and use

- † Occupational exposure/releases
- † Environmental releases
- † Consumer exposure
- † Ambient or general population exposure

Basis of profile is the exposure and production volume information in PMN

Focus Meeting

- Multidisciplinary Risk Management Meeting
- Decisions range from “dropping” a chemical from further review to banning a chemical pending further information.
- Decisions based on information compiled by the CRSS, SAT, and exposure-based reviews.

Risk Management Actions

When to Regulate?

- † **Magnitude/type of risk**
- † **Numbers/types of individuals exposed**
- † **Substitutes (relative risk)**
- † **Benefits**
- † **Other uses**
- † **Regulatory history**

Regulatory Actions

- † Drop
- † Drop with Concern Letter
- † Significant New Use Rule (SNUR)
- † Section 5(e) Consent Order
- † Ban-Pending Upfront Testing
- † Section 5(f) Action
- † Standard Review

No significant risk – “Drop” decision

A case is dropped from further review when it does not:

- † Meet any of the exposure-based criteria
- † Pose a significant health risk
- † Pose a significant environmental risk
- † Pose a potential hazard and possible increased production or other uses

Drop with Concern Letter

To inform submitter of potential hazard or risk, i.e.,

- † Hazard data exists for analogous substance
- † Small population is a risk (controllable)
 - » Personal Protective Equipment
- † Environmental controls

SNUR

SNUR covers potential new uses (not identified in PMN) that could result in increased exposures to, or release, of the PMN substance

Also used to follow-up 5(e) Consent Order

5(e) Exposure-based Order

- † Potential for *substantial human exposure or environmental release & insufficient information*
- † Established criteria
- † Requires development of specific health or environmental data at specified production volumes or Production Volume Triggers

5(e) Risk-based Order

- † EPA determines chemical may pose an *unreasonable risk & there is insufficient information*
- † Allows submitter to manufacture with **controls** pending development of data

5(e) Risk-based Order (cont'd)

MAY INCLUDE:

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

Ban Pending Upfront Testing

- † Substance may pose an *unreasonable risk & there is insufficient information*
- † *Exposure or release cannot be controlled*, e.g., concentration of PMN substance released in water exceeds concern concentration
- † Ban pending testing or other information to mitigate concern

Section 5(f) Action

If EPA determines that a new chemical will present an unreasonable risk before a TSCA Section 6 rule can be promulgated, EPA may:

- † Impose immediate limitations via a proposed rule
- † Completely prohibit by issuing proposed order or injunction

Standard Review

Standard Review

- † Repeat risk assessment
- † Weeks instead of days
- † Risk management decision by day 85