The New Chemicals Program PMN Review Process

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PMN Review Process Overview

- New Chemicals Program
- Days 1 – 20
- Regulatory actions
- Risk management decisions

Section 5 of TSCA

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.

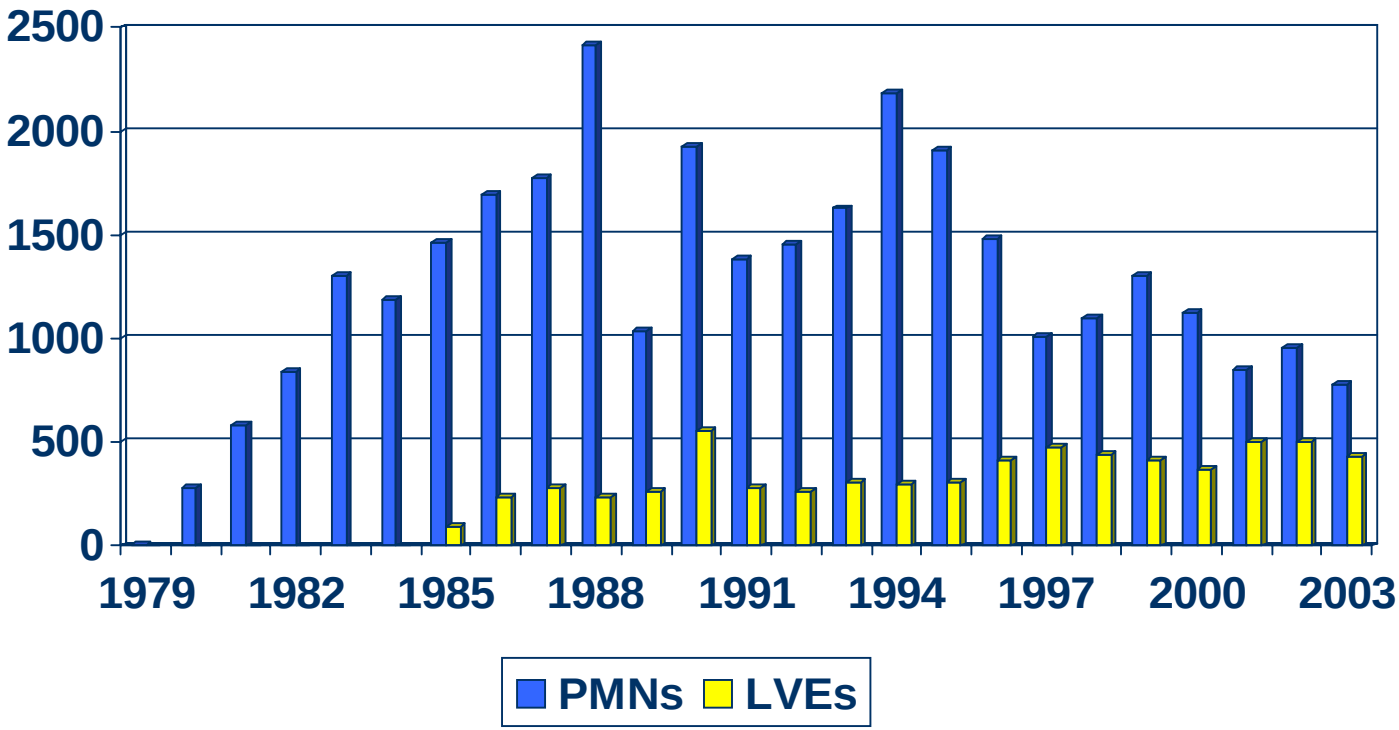
Program Overview

- Designed to prevent health and/or environmental risks before they occur
- Regulatory decisions are often made in the absence of data
- Proven track record: over 41,000 Section 5 notices reviewed to date

PMN Exemptions

- PMN not required
  - R & D chemicals
  - Certain polymers (annual reporting)
  - Export only
- Exemption submission required
  - Low volume (LVE)
  - Low release/exposure (LoREX)
  - Test Marketing (TME)

Program Statistics



Program Statistics

- The original TSCA Inventory had approx. 62,600 chemicals listed.
- As of FY2003, the Inventory contained 80,356 chemicals, of which 22% were from PMN chemicals.
- Over the last 12 years, the percentage of PMN chemicals that have a filing of a Notice of Commencement (NOC) to manufacture is consistently approx. 50%.

Program Statistics

- Approx. 200-300 polymer exemptions reported annually
- Approx. the same number of polymers that were eligible for exemption were submitted as PMNs
- FY2003
  - 775 PMNs
  - 434 LVEs
  - 5 TMEs
  - 3 LoREXs
  - 13 SNUNs

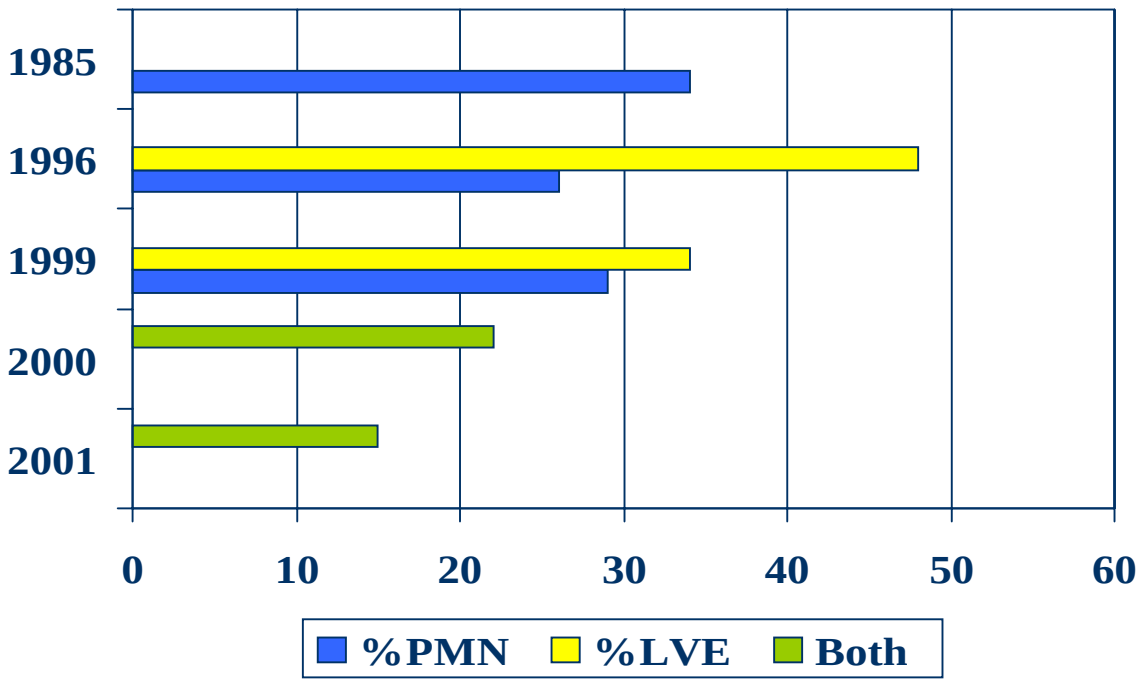
Information Required in PMN

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

Confidential Business Information (CBI)

- TSCA, Section 14, allows companies to assert CBI claims for certain information submitted to EPA under TSCA
- Only 5% of PMNs submitted to date have been completely non-confidential
- CBI handling requirements and procedures have a significant impact on the program

Test Data Received with Notification



Data Received with Notification

- Majority of submitted data pertains to acute toxicity testing in animals
- Very little environmental effects or fate data are submitted.

New Chemicals Review Process

- Day 1-7 Administrative, Inventory search
- Day 8-12 CRSS Meeting
- Day 9-13 SAT Meeting
- Day 10-19 Exposure Assessment
- Day 15-20 FOCUS Meeting

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- Day 21 Standard Review
- Day 79-82 Decision Meeting

Chemical Review/Search Strategy (CRSS) Meeting

Establishes chemical identity

- Nomenclature, molecular formula, structure
- Inventory status
- Chemical analogues
- Synthetic scheme
- Use – TSCA jurisdiction
- Physical-chemical properties

Structure Activity Team (SAT) Meeting

- Screening level assessment of potential hazard to human health and the environment
- Hazard profile based on:
  - P/C properties
  - Routes of absorption
  - PMN data
  - Structure activity relationship (SAR) analysis
  - QSAR estimates
  - PBT properties

Chemical Categories

- Currently 54 categories - human health and ecotoxicity
- Based on test data
- Identifies endpoints of concern
- Provides testing recommendations
- Delegated authority on structural analogues of these category compounds
- EPA needs relevant data to refine concerns

Exposure Assessment

- Entire life-cycle of chemical
  - Workplace
  - Media for releases
- Quantification of releases and exposures
  - P/C properties and environmental fate
  - Industrial practices
  - Use practices

Engineering Report

- Screening level assessment of exposures at the workplace
- Modeling by ChemSTEER
  - Estimates inhalation and dermal exposure to workers during manufacturing, processing and use operations
  - Estimates releases to air, water and land associated with manufacturing, processing and use

Exposure Report

- Screening level assessment of exposures to the environment and non-workers
- Modeling by E-FAST, exposures to:
  - Aquatic species
  - Consumers
  - General populations
    - Ambient air
    - Drinking water
    - Fish ingestion

TSCA, Section 5(e) Regulatory Decisions

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 . . .

Significant Risk

- Human health
  - Extra risk for cancer > 1.0E-6
  - Non-cancer endpoints, MOE < 100

- Aquatic species
  - Acute risk, surface water concentration exceeds the COC ≥ 4 days/yr
  - Chronic risk, surface water concentration exceeds the COC ≥ 20 days/yr

Significant Risk PBT Category

- PBT Policy Statement published at 64 FR 60194
- TSCA Section 5(e) action where:
  - Persistence (transformation half-life) is > 2 months
  - Bioaccumalation (Fish BCF or BAF) is ≥ 1,000
- Perfluorinated chemicals are potential PBTs

Substantial Exposure

- Criteria established in 1988
- PV ≥ 100,000 kg/yr
- Numerical values for substantial or significant human exposure
- Numerical values for substantial environmental release

Substantial or Significant Human Exposure

- Worker Exposure
  - ≥ 1000 workers
  - ≥ 100, with inhalation exp. ≥ 10 mg/d
  - ≥ 100, with inhalation exp. 1-10 mg/d for ≥ 100 d/yr
  - ≥ 250, with dermal exp. for ≥ 100 d/yr

Substantial or Significant Human Exposure

- Presence in consumer product where the manner of use would make exposure likely

- General population
  - ≥ 0.003 mg/kg/d (70 mg/yr) exposure via drinking water, groundwater, air or fish ingestion
  - ≥10,000 kg/yr released to environmental media

Substantial Environmental Release

≥ 1,000 kg/yr total released to surface water, calculated after wastewater treatment

Substantial Exposure PBT Category

- Exposure criteria are met over a 5-year period
- Data or estimated values indicate a potential for persistence and bioaccumulation
- Identification of a potential hazard to human health

Focus Meeting

- Risk management decision meeting by a multi-disciplinary group
- Delegated authority for “low concern” chemicals and chemical categories
- Reporting of hazard and exposure assessments (initial screen)
- Determination of significant risk, or significant and/or substantial exposure

Regulatory Actions

- Drop from further review
- Drop with a concern letter
- Regulate by:
  - Unilateral section 5(e) order (ban, pending testing)
  - Section 5(e) consent order
  - Section 5(a)(2) significant new use rule (SNUR)
  - Section 5(f) action -> section 6 ban or rule
- Standard review

“Drop” Decision

A case is dropped from further review when it:

- Does not meet any of the exposure-based criteria
- Does not present a significant health risk
- Does not present a significant environmental risk
- Does not present a potential hazard or risk from an increased production volume or other uses

Drop with a Concern Letter

- 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

Ban, Pending Upfront Testing

- 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

5(e) Risk-based Consent Order

- 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

5(e) Risk-based Consent Order Terms and Conditions

- PPE requirements
- Worker training programs
- Distribution/use/disposal restrictions
- Labels, MSDS and notification letters
- Restrictions on releases to water/air
- Recordkeeping requirements
- Testing is triggered at specified PV
- New Chemical Exposure Limit (NCEL)
- Product stewardship programs

5(e) Exposure-based Consent Order

- There is insufficient information, and

(1) substantial environmental exposure or

(2) significant/substantial human exposure.

- One or more EPA exposure criteria are met.
- Manufacturing can commence.
- Testing or other information will provide a more informed hazard assessment.
- Testing is triggered at specified PV.

Section 5(a)(2) SNUR

- A risk-based regulatory decision
- New activities/uses are those not identified in the PMN and they may result in an increased exposure or release
- Rule promulgated to cover activities that presents or may present an unreasonable risk of injury to health or the environment
- A significant new use notice (SNUN) is required if use changes.

SNURs

- 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
- Generic/expedited SNUR
  - Expedited rule-making
  - Standard provisions in rules define significant new uses

Section 5(f) Action

- EPA concludes that manufacturing activities presents or will present an unreasonable risk of injury to health or the environment before a TSCA, Section 6 rule can be promulgated.
- EPA may impose immediate limitations by a proposed rule.
- EPA may completely prohibit the activities by issuing a proposed order or an injunction.

Standard Review

- 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, PV, and benefits
- Risk management decision meeting chaired by CCD Division Director (day 85)

Reports for Standard Review

- Chemistry
- Human Health Hazard Assessment
- Ecological Hazard Assessment
- Engineering
- Exposure and Fate
- Economics
- Risk Assessment
- Briefing paper
- Decision document

Factors in Risk Management

- Magnitude and type of hazard
- Type of human/environmental exposure
- Substitutes - relative risk determination
- Benefits to human health/environmental
- Other uses – potential for increased risks
- Regulatory history – consistency in risk management decisions

Test Data Submitted under 5(e) Regulation

- 1999 172 studies
- 2000 42 chemicals (112 studies)
- 2001 35 chemicals (126 studies)

Additional Information

- New Chemicals Program
  www.epa.gov/oppt/newchems
- Chemistry assistance manual
  www.epa.gov/oppt/newchems/chem-pmn/index.htm
- Exposure assessment models
  www.epa.gov/oppt/exposure
- Pollution prevention screening tools
  www.epa.gov/oppt/p2framework