Overview of U.S. EPA’s New Chemicals Program under the Toxic Substances Control Act (TSCA)

Nhan Nguyen, Cathy Fehrenbacher
Risk Assessment Division
Office of Pollution Prevention and Toxics
US EPA
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Toxics Substances Control Act (TSCA)

• Enacted in 1976
• Gives EPA authority to:
  – Gather information on chemicals in commerce
  – Regulate chemicals by requiring testing
  – Control exposure by reviewing new chemicals before they are manufactured
Toxics Substances Control Act (TSCA) (cont’d)

• The following substances are not covered by TSCA:
  – Pesticides
  – Food
  – Drugs
  – Cosmetics
  – Tobacco and tobacco products
U.S. EPA New Chemicals Program

• Regulated under the Toxic Substances Control Act (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
PMN Exemptions

- PMN Not Required for
  - R&D Chemicals
  - Exempted Polymers
  - Low Volume (<10,000 Kg/Yr) - 30 Day Review
  - Low Release/Exposure (LOREX) - 30 Day Review
  - Test Market Exemption (TME) - 45 Day Review
Challenge: Evaluating Chemicals Lacking Data Under TSCA

• EPA reviews about 1200 - 1500 PMNs per year!
• Comparatively, the European Chemical Bureau receives 300-400 notifications per annum reflecting 250-300 new substances
• Submitters of PMNs are not required to conduct any new testing
• Comparatively, EC NC Directives require base set testing
• EPA can require testing if risk exists – but burden of proof is on EPA!
Chemical Review/Search Strategy (CRSS) Meeting (Day 8-12)

- Structure- Nomenclature
- Analogs - Inventory Status
- Synthesis
- Use - TSCA Jurisdiction
- Physical-Chem Properties
  - MP, BP, VP, Kow, Koc, etc.
- Environmental Fate Parameters
  - Where does it partition?
  - How does it degrade?
Structure Activity Team (SAT) Meeting (Day 9-13)

- Establish Toxicity Potential by Evaluating:
  - Physical/Chemical Properties and Env. Effects
  - Chemical Reactivity
  - Nearest Analog Analysis
  - Results of QSAR Estimates

- Determine
  - Aquatic Toxicity Profile
  - Absorption/Metabolism Considerations
  - Non-Cancer Human Health Effects
  - Cancer Potential
Exposures and Environmental Releases (Day 10-15)

• Develop estimates of exposures to:
  – Workers, Consumers, and the General Population
    • Via Inhalation, dermal, ingestion, etc.
  – Aquatic Environment

• Develop estimates of environmental releases from Manufacturing, Processing, and Use Activities:
  – Water, Landfills, Air (via Fugitive emissions), etc.
FOCUS Meeting (Day 15-19)

• Bring to the table:
  – P-chem and Fate
  – Human Health Toxicity
  – Environmental Toxicity
  – Exposure and Release Information
  – Risk Assessment
    • This information used to make initial assessment of risk, determine uncertainty in assessment, establish data needs and data gaps

  – Risk Management Activities Proposed
Standard Review

• Repeat risk assessment
• Weeks instead of days
• Risk management decision by day 85
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 opportunity for 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