

International Symposium on Chemicals Management in the Context of Global Trends; Chemical Management in the United States

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Chemical Management

- EPA employs both voluntary and regulatory approaches to chemical management
- Gatekeeper/Guardian
 - Regulatory authorities used to
 - Keep risky new chemicals out of the market
 - Manage risks from chemicals already in use
- Facilitation of Environmental Stewardship
 - EPA assists with information, analytic tools and advice
 - Voluntary agreements

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Chemical Management

- Both roles support EPA's goal of ensuring that industrial chemicals pose no unreasonable risk by:
 - Promoting pollution prevention
 - Promoting use and development of safer chemicals
 - Reducing risk from exposure to existing chemicals
 - Providing useful risk related information to the broadest audience possible
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Chemical Management

- EPA's Office of Pollution Prevention and Toxics is responsible for administering two key laws
 - Toxic Substances Control Act (TSCA)
 - Pollution Prevention Act (PPA)
 - Both PPA and TSCA are multimedia acts that are applicable to all phases of the chemical life cycle
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Toxic Substances Control Act (TSCA)

- TSCA is a primary law regulating chemical substances:
 - Requires, or authorizes EPA to require, maintenance of records and submission of reports on chemical substances and mixtures
 - Requires EPA to maintain an inventory of chemicals in commerce
 - Requires manufacturers to notify EPA before manufacturing a new chemical substance
 - Allows EPA, if necessary, to regulate the new chemical before it is manufactured

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Toxic Substances Control Act (TSCA)

- TSCA is a primary law regulating chemical substances (continued):
 - Authorizes EPA to compel testing of chemicals and mixtures
 - Compels submission of certain information indicating substantial risk
 - Provides EPA with the authority to ban or restrict activities involving chemicals or mixtures that present an unreasonable risk

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Pollution Prevention Act (PPA)

Establishes national policy

- Pollution should be prevented or reduced at the source whenever feasible
- Pollution that cannot be prevented should be recycled in an environmentally safe manner (ESM)
- Pollution that cannot be prevented or recycled in an ESM should be treated in an ESM
- Disposal or release of pollutants should be used as a last resort, and should be conducted in an ESM

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Risk Management Under TSCA

- TSCA distinguishes between new and existing chemicals
 - Existing chemicals are on the TSCA inventory of chemical substances
 - Any chemical not on the TSCA inventory is a new chemical

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Risk Management Under TSCA

New Chemicals

- EPA may prohibit or limit activities pending development of information if it finds
 - Insufficient information exists to evaluate the effects of the chemical, and
 - It may present an unreasonable risk, or
 - It will be produced in substantial quantities and there may be significant or substantial exposure or release

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Risk Management Under TSCA

New Chemicals and Existing Chemicals

- If EPA has sufficient information to evaluate the effects of the chemical, it may prohibit or limit activities if it finds:
 - A reasonable basis to conclude that an activity involving the chemical presents or will present an unreasonable risk
 - EPA must consider cost and benefits including availability of substitutes
 - EPA must show that its action is the “least burdensome” measure that provides adequate protection

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TSCA New Chemical Program

- Premanufacture Notice (PMN) must be submitted 90 days prior to manufacture/import of new chemical
 - EPA reviews notice
 - EPA may issue a 5(e) order to control the chemical pending the development of information

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TSCA New Chemical Program

- TSCA section 5(e) order
 - EPA must make required risk or exposure findings
 - Order may require
 - Exposure and release mitigation
 - Testing
 - Hazard communication
 - Record keeping
 - May be negotiated (Consent Order) or unilaterally imposed
 - Order applies only to PMN submitter

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Significant New Use Rules (SNUR)

- Rulemaking action
- Designates certain activities as Significant New Uses
- EPA must consider factors relevant to the new use such as anticipated changes in
 - production volume,
 - Nature, extent, and duration of exposure, and
 - Manner of manufacture, processing, and disposal

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Significant New Use Rules (SNUR)

- Anyone who intends to manufacture or process a chemical for a significant new use must notify EPA at least 90 days in advance
 - Procedure is analogous to PMN process
- A SNUR may be used to require persons to notify EPA prior to manufacturing or processing a chemical in a manner inconsistent with the terms of a 5(e) order
- SNURs may be used for both new and existing chemicals where EPA has concerns and information needs associated with uses that are not ongoing

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Chemical Testing Under TSCA

- EPA may issue a rule requiring manufacturers importers and processors to test for health and environmental effects
- EPA must make certain findings including
 - Insufficient data
 - May present unreasonable risk or
 - Chemical will be produced in substantial quantities and there may be significant or substantial exposure or release

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Chemical Testing Under TSCA

- Enforceable consent agreements (ECA) may be used to obtain testing
 - Terms are negotiated
 - Alternative to rulemaking
 - ECAs may also involve stewardship agreements

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TSCA Chemical Inventory

- Lists more than 80,000 chemicals
- New chemicals are added as they enter commerce
- EPA's information on chemicals on the TSCA Inventory is periodically updated
 - Manufacturers and processors are required to report on their chemicals
 - Inventory update reporting now includes more exposure related information for higher production volume chemicals

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Information Collection Under TSCA

- TSCA provides EPA with authority to collect a wide range of data
- EPA may issue rules to require maintenance of records and reporting on a wide variety of topics including but not limited to
 - Chemical structure
 - Production/import volumes
 - Use, exposure and disposal

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Information Collection Under TSCA

Health and Safety Studies

- EPA can issue rules to require submission of lists or copies of health and safety studies by manufacturers, importers, processors or distributors of a chemical substance or mixture
- Useful for obtaining unpublished studies
- Information collected is available online on the TSCATS database

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Information Collection Under TSCA

Notice of Substantial Risks

- EPA must be notified immediately of new information which reasonably supports a conclusion of substantial risk
 - Applies to manufacturers, processors and distributors
- Requirement applies but is not limited to data on toxicity, exposure and persistence
- Notifications of substantial risk are an important early warning mechanism

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Examples of Chemical Management

Perfluorinated Acids

- 8(e) notices raised initial concerns
- Most uses of perfluorooctyl sulfonate (PFOS) were voluntarily phased out
 - SNUR issued to restrict resumption of use
- Perfluorooctinoic acid (PFOA)
 - EPA initiated ECA process to identify sources of PFOA exposure and presence in the environment

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Examples of Chemical Management

Perfluorooctinoic acid (PFOA)

- Major domestic producers have accepted an invitation to join the 2010/15 PFOA Stewardship Program
- DuPont plans to cease domestic manufacture and use of PFOA by 2015

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Examples of Chemical Management

□ HPV Challenge Program

- Voluntary initiative to develop and make public screening-level information on organic chemicals produced or imported at high volume in the U.S.
- Consistent with the OECD's HPV SIDS Program
- A significant amount of unpublished data have now been made public by the sponsors.

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Examples of Chemical Management

□ HPV Challenge Program

- The HPV Information System (HPVIS) will help EPA meet its commitment to make this information readily accessible by the public.
- The HPVIS features a comprehensive website that allows a wide range of users to search and retrieve data on HPV chemicals.

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Facilitation of Environmental Stewardship

- Complements EPA's traditional role as a gatekeeper and guardian
 - Innovative programs stress pollution prevention and environmental stewardship.
 - Empower companies, states, tribes and the public by providing information, tools and incentives to develop, produce, supply, buy and use safer, greener chemicals.
 - EPA works with key stakeholders to make information both understandable and useful.

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Facilitation of Environmental Stewardship

- Design for the Environment (DfE) Program
 - Works in partnership with stakeholders to reduce risk by preventing pollution.
 - Partnerships evaluate the human health and environmental considerations, performance, and cost of traditional and alternative technologies, materials, and processes.
 - As incentives for participation and driving change, DfE offers unique technical tools, methodologies, and expertise.

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Facilitation of Environmental Stewardship

DfE Furniture Flame Retardancy Partnership (FFRP)

- Partnership included the furniture industry, chemical manufacturers, environmental groups, fire safety advocates, and government representatives
- PentaBDE was the primary flame retardant used in the manufacture of low-density, flexible polyurethane foam for furniture was about to be withdrawn from the market
- FFRP developed and disseminated information on alternative technologies for achieving furniture fire safety
- The information from that partnership supported real-time decision-making by foam manufacturers and others.

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Facilitation of Environmental Stewardship

Sustainable Futures

- Voluntary pilot project that encourages the application of pollution prevention principles to encourage the development of inherently low-hazard new chemicals.
- EPA provides companies with powerful hazard and risk screening tools, such as the Pollution Prevention Framework and the Persistent, Bioaccumulative, Toxic (PBT) Profiler
- These tools are combined with training, technical assistance, regulatory incentives, public recognition and assistance to small businesses.

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Facilitation of Environmental Stewardship

Green Suppliers Network (GSN)

- Collaborative venture among industry, EPA and the National Institute of Standards and Technology (NIST) Manufacturing Extension Partnership (MEP)
- NIST/MEP and EPA work together provide technical assistance to manufacturers in the supply chain
- Suppliers learn ways to increase efficiency, identify save costs, and optimizing resources to eliminate waste.
- The result is more effective processes, and products with higher profits and fewer environmental impacts.

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Challenges and Future Efforts

Emerging technologies

- Change the types of materials in commerce and in the environment,
- Add to the arsenal of testing and monitoring capabilities, and
- Change the understanding of “toxicity”.

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Challenges and Future Efforts

- Information technology will continue to revolutionize how data are collected, managed, and disseminated, and used
- Societal changes will play a large role in how chemical management takes shape
- The most important issue will be whether companies, governments, and individuals can respond to these challenges in a sustainable fashion