

Session 5: Information Quality & Rulemaking

Alexander Metcalf

U.S. Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention

Presentation Outline

- ▶ U.S. EPA: Ensuring Chemical Safety
 - ▶ Transition to a new legal framework
 - ▶ Risk-based safety standards
 - ▶ Scientific Requirements
 - ▶ Implementation
 - ▶ Current Status
- ▶ An Effective Approach
- ▶ Questions?

Ensuring Chemical Safety

- ▶ EPA regulates chemicals under the Toxic Substances Control Act (TSCA) of 1976
- ▶ TSCA was amended and updated by the “Frank R. Lautenberg Chemical Safety for the 21st Century Act” which went into effect on June 22, 2016.
- ▶ The amendments received large bipartisan support in both the U.S. House of Representatives and the U.S. Senate., as well as stakeholders.
- ▶ Separate requirements for reviewing existing chemicals vs. new chemicals
 - ▶ Note: chemicals on the market when original law was passed were previously “off limits” for EPA evaluation; new amendments require EPA to go back and assess their safety

Ensuring Chemical Safety

- ▶ Existing Chemicals:
 - ▶ Review process includes prioritization into “high” and “low” priorities
 - ▶ High Priority: chemical may present an unreasonable risk of injury to health or environment
 - ▶ Designation of High Priority triggers a mandatory risk evaluation
- ▶ New Chemicals must be pre-cleared by EPA before they can enter the market
- ▶ Decision rests on whether the chemical:
 - ▶ Presents an unreasonable risk
 - ▶ May present an unreasonable risk
 - ▶ Is not likely to present an unreasonable risk
 - ▶ Information is insufficient to permit a reasoned evaluation of the risk

Risk-Based Safety Standard

- ▶ Chemicals assessed against a new risk-based safety standard to determine whether a chemical use poses an “unreasonable risk”
 - ▶ Costs and other non-risk factors are excluded
- ▶ Risks to “potentially exposed or susceptible subpopulations,” including workers, must be considered
- ▶ Unreasonable risks identified in the risk evaluation must be eliminated through “risk management actions”
 - ▶ Costs and availability of alternatives
 - ▶ Possible exemptions for critical uses
 - ▶ Risk management actions must be taken within 2 years of completing the risk evaluation

Scientific Requirements

- ▶ EPA will base decisions on the “best available science” and on the “weight of scientific evidence” while also considering:
 - ▶ Whether the information and the methods to obtain the information are reasonable for and consistent with the intended use
 - ▶ Extent to which the information is relevant
 - ▶ Degree of clarity and completeness of data, assumptions, methods, quality assurance, and analyses
 - ▶ Extent to which the variability and uncertainty in the information are evaluated and characterized
 - ▶ Extent of independent verification or peer review of the information

Implementation

- ▶ “Fit-For-Purpose” Systematic Review
- ▶ Documentation and publication of the review process is nearing completion, with a web portal to be launched in the near future
- ▶ Examples: Data Integration/Weight of Evidence (WOE)
 - ▶ Highly comprehensive particular assessment, including all available literature
 - ▶ Screening level assessments for endocrine activity
 - ▶ Limited evaluations focusing on narrow scientific questions completed in accordance with statutory requirements

Implementation

- ▶ In addition, new guidance on how to develop and submit information to be considered during assessments of chemicals and pesticides
- ▶ Ensures that stakeholders understand precisely what is needed for EPA to assess the safety of a given chemical or pesticide
- ▶ Scope of this activity goes well beyond the world of chemicals and pesticides; likely that the rest of EPA will eventually follow suit
- ▶ End result: more detailed, more transparent decision making process that allows stakeholders to understand why regulatory decisions are made

Current Status

- ▶ First 10 existing chemicals for evaluation have been published:

1,4-Dioxane

1-Bromopropane

Asbestos

Carbon Tetrachloride

Cyclic Aliphatic Bromide Cluster
(HBCD)

Methylene Chloride (MC)

N-methylpyrrolidone (NMP)

Pigment Violet 29

Tetrachloroethylene, or perchloroethylene
(perc)

Trichloroethylene (TCE)

- ▶ In mid-June, EPA will propose a Final Rule for the Risk Evaluation Process
 - ▶ Currently undergoing review and clearance within the Agency
 - ▶ The scope of the risk evaluations of the 10 chemicals listed above will be published, as well

An Effective Approach

- ▶ Implementation is underway, and will continue to be refined going forward
- ▶ Legislative changes described here allow EPA to strengthen our risk-based, evidence-based approach to regulation in the field of chemicals
- ▶ Basing our regulatory decisions on sound science leads to a safer, cleaner environment for everyone
- ▶ Questions?