The New TSCA - Enhancing Transparency, Objectivity and Consistency in the Risk Evaluation Process

October 13, 2017
Achieving High Quality Risk Evaluation

Scientifically Defensible Evaluations

Objectivity

Consistency

Transparency
Lautenberg Chemical Safety Act
A More Effective Way to Regulate Chemicals

**EXISTING CHEMICALS**
- **Inventory Reset**
  - EPA maintains an inventory of chemicals, but it is difficult to tell which are used today and which are no longer in use.
  - LCRA requires the inventory be updated so EPA can focus on chemicals actually in use today.

- **Prioritization**
  - EPA will screen all chemicals in active use to identify low and high priorities for risk evaluation.
  - Prioritization will be based on factors including hazards, uses and exposures to people and the environment, including vulnerable groups like infants, children, pregnant women and the elderly.

- **Low Priority Chemicals**
  - Chemicals can remain in use but can be reprioritized based on new information.

- **High Priority Chemicals**
  - EPA will conduct a thorough risk evaluation.
  - The first 10 high priorities must be drawn from EPA’s existing TSCA Chemical Work Plan list.

**NEW CHEMICALS**
- **Information Submitted to EPA**
  - Manufacturers provide information about new chemicals and new chemical uses to EPA.

- **Risk-Based Review**
  - EPA reviews information including chemical characteristics, available testing and exposure data and intended uses.
  - EPA can request more information if needed.

- **Safety Determination**
  - If EPA finds the chemical is not likely to present an unreasonable risk, it proceeds to market.
  - If the chemical presents an unreasonable risk, EPA may apply risk management measures.

**Chemical Meets Safety Standard**
- Chemical may be used for its intended uses.

**Chemical Needs Risk Management**
- EPA’s options include:
  - Labeling Requirements
  - Use Restrictions
  - Phase Outs
  - Bans

**Risk Evaluation**
- EPA Risk Evaluations will:
  - Be based solely on health and environmental information.
  - Consider a chemical’s conditions of use.
  - Rely on the best available studies and weight of scientific evidence.
  - Consider risks to vulnerable groups.

- LCRA makes it easier for EPA to request more testing and data from producers when needed.

- 20 risk evaluations must be underway within 3.5 years.
Strengthens Transparency, Credibility, and Quality of Science in Decision-making

- Subjects all chemicals to an EPA review
- Requires a focus on chemicals that are the highest priorities
- Makes it easier to require additional health and safety testing of chemicals
- Sets multiple aggressive yet attainable timelines for EPA to complete its work
- Provides a full range of options to address risks posed by chemicals
- Allows stakeholders to request a risk evaluation on a specific chemical

Framework Rules Available
New Chemicals - LCSA Review

Information submitted to Agency

Manufacturers provide information about new chemicals & significant new chemical uses to EPA

Risk-Based Review Conducted:

Includes review of: chemical characteristics, available testing & exposure data & intended uses

* Agency can request more information, if needed
### Existing Chemicals - LCSA Review

#### Inventory Reset
- EPA’s TSCA chemical inventory did not distinguish between chemicals in use and those no longer produced.
- LCSA’s inventory reset will clarify which chemicals are in use today.
- All active chemicals must undergo screening for prioritization & possible risk evaluation.

#### Prioritization
- EPA will conduct risk-based screening of active chemicals from the inventory to identify those in need of a full evaluation.
- If more information is needed, the Agency can request testing/data.

<table>
<thead>
<tr>
<th>Low Priority Chemicals:</th>
<th>High Priority Chemicals:</th>
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<tbody>
<tr>
<td>Remain in use without further action</td>
<td>Require a risk evaluation</td>
</tr>
<tr>
<td>Can be reprioritized based on new information</td>
<td>First 10 from TSCA Work Plan</td>
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<td></td>
<td>1:1 ratio completed to newly designated</td>
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#### Risk Evaluation
- High Priority chemicals will undergo an evaluation of hazards, uses, exposure, to determine risk.

#### Risk Evaluations must:
- Consider sensitive groups.
- Be based on health & environmental considerations.
- Employ clear scientific standards for quality & reliability & the most relevant studies to ensure the most credible studies carry the most weight.
New and Existing Chemicals - LCSA Process

Safety Determination

EPA will determine if a chemical meets LCSA’s safety standard, meaning it does not pose an unreasonable risk.

- Chemicals that meet the safety standard are cleared for use
- Chemicals uses that do not meet safety standard require risk management

Risk Management

- Chemical uses that do not meet the LCSA’s safety standard are subject to risk management
- Risk management requirements must consider costs & benefits

Agency options include:
- Labeling requirements
- Handling instructions
- Use restrictions
- Phase Outs
- Bans
LCSA Scientific Standards

- **Best Available Science:**
  - Use most relevant and up to date science relative to human health and environmental risk
  - Describe and document any assumptions and methods used,
  - Address variability and uncertainty in the evidence
  - Use peer reviewed information, standardized test design and methods, and good laboratory practices

- **Weight of the Scientific Evidence:**
  - Use of pre-established protocols
  - Identify and evaluate each stream of evidence
  - Evaluate strengths, limitations, and relevance of each study
  - Integrate evidence
ACC Vision of Prioritization Process Steps

Progression of Information Gathering

1. Reasonably available information
2. Voluntary Call-ins
3. Section 8a and 8d rules
4. Section 4 rules, orders, consent agreements (if necessary; using tiered approach)

Sufficient Information to Designate High Priority or Low Priority

Initiate Priority Designation

Propose Priority Designation

Finalize Priority Designation

High Priority

Risk Evaluation

Low Priority

Subject to Judicial Review
ACC Two Step Process for Risk Evaluation

**STEP 1: SCOPE/SCREENING**
- High Priority Chemicals
- 10 Workplan Chemicals & Manufacturer Requested

**Scope/Screening Level Risk Evaluation**
- Exposures
- Hazards
- Susceptible Populations

**CONDITIONS OF USE**
- No further risk evaluation
- Refined risk evaluation needed

**STEP 2: REFINED RISK EVALUATION**
- High-Quality Refined Risk Evaluation
  - Exposure Assessment
  - Hazard Assessment

**Evaluation incorporating Sections 6 and 26 of the Lautenberg Chemical Safety Act (LCSA):**
- Scientific Standards
- Weight of Scientific Evidence Evaluations

**DRAFT Risk Evaluation**

**FINAL Risk Evaluation**
- Certain Conditions of Use
  - Present an unreasonable risk
  - Do not present an unreasonable risk

**RULEMAKING**
- No further action; PROCESS COMPLETE
Key Elements for Risk Evaluation

- Protocol Development
- Evidence Identification
- Evidence Evaluation
- Peer Review

Increases Transparency, Objectivity, and Consistency
Protocol Development

Identify the goals and scope of evaluation

- Are program and/or regional offices considering greater restrictions if the chemical is found to exhibit human health concerns not heretofore identified?
- What risk evaluation products (quantitative and qualitative) are needed by management for informed decision making? What is needed for other analyses (e.g., economic analysis)?

Discuss the potential areas of concern for human health associated with relevant exposure levels

- What current exposure scenarios and levels are of relevance to human health
- Generate appropriate questions to inform public health (e.g. “does chemical X cause outcome Y at or below exposure level Z.”)
Define the literature search strategy

• Should include the date of the search, and publication dates searched
• Should explicitly state the inclusion and exclusion criteria for studies
• Should include a search strategy for each systematic review question
Identify what considerations are needed to determine the scientific information to be of high, medium or low quality.

Identify quality characteristics and describe how scientific information being evaluated meets, or does not meet, these criteria.

Discuss how the quality evaluation influenced how the scientific information was used in the weight of evidence evaluation.
Peer Review

- Independent from Agency Science Experts
- Relevant Scientific Expertise
- Multi-Sector Representation
Key Take-Aways

- Establish Set Scientific Standards
  - Best Available Science
  - Weight of Evidence
  - Clear Protocols and Methods

- Be Transparent About the Science Underlying Safety Determinations

- Meet Deadlines for Timely Risk Evaluations
Ongoing Activities and Opportunities

- **EPA’s Science Advisory Committee on Chemicals**
  - Comprised of experts in: toxicology; environmental risk evaluation; exposure assessment; and other areas
  - Currently expanding membership
  - Provides independent scientific advice and recommendations on the scientific and technical aspects of risk evaluation

- **ACC Center for Chemical Safety Act Implementation**
  - Developing chemical specific use and exposure data
  - Managing generation of chemical information pursuant to EPA’s new authority under TSCA Section 4

- **Third Party Risk Evaluation**
  - Adhere to same scientific standards as Agency conducted review.
  - Clearly explain how the risk evaluation conforms to TSCA provisions.
  - All raw data used to support the risk evaluation will be disclosed and made publicly available.
QUESTIONS ?