THE FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21ST CENTURY ACT : *REQUIREMENTS AND EPA IMPLEMENTATION*

Jeff Morris, Director
Office of Pollution Prevention & Toxics
US EPA

Society for Risk Analysis
10 January 2017

ED_001625_00035646-00001

TSCA Amended

The "Frank R. Lautenberg Chemical Safety for the 21st Century Act" was signed by the President and went into effect on June 22, 2016

Amends and updates the Toxic Substances Control Act of 1976

Passed by large bipartisan margins in the U.S. House (403 to 12) and unanimously in Senate

Received support from chemical industry and downstream users of chemicals, NGOs and other stakeholders

ED_001625_00035646-00002

New Chemicals

Before a chemical can enter the market, EPA must make an affirmative determination that the chemical:

- *Presents* an unreasonable risk,
- *May present* an unreasonable risk,
- Is *not likely to present* an unreasonable risk, or that
- *Information is insufficient* to permit a reasoned evaluation of the risk.

ED_001625_00035646-00003

Existing Chemicals: Prioritization

Establish a risk-based process to identify high- and low-priority substances:

High priority – the chemical may present an unreasonable risk of injury to health or the environment due to potential hazard and route of exposure, including risk to "potentially exposed or susceptible subpopulations"

Low priority – the chemical does not meet the standard for high-priority

ED_001625_00035646-00004

Existing Chemicals: Risk Evaluation

- *High priority* designation triggers risk evaluation to be completed in 3 years
- For each risk evaluation completed, EPA must designate a new high-priority chemical
- Within 3 years, EPA must have 20 ongoing chemical risk evaluations
- Must consider risks to "potentially exposed or susceptible subpopulations," including workers

ED_001625_00035646-00005

Existing Chemicals: Initial 10 Risk Evaluations

- EPA must identify a list of 10 chemicals from the 2014 Update to TSCA Work Plan and formally initiate risk evaluations by mid-December 2016
  - 2014 Update to TSCA Work Plan lists 90 chemical substances for assessment by EPA
  - Methodology was developed in 2012 and involves screening process for hazard, exposure, persistence and bioaccumulation
- Release the scope for each of the first 10 assessments by mid-June 2017

ED_001625_00035646-00006

Existing Chemicals: Risk-Based Safety Standard

- Chemicals are evaluated against a new risk-based safety standard to determine whether a chemical use poses an "unreasonable risk"
  - The risk determination is to be made without consideration of costs or other non-risk factors
- Risks to "potentially exposed or susceptible subpopulations," including workers, must be considered
- EPA must take risk management action in 2 years to address unreasonable risks

ED_001625_00035646-00007

Existing Chemicals: Manufacturer-Requested Evaluations

Establishes a process for manufacturers to request that EPA evaluate specific chemicals, and pay costs as follows:

- For chemicals on the TSCA Workplan, manufacturers pay 50% of costs; and
- For all other chemicals, manufacturers pay 100% of costs

Manufacturer requests subject to the following limitations:

- Do not count toward the 20 risk evaluations EPA must have underway
- Administrator has discretion to grant manufacturer requests, but these requests must be 25% to 50% of ongoing reviews.

ED_001625_00035646-00008

Existing Chemicals: Persistent, Bioaccumulative and Toxic Chemicals

- Fast-track process for certain PBT chemicals already on TSCA Workplan
- No risk evaluation; only a use and exposure assessment
- Rules to reduce exposure to the extent practicable must be proposed within 3 years of enactment and finalized 18 months later, unless a manufacturer requested a risk evaluation by Sept. 19, 2016
- Additional requirements encourage prioritization of other PBTs in overall risk evaluation process

❖ Status
  - 5 chemicals will get expedited action under TSCA 6(h)
  - Manufacturer requests for risk evaluations were received for 2 PBT chemicals, which are thus excluded from the expedited action requirements

ED_001625_00035646-00009

Existing Chemicals: TSCA Inventory

Industry must report on the chemicals they manufactured or processed in previous 10 years to determine if chemicals are currently “active” in the marketplace

- Chemicals will be designated as “active” or “inactive”
- No PMN required to move from “inactive” to “active”

ED_001625_00035646-00010

Existing Chemicals: Ongoing Risk Management Rulemakings

For chemical uses with completed risk assessments before June 22, 2016 showing unreasonable risk, Section 26 allows EPA to propose and issue final Section 6 rules consistent with those assessments

- EPA anticipates issuing the following proposed rules:
  - TCE use in spot cleaning and aerosol degreasing
  - TCE use in vapor degreasing
  - Methylene chloride (MC) and N-methylpyrrolidone (NMP) in paint removers

The risk assessments for TCE, MC, and NMP all demonstrate significant risks and were finalized prior to June 22, 2016.

Testing Authority

New authority to issue *orders* to require testing, in addition to rulemaking authority, to speed the process of prioritization and risk evaluation.

- Must use tiered testing when possible.
- Must consider whether non-animal tests exist.

In 2 years, EPA must develop a strategic plan for promoting the development and implementation of alternative (non-animal) testing.

ED_001625_00035646-00012

Implementation

Initial Risk Evaluations

- ✓ Publish "First 10" – November 29, 2016
- Publish Scopes of "First 10" - June 2017

Final Prioritization Process Rule required by June 2017

- ✓ Proposal planned for January 2017

Final Risk Evaluation Rule required by June 2017

- ✓ Draft proposal received by OMB November 11, 2016

Final Active/Inactive Inventory Reporting Rule required by June 2017

Fees Rule (no statutory deadline)

Science Advisory Committee established by June 2017

- ✓ FRN published to establish committee and solicit membership August 26, 2016

ED_001625_00035646-00013

For More Information

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act

Contact EPA at

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/forms/assessing-and-managing-chemicals-under-tsca

ED_001625_00035646-00014