



Toxic Substances Control Act: Implementation Updates

Rachel Massey

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Massachusetts
Toxics Use Reduction



TSCA – Background

- Amendments adopted June 2016: Frank R. Lautenberg Chemical Safety for the 20th Century Act
- Created a new set of authorities, responsibilities and time lines for EPA

Implementation

- Framework actions
- Early mandatory actions
- Early rule making
- Implementation actions for individual chemicals
 - **Prioritization**
 - This step is skipped for the first 10 chemicals
 - **Risk evaluation**
 - Scope
 - Problem formulation
 - Draft risk evaluation, including risk determination
 - Final risk evaluation, including risk determination
 - **Risk management (Rulemaking)**

Early actions

- Amendments provided authority for EPA to bypass full scope & risk evaluation process for a few chemical uses that had been thoroughly assessed:
- Proposed rules for TCE:
 - spot cleaning & aerosol degreasing (issued Dec 2016)
 - vapor degreasing (issued Jan 2017)
- Would have prohibited TCE for these applications. Not finalized.
 - Proposed bans shifted from “active” to “long-term action” (Dec 2017)
 - Now being reconsidered as part of full TCE risk evaluation
- Draft rule restricting NMP and methylene chloride in paint stripping
- Final rule banning methylene chloride in paint strippers for consumer use, March 2019 (effective November 22, 2019)
 - Workplace use still permitted



News Releases

News Releases from Headquarters > Chemical Safety and Pollution Prevention (OCSPP)

EPA Bans Consumer Sales of Methylene Chloride Paint Removers, Protecting Public

03/15/2019

Contact Information:

EPA Press Office (press@epa.gov)

WASHINGTON — Today, the U.S. Environmental Protection Agency (EPA) issued a final rule to prohibit the manufacture (including import), processing, and distribution of methylene chloride in all paint removers for consumer use. EPA has taken this action because of the acute fatalities that have resulted from exposure to the chemical.

Prioritization

- High priority: “may present an unreasonable risk of injury to health or the environment” due to hazard + exposure potential
 - Consider “potentially exposed or susceptible subpopulation[s]”
 - Preference for chemicals on 2014 Work Plan update with high P&B score, high acute or chronic toxicity, or known human carcinogens
- Prioritization process for a chemical must be between 9 months & 1 year & includes public comment period

Risk evaluation

- First step, within 6 months of beginning risk evaluation: publish scope.
 - Scope includes “the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider”
- No consideration of cost or other nonrisk factors
- Consider, where relevant, likely “duration, intensity, frequency, and number of exposures”
- Describe the weight of the scientific evidence

Risk evaluation

- In 2016, EPA chose the first 10 from the 2014 update of the TSCA Work Plan
- At least 20 high-priority and low-priority must be designated within 3.5 years (i.e. December 2020)
 - Manufacturer-requested chemicals are in addition
- Each time finish one risk evaluation, designate another high priority substance & start its risk evaluation

First ten chemicals for risk evaluation

- Asbestos
 - **1-bromopropane**
 - Carbon tetrachloride
 - **1,4-dioxane**
 - **Cyclic aliphatic bromide cluster (HBCD)**
 - **Methylene chloride**
 - **N-methylpyrrolidone (NMP)**
 - Perchloroethylene
 - **Pigment violet 29**
 - Trichloroethylene
- **Scopes** issued June 2017
 - **Problem formulations** issued May 2018
 - **Risk evaluations** in process

Manufacturer requested risk evaluations

- Diisodecyl phthalate (DIDP)
- Diisononyl phthalate (DINP)

Methylene chloride – Draft risk evaluation October 2019

- Unreasonable risk determination for a number of use cases
- General public exposures and risks not accounted for
 - Including releases to air and water
- Worker exposures
 - Assumes consistent and fully effective use of PPE
 - Uses 1 in 10,000 cancer risk threshold
- Public comments accepted until December 30, 2019

N-methyl pyrrolidone (NMP) – Draft risk evaluation November 2019

- **Uses of NMP:**
 - **Solvent extraction**
 - “**Solvent cleaning and surface treatment** of metals, textiles, resins, and plastics.”
 - “Widely used in the **chemical manufacturing, petrochemical processing and electronics** industries.”
 - “Growing demand ... in **semiconductor** fabrication and **lithium ion** battery manufacturing.”
 - “In the commercial sector, NMP is primarily used for **producing and removing paints, coatings and adhesives.**”
 - Also used in “**solvents, reagents, sealers, inks and grouts**”

NMP

- **Population:** Adults (over 16) using NMP-containing products, including pregnant women
 - Plus: “individuals who do not use NMP but may be indirectly exposed due to their proximity to the user...”
- **Health effects:** “potential effects on fertility as well as developmental toxicity.”
 - “The lifestages of greatest concern for developmental effects are pregnant women and women of childbearing age who may become pregnant.”
- “Exposures that do not present risks based on sensitive reproductive and developmental endpoints are not expected to present risks for other potential health effects of NMP because other health effects occur at higher levels of exposure.”

NMP

- **Unreasonable risks** for “acute and chronic inhalation and dermal exposure to NMP under a variety of conditions of use.”
- **No unreasonable risk** for environment, bystanders, or occupational non-users.

Risk evaluations to date: Issues and themes

- Assumptions about PPE use
- Assumptions about “legacy” uses
- Assumptions about role of other regulations

PPE use

- Example: 1-bromopropane:
 - Cancer risk from dermal occupational exposure:
 - Risk was greater than 1 in 10,000 if no gloves used
 - Risk was less than 1 in 10,000 if gloves used
- Example: Manufacturing
 - Without PPE, cancer risk estimated at 5.54 per 10,000
 - Finding: no unreasonable risk of injury to health for workers and occupational non-users

Concept of “Legacy Uses”

- **Example: asbestos**

- Excluded from analysis:

- “asbestos-containing materials that remain in older buildings or are part of older products but for which manufacture, processing and distribution in commerce are not currently intended, known or reasonably foreseen.”



Role of other regulations

- Example: methylene chloride
 - No consideration of, or risk determination for, health effects on general population (e.g. via industrial releases to air, water, or land)
 - Relies upon existing regulation under CAA, SDWA, CWA, RCRA

Thank you

Contact information:

Rachel Massey

978-934-3124

massey@turi.org

www.turi.org

Massachusetts

Toxics Use Reduction Institute

University of Massachusetts Lowell

126 John St., Suite 14

Lowell, MA 01854