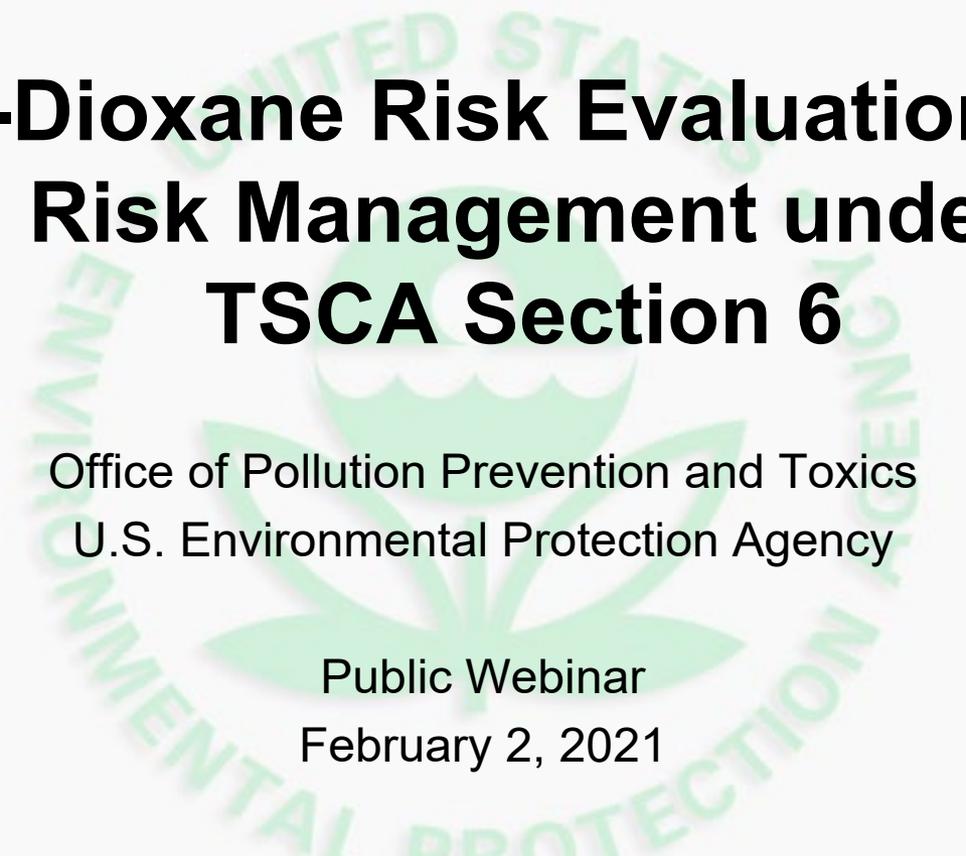




1,4-Dioxane Risk Evaluation and Risk Management under TSCA Section 6

Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Public Webinar
February 2, 2021





Agenda

- Background on Risk Evaluations
- Findings from Risk Evaluation for 1,4-Dioxane
- Risk Management Requirements under TSCA
- Types of Information to Inform Risk Management
- Principles for Transparency During Risk Management
- Additional Information

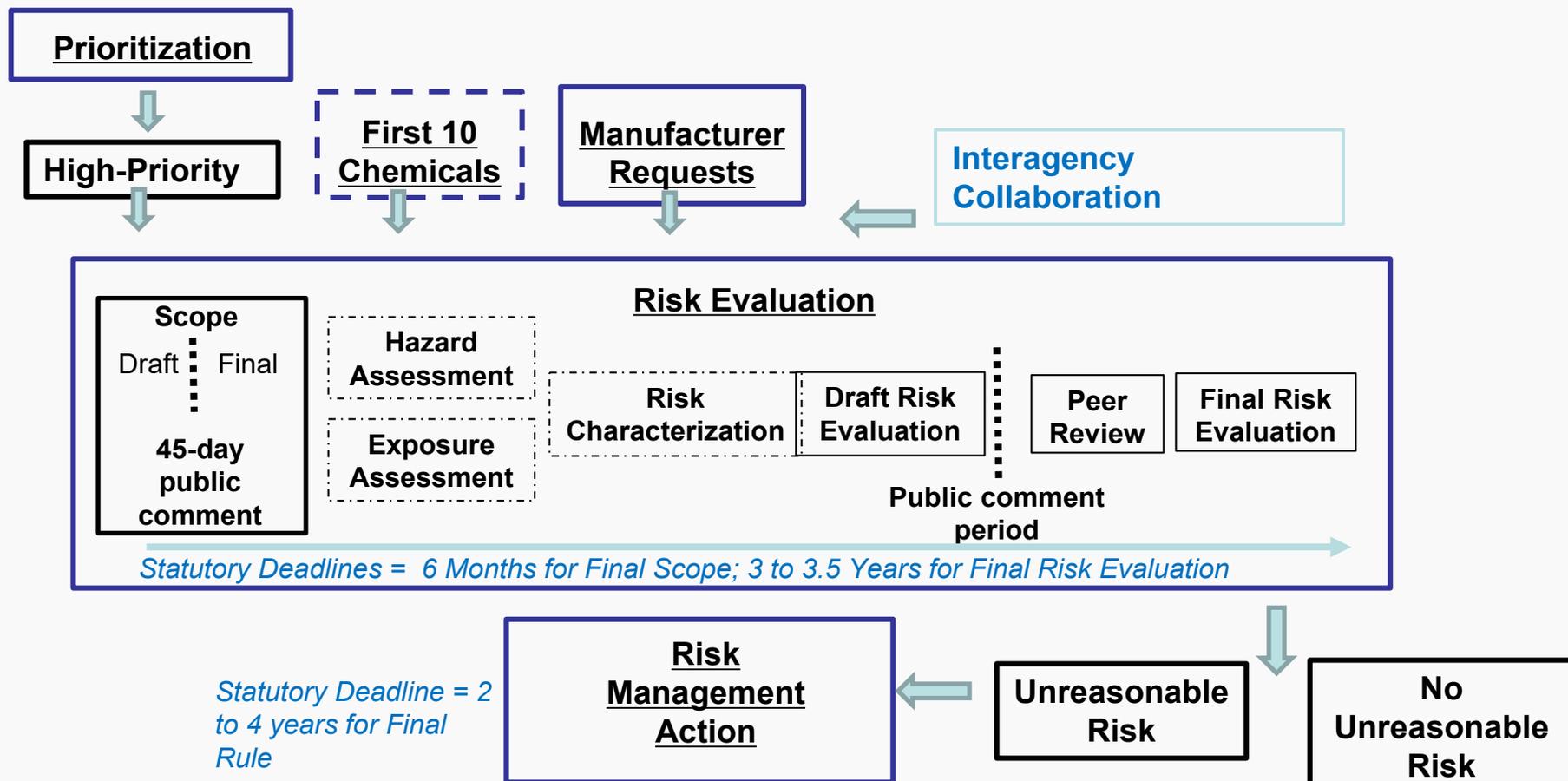


Risk Evaluation Statutory Requirements

- EPA must evaluate the risks presented by a chemical under the conditions of use and determine if the chemical presents an unreasonable risk of injury to health or the environment under the conditions of use
 - Without consideration of cost or other non-risk factors
 - Including unreasonable risk to potentially exposed or susceptible subpopulation(s) determined to be relevant to the evaluation
- TSCA requires a risk evaluation be completed within 3 – 3.5 years



Risk Evaluation Process and Timeline





Overview of Risk Evaluation for 1,4-Dioxane

- Final risk evaluation published January 8, 2021
 - 24 conditions of use were evaluated
 - Final risk evaluation follows a series of risk evaluation activities
 - 1,4-Dioxane supplemental analysis: November 2020; 1,4-dioxane draft risk evaluation: June 2019; 1,4-dioxane problem formulation: June 2018; 1,4-dioxane scope document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation
 - 34 public comments received on the draft risk evaluation (comment period closed August 30, 2019)
 - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (July 2019)
 - 16 public comments received on the supplemental analysis (comment period closed December 10, 2020)
- The final risk evaluation and supplemental materials are in docket [EPA-HQ-OPPT-2019-0238](#) with additional materials supporting the risk evaluation process in docket [EPA-HQ-OPPT-2016-0723](#) on www.regulations.gov



General Information on 1,4-Dioxane

- 1,4-Dioxane is a clear volatile liquid used primarily as a solvent
- EPA identified conditions of use during various life cycle stages of 1,4-dioxane, such manufacturing (including import), processing, distribution in commerce, use (industrial and commercial), and disposal
- 1,4-Dioxane is also found as a byproduct in commercial and consumer cleaning products and other products
- 1,4-Dioxane is used as a catalyst, intermediate, and process solvent in the production of other chemicals, including agricultural chemicals and plastics
- 1,4-Dioxane is also used in laboratory applications, functional fluids (e.g., metalworking fluid), film cement, printing inks, and dry film lubricant
- The total annual production volume was approximately one million pounds in 2015



Determinations of No Unreasonable Risk

- EPA determined that 1,4-dioxane does not present an unreasonable risk to the environment and general population under the conditions of use
- EPA determined that 11 of the 24 conditions of use of 1,4-dioxane do not present an unreasonable risk of injury to health or the environment
- These no unreasonable risk determinations are considered final agency actions and are issued by order pursuant to TSCA section 6(i)(1)



Determinations of No Unreasonable Risk

- Distribution in commerce
- Industrial and commercial use in functional fluids (open system)
- Industrial and commercial use in spray polyurethane foam
- Consumer use: Arts, crafts, and hobby materials – Textile dye
- Consumer use: Automotive care products – Antifreeze
- Consumer use: Cleaning and furniture care products – Surface cleaner
- Consumer use: Laundry and dishwashing products – Dish soap
- Consumer use: Laundry and dishwashing products – Dishwasher detergent
- Consumer use: Laundry and dishwashing products – Laundry detergent
- Consumer use: Paints and coatings – Paint and floor lacquer
- Consumer use: Other uses – Spray polyurethane foam



Unreasonable Risk Determinations

- EPA determined that 13 of the 24 conditions of use of 1,4-dioxane present an unreasonable risk of injury to health
- EPA's determinations are based on unreasonable risks of injury to workers during occupational exposures
- EPA's risk evaluation identified unreasonable risks for liver toxicity from acute inhalation and dermal exposures, and olfactory epithelium effects and increased risk of cancer from chronic inhalation and dermal exposures to 1,4-dioxane



Conditions of Uses that Present an Unreasonable Risk

- Manufacture: Domestic manufacture
- Manufacture: Import/repackaging (bottle and drums)
- Processing: Repackaging (bottle and drums)
- Processing: Recycling
- Processing: Non-incorporative
- Processing: Reactant
- Industrial use: Intermediate
- Industrial use: Processing aid
- Industrial use: Laboratory chemicals
- Industrial and commercial use: Adhesives or sealants
- Industrial and commercial use: Printing and printing compositions
- Industrial and commercial use: Dry film lubricant
- Disposal



Basis for Unreasonable Risk Determination: Workers

- The unreasonable risk determinations for workers are based on the following health hazards during occupational exposures of 1,4-dioxane:
 - Liver toxicity from acute inhalation and dermal exposures
 - Olfactory epithelium effects and increased risk of cancer from chronic inhalation and dermal exposures
- Personal Protective Equipment (PPE):
 - The OSHA permissible exposure limit (PEL) for 1,4-dioxane, established in 1971, is 100 ppm
 - Many conditions of use presented an unreasonable risk to workers even with use of gloves with PF of 20
 - No unreasonable risk to workers due to acute and chronic inhalation exposures assuming use of respirators with APF of 50 in industrial/commercial settings
 - EPA does not assume occupational non-users use PPE because they do not handle the chemical



Risk Management Requirements

- Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment
- EPA must issue a TSCA section 6(a) rule following risk evaluation to address all identified unreasonable risks within two years:
 - Proposed rule one year after risk evaluation
 - Final rule two years after risk evaluation
- Specific requirements on consideration of alternatives, selecting among options and statement of effects apply to risk management rules
- Input from stakeholders is critical to the process



TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase



TSCA Section 6(a) Regulatory Options

- TSCA provides authority to regulate entities including:
 - Distributors
 - Manufacturers and processors (e.g., formulators)
 - Commercial users (workplaces and workers)
 - Entities disposing of chemicals for commercial purposes



TSCA Section 6(c)

In promulgating any rule under TSCA section 6(a), EPA must consider and publish a statement of effects of the rule based on reasonably available information with respect to:

- The effects and magnitude of exposure to human health
- The effects and magnitude of exposure to environment
- The benefits of the chemical for various uses
- The reasonably ascertainable economic consequences of the rule, including consideration of:
 - The likely effect on the national economy, small business, technological innovation, the environment, and public health
 - The costs and benefits of the proposed and final regulatory action and one or more primary regulatory alternatives
 - The cost effectiveness of the proposed regulatory action and 1 or more primary regulatory alternatives



Executive Orders Relevant to 6(a) Rulemakings

- EO 12866: Regulatory Planning and Review
- EO 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
- EO 13045: Protection of Children from Environmental Health & Safety Risks
- EO 13132: Federalism
- EO 13175: Consultation and Coordination with Indian Tribal Governments
- EO 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
- EO 13272: Proper Consideration of Small Entities in Agency Rulemaking
- EO 13771: Reducing Regulation and Controlling Regulatory Costs



Types of Information to Inform Risk Management

- Suggestions on effective methods EPA can use to address the unreasonable risks
- Input on protective regulatory approaches
- Information related to controlling exposures, including current work practices, engineering, and administrative controls
- Information on essential uses, and the impacts if the chemical were not available
- Identification of uses that have been phased out, or can be phased out, and thus are no longer needed
- Any information on substitute chemicals that are safe and effective alternatives
- Suggestions on how EPA can further improve its regulatory processes or be more transparent



Principles for Transparency During Risk Management

- Transparent, proactive, and meaningful engagement
- One-on-one meetings, public webinars, and required consultations with state and local governments, Tribes, environmental justice communities, and small businesses
- Extensive dialogue will help people understand the findings in the risk evaluations, the risk management process required by TSCA, and the options available for managing unreasonable risks
- Seeking input from stakeholders on potential risk management approaches, their effectiveness, and impacts those approaches might have on businesses, workers, and consumers
- Input can help the agency develop regulations that are practical and protective



Coordination and Engagement

- In developing risk management approaches EPA:
 - Consults with stakeholders to learn about condition of use, existing engineering controls, personal protection equipment (PPE), available alternatives, or other programs to tailor effective risk management solutions
 - Conducts site visits as necessary to obtain detailed information on existing practices in chemical manufacturing, processing, and use
 - Develops an extensive network among stakeholders to ensure regulatory approaches are fully informed and based on current conditions



Opportunities for Engagement

- One-on-one meetings
- Webinars providing overviews of final risk evaluations and unreasonable risk determinations
- Consultations seeking targeted feedback, with:
 - States and local governments
 - Tribes
 - Small businesses
 - Environmental justice organizations and communities



Additional Information

- General TSCA: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>
- Current Chemical Risk Management Activities: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities>
- 1,4-Dioxane Risk Management: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-14-dioxane>
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