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Office of Chemical Safety and
Pollution Prevention

Non-Technical Summary of the Risk Evaluation for Trichloroethylene

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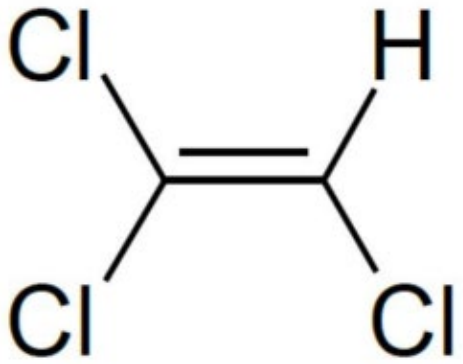

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BACKGROUND

- The TSCA risk evaluation for trichloroethylene (TCE) was issued in November 2020.
- Uses for TCE include a wide range of uses in consumer and commercial products and in industry. An estimated 84% of TCE's annual production volume is used as an intermediate in the manufacturing of refrigerants. Another 15% of TCE production volume is used as a degreasing solvent, leaving approximately 1% for other uses.
- According to 2020 Chemical Data Reporting (CDR), the total annual aggregate production volume ranges from 100 to 250 million pounds between 2015 and 2019.

ACTION

- EPA is releasing a final revision to the risk determination on TCE with an order withdrawing the TSCA section 6(i)(1) order previously included in the November 2020 risk evaluation. This action follows issuance of a draft revised risk determination that EPA issued for comment in July 2022 (87 FR 40520). EPA has determined that TCE presents an unreasonable risk of injury to health under its conditions of use.
- This final risk evaluation, which includes the 2020 risk evaluation and a 2022 final revised unreasonable risk determination, is conducted pursuant to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires EPA to prioritize and evaluate the risk of existing chemicals to determine whether a chemical presents an unreasonable risk of injury to health or the environment under the conditions of use. Under TSCA, if a chemical is determined to present an unreasonable risk, then EPA will propose risk management regulatory action to the extent necessary so that the chemical substance no longer presents an unreasonable risk.
- The 2020 risk evaluation, supplemental materials, 2022 revised unreasonable risk determination and corresponding response to public comments can be found in dockets EPA-HQ-OPPT-2019-0500 and EPA-HQ-OPPT-2016-0737 on www.regulations.gov.
- TCE was selected in 2016 as one of the first 10 chemicals for risk evaluation under section 6 of TSCA.

KEY POINTS

- EPA has identified risks for non-cancer adverse effects from acute and chronic inhalation and dermal exposures to TCE, and for cancer from chronic inhalation and dermal exposures to TCE. In the TCE risk determination, EPA identified immunosuppression effects as the endpoint for acute inhalation and dermal exposures, and autoimmunity effects as the endpoint for chronic inhalation and dermal exposures. Additionally, in the risk characterization, EPA identified significant risks associated with more than one adverse effect (e.g., developmental toxicity, reproductive toxicity, liver toxicity, kidney toxicity, immunotoxicity, neurotoxicity, and cancer).
- Public comments and external scientific peer review informed the development of the TCE final risk evaluation. EPA published the TCE final revised unreasonable risk determination in December 2022, the TCE draft revised unreasonable risk determination in July 2022, the TCE risk evaluation in November 2020, the TCE draft risk evaluation in February 2020 (for a 60-day public comment period), the TCE problem formulation document in June 2018, and the TCE scope document in June 2017.
- Additionally, EPA held a peer review meeting of the Science Advisory Committee on Chemicals (SACC) on the draft risk evaluation of TCE on March 24-27, 2020.

- In the revised unreasonable risk determination for TCE, EPA is making an unreasonable risk determination for TCE as a whole chemical substance, rather than a condition of use-specific approach. The whole chemical approach is appropriate for TCE because there are benchmark exceedances for a substantial number of conditions of use for human health and there are severe health effects associated with TCE exposures.
- After evaluating 54 conditions of use, EPA determined that TCE presents an unreasonable risk to human health under its conditions of use based on risk of injury to health of workers, occupational non-users (ONUs), consumers, and bystanders.
- In addition, EPA is revising the assumption that workers always or properly use personal protective equipment (PPE), although EPA does not question public comments received regarding the occupational safety practices often followed by industry. Information on the use of PPE as a means of mitigating risk will be considered during the risk management phase. Removing the assumption that workers wear PPE would not alter the conditions of use that drive the unreasonable risk determination for TCE, though additional risks for acute non-cancer and cancer effects from inhalation and dermal exposures have been found to also drive the unreasonable risk in many of those conditions of use (where previously those conditions of use were identified as presenting unreasonable risk only for chronic non-cancer effects and cancer).
- Overall, 52 of the 54 conditions of use evaluated drive the TCE whole chemical unreasonable risk determination due to risks identified for human health. These conditions of use include manufacturing; processing as a reactant/intermediate, processing into a formulation, processing into articles, repackaging and recycling; use in various industrial and commercial uses including as a solvent for cleaning or degreasing; industrial and commercial use in adhesives and sealants, lubricant and greases, functional fluids, paints and coating, and in a variety of cleaning products; commercial use in several products; several consumer uses; and disposal.
- The conditions of use that do not drive EPA's unreasonable risk determination for TCE are distribution in commerce and consumer use in pepper spray.
- For TCE, the exposure pathways that were or could be regulated under another EPA-administered statute were excluded from the November 2020 TCE Risk Evaluation. This resulted in the surface water, drinking water, and ambient air pathways for TCE not being assessed for human health exposures or the general population. EPA is conducting a screening approach to assess risks from the air and water pathways for several of the first 10 chemicals, including TCE. The goal of the recently-developed screening approach is to remedy this exclusion and to determine if there may be risks that were unaccounted for in the TCE risk evaluation. EPA expects to describe its findings regarding the chemical-specific application of this screening-level approach in the forthcoming proposed rule under TSCA section 6(a) for TCE.
- EPA did not identify risks of injury to the environment that drive the unreasonable risk determination for TCE.
- As noted above, EPA is releasing a final revision to the unreasonable risk determination with an order withdrawing the TSCA section 6(i)(1) order previously included in the November 2020 risk evaluation. EPA is also releasing a document with response to public comments received on the draft revised risk determination for TCE published in July 2022.

NEXT STEPS

- EPA has issued the final risk evaluation (2020 risk evaluation and 2022 revised risk determination) for TCE, meeting the requirements set forth in TSCA section 6(b) for chemical risk evaluations. EPA is now initiating the process to address the unreasonable risk identified. Following the issuance of the final risk evaluation, EPA will address, by rule, the unreasonable risk identified. The public will have an opportunity to comment on a proposed rule before EPA issues a final rule.

SUMMARY OF UNREASONABLE RISK DETERMINATION

EPA has determined that TCE presents an unreasonable risk of injury to human health under the conditions of use.

EPA's unreasonable risk determination for TCE is driven by risks associated with the following conditions of use, considered singularly or in combination with other exposures:

- Manufacturing: domestic manufacture;
- Manufacturing: import;
- Processing: processing as a reactant/intermediate;
- Processing: incorporation into a formulation, mixture or reaction product;
- Processing: incorporation into articles;
- Processing: repackaging;
- Processing: recycling;
- Industrial and commercial use as a solvent for open-top batch vapor degreasing;
- Industrial and commercial use as a solvent for closed-loop batch vapor degreasing;
- Industrial and commercial use as a solvent for in-line conveyorized vapor degreasing;
- Industrial and commercial use as a solvent for in-line web cleaner vapor degreasing;
- Industrial and commercial use as a solvent for cold cleaning;
- Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner and mold release;
- Industrial and commercial use as a lubricant and grease in tap and die fluid;
- Industrial and commercial use as a lubricant and grease in penetrating lubricant;
- Industrial and commercial use as an adhesive and sealant in solvent-based adhesives and sealants; tire repair cement/sealer; mirror edge sealant;
- Industrial and commercial use as a functional fluid in heat exchange fluid;
- Industrial and commercial use in paints and coatings as a diluent in solvent-based paints and coatings;
- Industrial and commercial use in cleaning and furniture care products in carpet cleaner and wipe cleaning;
- Industrial and commercial use in laundry and dishwashing products in spot remover;
- Industrial and commercial use in arts, crafts, and hobby materials in fixatives and finishing spray coatings;
- Industrial and commercial use in corrosion inhibitors and anti-scaling agents;
- Industrial and commercial use in processing aids in process solvent used in battery manufacture; process solvent used in polymer fabric spinning, fluoroelastomer manufacture

and Alcantara manufacture; extraction solvent used in caprolactam manufacture; precipitant used in beta-cyclodextrin manufacture;
- Industrial and commercial use as ink, toner and colorant products in toner aid;
- Industrial and commercial use in automotive care products in brake and parts cleaner;
- Industrial and commercial use in apparel and footwear care products in shoe polish;
- Industrial and commercial use in hoof polish; gun scrubber; pepper spray; other miscellaneous industrial and commercial uses;
- Consumer use as a solvent in brake and parts cleaner;
- Consumer use as a solvent in aerosol electronic degreaser/cleaner;
- Consumer use as a solvent in liquid electronic degreaser/cleaner;
- Consumer use as a solvent in aerosol spray degreaser/cleaner;
- Consumer use as a solvent in liquid degreaser/cleaner;
- Consumer use as a solvent in aerosol gun scrubber;
- Consumer use as a solvent in liquid gun scrubber;
- Consumer use as a solvent in mold release;
- Consumer use as a solvent in aerosol tire cleaner;
- Consumer use as a solvent in liquid tire cleaner;
- Consumer use as a lubricant and grease in tap and die fluid;
- Consumer use as a lubricant and grease in penetrating lubricant;
- Consumer use as an adhesive and sealant in solvent-based adhesives and sealants;
- Consumer use as an adhesive and sealant in mirror edge sealant;
- Consumer use as an adhesive and sealant in tire repair cement/sealer;
- Consumer use as a cleaning and furniture care product in carpet cleaner;
- Consumer use as a cleaning and furniture care product in aerosol spot remover;
- Consumer use as a cleaning and furniture case product in liquid spot remover;
- Consumer use in arts, crafts, and hobby materials in fixative and finishing spray coatings;
- Consumer use in apparel and footwear products in shoe polish;
- Consumer use in fabric spray;
- Consumer use in film cleaner;
- Consumer use in hoof polish;
- Consumer use in toner aid; and
- Disposal;

The following conditions of use do not drive EPA's unreasonable risk determination for TCE:
- Consumer use in pepper spray
- Distribution in commerce

EPA is not making condition of use-specific risk determinations for these conditions of use, is not issuing a final order under TSCA section 6(i)(1) for these conditions of use, and does not consider the revised risk determination for TCE to constitute a final agency action at this point in time.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management regulatory action to the extent necessary so that TCE no longer presents an

unreasonable risk. EPA expects to focus its risk management action on the conditions of use that drive the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) driving unreasonable risk, even if the upstream activities do not drive the unreasonable risk.