



Commonwealth of Massachusetts  
Executive Office of Energy & Environmental Affairs

# Department of Environmental Protection

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## MEMORANDUM

**To:** C. Mark Smith Ph.D., M.S., Director, Office of Research and Standards

**Through:** Sandra J.S. Baird, Ph.D., Chief, Toxicology Division, Office of Research and Standards  
Wendy Heiger-Bernays, Ph.D., Chief, Research Division, Office of Research and Standards

**From:** Tom Angus, Ph.D., M.S.P.H., Senior Toxicologist, Office of Research and Standards

**Date:** January 7, 2025

**Subject:** Review of LSPA White Paper and Recent EPA Evaluations of Trichloroethylene.

## SUMMARY

The Office of Research and Standards recommends retaining MassDEP's current method for calculating an Imminent Hazard for trichloroethylene (TCE) using a Hazard Quotient of one for serious health effects based on the risk of fetal heart malformations.

## INTRODUCTION

The Licensed Site Professional Association (LSPA) requested that MassDEP change the basis for the MassDEP Imminent Hazard (IH) concentration for trichloroethylene (TCE) based on updated toxicological information for fetal heart malformations, the current basis for the TCE IH. The Office of Research and Standards (ORS) reviewed recent evaluations by the U.S. Environmental Protection Agency (EPA) of TCE's noncancer effects, focusing on the EPA's assessment and discussion of fetal heart malformation weight of evidence (WOE) and the animal data in the white paper the LSPA provided in support of their recommendation.

This memo describes the LSPA request, recent EPA evaluations, and ORS's recommendations based on a review of these documents.

**2023 LSPA White Paper and Recommendations.** In November 2023, the LSPA submitted a document to MassDEP titled *Recommendations for Risk Management Under the MCP for Trichloroethene Exposures Based on Updated Toxicological Information* (LSPA, 2023). In their document, the LSPA recommended that MassDEP change how the current EPA Integrated Risk Information System (IRIS) reference

concentration is used to derive an Imminent Hazard for TCE. The LSPA recommended that MassDEP “exclude the developmental endpoint as a basis for risk management decisions.” The LSPA recommended that the developmental endpoint based on congenital heart defects not be used at MCP sites; instead, they recommend an Imminent Hazard value with a Hazard Quotient of ten be used for TCE at MCP sites based on the immunotoxicity endpoint listed in IRIS.

**EPA and ORS Evaluations for TCE.** In 2011, EPA’s Integrated Risk Information System (IRIS) office updated the reference concentration for TCE (EPA, 2011). It used two endpoints for its basis: (1) immunotoxicity based on decreased thymus weight in rats (Keil et al., 2009) and (2) increased fetal cardiac malformations in rats (Johnson et al., 2003). ORS evaluated the revised IRIS reference concentration for TCE and concluded it was an appropriate basis for developing residential and workplace Imminent Hazard levels for TCE, documented in a 2014 fact sheet (MassDEP, 2014). Because congenital heart defects are considered “serious health effects” under the Massachusetts Contingency Plan that could occur following short-term exposures (310 CMR 40.0955(2))<sup>1</sup>, a Hazard Quotient of one rather than ten was used for Imminent Hazards for TCE where pregnant women and those who may become pregnant are present. Therefore, Imminent Hazard levels based on a Hazard Quotient of one were developed for pregnant women or those who may become pregnant, and a Hazard Quotient of ten was used for Imminent Hazard levels for all other receptors.

ORS reviewed recent EPA evaluations, including:

- *Final Risk Evaluation for TCE* (EPA, 2020a),
- *Meeting Minutes and Final Report for the TSCA Science Advisory Committee on Chemicals. Peer Review for EPA Draft Risk Evaluation for Trichloroethylene (TCE)* (EPA 2020b)
- *Second Existing Chemical Exposure Limit (ECEL) (Developmental Toxicity) for Occupational Use of Trichloroethylene* (EPA, 2022),
- *Final Revised Unreasonable Risk Determination for Trichloroethylene* (EPA 2023),
- *Proposed Rule. Trichloroethylene (TCE); Regulation Under the Toxic Substance Control Act (TSCA)*(FR, 2023),
- *Final Rule. Trichloroethylene (TCE); Regulation under the Toxic Substances Control Act (TSCA)* (FR, 2024).

EPA’s Office of Chemical Safety and Pollution Prevention finalized the Risk Evaluation report for trichloroethylene under TSCA in 2020. The risk evaluation reviewed the animal and human studies published since the 2011 IRIS assessment (EPA, 2020). New studies were identified for congenital heart defects, including studies cited by LSPA (2023), and EPA conducted a new Weight of Evidence Evaluation for congenital heart defects incorporating these studies (EPA, 2020). EPA (2020) concluded that the database for congenital heart defects is reliable and relevant, providing:

- Suggestive evidence of positive association from multiple epidemiology studies;

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<sup>1</sup> 310 CMR 40.0955(2)(c); “The conditions at the disposal site pose an Imminent Hazard based upon the potential for non-cancer health effects if, for the oil and/or hazardous material evaluated and for each receptor, the non-cancer risk calculated is equal to or greater than a non-cancer risk limit of:

1. a Hazard Index (or equivalent ratio of exposure) equal to one for oil or hazardous materials that have the potential to cause serious effects (including, but not limited to, lethal, developmental, or neurological effects) following short-term exposures, for example lead or cyanide; and
2. a Hazard Index equal to ten for all other oil or hazardous materials.”

- Mixed evidence from animal toxicity studies; and
- Strong and consistent positive evidence from mechanistic studies.

Thus, EPA reaffirmed its previous conclusion that the weight of evidence supports a likely association of exposure to TCE with congenital heart defects (EPA 2020).

In their Final Rule, EPA concluded that “reasonable scientists would not disallow the use of the fetal cardiac defects studies, and that therefore other EPA program reliance on the fetal cardiac defects endpoint is scientifically valid (e.g., Integrated Risk Information System)” (FR, 2024).

## CONCLUSIONS AND RECOMMENDATIONS

Based on ORS's review of current information, ORS recommends Imminent Hazard evaluations for TCE continue to use the guidance provided in the MassDEP 2014 Fact Sheet for TCE for pregnant women and those who may become pregnant.

## References

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