

**New EPA TCE Toxicity Information: Implications for Chronic and Shorter-Term Exposure
and Status of MassDEP Review
January 23, 2013
(revised April 18, 2013)**

Trichloroethylene (“TCE”) is a common contaminant at disposal sites being assessed and remediated pursuant to M.G.L. Chapter 21E and the Massachusetts Contingency Plan (“MCP”, 310 CMR 40.0000). This update provides a summary of the available toxicity information for TCE, the status of the MassDEP review of this information, and an appropriate approach to assessing disposal sites during this review period.

Specific questions about the assessment and cleanup of TCE at MCP sites may be address to BWSC.Information@state.ma.us.

1. Available Chronic Toxicity Information for TCE

In September, 2011, the U.S. Environmental Protection Agency (“USEPA”) released its Final Assessment for TCE on its Integrated Risk Information System (“IRIS”). This Final Assessment for TCE is available online at <http://www.epa.gov/iris/subst/0199.htm>. The following toxicity information was included in the September 2011 update:

- Reference Dose for Chronic Oral Exposure (“RfD”) = 5×10^{-4} mg/kg/day
- Reference Concentration for Chronic Inhalation Exposure (“RfC”) = 0.002 mg/m³ (2 µg/m³)
- Quantitative Estimate of Carcinogenic Risk from Oral Exposure
Oral Slope Factor = 5×10^{-2} per mg/kg-day
- Quantitative Estimate of Carcinogenic Risk from Inhalation Exposure
Inhalation Unit Risk = 4×10^{-6} per µg/m³

**Target Risk Level Using September 2011 TCE Toxicity Values
(Residential Exposure Scenario)**

Method 3 Assessments	Estimated Indoor Air Concentration	Health Effect (new IRIS value)
No Significant Risk^{1,2} (Risk Driver)	2 µg/m³ (Chronic Exposure Noncancer Risk, HQ=1)	Fetal developmental and immune system effects (all receptors)

Table Notes:

(1) The risk-based estimate assumes a single chemical and single exposure route. Consideration of the Cumulative Receptor Risk from multiple exposure pathways and/or multiple chemicals with the same target organ/mechanism of action may further reduce the concentration associated with No Significant Risk on a site-specific basis. Conversely, a quantitative risk assessment that calculates a site-specific Hazard Quotient using residential exposure input parameters may conclude that incrementally higher concentrations – as high as 2.9 µg/m³ – also equate to a Hazard Quotient = 1 (rounded to one significant figure).

(2) This concentration is based upon a residential exposure. Site-specific adjustments such as for exposure frequency, may be appropriate for commercial/industrial settings and could result in somewhat higher indoor air concentrations associated with No Significant Risk.

MassDEP is highlighting the availability of these updated toxicity factors for the evaluation of chronic exposures under the MCP pursuant to 310 CMR 40.0993(5)(a). The MassDEP Risk Assessment ShortForms have been updated to reflect the USEPA TCE toxicity values¹. The Department is also preparing revised MCP Method 1 soil and groundwater standards and MCP Reportable Concentrations for soil and groundwater based on these values.

2. Consideration of Short-term (Subchronic or shorter) Exposures to TCE

Short-term exposure to TCE is evaluated pursuant to the MCP in part to determine if an Imminent Hazard exists at a site. An Imminent Hazard determination may be based on either excessive cancer- or noncancer-risk.

The IRIS Toxicological Review for TCE describes the basis for the chronic RfD and chronic RfC. One of the health endpoints is increased fetal cardiac malformations observed in laboratory animals exposed *in utero* to TCE. There is also some human evidence of developmental heart defects from TCE exposure in community studies (EPA/635/R-09/011F, Section 4.8.3.1.1). Because this health endpoint, by definition, is the result of a short-term exposure (during gestation), the chronic RfD and chronic RfC provide information to use to evaluate short-term exposures to TCE, including the potential for Imminent Hazards based on potential noncancer risk.

Some USEPA Regions and the Agency for Toxic Substances and Disease Registry (“ATSDR”) have recently relied on the chronic RfC value to evaluate shorter-term exposures. The USEPA has not published guidance on this use of the TCE chronic toxicity values and stakeholders have raised concerns about the use of these factors to evaluate short-term exposures.

3. Interim Approach for TCE Imminent Hazard Evaluations

It is important to note that increased fetal cardiac malformation is a developmental effect. Because the MCP (at 310 CMR 40.955(2)(c)1.) requires the use of a Hazard Quotient of 1 for Imminent Hazard evaluations of chemicals that cause development effects, the MCP Risk Assessment ShortForms have been updated with a notation indicating concerns about developmental effects that necessitate the use of a Hazard Quotient = 1 to manage potential risks. Conditions that pose or could pose an Imminent Hazard require notification to MassDEP within 2 hours of obtaining knowledge of the condition.

The MCP requires the implementation of Immediate Response Actions to abate, prevent or eliminate any Imminent Hazards identified at a site. Since the exposure duration of concern for developmental health effects is short – *measured at most in months* – MassDEP will work with responding parties to identify appropriate mitigation options and begin implementation quickly. The MassDEP *Interim Final Vapor Intrusion Guidance* (WSC #11-435, <http://www.mass.gov/dep/cleanup/laws/vifin.pdf>) includes a discussion of vapor intrusion pathway mitigation measures (Chapter 3). While the sequential approach to implementing mitigation measures described in the guidance is relevant to these TCE exposure conditions, the time-frame for implementation and subsequent evaluation may need to be expedited in consideration of the potential for developmental effects. Note that the low TCE concentrations that pose an Imminent Hazard in a residential setting may limit the feasibility considerations of the Critical Exposure Pathway (CEP) provisions.

¹ The Risk Assessment ShortForms are available online at:
<http://www.mass.gov/dep/service/compliance/riskasmt.htm#site>

Target Risk Levels Inferred from the September 2011 TCE Toxicity Values

Method 3 Assessments	Estimated Indoor Air Concentration	Health Effect (new IRIS value)
<i>Residential Exposure Scenario</i>		
Imminent Hazard ¹ (Risk Driver)	2 µg/m³ (Subchronic Exposure Noncancer Risk, HQ=1)	Fetal developmental effects (sensitive receptors are pregnant women and women of childbearing age assumed to be exposed 24 hours/day, 7 days/week, such as in a residential setting)
	20 µg/m³ (Subchronic Exposure Noncancer Risk, HQ=10)	Immune system effects (all receptors assumed to be exposed 24 hours/day, 7 days/week, such as in a residential setting)
<i>Commercial Exposure Scenario</i>		
Imminent Hazard ^{1,2} (Risk Driver)	8 µg/m³ (Subchronic Exposure Noncancer Risk, HQ=1)	Fetal developmental effects (sensitive receptors are pregnant women and women of childbearing age assumed to be exposed 8 hours/day, 5 days/week, such as in an office setting)
	80 µg/m³ (Subchronic Exposure Noncancer Risk, HQ=10)	Immune system effects (all receptors assumed to be exposed 8 hours/day, 5 days/week, such as in an office setting)

Table Notes:

(1) The risk-based estimate assumes a single chemical and single exposure route, calculated using the Risk Assessment ShortForm to identify the concentration associated with a Hazard Quotient equal to 1. Consideration of the Cumulative Receptor Risk from multiple exposure pathways and/or multiple chemicals with the same target organ/mechanism of action may further reduce the concentration associated with an Imminent Hazard on a site-specific basis. Conversely, a quantitative risk assessment that calculates a site-specific Hazard Quotient using standard exposure input parameters may conclude that incrementally higher concentrations – as high as 2.9 µg/m³ for residential Imminent Hazards or 12 µg/m³ for commercial Imminent Hazards – also equate to a Hazard Quotient = 1 (rounded to one significant figure).

(2) Site-specific adjustments such as for exposure frequency may be appropriate, such as for the commercial setting illustrated here. On a case-specific basis, the calculation could result in different (even somewhat higher) indoor air concentrations associated with Imminent Hazards.

4. MassDEP Review of the TCE Toxicity Information for Subchronic Exposures

The Department is undertaking a review of the information available for TCE in consultation with the MassDEP/MDPH Health Effects Advisory Committee. This review will address several issues associated with the use of the 2011 TCE toxicity values:

- Confidence in the chronic Reference Dose and Reference Concentrations, including whether the chosen studies are appropriate and the derivation of the numerical values;

- Appropriateness of using the same studies/numerical values to evaluate short-term exposures, including whether the values should be adjusted to reflect their application to a shorter exposure period; and
- Implementation concerns, including appropriate exposure frequency and duration factors to use for residential and non-residential exposure scenarios, and the timing of necessary response actions to address any identified Imminent Hazards.

This review is expected to take several months to complete. MassDEP understands that the U.S. EPA is preparing additional guidance on this issue as well. The Department will be monitoring and considering input from a range of sources during this period.

This Status Report will be updated as needed to reflect relevant developments from the ongoing state and federal review efforts.