

# NEW IRIS TRICHLOROETHENE TOXICITY CRITERIA: IMPACT OF NONCANCER HAZARD AT CLEANUP SITES IN CALIFORNIA

Day, K., Behrsing, T., Sciuillo, E., Bosan, B., Wade, M.  
Department of Toxic Substances Control (DTSC), CalEPA, Sacramento, CA, USA

## ABSTRACT

Trichloroethene (TCE) is an industrial solvent mainly used as a degreaser for metal-cleaning operations. TCE has been detected in groundwater, indoor air, soil, and soil gas; with inhalation of vapors and ingestion of contaminated groundwater the primary routes of exposure. DTSC is investigating over 550 sites with reported TCE contamination. Recently, USEPA/IRIS released new toxicity criteria for TCE. Previously, CalEPA's Office of Environmental Health Hazard Assessment (OEHHA) toxicity criteria were used to evaluate cancer risk and noncancer hazard at cleanup sites. The new IRIS noncancer inhalation reference concentration (RfC) and oral reference dose (RfD) are 300-fold and 1000-fold more protective and are based on multiple critical effects (immune, neurotoxicity, increased fetal cardiac malformations), from multiple studies. The impacts of the new TCE toxicity criteria are now becoming apparent. At sites, the noncancer threshold (hazard index-HI) may exceed 1 using the IRIS criteria, while the cancer risk is at the low end of the risk management (RM) range. We present three case studies demonstrating the impact of the new noncancer RfC and RfD: Site A where the proposed cleanup value for beneficial use of groundwater is 2.6 µg/L vs. 5 µg/L; Site B where 2 of the 4 homes had detected indoor air TCE concentrations greater than the noncancer RfC of 2 µg/m³ and now require vapor intrusion mitigation; and Site C with potential vapor intrusion issues from modeled groundwater due to the TCE HI which was less than 1 using OEHHA criteria for residential and industrial but is now 10 and 3.9, respectively. These examples illustrate that noncancer threshold may now play more of a role in RM decisions. Consideration of the new noncancer TCE criteria during the five year review process may also indicate previously proposed cleanup/remediation is not protective of human health. Thus, the TCE criteria updates (particularly for noncancer) have important implications on site risks and cleanup.

## INTRODUCTION

- September 28, 2011, the US Environmental Protection Agency (EPA), Integrated Risk Information System (IRIS) released new toxicity criteria for TCE (1). Prior to the new IRIS TCE toxicity criteria, risk assessment used the toxicity criteria published by the Cal/EPA Office of Environmental Health Hazard Assessment (OEHHA).
- Briefly, the new IRIS cancer inhalation unit risk (IUR) factor and oral cancer slope factor (CSF) are based on incidences of kidney cancer and adjusted for non-Hodgkin lymphoma and liver cancer from human inhalation exposure data. The IRIS IUR is 2-fold more protective than the OEHHA IUR, while the IRIS oral CSF is 8-fold more protective than the OEHHA CSF (1, 2).
- Epidemiologic data, experimental and mechanistic studies were considered by USEPA/IRIS when developing the noncancer inhalation reference concentration (RfC) and oral reference dose (RfD).
  - Both the RfC and RfD are based on multiple critical effects, from multiple studies that had similar results.
  - This approach provides more robust estimates of the RfC and RfD.
  - The principle studies used included: 1) increased fetal cardiac malformations in rats from a drinking water study, where exposure was from gestation day (GD) 1 to day 22 (3); 2) developmental immunotoxicity in mice from a drinking water study, where exposure was from GD 0 to 3 or 8 weeks of age (4); and 3) adult immunological effects in female mice from a 30-week drinking water study (5).
  - Supporting studies show that TCE has adverse effects on the kidneys, liver, central nervous system, and neurotoxicity (1).
- The IRIS RfC is 300-fold more protective than the OEHHA value.
- The IRIS RfD is 1000-fold more protective than the OEHHA value.

## SITE BACKGROUND

- Site A is an active industrial site in the California Central Valley. The groundwater is contaminated with TCE and is designated as beneficial use.
- Site B is a former industrial site in Southern California. The shallow groundwater and soil gas are contaminated with TCE. Previous on-site activities included the testing of aerospace components and systems using simulated physical and dynamic test environments. Currently, residential homes occupy the site. Initial indoor air quality (IAQ) sampling was conducted in twenty seven homes in 2006 and 2007. In 2012, four of the homes were resampled.
- Site C is a former industrial site in Southern California with shallow TCE contaminated groundwater. Soil gas data has not been collected at this site. The site is currently designated as mixed use, e.g., residential and industrial, and is under going redevelopment.

## OVERVIEW OF IRIS vs. OEHHA

Using multiple candidate RfDs and RfCs from multiple studies that fall into a narrow range provide robust support for the final IRIS RfD/RfC listed in the table. In comparison, OEHHA's RfC is based on a single study of occupational exposure to TCE.

	Noncarcinogenic – Chronic Toxicity		
	IRIS	OEHHA	Relative Health Protectiveness (IRIS to OEHHA)
RfD (mg/kg-day)	5E-04	5E-01	1000-fold
RfC (µg/m³)	2	600	300-fold

## WHAT IS CALIFORNIA DOING

- In April 2012, OEHHA revised their Proposition 65 no significant risk levels for TCE.
- OEHHA is currently reviewing all programs with toxicity criteria values for TCE (i.e., air, water, soil, soil gas) and revising the toxicity criteria as appropriate.
- DTSC has adopted and is implementing the IRIS TCE toxicity criteria at our sites.

## WHAT ARE OTHER STATES AND FEDERAL AGENCIES DOING TO ADDRESS SHORT TERM EXPOSURE TO TCE

Regulatory Agency	Criterion	Residential (µg/m³)	Industrial (µg/m³)	Basis
MassDEP	Imminent Hazard (Interim Approach)	2	-	Fetal developmental effects Pregnant women/women of child-bearing age HQ = 1 Immune system effects All receptors - HQ = 10
NJDEP	Rapid Action Level	4	18	USEPA noncancer indoor air RSL for TCE, rounded up, and multiplied by a factor of 2
USEPA Region IX	Proposed Remedial Action Level	-	15	USEPA RfC of 2 µg/m³ adjusted to 5 µg/m³ to account for a 10-hr work day, and then multiplied by a factor of 3 per EPA policy regarding short-term limits intended to account for uncertainty of non-carcinogenic risk values
USEPA Region X	Screening Level (short-term, noncancer)	2	8.4	Fetal cardiac malformations Not to be exceeded, average 21-day exposure
ATSDR	Minimum Risk Level (MRL)	2 (0.0004 ppm)	-	USEPA RfC selected as chronic duration MRL Chronic MRL considered protective of intermediate duration exposures

Footnotes: MassDep – Massachusetts Department of Environmental Protection; NJDEP – New Jersey Department of Environmental Protection; ATSDR – Agency for Toxic Substances and Disease Registry

Since one of the noncancer endpoints used to derive the RfC is increased fetal cardiac malformations, the issue of how to address short-term exposures to TCE has arisen. To address this issue, several States and other Federal Regulatory Agencies have developed recommended short-term exposure levels. All of the above criteria were based on USEPA's IRIS noncancer inhalation RfC for TCE (1).

## POTENTIAL IMPACT/SIGNIFICANCE

- Noncancer threshold (i.e., hazard index) may exceed 1 at sites when the cancer risk is at the low end of the risk management range or at the point of departure, 1E-06.
- Noncancer threshold may play more of a role in risk management decisions and must be discussed and considered.
- When reviewing the risk assessment during the Five Year Review process, there is a potential that the original proposed remediation, land use controls, and/or institutional controls will have to be revised.
- Will State and/or Federal Agencies consider re-evaluating closed sites in light of the new TCE noncancer toxicity criteria?

## REFERENCES

- USEPA (2011). Toxicological Review of Trichloroethylene. <http://www.epa.gov/iris/toxreviews/0199tr/0199tr.pdf>.
- OEHHA Toxicity Criteria Data Base. <http://www.oehha.ca.gov/tcdb/index.asp>.
- Johnson et al., (2003). Threshold of trichloroethylene contamination in maternal drinking waters affecting fetal heart development in the rat. *Environ Health Perspect* 111: 289-292.
- Peden-Adams et al., (2009). Developmental immunotoxicity of trichloroethylene (TCE): Studies in B6C3F1 mice. *J Environ Sci Health A Tox Hazard Subst Environ Eng* 41: 249-271.
- Keil et al., (2006). Assessment of trichloroethylene (TCE) exposure in murine strains genetically-prone and non-prone to develop autoimmune disease. *J Environ Sci Health A Tox Hazard Subst Environ Eng* 44: 443-453.

## DISCLAIMER

Professional affiliations are listed for contact purposes only. Analysis and conclusions contained herein are solely those of the authors and do not represent guidance or official policy of the California Department of Toxic Substances Control or California Environmental Protection Agency.

## CASE STUDIES

### Site A – Groundwater – Beneficial Use



#### Industrial Site in the Central Valley

	µg/L	Hazard	Risk
<b>Proposed Cleanup Value</b>	2.6	1.0	5.9E-06
<b>CA and Federal MCL</b>	5.0	2.0	1.1E-05

In lieu of the California or Federal maximum contaminant level (MCL), regional regulators have proposed to use the noncancer USEPA tapwater regional screening level (RSL) of 2.6 µg/L. The proposal reflects the belief that the MCL may not be protective due to the fetal cardiac malformation endpoint, used in part to derive the oral RfD.

### Site C – Groundwater – Vapor Intrusion



#### Former Southern California Industrial Site - Currently Mixed Use

	Residential		Industrial	
	Hazard	Risk	Hazard	Risk
<b>GW Well 1</b>	10	3.6E-05	3.7	1.1E-05
<b>GW Well 2</b>	2.0	7E-06	--	--
<b>GW Well 3</b>	--	--	1.0	3.3E-06

In the absence of soil gas data, the vapor intrusion pathway was evaluated using the Johnson & Ettinger (J&E) Model for groundwater. The concentration of TCE in the groundwater ranged from 0.5 µg/L to 7,300 µg/L. While the TCE cancer risk is within the risk management range of 1E-04 to 1E-06, the non-cancer hazard index exceeds 1. Thus, the noncancer threshold may now play more of a role in risk management decisions and must be discussed and considered.

### Site B – Indoor Air

- In 2007, 27 homes were sampled and 4 homes showed indoor air levels of TCE above ambient/outdoor air levels. At that time, the TCE levels did not represent an indoor air risk.
- However, due to the revised TCE toxicity criteria, resulting in more stringent indoor air screening levels, these same 4 homes were re-sampled in 2012.
- Based on the IAQ sampling results, DTSC required vapor intrusion mitigation in 3 of the 4 homes.

Home	[TCE] (µg/m³)	Home	[TCE] (µg/m³)	Home	[TCE] (µg/m³)	Home	[TCE] (µg/m³)
<b>Home "A"</b>		<b>Home "B"</b>		<b>Home "C"</b>		<b>Home "D"</b>	
Bath	11/29/2006 1.1 7/5/2007 3.3 7/10/2012 1.5 7/10/2012-DTSC 1.5 7/10/2012-DTSC 2.0	Bath	11/29/2006 2.6 7/9/2007 0.39J 7/10/2012 0.4 12/12/2012 1.5	Bath	11/15/2006 4.3 6/27/2007 1.5 7/9/2012 5.4 7/9/2012-DTSC 4.7 7/9/2012-DTSC 4.6	Bath	11/29/2006 <0.13 7/5/2007 3.9 7/10/2012 0.58 12/12/2012 2.0 12/12/2012-DTSC 1.9
Living Room	11/29/2006 0.31 7/5/2007 1.7 7/10/2012 1.5 7/10/2012-DTSC 1.9	Living Room	11/29/2006 4.5 7/9/2007 0.56 7/10/2012 0.63 12/12/2012 0.93	Living Room	11/15/2006 2.3 11/15/2006-dup 2.5 6/27/2007 0.95 7/9/2012 5.1 7/9/2012-DTSC 6.7	Living Room	11/29/2006 2.4 11/29/2006-dup 3.2 7/5/2007 3.6 7/10/2012 0.72 12/12/2012 1.8
Out-door	11/29/2006 <0.13 7/5/2007 <0.13 7/10/2012 <0.13 7/10/2012-DTSC 0.19	Out-door	11/29/2006 <0.13 7/9/2007 <0.13 7/10/2012 <0.13 12/12/2012 0.20	Out-door	11/15/2006 0.55 6/27/2007 0.56 7/9/2012 0.41 7/9/2012-DTSC 0.45	Out-door	11/29/2006 <0.13 7/5/2007 <0.13 7/10/2012 <0.13 12/12/2012 <0.13
<b>Recommended VI Mitigation</b>		<b>Continued Monitoring</b>		<b>VI Mitigation Installed</b>		<b>Recommend VI Mitigation</b>	

Black = 2006/2007 Sampling Event  
Red = 2012 Sampling Event

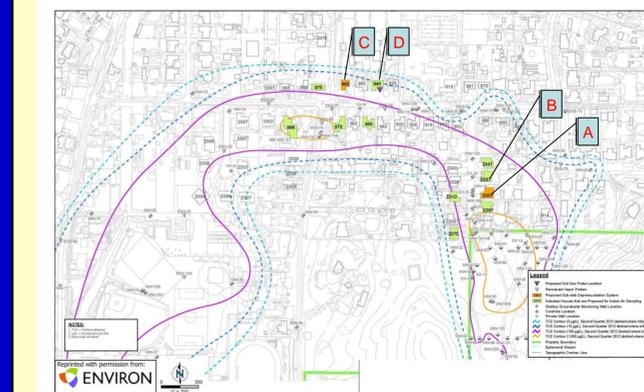


Figure 1. Map of Site B. Indoor air sampling was proposed for the homes in light green. Installation of a sub-slab depressurization system was proposed for the homes in orange.

The results shown in the above tables correspond to the homes called out in the Figure.