



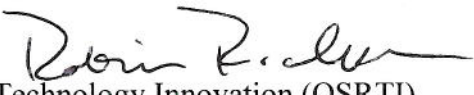
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

AUG 27 2014

OFFICE OF  
SOLID WASTE AND  
EMERGENCY RESPONSE

**MEMORANDUM**

**SUBJECT:** Compilation of Information Relating to Early/Interim Actions at Superfund Sites and the TCE IRIS Assessment

**FROM:** Robin H. Richardson, Acting Director   
Office of Superfund Remediation and Technology Innovation (OSRTI)

**TO:** Superfund Division Directors, EPA Regions 1 - 10

**Purpose**

This compilation of information was prepared in response to requests from U.S. Environmental Protection Agency (EPA) Regional Offices. It provides information regarding existing EPA guidance on early or interim actions at Superfund sites. It also provides current information about the toxicity of trichloroethylene (TCE). The information referenced in this document may be used to support Superfund decision making at sites with actual or potential inhalation exposures to TCE.

**Background**

In September 2011, the U.S. Environmental Protection Agency (EPA) published a toxicological assessment for TCE<sup>1</sup>. Based upon a weight-of-evidence evaluation of the available information, including human epidemiologic studies, animal dosing studies, and experimental mechanistic studies, the assessment concluded that TCE poses a potential human health hazard for noncancer toxicity to the central nervous system, kidney, liver, immune system, male reproductive system, and the developing fetus, and is "carcinogenic to humans" by all routes of exposure. The assessment for IRIS derived a chronic inhalation reference concentration (RfC) for noncancer effects of TCE, which is two micrograms per cubic meter (2 µg/m<sup>3</sup>). This RfC is based in part on the developmental toxicity endpoint of increased incidence of fetal cardiac malformations.

**Early or Interim Action for TCE**

In considering how the 2011 TCE IRIS assessment should be used in Superfund decision making, the existing Federal statutes and EPA guidance offer the following:

<sup>1</sup> U.S. EPA (2012). *Toxicological Review of Trichloroethylene in Support of the Integrated Risk Information System (IRIS)*. Currently available online at: <http://www.epa.gov/iris/toxreviews/0199tr/0199tr.pdf>.

- *Early or interim actions*: EPA expects to take early actions at Superfund sites where appropriate to eliminate, reduce, or control the hazards posed by a site. In assessing such cases, EPA will act with a bias for initiating response actions to ensure protection of human health<sup>2</sup>.
- *Considering noncancer health effects*: For purposes of the Superfund program and consistent with the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), unacceptable risk occurs when exposures exceed concentrations to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime, as appropriate to address teratogenic and developmental effects<sup>3</sup>.
- *Developmental toxic effects*: In most cases, it is assumed that a single exposure at any of several developmental stages may be sufficient to produce an adverse developmental effect,<sup>4</sup> but the RfC for a single exposure hasn't been determined yet by EPA.
- *IRIS Database*: IRIS normally represents the official Agency scientific position regarding the toxicity of the chemicals based on the data available at the time of the review and is the generally preferred source of human health toxicity values used to support Superfund response decisions<sup>5</sup>. For noncancer effects, a concentration of 2 µg/m<sup>3</sup> TCE in indoor air is expected to be a reasonable maximum exposure condition for a continuous chronic exposure to prevent risk of adverse health effects during a lifetime.
- *Risk Assessment Guidance for Superfund: Volume I Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment)*<sup>6</sup> addresses the use of inhalation toxicity values in Superfund risk assessments, including discussion of estimating exposures in microenvironments<sup>7</sup> by calculating time-weighted average exposures concentrations for each exposure period characterized by a specific activity pattern. It also recognizes that chemical-specific elements of metabolism and kinetics, reversibility of effects, and recovery time should be considered when defining the duration of a site-specific exposure scenario.
- *ARARS*: At sites contaminated with TCE addressed by CERCLA, additional (non-EPA) TCE concentration or toxicity values may exist that could represent applicable or relevant and appropriate requirements (ARARs), including more stringent state standards or policy.<sup>8</sup>

<sup>2</sup> National Oil and Hazardous Substances National Contingency Program (NCP) ((see 40 CFR 300.415 (b)(1)-(3) and 300.430 (a)(1)(ii)(A)).

<sup>3</sup> U.S. EPA (1991). *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions*. OSWER Directive 9355.0-30. Currently available on-line at: <http://www.epa.gov/oswer/riskassessment/pdf/baseline.pdf>

<sup>4</sup> U.S. EPA (1991). *Guidelines for Developmental Toxicity Risk Assessment* (EPA/600/FR-91/001) describes the procedures that EPA follows in evaluating potential developmental toxicity associated with human exposure to environmental agents. Currently available online at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=23162>

<sup>5</sup> U.S. EPA (2003) *Human Health Toxicity Values in Superfund Risk Assessments* (OSWER Directive 9285.7-53). Currently available online at <http://www.epa.gov/oswer/riskassessment/pdf/hhmemo.pdf>

<sup>6</sup> U.S. EPA (2009). *Risk Assessment Guidance for Superfund: Volume I Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment)*. This document is currently available on-line at: [http://www.epa.gov/oswer/riskassessment/ragsf/pdf/partf\\_200901\\_final.pdf](http://www.epa.gov/oswer/riskassessment/ragsf/pdf/partf_200901_final.pdf)

<sup>7</sup> U.S. EPA (2004). *Air Quality Criteria for Particulate Matter: Volume II*. Microenvironments are defined as a space that can be treated as a well-characterized, relatively homogeneous location with respect to pollutant concentration for a specified time period (e.g., rooms in homes, restaurants, schools, offices, inside vehicles, or outdoors). Currently available online at: <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=95398>

<sup>8</sup> For a description of ARARs, see, for example: <http://www.epa.gov/superfund/policy/remedy/sfremedy/arars.htm>

## **Summary**

Existing guidance provides that responders should consider *early or interim* action(s) where appropriate to eliminate, reduce, or control the hazards posed by a site. In doing so, IRIS generally provides the best available toxicological information in support of *early or interim* action for buildings where investigations of indoor air contamination identify site-related concentrations of TCE.

## **Additional Information**

Additional information related to vapor intrusion and existing OSWER guidance can be found at <http://www.epa.gov/oswer/vaporintrusion/> and <http://www.epa.gov/oswer/riskassessment/>. Please contact Michael Scozzafava (Chief, Science Policy Branch) at (703) 603-8833 if you have questions or require further information.

cc: Mathy Stanislaus, OSWER/IO  
Nitin Natarajan, OSWER/IO  
Barry Breen, OSWER/IO  
Reggie Cheatham, OSWER/OEM  
David Lloyd, OSWER/OBLR  
Charlotte Bertrand, OSWER/FFRRO  
Carolyn Hoskinson, OSWER/OUST  
Kent Benjamin, OSWER/IPCO  
Barnes Johnson, OSWER/ORCR  
Nigel Simon, OSWER/OPM  
Cyndy Mackey, OECA/OSRE  
John Michaud, OGC/SWERLO  
Franklin Hill, OSWER/OSRTI  
Dana Stalcup, OSWER/OSRTI  
Michael Scozzafava, OSWER/OSRTI  
Richard Kapuscinski, OSWER/OSRTI  
Barbara Hostage, OSWER/PARMS  
Stiven Foster, OSWER/PARMS