UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
ENVIRONMENTAL ASSESSMENT

MEMORANDUM

SUBJECT: OEA Recommendations Regarding Trichloroethylene Toxicity in Human Health Risk Assessments

FROM: Joyce C. Kelly, Director
Office of Environmental Assessment

TO: Rick Albright, Director
Office of Environmental Cleanup

Kate Kelly, Director
Office of Air, Waste & Toxics

This memorandum supersedes previous communications from this office regarding the selection of toxicity values for trichloroethylene (TCE) in human health risk assessments, including a September 23, 2008 memorandum from me to Dan Opalski, then the director of the Office of Environmental Cleanup (ECL). We also have communicated our recommendations in recent years to each of the four states in Region 10, as we will do with these new recommendations. Please share the information in this memorandum with your staff who are involved with the investigation or cleanup of RCRA or CERCLA sites, where TCE is a common chemical of concern.

We previously had a need to make recommendations regarding TCE toxicity because there were various available values from different sources, but none on the EPA Integrated Risk Information System (IRIS), typically the preferred source of toxicity information for EPA. EPA's Office of Research and Development (ORD) finalized its toxicological review of TCE in 2011, and IRIS was updated in October of that year with values for chronic oral and inhalation exposures to TCE. This office recommends that the values now available on IRIS for chronic TCE exposures be utilized for risk assessment purposes in Region 10. We would like to take this opportunity to point out that media concentrations of TCE that are based on chronic exposures, noncancer endpoints and a hazard quotient of 1 should be given special attention, as the hazard quotient may be exceeded at media concentrations that are calculated to represent individual excess lifetime cancer risks of 1E-4 and 1E-5. The precise concentrations will depend upon the media and the exposure scenarios of concern. Examples are provided in Table 1 of this memorandum.

There remains one exposure issue that is not resolved on IRIS regarding TCE, although it is our understanding that OSWER is attempting to formally do so by consulting with ORD and other EPA program offices. Because there is a current need to address this exposure issue at numerous CERCLA and RCRA waste sites in Region 10, we have decided that it is prudent for this office to make recommendations regarding this exposure, while waiting for OSWER to issue guidance on the matter. This is the primary subject of the rest of this memorandum.

Pursuant to the October 2011 IRIS Toxicological Review for TCE, the noncancer outcomes used for deriving the inhalation reference concentration (RfC) and oral reference dose (RfD) are based in part on immunotoxic and developmental effects, including fetal cardiac malformations that may occur when the mother is exposed to TCE during a 21-day early gestation window. Information on IRIS and in the Toxicological Review does not provide a specific methodology to estimate protective media concentrations for this window of vulnerability. Region 10 human health toxicologists have determined that, to protect against potential noncancer fetal malformation outcomes, it is appropriate to recommend that average exposures over any 21-day period of time not exceed the concentrations in air or other media that are calculated to be protective for this exposure, using the RfD and RfC provided in IRIS.

In order to calculate a health-protective TCE concentration for indoor air in a residential setting, the default Superfund chronic scenario assumes exposure of 24 hours per day, 350 days per year, which provides for a period of absence of two weeks per year. This yields a noncancer TCE concentration of 2.1 $\mu g/m^3$, representing a hazard quotient of 1.0.[1] For short-term exposure concerns (i.e., to protect against fetal cardiac malformations) during any 21-day period of time in a given year, the exposure frequency should be adjusted to 365 days per year, resulting in a calculated concentration of 2.0 $\mu g/m^3$.

For calculation of a protective concentration of TCE in indoor air in a commercial/industrial setting, the default Superfund chronic scenario assumes 8 hours/day, 5 days/week, 250 days per year, which like the default residential calculation assumes an absence of two weeks during a year. The chronic indoor air concentration representing a hazard quotient of 1.0 for this scenario is 8.8 $\mu g/m^3$.[2] For the short-term exposure concern, when women of reproductive age may be present at any time, the exposure frequency should be increased to 260 days per year to eliminate the assumption that there is a yearly two-week absence, since any given 21-day period is to be protective. This results in an indoor air criterion of 8.4 $\mu g/m^3$ representing a hazard quotient of 1.0. If the exposure time and frequency at a given commercial/industrial building is known to be other than the default Superfund assumption of 8 hrs/day, 5 days/week, 250 days/year, additional adjustments may be made in the calculation of building-specific, short-term exposure concentrations, just as they also may be made for the calculation of the building-specific chronic exposure concentrations.

To calculate short-term, noncancer TCE concentrations for other exposure media, Superfund default exposure-related variables should be changed, where necessary, to include adult-only values (e.g., exposure frequencies and durations, body weights, soil and other media ingestion rates, and dermal surface areas exposed), with no assumed hiatus times (i.e., no assumed vacations or other absences).

This office recommends that media TCE concentrations calculated for the noncancer, short-term scenario to protect against fetal heart malformations be considered as not-to-be-exceeded concentrations, as averaged over any 21-day period of time, when women of reproductive age

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[1] The air TCE screening level concentration representing an individual excess lifetime cancer risk of 1E-6 is 0.43 ug/m3 for the default residential exposure scenario.

[2] The air TCE screening level concentration representing an individual excess lifetime cancer risk of 1E-6 is 3.0 ug/m3 for the default commercial/industrial exposure scenario.

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may be exposed. If such concentrations are exceeded, measures to expeditiously reduce exposure should be considered.

The available scientific information does not allow for a determination of whether transient spikes in TCE exposures during a 21-day window of early gestation vulnerability may result in fetal heart malformations, when average media exposure concentrations during that window are not exceeded. If there is evidence that such media excursions may be occurring, they should be considered a qualitative, nonconservative uncertainty for risk assessment and risk management purposes.

EPA Region 10 generally recommends that media screening levels for chronic exposures be based on the lower of 1E-6 individual excess lifetime cancer risk or a hazard quotient of 0.1 (protective where there are multiple chemicals with similar chronic noncancer effects). The chronic cancer and noncancer screening concentrations in TCE-contaminated media are screening levels for risk assessment purposes. The short-term media concentrations of TCE should be considered separately, as appropriate to the exposure situation.

Table 1 below contains recommended cancer and noncancer screening concentrations for TCE in air, drinking water and soil using default Superfund exposure assumptions for chronic cancer and noncancer exposures, and recommended noncancer, not-to-be-exceeded concentrations for short-term, exposure scenarios when women of reproductive age may be present.

If you have any questions or comments on the issues discussed in this memorandum, please contact Dr. Marcia Bailey of the Risk Evaluation Unit in this office at (206) 553-0684 or bailey.marcia@epa.gov.

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Table 1. EPA Region 10 Recommended Media Concentrations of TCE in Standard Environmental Media for Use at Superfund and RCRA Waste Sites

		Cancer risk of 1x10-6 from EPA Regional Screening Level Tables[1]	Chronic noncancer, from EPA Regional Screening Level Tables, adjusted to a hazard quotient of 0.1 [2]	Short-term noncancer Not to be exceeded, average 21-day exposure to women of reproductive age to prevent fetal cardiac malformations HQ=1.0
Residential	Drinking water	0.44 µg/L	0.26 µg/L	3.4 µg/L
	Soil	0.91 mg/kg	0.44 mg/kg	4.7 mg/kg
	Air	0.43 µg/m3	0.21 µg/m3	2.0 µg/m3
Commercial/ Industrial	Drinking water[3]			
	Soil	6.4 mg/kg	2.0 mg/kg	19.2 mg/kg
	Air	3.0 µg/m3	0.88 µg/m3	8.4 µg/m3

[1] Updated twice per year; available at http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/index.htm

[2] Use of a hazard quotient of 0.1 for screening purposes is intended to prevent elimination of chemicals of concern for further inclusion when doing so may result in an inadvertent exceedance of a hazard index of 1.0. Use of a screening level hazard quotient of 1.0 is acceptable at a site when there are few contaminants of concern with similar noncancer outcomes being evaluated. In that case, multiply the concentrations in this column by 10.

[3] While EPA does not provide regional screening levels for industrial/commercial drinking water, it may be desirable, on a site-specific basis, to do so to account for short-term exposures to women of reproductive age. Otherwise, the residential drinking water value may be used.

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References

U.S. Environmental Protection Agency (1991). Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors. Washington, DC, Office of Emergency and Remedial Response. http://www.epa.gov/oswer/riskassessment/pdf/oswer_directive_9285_6-03.pdf

U.S. Environmental Protection Agency (2011). IRIS Toxicity Profile for Trichloroethylene (CASRN 79-01-6). Washington DC, USEPA. http://www.epa.gov/iris/subst/0199.htm

cc: Helen Dawson, OSWER
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