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December 7, 2017

Darsi Foss
Director, Remediation and Redevelopment Program
Wisconsin Department of Natural Resources
101 S. Webster Street, Box 7921
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Subject: DHS response to Request for Opinion on risk guidelines in DNR's Vapor Intrusion Guidance RR800; comments to immediate action criteria and Trichloroethylene (TCE) acute risk.

Dear Ms. Foss:

In your October 26, 2017 letter, you asked for a formal response from the Department of Health Services (DHS) to two areas of comments received on the Wisconsin Department of Natural Resources (DNR) draft revision to RR800 – Addressing Vapor Intrusion at Remediation and Redevelopment Sites in Wisconsin:

1. Immediate action criteria. *Please review the guidelines for immediate action in RR800, and provide written opinion of the DNR's proposed immediate action guidelines (sec. 7.1, RR800 draft).*
2. Trichloroethylene (TCE) Acute Risk. *Please review the ACC's September 8, 2017 letter to DNR under the heading "DNR should not adopt a policy for TCE remediation based on potential acute (short-term) risks," and provide written opinion if there is sufficient weight of scientific evidence to continue with more urgent/immediate response when TCE is the contaminant of concern and women of childbearing age are present.*

DHS response:

Immediate Action Criteria: DHS concurs with DNR's proposed immediate action guidelines.

The central feature of the immediate action criteria allows for immediate intervention if:

- indoor air concentrations are over 10 times the Vapor Action Limit (VAL) for carcinogens or,
- indoor air concentrations are over 3 times the VAL, for non-carcinogens

These immediate action guidelines are consistent with EPA guidance for a Category 4 – High priority removal site.¹ They are also consistent with the EPA *Regional Removal management Levels Users Guide*,² which includes supporting RML tables that use a 10^{-4} risk level for carcinogens (equivalent to 10-fold over the 10^{-5} target risk level for the VAL) and an HQ (hazard quotient) of 3 for noncarcinogens (3-fold over the VAL). There is a mechanistic basis for using differing concentration magnitudes over the Vapor Action Limits with regard to acute exposures to carcinogens versus non-carcinogens. The EPA has noted there is a reasonable assumption that non-carcinogenic effects result from acute to subacute exposures, and plausibly from a single exposure: “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, but the RfC for a single exposure hasn’t been determined yet by EPA.”³ For these reasons DHS agrees with the precaution of using DNR’s proposed immediate action criteria. As noted, these would be 3 times the VAL for non-carcinogenic (including developmental) effects, and 10 times the VAL for carcinogenic effects, where the probability of genotoxic carcinogenesis is calculated on the basis of exposures over long exposure durations at low concentrations not expected to cause acute effects.

TCE Acute Risk: DHS recommends urgent/immediate response when TCE is the contaminant of concern and women of childbearing age are present.

In a September 8, 2017 letter to DNR, one commenter, the American Chemistry Council (ACC), disagrees with using the acute risk of fetal heart malformation as basis for decisions for sites with TCE contamination because of controversy over the risk assessments. There is a substantial body of literature on the toxicological effects of TCE that considers both cancer and non-cancer endpoints, including the effects of TCE on fetal heart development in rodent and avian models (for more information, see reviews by the U.S. Environmental Protection Agency⁴ and the Agency for Toxic Substances and Disease Registry⁵). This literature will be more complete with better demonstrations of congenital fetal heart defects through the inhalation route. There are uncertainties in the use of animal models, such as subtle differences in the developmental windows of rats, chickens, and humans; species-level metabolism; and metabolic differences in oral exposure vs respiratory exposure (*i.e.*, uptake rates and tissue-specific enzyme expression). Any of these could confound the extrapolation of a relevant drinking water dose to a comparable respiratory dose calculated solely on the basis of ventilation rates. Nonetheless, based upon

¹ EPA. 2010. Vapor Intrusion Guidebook. United States Environmental Protection Agency. Internet <https://www.epaossc.org/sites/3806/files/VI%20Guidebook%20-%20%2010-1-10%20-%20final%20version.pdf>.

² EPA. 2017. Regional Removal Management Levels for Chemicals (RMLs). United States Environmental Protection Agency. Internet <https://www.epa.gov/risk/regional-removal-management-levels-chemicals-rmls>

³ Richardson, RH. Aug 27 2014. EPA Memo from Office of Superfund Remediation and Technology Innovation: *Compilation of Information Relating to Early/Interim Actions at Superfund Sites and the TCE IRIS Assessment*.

⁴ EPA. 2011. Toxicological Review of Trichloroethylene. United States Environmental Protection Agency, Integrated Risk Information System. EPA/635/R-09/011F. Internet <https://www.epa.gov/iris/supporting-documents-trichloroethylene>

⁵ ATSDR. 2014. Toxicological profile for Trichloroethylene (TCE) (Draft for Public Comment). Agency for Toxic Substances and Disease Registry (ATSDR). Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service. Internet <https://www.atsdr.cdc.gov/toxprofiles/TP.asp?id=173&tid=30>.

available evidence, we cannot exclude the relationship between TCE exposure and heart defects, and recommend a precautionary approach to continue with a more urgent and immediate response when TCE is the contaminant of concern and women of childbearing age are present.

Of note, we reviewed the reviewed the California Office of Environmental Health Hazard Assessment (OEHHA) document showcased in the argument by the ACC. The ACC provides a long quote from OEHHA,⁶ presenting this as the basis of OEHHA decision to “reject the findings” of TCE-related fetal heart malformations. We disagree with this characterization. In our review of this 2009 document, it appears that OEHHA thoroughly reviews the TCE/heart malformation literature, noting both strengths and shortcomings of this research, but the 2009 document does not present an independent conclusion or policy recommendation based on this review. Later, in a 2013 OEHHA *Request for Information*,⁷ OEHHA clearly states their determination that “*TCE appears to meet the criteria for listing as known to the State to cause reproductive toxicity under Proposition 65, based on findings of the U.S. EPA*” This reference goes on to detail their determination, on the basis of male reproductive toxicity and developmental toxicity:

“The critical effects identified as the basis for the chronic oral reference dose (RfC) in the TCE IRIS entry (U.S. EPA, 2011a) and the Toxicological Review (U.S. EPA, 2011b) include developmental toxicity manifested as increased fetal cardiac malformations in rats and developmental immunotoxicity in mice following prenatal exposure. This appears to meet the criterion in Section 25306(d)(1) that the chemical “has otherwise been identified as causing ...reproductive toxicity by the authoritative body in a document that indicates that such identification is a final action”.

We refer you to these OEHHA documents for more information. It should be noted that California’s review is focused on drinking water, not indoor air. With regard to ACC’s reference to conclusions made by the Indiana Department of Environmental Management (IDEM), ACC quotes a one-page memo from IDEM that concludes “an accelerated response [to TCE and fetal cardiac malformations] is not scientifically supportable based upon current information.” Although the ACC accurately quotes the memo, the memo provides no details or references supporting IDEM’s conclusion. Several other states, including Alaska, Massachusetts, New Jersey, Connecticut, Minnesota, and New Hampshire have revised their TCE action levels in response to the EPA assessment (reviewed by Clapp et al.⁸). We have not examined these other

⁶OEHHA. 2009. Public Health Goals for Chemicals in Drinking Water: Trichloroethylene. California Office of Environmental Health Hazard Assessment. Internet https://oehha.ca.gov/media/downloads/water/chemicals/phg/tcephg070909_0.pdf

⁷OEHHA. 2013. Request for Relevant Information: Trichloroethylene (TCE). California Office of Environmental Health Hazard Assessment. Internet <https://oehha.ca.gov/proposition-65/crnrr/request-relevant-information-trichloroethylene-tce>.


⁸Clapp B, Frost DJ, Kray SE. 2016. Environmental Law News (25)31-39. Internet https://files.skadden.com/sites%2Fdefault%2Ffiles%2Fpublications%2FThe_Evolving_Regulation_of_TCE_Vapor_Intrusion_Issues.pdf.

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state's revisions in detail, but are aware that the Wisconsin DNR regularly discusses these topics with other U.S. EPA Region 5 states. DHS is available to participate in discussions with other states as needed.

Thank you for the opportunity to comment on this topic. For further discussion, please contact Robert Thiboldeaux, robert.thiboldeaux@wi.gov, 608-267-6844.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jeffrey Phillips', with a long horizontal flourish extending to the right.

Jeffrey Phillips
Acting Director, Bureau of Environmental and Occupational Health

cc: Robert Thiboldeaux, PhD, Senior Toxicologist, BEOH
Roy Irving, PhD, Chief, Hazard Assessment Section, BEOH
Jonathan Meiman, MD, Chief Medical Officer, BEOH