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In The News

EPA Releases Final Health Assessment of TCE -- Results in Lower Screening Levels

*By: Robert A. Ettinger, Geosyntec Consultants
Edward L. Strohhahn Jr., Bingham McCutchen LLP*

On September 28, 2011, EPA released its final health assessment for trichloroethylene (TCE) to the Integrated Risk Information System (IRIS) database. The final health assessment may have significant implications for risk-based corrective action activities at chemical release sites where TCE is a chemical of concern. The toxicity assessment may lead to increases in risk estimates by a factor of 2 to 9 depending on the assumptions used and may lead to more costly cleanup requirements at sites where TCE has been released to soil or groundwater.

History and Process of EPA TCE Health Assessment

EPA’s TCE health assessment has been the focus of scientific study and political debate since EPA withdrew the previous TCE cancer assessment more than 20 years ago. In the absence of an EPA consensus toxicity factor, various state and federal agencies used provisional toxicity factors that sometimes differed by orders of magnitude. In its September 28, 2011 *News Release* announcing the final health assessment, EPA noted that the assessment “has undergone several levels of peer review including, agency review, interagency review, public comment, external peer review by EPA’s

in January 2011, and a scientific consultation review in 2006 by the National Academy of Sciences.” EPA reported that the final health assessment addresses the comments EPA received.

EPA’s Uses of the TCE Health Assessment

In the *News Release*, EPA announced that the TCE toxicity values in the assessment “will be considered” by EPA in:

- “Establishing cleanup methods at the 761 Superfund sites where TCE has been identified as a contaminant.”
- “Understanding the risk from vapor intrusion as TCE vapors move from contaminated groundwater and soil into the indoor air of overlying buildings.”
- “Revising EPA’s Maximum Contaminant Level for TCE as part of the carcinogenic volatile organic compounds group in drinking water, as described in the agency’s drinking water strategy.”
- “Developing appropriate regulatory standards limiting atmospheric emissions of TCE -- a hazardous air pollutant under the Clean Air Act.”

EPA noted that the final health assessment provides “federal, state, local and other policy makers the latest scientific information to make decisions about cleanup and other actions to protect people’s health.”

Key EPA Findings

Key findings of EPA’s TCE toxicity assessment are:

- EPA strengthened its confidence in the conclusion that TCE causes cancer in humans;
- EPA determined that TCE causes reproductive effects, specifically threats to developing fetuses;
- EPA found that TCE causes non-cancer effects to the nervous system, kidneys, liver and immune system; and
- EPA identified a mutagenic mode of action for kidney cancer. EPA may include additional safety factors to account for risks when children are exposed to TCE.

Screening Levels Based on the New TCE Toxicity Values

To illustrate the effect of the new TCE toxicity values on cleanup levels, a comparison of current and expected revised screening levels are shown in the table below. This table includes the June 2011 EPA Regional Screening Level and a range of revised screening levels calculated following the potential EPA methodologies and revised toxicity criteria. The screening levels listed in the table are for illustration and are not published regulatory guidance values.

	Residential Screening Level			Commercial /Industrial Screening Level	
	Soil mg/kg	Ambient Air $\mu\text{g}/\text{m}^3$	Tap water $\mu\text{g}/\text{L}$	Soil mg/kg	Ambient Air $\mu\text{g}/\text{m}^3$
Current Values	2.8	1.2	2	14	6.1
Revised Values	0.4 – 1.3	0.2 – 0.6	0.2 – 0.7	~6	~3
Potential Factor De-	2 to 7 fold	2 to 6 fold	3 to 9 fold	2 fold	2 fold

*Screening levels computed only for a cancer endpoint assuming one in one million target risk threshold.
* Current Value/Revised Value.*

Note that a range of revised screening levels has been reported. This is the result of different technical approaches to address the mutagenic mode of action for TCE .

The table above does not include soil vapor and groundwater screening levels for the vapor intrusion pathway. A wide range of values for the vapor intrusion pathway have been published by different state cleanup programs due to different assumptions made by the different regulatory programs. However, because the EPA TCE health assessment does not affect the vapor intrusion fate and transport of TCE (commonly referenced as attenuation factors), the soil vapor and groundwater screening levels for the vapor intrusion pathway will scale directly with the changes to the indoor air screening level. Consequently, the soil and vapor groundwater screening levels for the vapor intrusion pathway may be decreased by a factor of approximately 2 to 6.

Potential Regulatory Implications of the New TCE Toxicity Values

IRIS health assessments present the results of scientific analyses but are not regulations. Because the IRIS assessments are the product of an extensive, rigorous, peer reviewed scientific process, of an extensive public review and comment process, and of a broad interagency review process, the recently published EPA TCE toxicity factors may

have the following potential regulatory implications.

- Formal risk assessments for site cleanup typically utilize current toxicity factors. Therefore, these new IRIS toxicity factors for TCE are likely to impact risk assessments. The new toxicity factors may result in increases in risk estimates by a factor of 2 to 9.
- Maximum Contaminant Levels (MCLs) for drinking water are not solely health-based and take other factors into consideration such as technological factors and practical quantitation limits (PQLs). The TCE MCL was last reviewed in 2010 and the next review cycle would be 2016, unless USEPA decides to perform an interim update based on analytical or other considerations.
- State and/or federal rules or guidance documents may be updated over varying timeframes to reflect the revised toxicity factors.
 - * The USEPA Regional Screening Levels are updated approximately two times per year, so these are



likely to be among the first to be updated (expected December 2011).

- * The time frames for modifications to screening levels in state cleanup programs are expected to be variable. To a large degree, modifications to state screening levels will depend on state policy and whether screening levels are published in guidance or regulation (guidance documents can likely be modified more quickly than regulations).
- Vapor intrusion investigations are likely to be affected. For example:
 - * Lower soil vapor and groundwater screening levels will likely lead to more detailed vapor intrusion assessments including indoor air sampling at more release sites.
 - * Revised indoor air screening levels for TCE may be more difficult to distinguish from background concentrations of TCE. EPA has reported indoor air background concentrations (i.e., concentrations in residences not affected by vapor intrusion) for TCE ranging from 1.1 (median) to 2.1 (90th percentile) ug/m³, and these values are higher than the expected revised indoor air screening levels.)

Conclusion

As noted above, EPA's final TCE toxicity health assessment is the product of more than 20 years of development involving extensive participation, review and comment by the scientific community, regulatory agencies, and public stakeholders. The TCE health assessment may lead to increases in health risk estimates for TCE exposures by a factor of from 2 to 9. These increased risk estimates may have important regulatory implications for on-going and future site remediation in addition to potential reopeners at closed sites.

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HAPPY HOLIDAYS FROM EBA HEADQUARTERS!

*We wish each of you
happy holidays, Merry
Christmas and Happy
New Year. We look
forward to seeing each
of you over the course of
2012, either in Santa Fe,
NM in January or in
Newport, RI in June
2012.*

