Editor's Perspective—The Controversy Surrounding Screening Levels for Trichloroethene and Other Chlorinated Solvents

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Risk-assessment science is a critical tenet of the remediation industry, as it is the underlying basis of the majority of cleanup work performed. However, risk-assessment science is, for the most part, poorly understood by a large portion of environmental professionals. Most seasoned professionals understand the basic risk-assessment concepts related to the dose-response and exposure duration principles that determine the difference between a cleanup suitable for residential and commercial/industrial land uses. However, the underlying science of how toxicological factors used in risk-assessment equations are calculated is lost on most remediation professionals. To be fair, this is because toxicology is a complicated field and remediation professionals do not have control over the risk factors; therefore, the "need to know" is somewhat limited.

Toxicologists and risk assessors evaluate potential chemical exposures at hazardous sites to: (1) determine the potential risks posed by a site and, thus, whether cleanup is warranted and (2) derive cleanup levels that are protective of human health and the environment, typically, with a focus on human health because, at most sites, that is what drives the cleanup (although ecological risks are beginning to be examined more carefully). When examining the equations used by risk assessors to determine the potential risks at hazardous sites, it becomes clear that the toxicity factors used are critically important, and can result in a swing of a cleanup level by several orders of magnitude. However, toxicity factors are under constant review by the U.S. Environmental Protection Agency and state regulatory agencies, as new studies are published and the review of existing studies is completed. An excellent example of this is related to the toxicity factors for chlorinated solvents, notably trichloroethene (TCE), which has undergone intense review and evaluation in the last decade. Recently, the US EPA formed a task group to address the most recent TCE risk assessment and, concurrently, several states are moving forward with developing specific policies that are affecting remediation projects at sites with TCE and other types of chlorinated solvent contamination.

In this Editor's Perspective, the development of toxicity values for TCE and other chlorinated solvents is explored. However, before delving into a specific discussion regarding the risks from exposure to chlorinated solvents, the overall process of calculating screening levels for carcinogenic chemicals is explained to clarify some of the risk-assessment magic. Then, the discussion focuses on the development of risk-based

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values for several chlorinated solvents, including the controversial events relative to establishing risk-based values for TCE. The focus of this column is primarily related to inhalation risk in order to not cloud the discussion with too many numerical values; however, the discussion would be remarkably similar for other exposure-related risks.

UNDERSTANDING HOW RISK FACTORS ARE USED TO CALCULATE CLEANUP LEVELS

From a professional perspective, the risk-assessment process is generally not well understood by engineers, geologists, and environmental scientists involved in site investigation and cleanups. Typically, the concentration of the chemical found at the site is compared to an established table of generic cleanup values, often referred to as "lookup tables." However, if the regulatory program has not established generic values or if the site conditions do not fit into one of the default scenarios used to develop the generic cleanup values, a risk-assessment scientist performs a risk assessment to develop cleanup levels. The risk assessor examines the property, current and future exposure pathways (including routes of exposure, e.g., ingestion), and the chemicals of concern. Following a process established by the US EPA Superfund program, defined in a document called "RAGS" (Risk Assessment Guidance for Superfund), the risk assessor determines the cleanup levels using some relatively standard equations and accepted toxicity values for the chemicals. This process has a certain magical "Voilá!" to it as the risk assessor emerges from behind a black curtain with cleanup levels used to guide remediation projects.

The risk-assessment process followed by the risk-assessment scientist is a relatively straightforward, methodical process. Although there is some flexibility in some of the input parameters for the site exposures, for the most part the calculations are routine. However, the toxicity values input into the equations can have a profound affect on the cleanup levels derived from the process. As described below, changes in the toxicity levels established by the US EPA or state regulatory agencies can significantly shift the cleanup levels. For groundwater cleanups driven by drinking-water standards, the industry is not significantly affected because the maximum contaminant levels established by the US EPA under the Safe Drinking Water Act are generally the default parameters (for most federal and state sites, although some states vary groundwater cleanup levels as well). However, changes in toxicity values that affect soil and indoor-air-based cleanup levels are under way for two key chlorinated solvents, TCE and tetrachloroethene (PCE). Changes in the risk values will result in changes in the cleanup levels established for soil exposures and vapor-intrusion risks, resulting in more of a moving target for remediation professionals.

OVERVIEW OF HOW RISKS ARE DEFINED

Chlorinated solvents, including TCE, pose a risk related to both carcinogenic and noncarcinogenic risks. For TCE and many other chlorinated solvents, the carcinogenic risks are deemed to pose a greater risk than the noncarcinogenic risk and, thus, for the purposes of this discussion, only carcinogenic risks are explored. In developing cleanup standards for carcinogens, the key input parameter is related to the amount of the chemical that can be inhaled or ingested over a designated period of time without posing an unacceptable risk of developing cancer. A common bright line for defining

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unacceptable potential carcinogenic risks is one in one million (one person out of one million exposed would, theoretically, develop cancer). This risk level is referred to as the 1×10^{-6} risk level. The controversial input parameter that drives this risk is the dose that results in a measurable cancer risk, typically referred to as the cancer slope factor. In RAGS, the US EPA defines the cancer slope factor as:

> A plausible upper-bound estimate of the probability of a response per unit intake of a chemical over a lifetime. The slope factor is used in risk assessments to estimate an upper-bound lifetime probability of an individual developing cancer as a result of exposure to a particular level of a potential carcinogen. Slope factors should always be accompanied by the weight-of-evidence classification to indicate the strength of the evidence that the agent is a human carcinogen. Oral slope factors are toxicity values for evaluating the probability of an individual developing cancer from oral exposure to contaminant levels over a lifetime. Oral slope factors are expressed in units of $(\text{mg/kg-day})^{-1}$.

With respect to inhalation, the current US EPA methodology to calculate inhalation risks uses the concentration of the chemical in the air as the exposure concentration instead of the mass of the chemical inhaled on a per body weight basis. The concentration-based inhalation risk assumes a standard inhalation rate and body weight. The resultant inhalation toxicity factor, called the inhalation unit risk (IUR), is defined by the US EPA in its Integrated Risk Information Web site (www.epa.gov/iris/help.gloss.htm) as:

> The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 $\mu g/m^3$ in air. Inhalation unit risk toxicity values are expressed in units of $(\mu g/m^3)^{-1}$.

Regardless of whether the slope factor or inhalation unit risk is being considered, the higher the value, the greater the cancer risk. Likewise, the higher the slope factor or IUR, the lower the cleanup level that will be calculated through the risk-assessment process.

Although the determination of slope factors and IUR is generally based on relatively complex toxicological concepts, the cleanup-level calculation is a relatively straightforward spreadsheet calculation involving the average daily exposure that will yield an acceptable risk of 1×10^{-6}, 1×10^{-5}, or 1×10^{-4}, depending on the regulatory program guiding the cleanup. Obviously, the 10^{-6} risk levels are more stringent and generally employed for residential cleanups, whereas the 10^{-5} and 10^{-4} levels are often used for commercial and industrial cleanups.

ISSUES RELATED TO TRICHLOROETHENE AND OTHER CHLORINATED SOLVENT CONTAMINANTS

Trichloroethene is a particularly prickly subject when it comes to the calculation of toxicity factors. Without getting into too many complex details, there are several modes whereby the toxicity factors can be calculated and various safety factors that can be employed, and the differences are important. The most recently proposed toxicity factor for TCE is based on human epidemiological research related to kidney cancer and is supported by animal studies. The importance of the toxicity factors for TCE is increased because the chemical is likely the most prevalent chlorinated solvent at hazardous sites (excluding dry cleaning sites), it is relatively volatile, and it is a carcinogen for both the ingestion and inhalation exposure routes. In addition, the toxicology of the chemical is

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Exhibit 1. Timeline of US EPA developments regarding TCE toxicity values

August 2001	The US EPA released an "External Review Draft Trichloroethylene Health Risk Assessment: Synthesis and Characterization" for public review and comment.
December 2002	The US EPA's Science Advisory Board released an independent peer review report, "Review of Draft Trichloroethylene Health Risk Assessment: Synthesis and Characterization: An EPA Science Advisory Board Report."
February 2004	The US EPA hosted a "Symposium on New Scientific Research Related to the Health Effects of Trichloroethylene" held in Washington, D.C.
September 2004	The National Academy of Science (NAS) initiated the project "Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues" under sponsorship of the US EPA and other federal agencies.
February 2005	The US EPA submitted four TCE issue papers on key scientific issues to the National Academy of Science (NAS).
July 2006	The NAS released the report "Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues Consultation."
January 2009	The US EPA releases "Interim Recommended Trichloroethylene Toxicity Values to Assess Human Health Risk and Recommendations for the Vapor Intrusion Pathway Analysis" (later revoked).
September 2009	The US EPA hosted an interagency science discussion on the review of the draft "Toxicological Review of Trichloroethylene."
October 2009	The US EPA Science Advisory Board (SAB) releases October 22, 2009 *Federal Register* notice requesting nominations of experts for the SAB TCE Review Panel.
November 2009	The US EPA releases the External Review Draft for public review and comment.
December 2009	The US EPA announces listening session to be held on January 26, 2010, in a December 21, 2009 *Federal Register* notice; more details can be found in a prior release in the December 11, 2009 *Federal Register* notice.
January 2010	The SAB releases the names and biosketches of the "Short List Candidates" for the upcoming TCE Review Panel.

The above information (except the January 2009 entry) was downloaded from http://cfpub.epa.gov/ncea/CFM/recordisplay.cfm?deid=215006 on January 18, 2010.

constantly being reviewed, and there seems to be an ongoing debate over what exposure levels pose a risk. In other words, the scientific and regulatory communities are having a difficult time agreeing on the acceptable risk levels used to calculate the slope factors and IURs for TCE.

As mentioned above, there is considerable debate over the risks associated with TCE, and the US EPA and the scientific community continue to explore its risks. A timeline of the various decisions related to inhalation risks associated with TCE is presented in Exhibit 1. As shown in this exhibit, the TCE toxicity values for inhalation (the IUR for inhalation) have been altered over time. Due to the controversy surrounding TCE risk factors, the US EPA has been hesitant to establish toxicity factors for this chemical. In fact, in January 2009, the US EPA issued interim toxicity values that were then quietly withdrawn in April 2009.

The most recent development related to TCE suggests that the US EPA is approaching a decision on the accepted slope factor and IUR for TCE. On November 3, 2009, the US EPA released the Toxicological Review of Trichloroethylene (External Review Draft). This document proposes an updated IUR of 4×10^{-6} $(\mu g/m^3)^{-1}$ for TCE. This value predicts that TCE is more carcinogenic (higher IUR) than the IUR of 2×10^{-6} $(\mu g/m^3)^{-1}$ currently listed as the US EPA Regional Screening Levels (these levels

Exhibit 2. TCE inhalation screening levels

Document	TCE IUR $(\mu g/m^3)^{-1}$	TCE Residential Screening Level $(\mu g/m^3)$	TCE Commercial Screening Level $(\mu g/m^3)$
Existing US EPA Regional Screening Level	2×10^{-6}	1.2 $\mu g/m^3$	6.1 $\mu g/m^3$
Draft US EPA Toxicological Review	4×10^{-6}	0.6 $\mu g/m^3$	3.1 $\mu g/m^3$

were established by the California EPA but have been adopted as screening levels by the US EPA on an interim basis).

Based on the residential and commercial toxicity values and the standard default equations used by the US EPA, the inhalation screening levels for TCE in Exhibit 2 were developed based on both the existing and proposed IUR.

As shown in Exhibit 2, the vapor-intrusion screening level for TCE, based on the proposed US EPA toxicity value, would result in a 50 percent reduction from the existing Regional Screening Level, which was based on the California EPA toxicity values. To put this in perspective, the US EPA routinely collects background data on TCE and other chemicals and compiles the information in a database. The data from 2006, summarized in the US EPA Toxicity Report for TCE, are from 258 outdoor air monitoring points in 37 states. The data show a mean TCE concentration of 0.23 $\mu g/m^3$ and standard deviation of 0.55. The range of TCE concentrations detected in ambient air samples was 0.03 to 7.73 $\mu g/m^3$, with a mean of 0.13 $\mu g/m^3$. Thus, the potential range of TCE for ambient air clearly includes the screening-level concentration. This suggests that the screening level at many sites will essentially be background and underscores how stringent the screening levels are and the critical importance of collecting background ambient air-quality data for all vapor-intrusion studies involving TCE (and many other carcinogenic chemicals with high toxicity values).

The US EPA intends to review the draft Toxicological Review of TCE with rigor. There was a public comment period that ended on February 1, 2010. In addition, the US EPA's Scientific Advisory Board requested the nomination of experts to form an *ad hoc* panel to review the Toxicological Review that was published in a *Federal Register* notice on October 22, 2009. The *Federal Register* notice announcing the *ad hoc* panel did not provide a time frame for the panel's review; however, the period for nominations ended on November 12, 2009, a mere three weeks following the *Federal Register* notice—suggesting that the Agency intends to move this review forward expeditiously.

TOXICITY VALUES FOR PCE AND OTHER CHLORINATED SOLVENTS

For the most part, the toxicity values for most chlorinated solvents other than TCE do not appear to be as highly debated a topic, although the values do drive the cleanup levels established for these chemicals. However, there is still some debate related to PCE. The most recent Toxicological Review for PCE was published in June 2008. This document proposed recommended IUR risk ranges for PCE of 2×10^{-6} to 2×10^{-5} $(\mu g/m^3)^{-1}$, which are considerably more stringent than the previous US EPA unit risk of 5.8×10^{-7}

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Exhibit 3. Carcinogenic toxicity values for commonly detected chlorinated solvents

Chemical Name	RfC $(\mu g/m^3)^{-1}$	Screening Value $(\mu g/m^3)$	Source
Trichloroethene (TCE)	2×10^{-6}	1.2	California EPA
Tetrachloroethene (PCE)	5.9×10^{-6}	0.41	California EPA
Vinyl chloride	4.4×10^{-6}	0.16	US EPA
Methylene chloride	4.7×10^{-7}	5.2	US EPA
Chloroform	2.3×10^{-5}	0.11	US EPA
1,1-Dichloroethane	1.6×10^{-6}	1.5	California EPA
1,1,2,2-Tetrachloroethane	5.8×10^{-5}	0.042	US EPA

Source: US EPA Regional Screening Level Table, downloaded from http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/index.htm on January 18, 2010.

$(\mu g/m^3)^{-1}$. The California EPA IUR for PCE is 5.9×10^{-6} $(\mu g/m^3)^{-1}$, which is within the risk range of the US EPA Toxicological Review and is the basis of the Regional Screening Level currently published by the US EPA. However, if the proposed US EPA IUR ranges are adopted and the IUR used for risk assessments becomes the upper bound of the risk range, the inhalation Regional Screening Levels could become more than three times more stringent than the current Regional Screening Levels. The current residential Regional Screening Level for PCE is 0.41 $\mu g/m^3$; thus, the level could decrease to below 0.15 $\mu g/m^3$.

The majority of the other chlorinated solvents do not appear to have toxicity values as controversial as TCE and PCE and, for the most part, were established in the late 1990s or early 2000s. A list of several carcinogenicity-related toxicity values for chlorinated solvents that are frequently detected at hazardous sites is provided in Exhibit 3. As indicated in the exhibit, the toxicity values tend to vary widely, which reflects the differing risks based on toxicological studies.

SUMMARY

There are a couple of important points relative to the above discussion:

- As described earlier, the risk factors for TCE and PCE are under review and the proposed changes could decrease screening levels and, ultimately, cleanup levels for both chemicals. The levels could easily approach ambient background criteria, which then could become the cleanup levels.
- The Regional Screening Levels were developed as screening levels based on default scenarios for exposure duration, body weight, and inhalation rates and do not consider any type of engineering or institutional controls. Although often adopted as cleanup levels, a risk assessor and remediation professional can work together to develop cleanups with different exposure scenarios and cleanup levels that are less stringent (higher) than the Regional Screening Levels.
- The proposed US EPA toxicity factors for TCE and PCE are under review, as they have been in the past, and are subject to revision. These proposed values should not

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> be relied on until the US EPA issues a notice that these values, or some derivation of these values, are to be used in risk assessments.

The US EPA's review of the proposed risk factors for chlorinated solvents, particularly for TCE and PCE, will be an important development relative to future site cleanups and, as described, could lower the cleanup levels to ambient background concentrations.

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