Practical Guidance for Contaminated Sites: Trichloroethylene (TCE) Risk Assessment Case Study

Webcast Agenda and Topic Summary: November 4, 2013 1-5 PM

Moderator: Ed Pfau
HULL, Dublin, Ohio

1:00-1:15 Introduction

Oliver Kroner
Alliance for Risk Assessment

A summary of the purpose and general process used by the Alliance for Risk Assessment (*ARA*) to evaluate and develop practical application guidance for risk assessors and contaminated site managers when addressing risks from non-cancer exposure. The case example used here is the Reference Concentration (RfC) for Trichloroethylene (TCE) established by USEPA in the Integrated Risk Information System (IRIS) in September 2011 as it relates to the evaluation of indoor air exposures, and remedial decisions regarding the vapor intrusion pathway. Overview of the formation of a coalition of interested parties through the *ARA* whose purpose was to develop guidance that could be used by risk managers for evaluating actionable TCE exposure risk and clean-up standards in site closure. These efforts included a comprehensive evaluation of the uncertainty and imprecision inherent in the development of the RfC and other meaningful considerations. This framework for evaluating exposures based on the RfC for TCE may serve as a model for the evaluation of the non-cancer endpoints associated with exposures to other chemicals, particularly when the Reference Dose (RfD) or RfC is based on probabilistic models which predict effects in a human population at doses or concentrations below the level of observed effects in the test population.

1:15-2:30 Practical Application Overviews

Rod Thompson
Alliance for Site Closures, on the U.S. State perspective

Lenny Siegel
Center for Public Environmental Oversight, on the Risk Communication & Management perspective

Tania Onica
Ontario Ministry of the Environment, on the Community/Public perspective

Dr. Helen Dawson
Geosyntec Consultants, Inc., on the Consultant perspective

David Gillay
Barnes & Thornburg LLP, on the Business perspective

This session presents specific issues describing the practical difficulties faced by state and federal project managers, public health officials, industrial hygiene officers, business leaders and the general public in understanding and applying the RfD or RfC for TCE. This experience may serve as a model for the evaluation of non-cancer effects based on environmental exposures to other chemicals. For TCE in particular, the USEPA RfC poses important considerations for short-term, medium-term and long-term exposures, even at very low environmental concentrations. For example, residential indoor air screening levels developed on the basis of the RfC and default exposure assumptions are at the upper end of reported indoor air background levels of TCE in common household settings. Acceptable indoor air exposure levels are the starting point for determining groundwater and soil gas screening levels in the burgeoning field of vapor intrusion. All of these factors complicate the implementation of effective remedial measures by responsible parties and public agencies. The inclusion of the fetal cardiac malformation endpoint in the derivation of the RfC for TCE has heightened awareness and concern about the assessment of developmental effects to potentially affected receptor populations, including families at home and employees in the workplace. The incorporation of developmental effects in the evaluation of acceptable long-and short term exposures introduces significant complications with exposure assessment, including not only the determination of the exposure intake or exposure concentration of the receptor population, but also the frequency and duration of exposure which might also elicit the developmental toxic response.

Also discussed will be the growing uncertainty and inconsistent approaches within and between several federal agencies, US EPA regional offices, and the States. This has the potential to create disparity among the agencies, and the risk managers and public health officials who represent them, regarding safe indoor air concentrations in the home and the work place. This disparity has the potential to slow down site closure, increase cleanup costs, and curtail brownfield redevelopment projects. Consequently, effective risk communication to homeowners, employees, business owners and other concerned individuals about the potential health risks has proven to be challenging, emphasizing the importance of stakeholder education and community outreach. Stakeholder education and outreach is particularly critical in a vapor intrusion (VI) investigation and assessment. The toxicology of VI is perhaps the most challenging aspect of this communication, partly because most VI practitioners are engineers or environmental scientists, and partly because the uncertainty surrounding a toxicity value, and its use in risk-based screening, assessment, and action, has been poorly characterized in the terms of the site decisions it is intended to support. Presentation will address the need to understand and communicate the differences between screening and cleanup and/or mitigation, how toxic effects are considered in developing current screening and cleanup levels and the need for clear decision points when making action decisions on exposure levels.

2:30-3:00 Range in the Non-cancer RfD/C: TCE as a case study

Michael Dourson
Toxicology Excellence for Risk Assessment (TERA)

This session presents an analysis of the uncertainty and imprecision in RfD and RfC generally, and the quantitative development of a dose or concentration range which can be used to assist risk managers in understanding TCE exposure and risk, specifically. Based on readily available information from USEPA and elsewhere, the uncertainty and imprecision implicit in the RfC for TCE indicates that the point value RfC of 2 $\mu g/m^3$ is associated with a range of 3 $\mu g/m^3$ to 20 $\mu g/m^3$, based on the evaluation of several endpoints (*i.e.*, decreased thymus weight in female rats, fetal heart malformations in rats, and toxic nephropathy in female rats). When site-specific exposures are primarily below this range, then the probability of inducing any noncancer effects in the exposure population is low and the priority for any management action is reduced. In contrast, when the exposures are primarily above this range, then the probability of inducing noncancer effects is higher and the priority for risk management action is increased.

An in-depth look at how this range was developed and the methods used to determine this range are shown, which can also be used to develop similar guidance for other chemicals. For TCE specifically, USEPA (IRIS) developed the RfCs by using probability-based models in several critical steps of the process. These probability based models and the limitations on how they are applied create a fundamental shift in the way the RfC is now derived and used. The use of the probabilistic models makes the new RfC derivation more similar to how the cancer Inhalation Unit Risk is derived and used. The new "RfC derivation process" necessitates a new non-cancer probability based application in risk assessments, similar to the methods commonly used to evaluate the probability of increased excess lifetime cancer risks.

3:00-3:30 Webinar Questions

Participants

3:30-4:30 Developmental Toxicity

Calvin C. Willhite
Chair
Risk Sciences International

Edward W. Carney
Speaker
The Dow Chemical Company

Linval Depass
Panelist
Durect Corporation

Stephen B. Harris
Panelist
Stephen B. Harris Group

Melissa Marr
Panelist
RTI International

The process USEPA recently used for incorporating a developmental study in the derivation of the TCE RfC will be explored relative to past USEPA developmental guidance policy and the common science understanding of developmental risk. One of the studies USEPA used had a developmental toxicity endpoint, fetal heart malformation. Risk Assessment and Risk Management decisions regarding TCE non-cancer toxicity must now consider developmental toxicity. There is considerable national science and science policy debate regarding the use of the developmental study in the derivation of the RfC. This has resulted in widely variable approaches to what exposure levels would constitute actionable acute and chronic risk, and how to assess exposure levels in the field that can be used to determine risk. The science and science policy of how to address and assess developmental toxicity will be presented.

4:30-5:00 Webinar Questions

Participants