

Smart Data. Smarter Workflow.

The TCE Revolution and Its Permanent Impact on Environmental Due Diligence

June 24, 2015



TODAY'S SPEAKERS

MODERATOR:

Dianne Crocker, Principal Analyst, EDR Insight



PRESENTERS:

- **David Gillay, Partner and Chair of Brownfields & Environmental Transactional Diligence Practice Areas, Barnes & Thornburg LLP**
- **Dr. Michael Dourson, Ph.D., Alliance for Risk Assessment**





The TCE Revolution & Its Permanent Impact On Environmental Due Diligence

EDR Insight: Legal & Practical Perspective

National Webinar: June 24, 2015

David R. Gillay, Esq.

Overview

- TCE Toxicity & Its Dramatic Ripple Effect
 - IRIS update (2011; final change to late 1980s)
 - ATSDR (2015; draft change to 1997 Toxicity Profile)
 - Harmonizing national approach?
- Transactions & Redevelopment Impacts
 - Due Diligence + increase of potential sites
 - US EPA Final VI Guidance (June 2015)
- Some common Q&A to help manage risk/liability

Toxicity Revolution

- TCE – most common groundwater contaminant
- 2011 TCE IRIS assessment – represents EPA's official scientific position and preferred source of HH tox values
- Lowered non-cancer inhalation toxicity value (reference concentration [RfC]) from 10 ug/m³ to 2 ug/m³
- Paradigm Shift – non-cancer endpoint drives risk at a single exposure and there are only bright lines ...
- *Regulators were not prepared for this ...*

Toxicity Revolution

- “RfC is an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.”
- RfC is based on developmental toxicity endpoint of increased incidence of fetal cardiac malformations (rat).
- This concern has created short term exposure issues during 21-day gestational period.

National Landscape

- During EPA HQ science policy update for TCE concerns and lack of guidance with the developmental non-cancer endpoint = divergent approaches impacting transactions.
- Many States [MA, MN, CT, NJ] have adopted short-term action levels ranging from 2 – 60 ug/m³
- US EPA Regions 9, 10 have published guidelines for accelerated and urgent responses
- Recommended time-frames for action may be immediate evacuation or within 21 days (developmental)
- Inconsistent methodologies to sample, monitor, assess

Toxicity Revolution

- Aug 2014 EPA HQ Position on TCE short-term exposure:
 - “the RfC for a single exposure hasn’t been determined yet by EPA.”
 - “2 ug/m³ in indoor air is expected to be a reasonable maximum exposure condition for a continuous chronic exposure to prevent risk of adverse health effects during a lifetime ...”
- June 2015 EPA Final VI Guide : “EPA IRIS does not have short term or acute exposure toxicity values ... EPA will work to develop expanded policy direction to address short-term exposures ... ”
- However, uncertainty and concerns prevail.

Harmony? - ATSDR's Ongoing Efforts

- ATSDR: Proposed Updated Toxicity Profile for TCE (Oct. 2014)
- Federal statutes mandate updates (TCE; 1997)
- Local public health officials use; EPA Hierarchy
- Toxicity Profiles establish estimates of exposure levels posing minimal risk to humans (MRLs)
- ATSDR provides acute (up to 14 days), intermediate (15-364 days), and chronic (365 +) MRLs

ATSDR (cont'd)

- ATSDR proposes to use the same RfC (2 ug/m^3) for both chronic and intermediate inhalation exposure
- ATSDR's past Health Consultation (2013) and Public Health Assessment (2013) determined an IIMRL at 21 ug/m^3
- Comment Period closed April 10, 2015 (3 comments)
 - American Chemistry Council
 - Halogenated Solvents Industry Alliance, Inc.
 - B&T, Prof. Thompson, & the Alliance for Risk Assessment
- Issues: Single exposure, response actions, sampling methodologies, frequencies, durations ...

New Due Diligence Standard

- New Phase I ESA effective October 6, 2015
- US EPA's assertions on "vapor" in Phase I ESA

"The scope of the AAI Rule and ASTM E1527-05 standard always included the requirement to identify all indications of releases and threatened releases of hazardous substances or 'recognized environmental conditions (RECs)', including indications of vapor migration or vapor releases." (79 FR 60088, October 6, 2014).

- ASTM's companion 'Vapor Encroachment Condition'
 - Search distances (all cardinal directions)
 - Increased Transactional scrutiny with File Reviews

Vapor Shroud Has Fallen

- June 11, 2015 US EPA unveiled its Final VI Policy
- Incorporates responses to certain VI topics that received substantive public comments (Table 1-3)
- Updated VISL Calculator (2015) (added 50+ chemicals including PCBs, some cPAHs, and 1,4 dioxane)
- VI Inclusion Zone (100 + or -)

Vapor Shroud Has Fallen

- Growing controversy and recent headlines about Occupational Exposure Limits and OSHA
- VI CSM and sampling recommendations
- Pre-emptive VI Mitigation + OM&M
- Paves way for rulemaking effort to add VI to HRS for new Superfund Sites

Redevelopment Issues with TCE/VI

- Brownfield Amendments (2002) add important landowner liability protections; can buy with knowledge of contamination and not be liable for cleanup but eliminate exposure (VI pathway)
- Threshold Test – Conduct All Appropriate Inquiry
 - new Phase I ESA Standard E1527-13
 - vapor migration/encroachment; state guidance; EPA policy
- Post- Closure Continuing Obligations
 - *Prevent or limit any human, environmental or natural resource exposure to any previously released hazardous substances.*

Continuing Obligations



Designation: E2790 – 11

Standard Guide for
Identifying and Complying With Continuing Obligations¹

Step 1

Review Phase I Findings for Whether Continuing Obligations Apply

Step 2

Review and Evaluate Environmental Conditions and AULs at the Property

Does a REC, ICs or LURs exist at the Property?

NO

YES

NO

No Continuing Obligations*

YES

Perform Continuing Obligations

Step 3

Perform Initial Continuing Obligations

Step 4

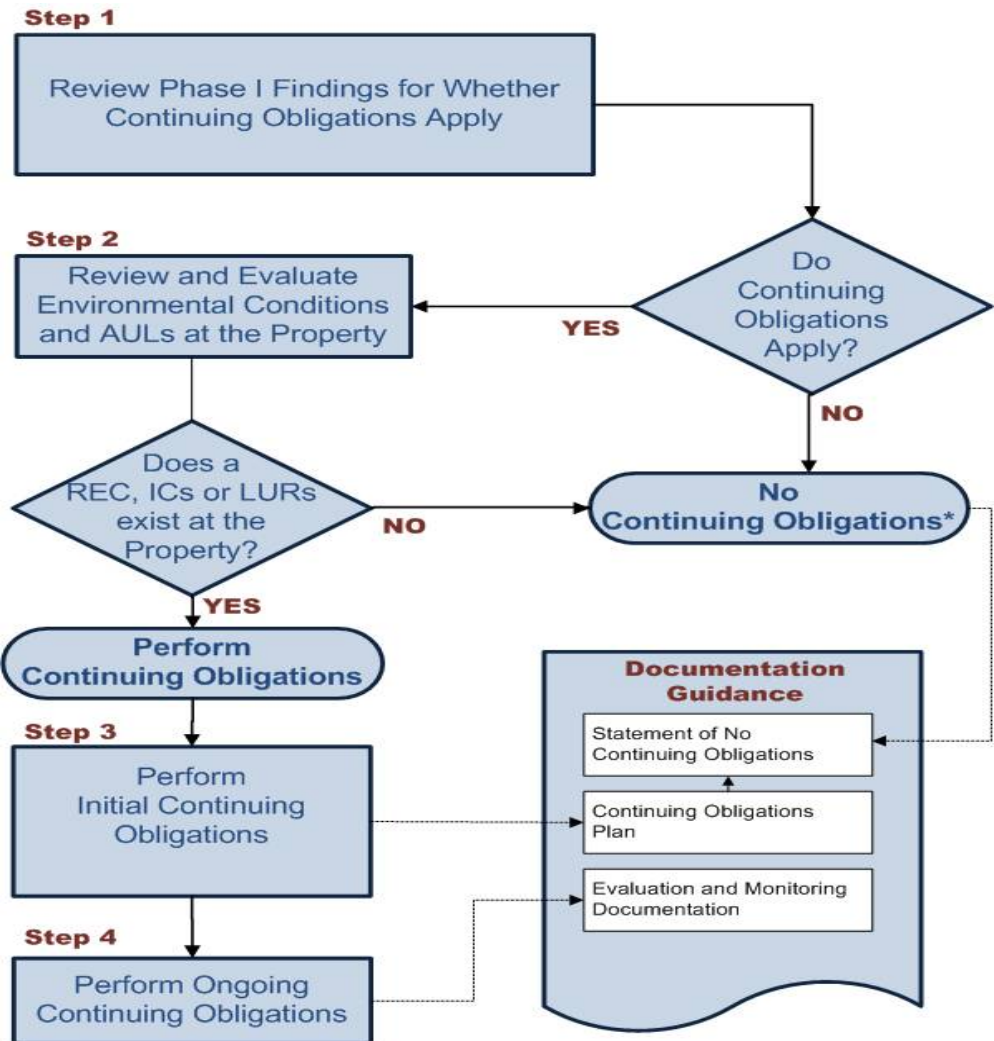
Perform Ongoing Continuing Obligations

Documentation Guidance

Statement of No Continuing Obligations

Continuing Obligations Plan

Evaluation and Monitoring Documentation



Analogous Guidance

- Long-Term Stewardship Studies & Initiatives
[www.epa.gov/landrevitalization/ltstf_report/appendixb.htm]
 - National Association of Attorneys General (NAAG) on Legal Handbook of Institutional Controls
 - Association of State & Territorial Solid Waste Mgmt Officials (ASTSWMO)
 - Interstate Technology & Regulatory Council (ITRC) – Issues of Long Term Stewardship: State Regulators' Perspectives (2004 + 2014/5 update)
 - Growing databases with sites where residual contamination is being managed with ICs

Frequent Q&A

- *Does TCE in groundwater constitute a VEC and/or a REC?* **probably, but...**
 - VI GWSLs at 2 ug/m³ is basically the TCE MCL (5 ug/l)
 - Whether a pVEC, VEC, REC, data gap, etc. depends on multiple factors and professional judgment of the EP
 - Need a multi-disciplinary decision team
 - Depends where the TCE was sampled in the aquifer
 - Depends on soil stratigraphy
 - Receptor survey, property uses

Q&A

- *How should an EP manage variability with short-term standards in multi-state transactions?*
 - Consult with an experienced developmental toxicologist
 - Develop a QAPP – key tool to document type and quality of data needed to make decisions and to describe the methods for collecting and assessing the quality and integrity of the data
 - Integrate DQOs in the QAPP with a VI decision Matrix with regulatory buy-in
 - Discuss your client's risk tolerances/preference for sampling/analysis vs PEM (have these discussions early and include LTS/CO)

Q&A

- *What steps can an EP take to minimize exposure to potential liability?*
 - Consult with an experienced developmental toxicologist
 - Educate staff and clients on short-term exposure issues with TCE and the disparate, divergent national approaches
 - Develop consistent policies for addressing vapors in the Phase I
 - Determine if your firm wants to continue to conduct Phase Is
 - Update your Firm's General Terms & Conditions
 - Increase policy limits ...

Q&A

- *How should an EP communicate potential risk associated with TCE to clients?*
 - Carefully educate your clients. This is not a surprise; on 9/29/2011 it was evident where the TCE non-cancer risk was headed.
 - Given the uncertainty, consider steps to eliminate/reduce exposure [seal cracks, adjust HVAC, eliminate indoor sources, hybrid-SVE, passive, ASD]
 - Include the potential CO/LTS obligations and need for ICs
 - Contextualize – Radon, indoor background sources, etc.
 - Insurance products
 - For commercial/industrial land use, OSHA/EPA jurisdictional debate

Questions or Comments

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What the New Screening Levels Mean

- Historically, the cancer screening levels have always been the lowest values
- Users understood an acceptable cancer risk range as 1 in 10,000 to 1 in a million
- Users were able to understand risk above screening levels using this “risk range” and some level of flexibility between screening levels and long term remedy or closure levels was allowed based on this range

New Screening Levels (cont'd)

- Now, the non-cancer screening level is so low that it frequently trumps the cancer screening level
- There is little to no real science guidance on how to interpret the developmental risk of fetal heart malformations
- This has created a number of problems:
 - Most regulators do not understand anything about non-cancer risk
 - No national guidance is available on the meaning of the risk when exposure levels are above RfC

New Screening Levels (cont'd)

- This has created a number of problems (cont):
 - There does not appear to be any flexibility between screening and long term closure levels.
 - What is an appropriate short term exposure level given consideration of possible fetal heart malformations?
- Dr. Dourson leads an experienced workgroup to address these issues. Using well accepted USEPA guidance, it turns out we can define the non-cancer risk above the screening levels and there is significant flexibility in the closure levels.
- Now ... the Godfather of Toxicity

Defining the range of the reference dose: imprecision versus uncertainty. *Dourson ML*, Gadagbui B, Pfau E, Thompson R, Lowe J*



* *Alliance for Risk Assessment (ARA);
Toxicology Excellence for Risk Assessment;
Hull & Associates, Inc.; Alliance for Site
Closures; CH2M-Hill*

Hazard Range and Problem Formulation

- The development of a hazard range should help to address the following problems:
 - Hazardous waste site remedial objectives for chronic exposures
 - Communicating risk/hazard of exposure above RfC
 - Prompt/short term exposure action levels
 - Inform the confounding effects of assessing ambient background concentrations in air



TCE Residential Indoor Air Acceptable Exposure Levels

- Based on CalEPA values (2000)
 - HQ = 1: 630 $\mu\text{g}/\text{m}^3$
 - ELCR = 1×10^{-6} : 1.2 $\mu\text{g}/\text{m}^3$
 - ELCR = 1×10^{-5} : 12 $\mu\text{g}/\text{m}^3$
 - ELCR = 1×10^{-4} : 120 $\mu\text{g}/\text{m}^3$
- Based on US EPA IRIS (October 2011)
 - HQ = 1: 2.1 $\mu\text{g}/\text{m}^3$
 - ELCR = 1×10^{-6} : 0.48 $\mu\text{g}/\text{m}^3$
 - ELCR = 1×10^{-5} : 4.8 $\mu\text{g}/\text{m}^3$
 - ELCR = 1×10^{-4} : 48 $\mu\text{g}/\text{m}^3$

Risk Assessment and Risk Management

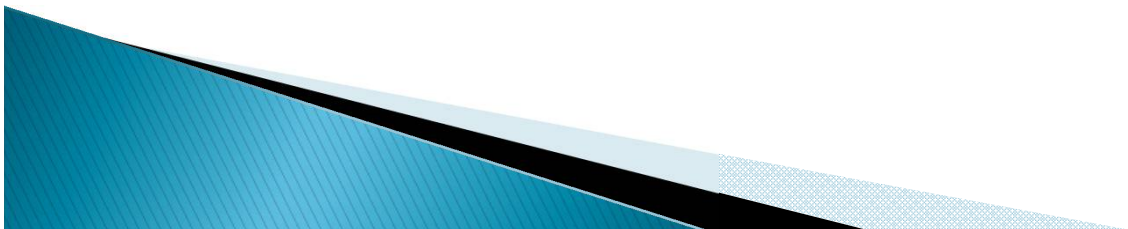
- ▶ Excess Lifetime Cancer Risk (ELCR)
Range: 10^{-6} to 10^{-4}
 - Provides risk managers flexibility to balance acceptable exposure levels with closure needs:
 - Technical feasibility
 - Implementability
 - Timeliness
 - Economic considerations
 - Cultural or other concerns
- ▶ **How may a similar evaluation be performed with respect to the non-cancer endpoint?**

Problem Response: Alliance for Risk Assessment (*ARA*)

- *ARA* TCE Workgroup formed in the Fall of 2012
 - Open invitation, broad interest and participation
 - Trichloroethylene (TCE) Risk Assessment Guidance for Contaminated Sites (April 2013)
 - Webcast: Practical Guidance for Contaminated Sites: TCE Risk Assessment Case Study (November 4, 2013)
 - Observers: over 300 scientists from multiple international organizations, including government, industry, academia and NGOs, on 6 conference calls and one webinar.

NAS (2014) & IRIS Process

- ▶ **“Finding:** EPA could improve documentation and presentation of dose-response information.
- ▶ **Recommendation:** EPA should clearly present two dose-response estimates: **a central estimate (such as a maximum likelihood estimate or a posterior mean) and a lower-bound estimate for a POD from which a toxicity value is derived.** The lower bound becomes an upper bound for a cancer slope factor but remains a lower bound for a reference value.” [emphasis added]



NAS (2014) & IRIS Process

- ▶ **"Finding:** IRIS-specific guidelines for consistent, coherent, and transparent assessment and communication of uncertainty remain incompletely developed. The inconsistent treatment of uncertainties remains a source of confusion and causes difficulty in characterizing and communicating uncertainty.
- ▶ **Recommendation:** Uncertainty analysis should be conducted systematically and coherently in IRIS assessments. To that end, EPA should develop IRIS-specific guidelines to frame uncertainty analysis and uncertainty communication. Moreover, uncertainty analysis should become an integral component of the IRIS process."

Reference Dose (IRIS)

- ▶ “The RfD (expressed in units of mg of substance/kg body weight-day) is defined as an estimate (**with uncertainty spanning perhaps an order of magnitude**) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.” [emphasis added]
- ▶ That is, the RfC/RfD is expected to be below the actual threshold for adverse effect in a sensitive subgroup.



Uncertainty vs. Imprecision

- Alternative interpretations:
 - Imprecision of a RfC is on both sides of the RfC. This is because a 2nd expert group might estimate a RfC higher or lower than the 1st group, if given the same information.
 - Uncertainty in a RfC, in contrast, lies mainly above the RfC. This is because RfCs are based on lower bounds on PODs and UFs are known to be protective.
 - For risk management decisions, uncertainty in the RfC is generally more important than imprecision.
 - Managers are interested in making decisions that protect public health and uncertainties in a RfC are generally more informative.

Hazard Range Development

- ▶ Hazard Range
 - Floor
 - Intermediate value (Midpoint)
 - Ceiling



Floor of the Hazard Range

- ▶ Identified as the RfC/RfD based on a single candidate value
- ▶ In the case of an RfC/RfD based on two or more candidate values
 - identified as the candidate RfC/RfD with the higher(est) confidence.
 - The reference value is not likely to change with further testing, except for mechanistic studies that might affect the interpretation of prior test results.
 - RfC could be modified if refined data are obtained to modify uncertainty factors – e.g., kinetic data for chemical-specific adjustment factors.



Floor of the Hazard Range

- ▶ The RfC/RfD is developed:
 - using UFs that are protective based on the observed behaviors of a typical toxicant
 - so that the RfC/RfD is an underestimate of the expected threshold value.
 - The floor of the hazard range may be denoted as a point below which risk managers are unlikely to recommend remedial action or exposure control.



Ceiling of the Hazard Range

- ▶ Is defined as the adjusted point of departure (POD_{adj})
- ▶ POD based on the critical concentration/dose of chosen study.
- ▶ Managers likely to take regulatory action above this ceiling since specific toxic effects can sometimes be seen.



Ceiling: Adjusted POD

- ▶ Adjustments for the dosing regime in the critical study, such as...
- ▶ Toxicokinetic differences between the test organism and humans
- ▶ Database quality, lack of NOAEL, and study duration; reductions are based on available data, or a factor of 3 used as a default for each area.
- ▶ The intent of these adjustments and reductions is to estimate the likely ceiling of the RfD/C by using the median value of the Ufs.



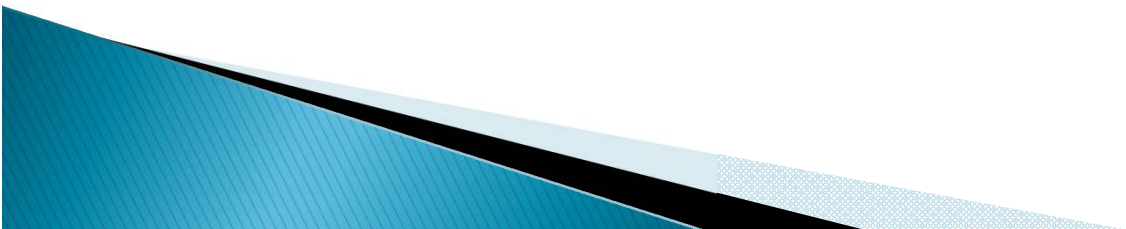
Midpoint of the Hazard Range

- ▶ Unlikely to be associated with adverse effects in a human population, based on...
 - Greater understanding of the range of uncertainty associated with RfC/RfD development and
 - Consistent with the definition of “uncertainty of up to an order of magnitude” impacts the RfC/RfD
- ▶ It is a plausible estimate of the upper concentration or dose that is likely to be protective of the general population, including sensitive subpopulations



Midpoint of the Hazard Range

- ▶ Is a judgment that meshes four considerations:
 - Collective magnitude of the UFs
 - Steepness of the hazard slope describing exposures above the RfC/RfD
 - The confidence in the selection of the critical effect
 - The confidence in the POD



Johnson et al., 2003

$$\text{RfC} = 2 \mu\text{g}/\text{m}^3$$

- ▶ Fetal malformation endpoint
 - Intermediate value of $10 \mu\text{g}/\text{m}^3$ is judged to be 5-fold above the candidate RfC due to:
 - Its small UF of 10,
 - Shallower hazard slope,
 - Low confidence in the critical effect, and
 - Low confidence in the choice of a benchmark response of 1% (BMDL_{01})



Hazard Ranges of Two Candidate RfCs for TCE (as per Gentry et al.)

Figure 2. Hazard Range of Heart Malformations POD = BMD

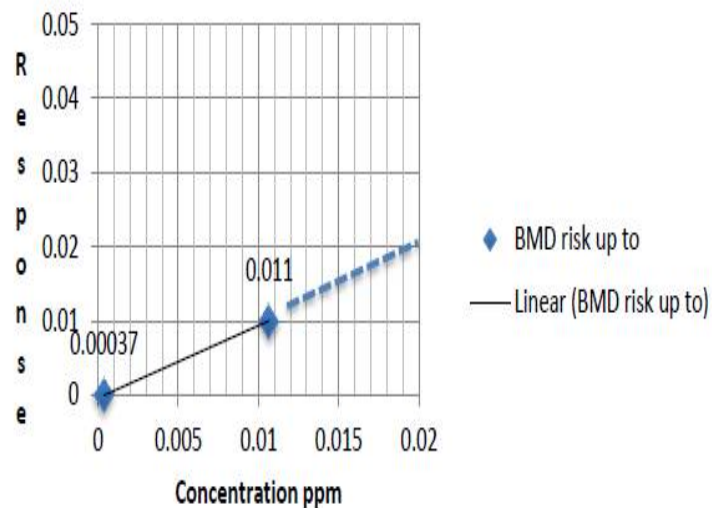
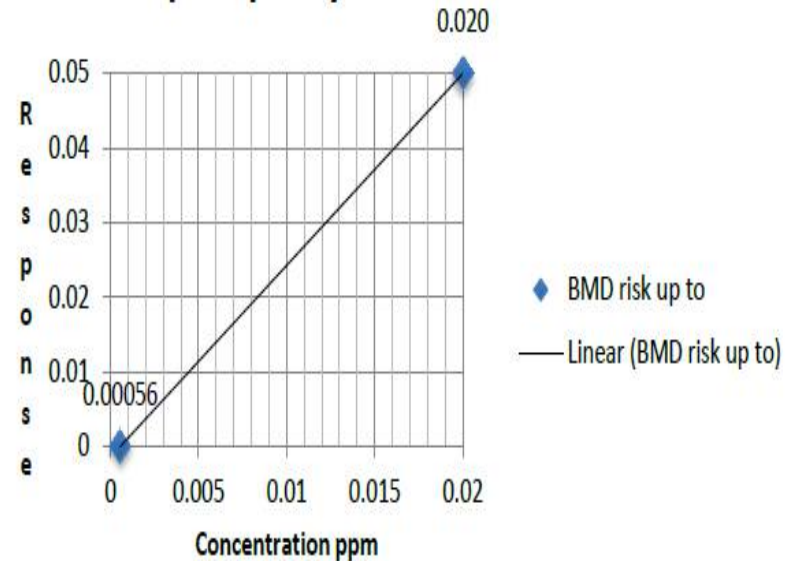


Figure 4. Hazard Range of Nephropathy POD=BMD



NTP, 1988

RfC = 3 $\mu\text{g}/\text{m}^3$

- ▶ Toxic nephropathy endpoint
 - Intermediate value of 9 $\mu\text{g}/\text{m}^3$ is judged to be 3-fold above the candidate RfC due to:
 - Its small UF of 10,
 - Steeper hazard slope,
 - Medium confidence in the critical effect, and
 - Medium to low confidence in the choice of a benchmark response of 5% (BMDL_{05})



Keil et al., 2009

RfC = 2 $\mu\text{g}/\text{m}^3$

- ▶ Decreased thymus weight endpoint
 - Intermediate value of 20 $\mu\text{g}/\text{m}^3$ is judged to be 10-fold above the candidate RfC due to:
 - Its larger UF of 100,
 - The effect shown by Keil et al. (2009) does not lend itself to dose-response modeling, so steepness of the slope was not assessed
 - Medium confidence in the critical effect, and
 - Medium to low confidence in its choice of a LOAEL as the POD

TCE as an Example

Table 7. Different uncertainty ranges for different TCE RfCs. All values are in $\mu\text{g}/\text{m}^3$. Shaded areas indicate best **overall uncertainty range** for risk management purposes.

Study	Endpoint	IRIS UF ^a	Steep ^b Slope	Confidence		Uncertainty Ranges		
				Critical ^c Effect	Point of ^d Departure	Floor	Intermediate	Ceiling
Johnson et al (2003)	Fetal malformation	10	Lower	Low	Low	2	10	20
NTP (1988)	Toxic nephropathy	10	Higher	Medium	Medium to Low	3	9	30
Keil et al. 2009	Decreased thymus weight	100	NA	Medium	Medium to Low	2	20	60

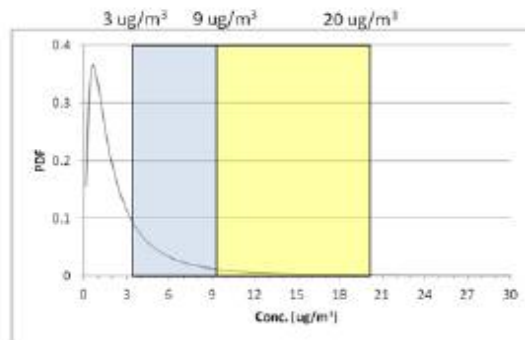
a. Size of the uncertainty factor as on IRIS

b. Steepness of the hazard slope (*i.e.*, the slope of the line describing hypothetical population responses at concentrations above the RfC), as per Section 3.

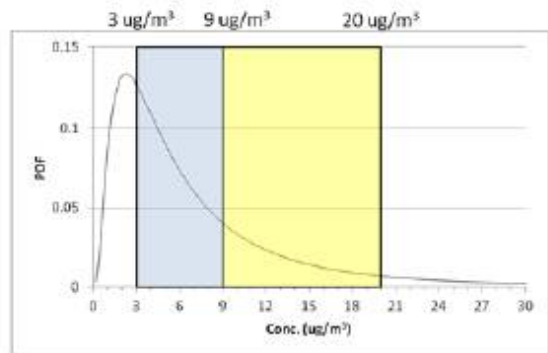
c. Confidence in the choices of critical effect, as per Section 4.

d. Confidence in the POD, as per Section 4.

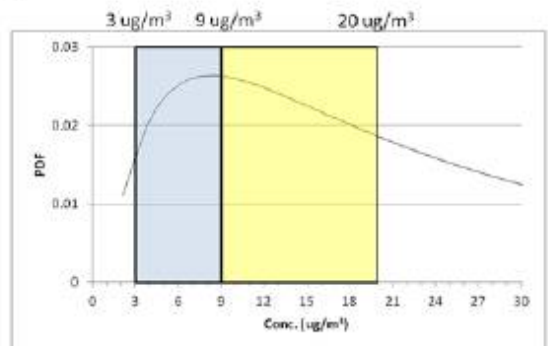
Practical Application of the Hazard Range for TCE



ES Figure 1a. Exposure distribution of indoor air concentrations primarily below the $3 \mu\text{g}/\text{m}^3$ to $20 \mu\text{g}/\text{m}^3$ hazard range. Relatively small proportion of exposures is higher than $3 \mu\text{g}/\text{m}^3$. Nominal actions or no further action may be warranted for risk management.



ES Figure 1b. Exposure distribution of indoor air concentrations falling within the $3 \mu\text{g}/\text{m}^3$ to $20 \mu\text{g}/\text{m}^3$ hazard range. Relatively small proportion of exposures is higher than $9 \mu\text{g}/\text{m}^3$. Limited action may be warranted for risk management

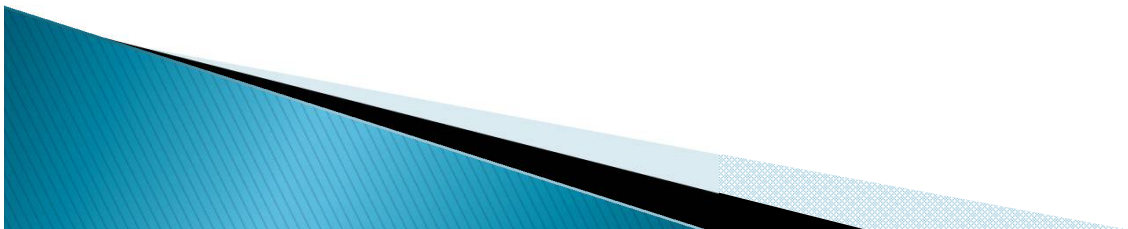


ES Figure 1c. Exposure distribution of indoor air concentrations primarily above the $3 \mu\text{g}/\text{m}^3$ to $20 \mu\text{g}/\text{m}^3$ hazard range. Actions to reduce exposures may be warranted for risk management.

For more
information <http://www.allianceforrisk.org/Projects/TCE.html>

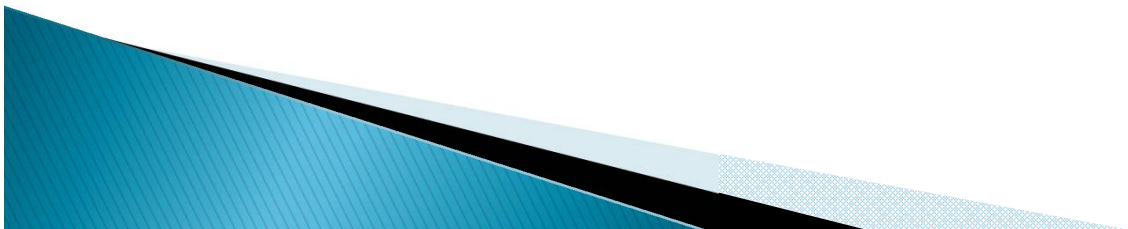
Guidance for Contaminated Sites:
Trichloroethylene Case Study. Gadagbui, et al.,
SOT, 53rd Annual Meeting & ToxExpo, 23-27
March 2014, Phoenix, AZ.

Development of a Non-cancer Hazard Range for
Effective Risk Assessment and Risk Management
of Contaminated Sites: A Case Study with TCE
and Other Chemicals, Beyond Science &
Decisions: Problem Formulation to Dose-
Response Assessment, Workshop VIII, 21-22
May 2014, Austin, TX.



Thank you!

Dr. Michael Dourson, Ph.D.
Alliance for Risk Assessment





Q&A

SUPPLEMENTAL SLIDES:

Defining the range of the reference dose:
imprecision versus uncertainty. *Dourson ML**,
Gadagbui B, Pfau E, Thompson R, Lowe J



* *Alliance for Risk Assessment (ARA);
Toxicology Excellence for Risk Assessment;
Hull & Associates, Inc.; Alliance for Site
Closures; CH2M-Hill*

TCE Criteria: *Through the Years*

- Withdrawn US EPA IRIS (1989)
 - Inhalation Unit Risk = $1.7 \times 10^{-6} (\mu\text{g}/\text{m}^3)^{-1}$
- CalEPA values (2000)
 - Chronic inhalation REL = $600 \mu\text{g}/\text{m}^3$
 - Inhalation Unit Risk = $2 \times 10^{-6} (\mu\text{g}/\text{m}^3)^{-1}$
- Draft US EPA TCE Assessment (2001)
 - Prov. RfC = $0.04 \text{ mg}/\text{m}^3 = 40 \mu\text{g}/\text{m}^3$
 - Prov. Inhalation Unit Risk = $5.7 \times 10^{-6} (\mu\text{g}/\text{m}^3)^{-1}$
to $1.1 \times 10^{-4} (\mu\text{g}/\text{m}^3)^{-1}$
- US EPA IRIS (October 2011)
 - RfC = $0.002 \text{ mg}/\text{m}^3 = 2 \mu\text{g}/\text{m}^3$
 - Inhalation Unit Risk = $4.1 \times 10^{-6} (\mu\text{g}/\text{m}^3)^{-1}$

Consequences of the New TCE Toxicity Values (Problem Formulation)

- Risk-based indoor air levels now based upon non-cancer endpoint (RfC)
- The RfC is based on both chronic and developmental endpoints
- Prompt/short term exposure action levels based on the RfC
 - Prompt action exposure concentrations
 - Application of lifetime RfC to acute and subchronic exposures
- Confounding effects of assessing ambient background concentrations of TCE in air



NAS Science and Decisions: Advancing Risk Assessment (2009)

- ▶ “For noncancer end points, it is assumed that homeostatic and defense mechanisms lead to a **dose threshold** (that is, there is low-dose nonlinearity), below which effects do not occur or are extremely unlikely. For these agents, risk assessments have focused on defining the reference dose (RfD) or reference concentration (RfC), a putative quantity that is ‘likely to be without an appreciable risk of deleterious effects’ (EPA 2002a, p. 4-4).” [emphasis added]
- ▶ That is, the RfC/RfD is expected to be below this actual threshold for adverse effect.

NAS Science and Decisions: Advancing Risk Assessment (2009)

“The “hazard quotient” (the ratio of the environmental exposure to the RfD or RfC) and the “hazard index” (HI)... An HI less than unity is generally understood as being indicative of lack of appreciable risk, and a value over unity indicates some increased risk.

The larger the HI, the greater the risk, but the index is not related to the likelihood of adverse effect except in qualitative terms: ‘the HI cannot be translated to a probability that adverse effects will occur, and is not likely to be proportional to risk’ (EPA 2006a).” [emphasis added]

NAS (2009) & Hazard Assessment

- ▶ NAS (2009):
 - Suggested that methods for assessing non-cancer toxicity have the capability of determining hazard ranges.
- ▶ ARA project “Beyond Science and Decisions: From Problem Formulation to Dose Response”
 - Built on NAS (2009) report
 - Six of its cases studies are about evaluating noncancer *risk* (at different doses)
 - Each was vetted by a Science Panel
- ▶ We focus on:
 - modeling risk above the RfC/RfD using the benchmark dose method (Gentry *et al.*, 2011).

Problem Response: Alliance for Risk Assessment (ARA)

- ▶ *Guidance for Contaminated Sites: Trichloroethylene Case Study.* Gadagbui, *et al.*, SOT, 53rd Annual Meeting & ToxExpo, 23-27 March 2014, Phoenix, AZ.
- ▶ *Development of a Non-cancer Hazard Range for Effective Risk Assessment and Risk Management of Contaminated Sites: A Case Study with TCE and Other Chemicals,* Beyond Science & Decisions: Problem Formulation to Dose-Response Assessment, Workshop VIII, 21-22 May 2014, Austin, TX.