The Changing Landscape of Chemical Toxicity Values and Challenges Presented with Trichloroethylene

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Emerging Contaminants (ECs)

- Are chemicals or materials of interest that are characterized by:
  - a perceived or real threat to human health or environment, and
  - there is no currently published health standard or there is an existing health standard, but *the standard is evolving or being re-evaluated*.

Source: "Initiation of Emerging Contaminants Characterization and Response Actions for Protection of Human Health" Issue Paper (ECOS & DoD Sustainability Workgroup, 2008)

DoD's Scan, Watch, Action Process: Identifying, Prioritizing & Pursuing Risk Management

Over -the- horizon

EC News

Review literature, periodicals, regulatory communications, etc.

Possible DoD impacts

Phase I Assessment

Monitor events; Conduct Phase I qualitative impact assessment; Manage obvious risks.

Probable high DoD impacts

Phase II Assessment

Conduct Phase II quantitative impact assessment; Develop & rank risk management options (RMOs); Implement approved RMOs; Track implementation and reduce high risks; Revisit list annually for risk reduction progress and triggers for listing

Risk Management Options to ECGC

Approved RMOs become Risk Management Actions (RMAs)

IRIS Documents Reviewed by DoD Services

- Benzo(a)pyrene
- Trimethylbenzenes
- Dioxin

Other Chemicals of DoD Interest Undergoing IRIS Reassessment

- 1,4-Dioxane
- Dioxin (cancer)
- RDX
- Arsenic
- Phthalatates (multiple)
- Vanadium pentoxide
- Relative potency factors for PAHs
- Hexavalent chromium

Trends Observed During Review of IRIS Documents

- Candidate RfDs and RfCs
- Biological based models reducing uncertainty factors
- Identification of developmental endpoints
- Some recommendations from NAS formaldehyde panel are being incorporated
  - ▶ Preamble describes process
  - ▶ Evidence tables
  - ▶ Manageable length

Trichloroethylene Case Study

- IRIS Toxicological Review published September 2011
- Chronic oral RfD of 0.0005 mg/kg/day, a chronic inhalation RfC of 0.002 mg/m^3; classified as "carcinogenic to humans" with an oral slope factor of 4.6×10^{-2} per mg/kg/day and an inhalation unit risk of 4.1×10^{-6} per $\mu g/m^3$

Inhalation Unit Risk and Oral Slope Factor

- Non-Hodgkins lymphoma
- Liver cancer
- Kidney cancer
  - Mutagenic mode of action
  - Apply age dependent adjustment factors to kidney only
- Oral values route extrapolated from inhalation unit risk

Reference Dose and Reference Concentration

- Decreased thymus weight in mice
- Developmental immunotoxicity
- Fetal cardiac malformations

RfC:

- Decreased thymus weight in mice
- Fetal cardiac malformations
- Route extrapolated from drinking water studies

Risk-based Screening Levels for TCE

- Under CERCLA acceptable risks are between 1E-04 and 1E-06
- 1E-06 is point of departure for remediation goals once determined an action is necessary

Risk-Based Screening Levels*		
	Res. Water (µg/L)	Air (µg/m^3)
Non-Cancer Hazard of 1	2.6	2.1
10^{-6} Cancer Risk	0.43	0.44

Industrial/Commercial 8.8 µg/m^3 vs. OSHA 535 mg/m^3

* EPA Regional Screening Levels (residential)

Challenges presented by IUR and OSF

- Multi step process to which yields no major difference for risk managers

0.59 vs 0.44 µg/m³

- Low air screening level of 0.44 µg/m³ is below common background value of 1 µg/m³ TCE

1. Run the RSL calculator with the mutagenic option switched on to incorporate the ADAF (Age-Dependent Adjustment Factor) and estimate a TCE concentration based on kidney mutagenic endpoint (IUR of 1E-06 $(\mu g/m^3)^{-1}$ and oral slope factor of 9.3E-03 $(mg/kg\text{-}day)^{-1}$). The first page of the calculator should look like this if calculating residential soil, air and tapwater RSLs. Then, make the following changes to the toxicity values and the properties (VOC?, Mutagen? and EPD?). The soil, air and tapwater results are then displayed for the mutagenic RSLs.
2. Run the RSL calculator with the mutagenic option switched off and estimate a TCE concentration based on non-kidney (NHL/liver) cancer endpoint (IUR of 3.1E-06 $(\mu g/m^3)^{-1}$ and oral slope factor of 3.7E-02 $(mg/kg\text{-}day)^{-1}$). The first page of the calculator should look like this if calculating residential soil, air and tapwater RSLs. Then, make the following changes to the toxicity values and the properties (VOC?, Mutagen? and EPD?). The soil, air and tapwater results are then displayed for the mutagenic RSLs.
3. For each environmental media, take the reciprocal of the two resulting TCE RSL concentrations, and add them together (1/conc_mutagen + 1/conc_cancer) before inverting back to a final RSL concentration. (1/(1/conc_mutagen + 1/conc_cancer). The detailed equations for resident soil, air and tapwater are presented.

Case Study: TCE Vapor Intrusion Project

- TCE used between 1960s and 1980s
  - Underground storage tanks and piping
  - Secondary loop of coolant for ice pool inside one building
  - Underground refrigerant
- Confirmed vapor intrusion into buildings; investigation and mitigation is ongoing
- Site specific action levels exceeded – child-care and industrial values

Case Study: TCE Vapor Intrusion Project

Various management options pursued

- HVAC system
- Sub slab depressurization
- Air purifiers
- Office relocation

Some samples of outdoor air exceed residential screening level

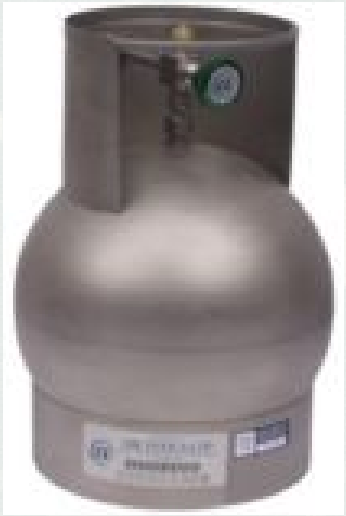
Challenges Presented by Noncancer Values

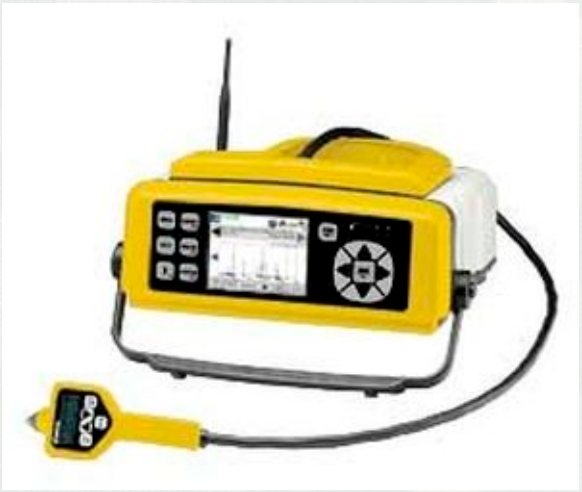
- The chronic RfC is protective of long-term exposures to sensitive subpopulations
  - ► But what about critical exposure period?
- Vapor intrusion is highly variable
  - ► Seasonally influenced by heating/cooling; groundwater table
  - ► Daily influences, wind, doors opening/closing
- How should excursions above action level be monitored and managed?

Management/Communication Challenges

- Who's OK and who is not?
  - Privacy concerns regarding requests for relocation
- Credibility – how long do we wait for an answer from HQEPA?
- Management of real time data and variability– when do we take action? Readings may be high one hour and not the next.

Monitoring Strategies





Remaining Questions and Issues

- Differing interpretations by EPA Regions and States
- Does a chronic RfC represent a critical exposure window of ~ 2 weeks?
- RAGS Pt F: Exposure duration evaluated should be consistent with exposure duration represented by the toxicity value
- Why not publish developmental RfC/RfDs per the EPA *Guidelines for Developmental Toxicity Risk Assessment?*