APPROACHES TO MANAGING TCE ACUTE RISKS

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Issues
- Cardiac Defects - inconsistent data
- No clear guidance from EPA HQ on implementing RfD for acute exposure
- How short-term is the developmental risk
- How much above RfD is an urgent risk
Outline

- Review of TCE RfD
  - Use of the RfC for Vapor Intrusion
  - Implications of a Developmental RfD for VI
  - Review of the science for TCE
- Federal Approach
  - USEPA HQ
  - USEPA Regions
- Northeast States
- OSHA PEL
- Summary

Use of RfC in Vapor Intrusion

- RfC used to set Target Indoor Air Concs
  - Used to derive soil VC and GW VC
  - Can also be used as indoor air guideline for
    - Evaluating indoor air test results
    - Possible outcomes:
      - Need to continue monitoring
      - Need to remediate
      - Need to warn
      - Need to evacuate
- RfC becomes a different TAC for residential vs industrial/commercial
  - (24/8* 7/5) to adjust RfC to workplace
- RfC can be applied to different time frames depending upon endpoint
Implications of a Developmental RfD

- Short term exposures may trigger need to act
  - Unlike most RfDs and cancer targets which assume the need for chronic exposure
- Levels and speed of intervention for TCE VI
  - Cancer-based target: 0.2 ug/m$^3$; may take years to achieve
  - Developmental-based target: 2 ug/m$^3$; days to weeks
- Site-specific considerations
  - Timing of exposure, # and type of occupants; hours/day exposed
  - Just pregnant women or also women of reproductive age?

Basic Elements

- Site presents TCE VI issue due to GW or soil gas
  - What are projected indoor air concs
  - Sampling indoor air
  - If high – intervention steps
    - Immediate sealing and ventilation
    - Potentially warn or evacuation sensitive receptors
    - Longer term sub-slab system or intervention of plume
  - If low – monitor under different IAQ conditions
### Basic Elements (cont)

- When, where and how to monitor
  - Triggered by gw or soil gas data
    - Sample locations of at risk workers and likely hot spots
  - Post ventilation sampling
  - Confirmation of long-term fix
  - Field GC could be very helpful

### TCE Toxicology

**Wt of Evidence on Cardiac Defects**

- Rats: two positive studies, two negative studies
  - Positive studies, from one research group, somewhat unusual dose response
- Supported by two positive studies in rats on metabolites
- Supported by chick embryo studies with TCE and metabolites
- Supported by mechanism studies
- Supported by epidemiology studies
TCE Developmental EPI

- Bove et al. 1995, ‘96, 2002
  - Ecological study - public drinking water and birth outcomes
  - TCE associated with SGA, NTDs, cleft palate, cardiac defects
- ATSDR 2008 Study of TCE VI at Endicott NY
- NRC 2006 Review: “the epidemiologic studies—although limited individually—as a whole showed relatively consistent elevations for cardiac malformations with similar relative effect sizes of 2- to 3-fold, some of which were statistically significant, associated with TCE exposure across multiple studies.”
- Camp Lejune (Ruckart et al., 2014)
  - TCE associated with SGA and NTDs

Forand et al. 2012 Endicott NY

- TCE Vapor Migration, no drinking water exposure
- N= approx 2500 in TCE study area
- TCE indoor measurements median = 16 ug/m3, up to 140 ug/m3
Forand et al. Endicott Results

- Higher smoking in study area but not well controlled – LBW, SGA affected in a subanalysis
- Recent meta-analysis: maternal smoking assoc with cardiac defects (Lee and Lupo, 2013)

TCE Developmental Immunotox

- TCE well established as immunotoxicant
  - Impairs some immune functions
  - Stimulates autoimmunity, mice and humans
  - Developing immune system appears sensitive to low level exposure
- TCE RfC equally dependent upon developmental immunotox
Federal Approach: USEPA HQ

- Richardson memo (Aug 2014)
  - Regional Superfund Managers

Existing guidance provides that responders should consider *early or interim* action(s) where appropriate to eliminate, reduce, or control the hazards posed by a site. In doing so, IRIS generally provides the best available toxicological information in support of *early or interim* action for buildings where investigations of indoor air contamination identify site-related concentrations of TCE.

Region 9 Approach, July 2014

- Rapid intervention to avoid developmental risk
  - Vulnerable period – 3 wks of heart development in first trimester
  - Acute intervention concentrations for residential and industrial/commercial
    - Accelerated vs Urgent Action

USEPA Region 9 Numerical Recommendations

<table>
<thead>
<tr>
<th>Exposure Scenario</th>
<th>Accelerated Response Action Level (HQ=1)</th>
<th>Urgent Response Action Level (HQ=3)</th>
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<tbody>
<tr>
<td>Residential *</td>
<td>2 µg/m³</td>
<td>6 µg/m³</td>
</tr>
<tr>
<td>Commercial/Industrial **</td>
<td>8 µg/m³</td>
<td>24 µg/m³</td>
</tr>
<tr>
<td>(8-hour workday)</td>
<td></td>
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<tr>
<td>Commercial/Industrial **</td>
<td>7 µg/m³</td>
<td>21 µg/m³</td>
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<tr>
<td>(10-hour workday)</td>
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</tbody>
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Accelerated Action: rapid mitigation, sampling confirmation
Urgent Action: immediate cessation of exposure, relocation of workers

USEPA Region 1 Approach

- Site-specific, case-by-case
- Multiple lines of evidence
  - Soil gas, indoor air
- At least one site so far which required more immediate action
USEPA HQ Response to Recent Challenge

- Halogenated Solvents Industry Assoc Challenge to RfC
  - Inappropriate dependence upon Johnson 2003 cardiac defect study
  - Invoked Information Quality Act (IQA)
    - IRIS not being objective, key study not reproducible
- NCEA March 19, 2015 letter strongly defended use of cardiac endpt in RfC
  - HSIA concerns raised during IRIS SAB deliberations
  - RfC relies upon 21 developmental studies, numerous support cardiac endpoint
  - RfC based upon several different candidate endpoints all in same range
  - Addresses details of the Johnson et al. 2003 study (e.g., concurrent controls)

Connecticut Approach, Feb 2015

- Current TAC is 5 ug/m3 – background
- Recognize that development risks in this range
  - 2 ug/m3 – full time exposure, residential
  - 8 ug/m3 – workplace exposure
- If I/C site exceeds limits it is prioritized for immediate followup
  - > 8 ug/m3 indoor air,
  - 1.6 fold greater than GWVC or SVVC, occupational
Connecticut Approach (cont)

- Occupational Alert for female TCE workers
  - Contrasts developmental targets with OSHA PEL
  - Alert for women of reproductive age
  - Provides manufacturers with 9 steps to reduce TCE in workplace including alternative solvents
    - TURI – Lowell Mass

Update TCE MCL

- Federal MCL of 5 ug/L from 1980s
- Several reasons to consider updating
  - New toxicology
  - New detection limits
  - Developmental risk
    - MCL enforcement based upon yearly average of quarterly results
    - A quarter could have **up to 20 ug/L** and still pass
    - This is **4.6 fold above RfD**
  - Lowering MCL to 1 ug/L would address this risk
Massachusetts Approach, Aug 2014

- Mass DEP extensive review of the toxicology
  - Health Effects Advisory Committee
- TCE a developmental toxin with potential to cause cardiac defects
- Cardiac development early before realize pregnant, TCE a concern to early pregnancy and women who may become pregnant
- Cardiac development is completed within the first 8 weeks of pregnancy exposures after that period do not present a risk
- Risk a function of indoor air concentration and exposure duration
- Exposures of a few days to weeks during critical periods of fetal cardiac development of potential concern.

Mass Approach (cont)

- Residential – > 2 ug/m3 – ultimate goal, expeditious achievement
- Residential - > 6 ug/m3 – Imminent Hazard - 2 hr notice to DEP, immediate notification of vulnerable individuals, short-term measures
- Residential - > 20 ug/m3 – More Urgent – consider evacuation of vulnerable individuals
  - Occupational > 8 ug/m3 – Expeditious Action;
  - Occupational > 24 ug/m3 – Imminent Hazard
  - Occupational > 60 ug/m3 – More Urgent
Possible Confusion Across States
What is the immediate response level?

• Mass (Aug 2014): 8 ug/m3 – Expeditious action
  24 ug/m3 - Imminent Hazard
• NH (Feb 2013): 8 ug/m3 – Immediate action,
  warnings, relocation
• CT (Feb 2015): 8 ug/m3 – Prioritization of site,
  immed action to ↓ conc
  • CT has no employee warning level
• USEPA Region 9: 8 ug/m3 – Accelerated action;
  24 ug/m3 – Urgent action

Other States in Region

• NYS: draft recommendation
  • immediate action > 20 ug/m3
  • no distinction between resi and I/C
  • In general, endeavor to bring indoor air to background or risk-based
    goal as quickly as possible regardless of chemical or endpoint
• Maine: Still studying issues
• VT: focus on cancer risk; site-specific consideration of
  RfD/acute risk
• Rhode Island - In general, endeavor to bring indoor air to
  background or risk-based goal as quickly as possible
  regardless of chemical or endpoint
OSHA PEL

• Remains at 100 ppm – 1980s
  • Based upon acute CNS effects, liver and kidney tox
  • Carcinogen status acknowledged
• PEL is 270,000 times > USEPA RfD
  • PEL doesn’t apply to general public
    • Vulnerable receptors vs healthy workers, voluntary vs involuntary risk, continuous vs. workplace exposure
  • PEL doesn’t apply same risk methodology and level of public health protection as RfD
• ACGIH TLV – lowered to 10 ppm - 2007
  • STEL = 25 ppm
  • TLV basis – CNS effects, renal toxicity
    • Developmental toxicity mentioned briefly
    • Cancer discussed but not part of PEL derivation

Summary

• TCE developmental effects make acute risk more urgent than cancer risk
• Impacts on VI, workplace safety, MCL
• Variety of Responses in Region
  • Numerical guidelines, intervention protocols
  • Case-by-case
  • Still Studying issues
• 8 ug/m3 short-term remediation target
• 24 ug/m3 warning/evacuation target
• Monitor evolving science and reg determinations