Why Toxicity Values Are in Flux: A Summary and Perspective on Recent IRIS Assessments

Anita K. Meyer DABT
Environmental & Munitions CX
Huntsville Engineering and Support Center

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Role of Risk Assessment on Environmental Projects

- Used to determine whether site requires further study or remediation
- Used with regulatory values to determine cleanup levels
- Risk-based screening levels (aka PRGs, RBCs, RSLs)
  - Screen sites early in project lifecycle
  - Determine project quantitation limits
Risk-Based Values Function of Toxicity and Exposure

Risk = \( \text{Intake} \) / \( \text{Toxicity} \)

\[ \text{Toxicity} = \text{Criteria} \]

- Tiered approach used to identify toxicity values for site risk assessments
- Integrated Risk Information System (IRIS)
- IRIS values also inform regulatory decisions (MCLs etc.)
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.

DoD Participation in IRIS Interagency Reviews

Assessment Development Process for New IRIS

1. Complete Draft IRIS Assessment
2. Internal Agency Review
3. Science Consultation on the Draft Assessment with other Federal Agencies and White House Offices
4. Independent Expert Peer Review, Public Review and Comment, and Public Listening Session
5. Revise Assessment
6A. Internal Agency Review and EPA Clearance of Final Assessment
6B. EPA-led Interagency Science Discussion
7. Post Final Assessment on IRIS

- Completed lit searches posted on Web and announced in FRN
- FRN requesting information about studies not in lit search and new research
- Address peer review and public comments; prepare response to comments document
- Science feedback on final assessment from other Federal Agencies and White House offices
- Draft assessment and peer review charge posted on Web site
- Public comment period and Listening Session announced in FRN
- Peer review meeting announced in FRN

Includes IRIS summary, Toxicological Review and response to comments
Potential Changes in Risk Assessment of PAHs

- Relative potency factors used to assess carcinogenicity of PAHs – all set relative to benzo(a)pyrene
  - Under review by EPA Science Advisory Board
- RPF approach retained but updated by new data/science
## Carcinogenic PAHs and Relative Potency Factors

<table>
<thead>
<tr>
<th>Compound</th>
<th>Current RPF</th>
<th>Draft RPF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzo(a)pyrene</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Benz(a)anthracene</td>
<td>0.1</td>
<td>0.2</td>
</tr>
<tr>
<td>Benzo(b)fluoranthene</td>
<td>0.1</td>
<td>0.5</td>
</tr>
<tr>
<td>Benzo(k)Fluoranthene</td>
<td>0.01</td>
<td>0.03</td>
</tr>
<tr>
<td>Chrysene</td>
<td>0.001</td>
<td>0.1</td>
</tr>
<tr>
<td>Dibenzo(a,h)anthracene</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Indeno(1,2,3-c,d)pyrene</td>
<td>0.1</td>
<td>0.07</td>
</tr>
</tbody>
</table>
Additional PAHs from 2010 RPF Assessment

- Anthanthrene
- Benzo[g,h,i]perylene
- Benzo[j]fluoranthene
- Cyclopenta[c,d]pyrene
- Dibenzo[a,e]fluoranthenes
- Dibenzo[a,e]pyrene
- Dibenzo[a,h]pyrene
- Dibenzo[a,i]pyrene
- Dibenzo[a,l]pyrene
- Fluoranthene
- Benz[b,c]aceantrhylene
- Benz[e]aceantrhylene
- Benz[j]aceantrhylene (60x)
- Benz[l]aceantrhylene
- Cyclopenta[d,e,f]chrysene
- Naphtho[2,3-e]pyrene
Tetrachloroethylene

Status: External Peer Review

- 1998 initiated
- June 2008 external review version released
- Nat’l Academy Review Feb 2006
- Current external (SAB) and public review

### Risk-Based Screening Levels*

<table>
<thead>
<tr>
<th>Source</th>
<th>Res. Soil (mg/kg)</th>
<th>Res. Water Use (µg/L)</th>
<th>Indoor Air (µg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>0.55</td>
<td>0.11</td>
<td>0.41</td>
</tr>
<tr>
<td>New (draft)</td>
<td>0.293</td>
<td>0.179</td>
<td>0.122</td>
</tr>
</tbody>
</table>

Sources of current toxicity values include EPA IRIS, ATSDR and CalEPA. Lowest RSL target risk = 10⁻⁶. Draft values not suitable for project use.

*Using EPA Regional Screening Level Calculator
Trichloroethylene
Status: External Peer Review

- IRIS values withdrawn late 1980s
- 2001 draft released
- 2006 NAS review
- 2009 re-released
- Lowest RSLs based on $10^{-6}$ cancer risk

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<tr>
<th>Risk-Based Screening Levels*</th>
<th>Res. Soil (mg/kg)</th>
<th>Res. Water Use (µg/L)</th>
<th>Indoor Air (µg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>2.8</td>
<td>2</td>
<td>1.2</td>
</tr>
<tr>
<td>New (draft)</td>
<td>0.48</td>
<td>0.23</td>
<td>0.24</td>
</tr>
</tbody>
</table>

CalEPA source of current values.
Lowest RSL target risk = $10^{-6}$. Draft values not suitable for project use.

*Using EPA Regional Screening Level Calculator
Dioxin
Status: External Peer Review

- Assessment initiated in 1990
- Released for public and peer review 2010
- Using cancer toxicity values in this draft residential screening levels could be as low as 0.45 ppt dioxin toxicity equivalent (TEQ, for dioxin-like compounds)
- Current EPA policy recommends 1000 ppt
  - EPA may release an Interim PRG
Hexavalent Chromium
Status: External Peer Review

- Derives an oral slope factor using 2008 National Toxicology Program studies
- NTP studies also used to update noncancer ingestion value (3x change)
- Lowest RSLs based on $10^{-6}$ cancer risk

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<th>Res. Water Use (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Old</td>
<td>2300</td>
<td>11</td>
</tr>
<tr>
<td>New (draft)</td>
<td>0.29</td>
<td>0.043</td>
</tr>
</tbody>
</table>

Draft values not suitable for project use. Cancer risk drives new RSLs.

*Using EPA Regional Screening Level Calculator
Final IRIS Reference Dose for Cis-1,2-Dichloroethylene (September 2010)

- Oral noncancer reference dose (RfD) = 0.002 mg/kg-day; increased kidney weight
  - PPRTV used until this time
  - MCL = 70 µg/L
- No cancer toxicity values published

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<th>Residential Soil (mg/kg)</th>
<th>Residential Water Use (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Old</td>
<td>780</td>
<td>370</td>
</tr>
<tr>
<td>New</td>
<td>156</td>
<td>73</td>
</tr>
<tr>
<td>Fold Change</td>
<td></td>
<td>5x</td>
</tr>
</tbody>
</table>

*Using EPA Regional Screening Level Calculator
Final IRIS Reference Dose for Trans-1,2- Dichloroethylene (September 2010)

- Oral noncancer reference dose (RfD) = 0.02 mg/kg-day;
- Based on decreased antibody production by the spleen
- No change in RfD value, but change of critical effect
- MCL = 100 µg/L
- No cancer toxicity values published
Final IRIS Values for 1,4-Dioxane (August 2010)

- Oral noncancer reference dose (RfD) = 0.03 mg/kg-day; Liver & kidney effects
  - Inhalation RfC will be developed in separate document

- Oral cancer slope factor (SF) = 0.1 mg/kg-day⁻¹; Rodent liver tumors

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<th>Residential Water Use (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Old</td>
<td>44.1</td>
<td>6.1</td>
</tr>
<tr>
<td>New</td>
<td>4.85</td>
<td>0.67</td>
</tr>
<tr>
<td>Fold Change</td>
<td></td>
<td>9x</td>
</tr>
</tbody>
</table>

*Using EPA Regional Screening Level Calculator
Basis for Changes

- New study data
  - Sensitive measurements
- Science policy
  - Mutagenic mode action adjustment
  - Uncertainty factor application
  - Benchmark Dose
- Other impacts
  - Critical study selection
  - Linear low dose extrapolation
The future! EPA Next Generation Risk Assessment

New technology will lead to greater capacity and speed. Interpretation of results is a challenge; studies underway to link known effects with screening assay data.

Systems Exposure Science: Extending Network Analysis

Consider coupled networks spanning multiple levels of biological organization.