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Selecting Provisional Toxicity Values in the Absence of IRIS Values and Implication for Emerging Contaminants

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About the ECOS-DoD Sustainability Work Group

Partnering to Find Solutions to Environmental Issues.

The Environmental Council of the States and the Department of Defense formed the ECOS-DoD Sustainability Work Group in 2004 to exchange ideas across jurisdictional boundaries, and to help create sustainable bases and ranges in harmony with local communities. The Sustainability Work Group is comprised of state and federal stakeholders who are working to find solutions to complex environmental challenges, such as Emerging Contaminants, and Compatible Use and Sustainability.

Addressing Emerging Contaminants.

Work group participants focusing on Emerging Contaminants seek to develop a common understanding of emerging contaminants and develop mutually acceptable processes to address them. Clarity of "EC" issues will increase public confidence in government's abilities to protect public health and the environment, and help sustain DoD's mission. Several work products on distinct EC issues have been prepared, each a collaborative effort of state, EPA and DoD stakeholders. Products include a state survey

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What is an emerging contaminant?

- A perceived or real threat to human health or environment.
- No currently published health standard or there is an existing health standard, but the standard is evolving or being re-evaluated.
- Emerging contaminants may have insufficient or limited health, science or technology information available. They may also become of interest because a new source, pathway or detection limit has been discovered.

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Toxicity Values in Risk Assessment

- Toxicity value identification crucial step in risk assessment process
- Risk = Intake (*or concentration)* x Toxicity
- EPA has hierarchy for selecting values for Superfund
  - OSWER Dir. 9285.7-53, Dec. 2003
- Other agencies may have their own:
  - Hierarchy
  - Process for peer-review
  - Process for identifying and addressing scientific uncertainties

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Toxicity Values in Project Planning/Development of QAPP

- Concentration = Target Risk/Toxicity
- Detection limits
- Analytical method selection
- $$

Example: Is TCE really any more toxic in Oregon than in California?

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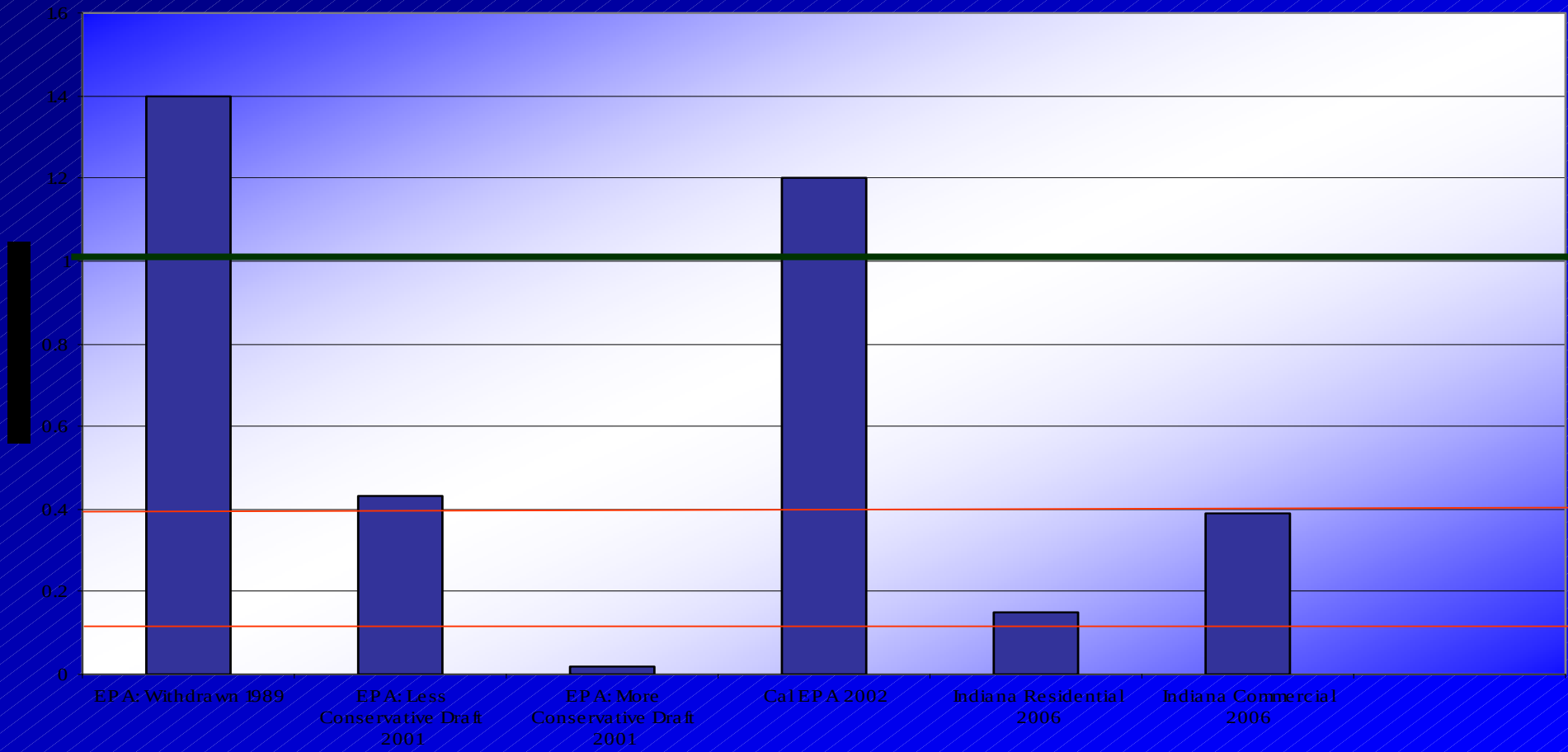
TCE in Air Concentrations at 10^{-6} Risk



Red lines: Detection limits scan and SIM mode
Green line: Mean outdoor air, EPA BASE study

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Inconsistent Toxicity Values

- Unnecessarily increase project costs
- Can lead to re-work of projects
- Lead to inconsistent messages to public stakeholders; many times we are on a national, as well as local stage when we communicate risks
- Lead to disputes between parties

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Goal of ECOS DoD Paper

- Provide a consistent process to identify human health toxicity values when none exist in the Integrated Risk Information System (IRIS) database maintained by EPA
- Consistent process will help minimize disputes over toxicity values for emerging contaminants
- If disputes still occur the process will be useful to distill disagreements

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Overriding Principle

Risk assessors should not seek to identify higher or lower toxicity values. Effort should continue to be to identify a scientifically defensible toxicity value.

Issue paper is not on how to perform chemical risk assessment but process for selecting from already developed values.

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EPA's Hierarchy for Toxicity Values

- Tier 1: Integrated Risk Information Ssystem (IRIS)
- Tier 2: Provisional Peer Reviewed Toxicity Values (PPRTVs)
- Tier 3: Other sources
  - CalEPA
  - ATSDR MRLs
  - Health Eeffects Assessment Summary Tables (HEAST)
- Notes other Tier 3 sources may exist

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OSWER Directive Also States:

"In general, draft toxicity assessments are not appropriate for use until they have been through peer review, the peer review comments have been addressed in a revised draft, and the revised draft is publicly available"

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Issue Paper Encourages Flexibility

- **IRIS is primary source but….**

  "..in some cases more recent, credible and relevant data may come to the Agency's attention."
  "EPA and state personnel may use and accept other technically sound approaches, either on their own initiative, or at the suggestion of potentially responsible parties, or other interested parties."

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PPRTVs

- Provisional Peer Reviewed Toxicity Values
- Do not undergo EPA multi-program review as IRIS does
- Developed for use in Superfund
- Issue paper describes their development
- Not publicly available
- Issue paper urges EPA to open availability

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PPRTV Process

- Consistent with EPA methods for developing RfDs/RfCs and slope factors
- Internal review by 2 EPA scientists
- Review by 3-5 external scientists
- No multi-program consensus as with IRIS values

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Other Sources

- No comprehensive list, could include:
- CalEPA
- ATSDR MRLs
- HEAST
- US Federal agencies
- States
- International Agencies (UN)
- Foreign Governments

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Potential Pitfalls of Other Values

- Administrative, risk assessment not used in derivation
- Risk management applied e.g. MCLs
- Outdated
- Outdated studies used in derivation

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Preferences for Selecting Toxicity Values

- Transparent assessments
- External and independent review
- Use of established and publicly available methodology
- Methods informed by current best scientific practices

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Preferences for Selecting Toxicity Values

- Assessments should consider quality of studies and make best use of all available science
- Values and assessment are publicly available
- Public comment encouraged, but not in lieu of external peer review
- Values consistent with duration of human exposure being assessed

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No appropriate values?

- Develop own value, principles may provide a starting point
- Use surrogate value
  - —Address uncertainties
- If no appropriate surrogate discuss as uncertainty in risk characterization

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Why Does This Matter? Example: IRIS Reassessment List

Acetaldehyde
Acetone
Acrolein
Acrylamide
Acrylonitrile
Aldicarb
Aldicarb sulfone
Aldicarb sulfoxide
Ammonim Perchlorate
And other perchlorate salts
Arsenic, inorganic
Asbestos (noncancer effects)
Benzene (noncancer)
Benzo(a)pyrene
Beryllium (cancer effects)
BoronBromobenzene
Bromodichloromethane
Bromoform
Cadmium
Carbon Tetrachloride
Chloroethane
Chloroform
Chloroprene
Cobalt
Copper
Cryptosporidium
Cyclohexane
Di-(2-ethylhexyl)adipate (DEHA)
Di-(2-ethylhexyl)phthalate
Dibromochloromethane
Dibutyl phthalate
Dichloroacetic acid
Diesel engine exhaust
Ethanol
Ethylbenzene
Ethylene dibromide
Ethylene dichloride
Ethylene glycol monobutyl ether
Ethylene oxide (cancer effects)
Ethyl tertiary butyl ether
Formaldehyde
Hexachlorobutadiene
Hexachloropentadiene
RDX
Hydrogen cyanide
Hydrogen Sulfide
Isopropanol
Kepone
Lead
Methanol
Methyl ethyl ketone
Methyl isobutyl ketone
MTBE
Methylene chloride
Naphtalene
n-Hexane
Nickel (soluble salts)
Nitrobenzene
PAH mixtures
Pentachlorophenol
Perfluorooctane sulfonate-potassium salt
Perfluorooctanoic acid-ammonium salt
Phosgene
Polybrominated diphenyl ethers (PBDEs)
PCBs
Propionaldehyde
Refractory ceramic fibers
Styrene
Tetrachloroethylene
Tetrahydrofuran
Thallium
Toluene
Trichloroacetic acid
Trichloroethylene
Uranium (natural)
Vinyl acetate
Xylenes
Zinc