

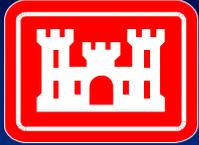
Selecting Provisional Toxicity Values in the Absence of IRIS Values and Implications for Emerging Contaminants

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JSEM Conference

Columbus, OH



Overview



- Toxicity values and why they matter
- Need for consistent approach between agencies for identifying toxicity values
- Process agreed upon by ECOS and DoD
- Examples



About the ECOS-DoD Sustainability Work Group



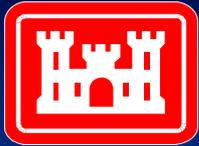
Partnering to Find Solutions to Environmental Issues.

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.

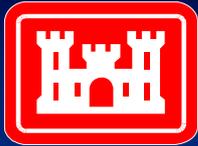
Work group participants focusing on [Emerging Contaminants](#) seek to develop a common understanding of emerging contaminants and develop mutually acceptable processes to address them. Clarity of "EC" issues will increase public confidence in government's abilities to protect public health and the environment, 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



What is an emerging contaminant?



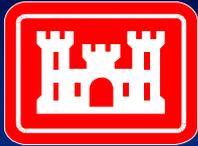
- A perceived or real threat to human health or environment.
- No currently published health standard or there is an existing health standard, but the standard is evolving or being re-evaluated.
- Emerging contaminants may have insufficient or limited health, science or technology information available.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



Toxicity Values in Risk Assessment



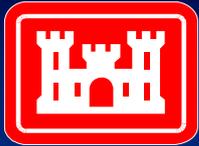
- Toxicity value identification crucial step in risk assessment process
- Risk = Concentration* x Toxicity
- EPA has hierarchy for selecting values for Superfund
 - OSWER Dir. 9285.7-53, Dec. 2003
- Other agencies may have their own:
 - Hierarchy
 - Process for peer-review
 - Process for identifying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



Dose Makes the Poison—BUT Depends on the Chemical---Toxicity Greatly Influences Screening and Cleanup Goals



- Concentration (mg/kg)= Target Risk/Toxicity
- Detection limits—can we even ‘see’ it?
- Influences several decision points in project lifecycle
 - Screening in site assessment; # of sites that move to investigation phase
 - Risk assessment outcome; necessity of remedial alternatives development in Feasibility Study
 - How clean is clean; can I turn off the pump or stop the backhoe?
 - Are five-year reviews warranted?
- Cost, and time to project completion

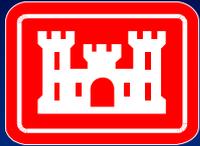


Inconsistent Toxicity Values

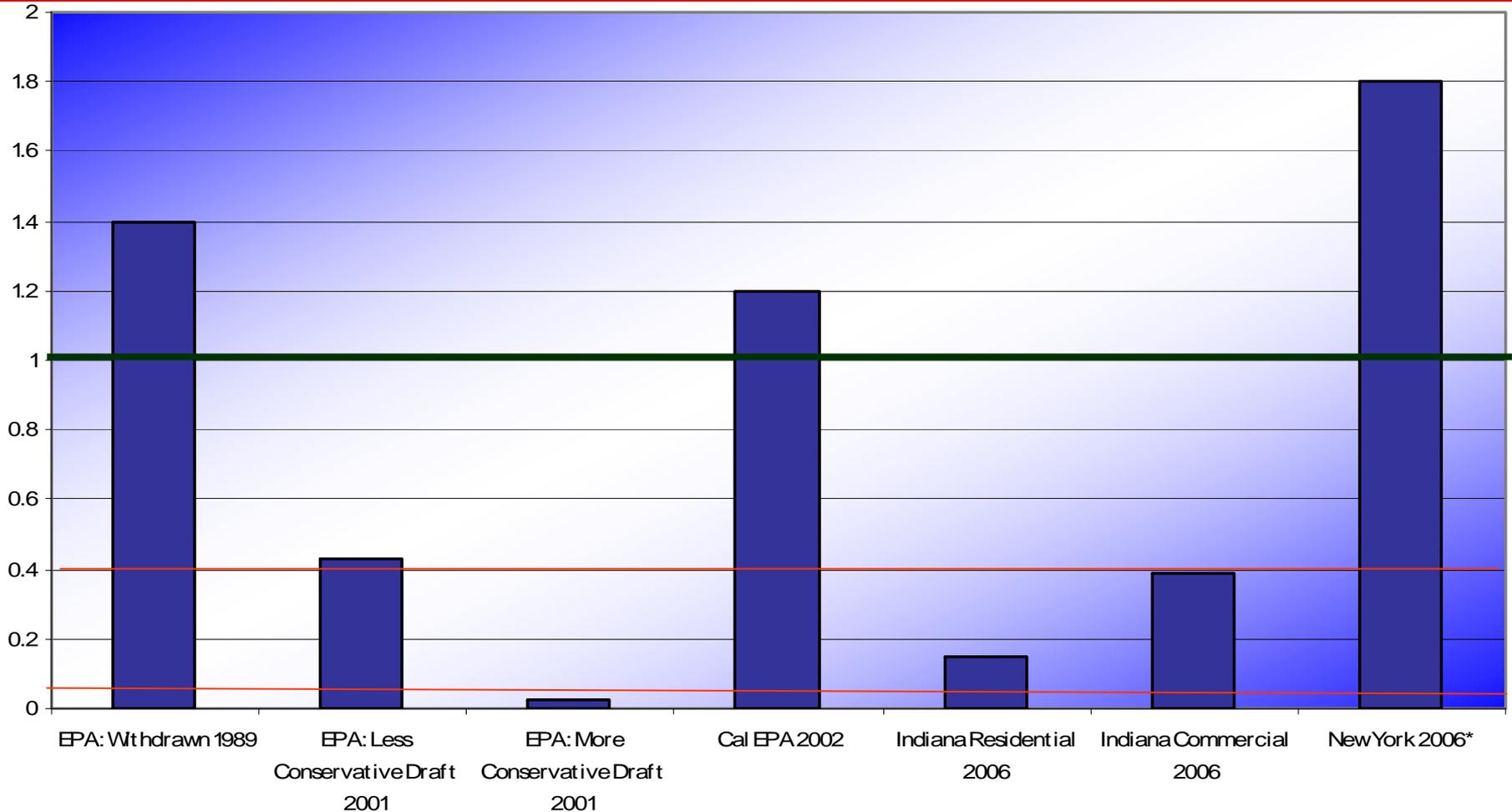


- Can lead to re-work of projects
- Lead to widely varying messages to public stakeholders; many times we are on a national, as well as local stage when we communicate risks
- Can lead to questions of agency credibility and trustworthiness in the public's mind

Example: Is TCE really any more toxic in Washington than in its neighbor California?



Target Air Concentrations Using Various TCE Toxicity Values



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

*Uses more potent value for liver.

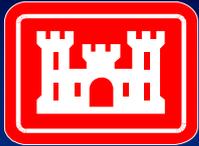


Selecting Provisional Toxicity Values in the Absence of IRIS Values



EPA Office of Superfund Remediation and
Technology Innovation (OSRTI, aka
OSWER)

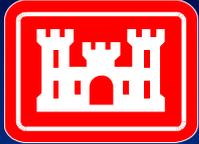
- EPA Office of Research and Development
- California EPA
- Navy
- Air Force
- Army



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

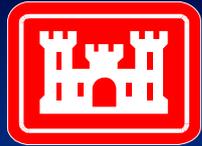


Overriding Principle



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

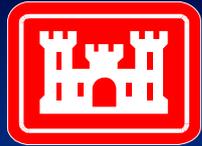
Issue paper is not on how to perform chemical risk assessment but process for selecting from already developed values.



EPA's Hierarchy for Toxicity Values



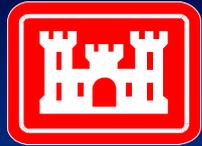
- Tier 1: Integrated Risk Information System (IRIS)
- Tier 2: Provisional Peer Reviewed Toxicity Values (PPRTVs)
- Tier 3: Other sources
 - CalEPA
 - ATSDR MRLs
 - Health Effects Assessment Summary Tables (HEAST)
- Notes other Tier 3 sources may exist



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”



Issue Paper Encourages Flexibility in the Use of IRIS Values

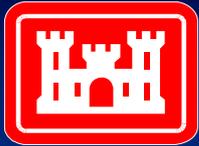


- IRIS is primary source but....

“..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.”

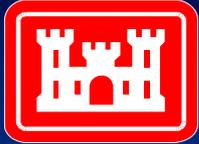
- Important nuance



Tier 2: PPRTVs



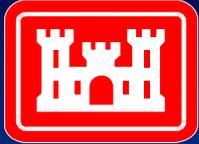
- Provisional Peer Reviewed Toxicity Values
- Do not undergo EPA multi-program review as IRIS does
- Developed for use in Superfund
- Issue paper describes their development
- Not publicly available
- Issue paper urges EPA to open availability



PPRTV Process



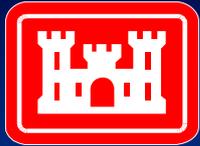
- Consistent with EPA methods for developing RfDs/RfCs and slope factors
- Internal review by 2 EPA scientists
- Review by 3-5 external scientists
- No multi-program consensus as with IRIS values



Other Sources



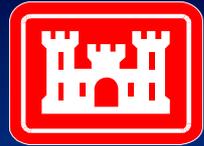
- No comprehensive list, could include:
- CalEPA
- ATSDR MRLs
- HEAST
- US Federal agencies
- States
- International Agencies (UN)
- Foreign Governments



Potential Pitfalls of Other Values



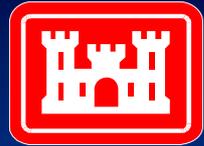
- Administrative, risk assessment not used in derivation
- Risk management applied e.g. MCLs
- Outdated
- Outdated studies used in derivation



Heart of the Paper: Preferences for Selecting Toxicity Values



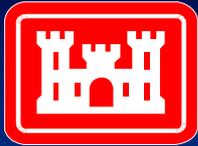
- Transparent assessments
- External and independent review
- Use of established and publicly available methodology
- Methods informed by current best scientific practices



Heart of the Paper: Preferences for Selecting Toxicity Values



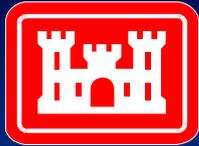
- Assessments should consider quality of studies and make best use of all available science
- Values and assessment are publicly available
- Public comment encouraged, but not in lieu of external peer review
- Values consistent with duration of human exposure being assessed



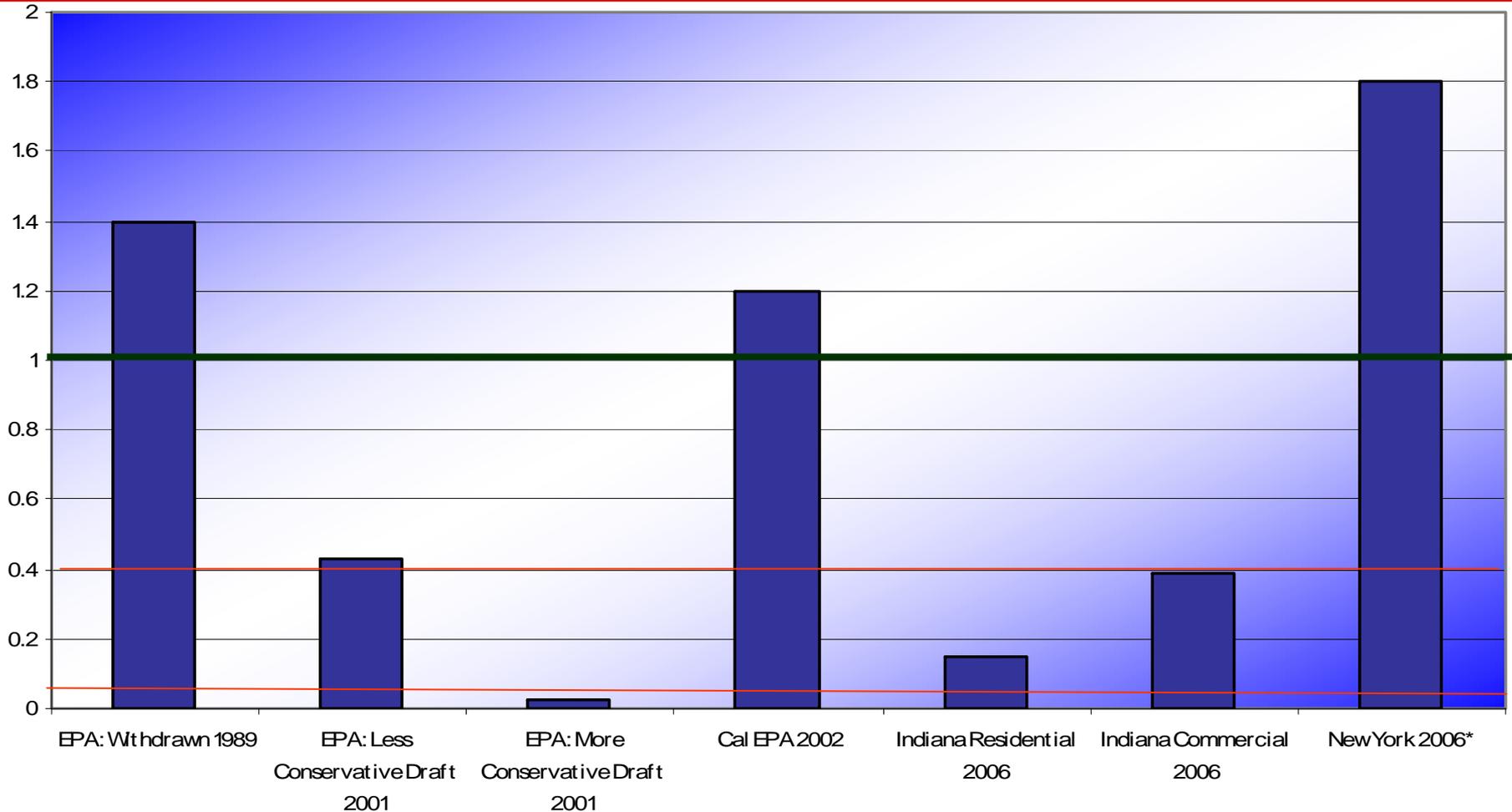
No appropriate values?



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

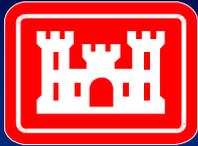


Target Air Concentrations Using Various TCE Toxicity Values



Red lines: Detection limits scan and SIM mode
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*Uses more potent value for liver.



Why Does This Matter?

Example: IRIS Reassessment List

Acetaldehyde

Acetone

Acrolein

Acrylamide

Acrylonitrile

Aldicarb

Aldicarb sulfone

Aldicarb sulfoxide

Ammonium Perchlorate

And other perchlorate salts

Arsenic, inorganic

Asbestos (noncancer effects)

Benzene (noncancer)

Benzo(a)pyrene

Beryllium (cancer effects)

Boron

Bromobenzene

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

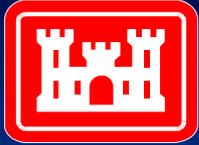
Trichloroethylene

Uranium (natural)

Vinyl acetate

Xylenes

Zinc



Next Steps



- Paper has been through extensive review within Workgroup
- Completed review by States
- Seeking vote in the coming months by ECOS organization to adopt as a resolution

Acknowledgments:

- Department of Army
- Army Environmental Command
- USACE Formerly Used Defense Site Program
- Team as well as Stateside & Associates