

Soil Remediation Standards

Stakeholders Meeting – 10/14/14

Hierarchy of Tox Info



Hierarchy Sources of Toxicity Values

Hierarchy	Basis			
Tier I	NJDWQI			
Tier II	EPA IRIS			
Tier III	NJDEP PPRTV EPA ECAO Policy RSL Appendix ATSDR CAL EPA HEAST			



Importance of Hierarchy

- Standardized
- Peer Reviewed Science
- Consistency
- Equivalency



Governor Christie Executive Order #2 Established "Common Sense Principles"

- 1. Engage in the "advance notice of rules" by soliciting the advice and views of knowledgeable persone from outside of New Jersey government, including the private sector and academia, in advance of any rulemaking...
- 2. Employ the use of cost/benefit analyses, as well as scientific and economic research from other jurisdictions, including but not limited to the federal government when conducting an economic impact analysis on a proposed rule.
- 3. Detail and justify every instance where a proposed rule exceeds the requirements of federal law or regulation. State agencies shall, when promulgating proposed rules, not exceed the requirements of federal except when required by State statute or in such circumstances where exceeding the requirements of federal or regulation is necessary in order to achieve a New Jersey specific public policy goal



Deviations

- Per Executive Order #2, Deviations should be explained in detail (Why?)
- Implications:
 - Non-competitive environment (neighboring states)
 - Redevelopment
 - Time and Resources (Regulatory / Industry)



Example: Ethyl Benzene

- Residential Soil Standard Current = 7800 mg/kg
- Proposed change to 10 mg/kg
 - 3 orders of magnitude change
 - CAL EPA classification of ethyl benzene as a possible human carcinogen (Class 2B) based upon study completed by the International Agency for Research on Cancer (IARC).
- Need to further explain deviation of hierarchy especially due to contradictory view on animal studies.
 - Inconclusive evidence on human exposure at industrial sites
 - Uncertainty factors
 - Mode of Action & Predominant Pathway



Updates of NJDEP SRS

- 7:26D-6:
 - NJDEP has ability to file a notice of administrative change on website and in register when the USEPA changes:
 - the carcinogenic slope or
 - the reference dose data contained in IRIS, so:
- NJDEP has ability to change the standard immediately, if new information becomes available. If based upon peer reviewed science, USEPA adopts to change toxicity of ethyl benzene, then NJDEP should make change, but not until that time.



Ethyl Benzene – Peer Reviewed Science

- Human Exposure (industrial) has proven to be inconclusive.
- Adaptive vs adverse effects in animal studies below metabolic saturation levels (200 ppm).
- No toxicity or increased tumors are seen in rats or mice at levels below 750 ppm.
 - Most of key toxicity findings of ethyl benzene in test animals (e.g. cancer) are observed at levels above the metabolic saturation level of 200 ppm.
 - At same time, the population of the US is exposed to levels of ethyl benzene that are less than 10 ppb.
 - Existing practice within EPA as well as recommendations contained in the Organization for Economic and Co-operation and Development Guidelines indicate that toxicity findings above the inflection point of the onset of the metabolic saturation and are well separated from real world exposure have limited relevance to potential human risks.



<u>Predominant Pathway – Mode of Action</u> <u>Considerations for Ethyl Benzene</u>

- Formation of lung tumors in mice:
 - Mice typically have a large amount of enzyme CYP2F2 in their lungs.
 - Rats have less of similar enzyme CYP2F4 in their lungs.
 - Humans have minimal CYP2F1 enzyme in their lungs.
- Metabolism by CYP2F2 creates different metabolites that are toxic to lung cells.
- In preliminary short term testing of ethyl benzene, CYP2F2 knockout mice show that measures of initial effects do not occur and therefore, species differences will cause lung tumors in mice, but not in humans.
- Need time to validate in 2-year cancer study for ethyl benzene. Tested with styrene.



Regulatory Review of Ethyl Benzene

- EPA is currently performing an IRIS evaluation on ethyl benzene.
 - No other states have changed ethyl benzene standards
 - Germany, Canada, & Danish EPA have not changed classifications after reviews.



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Ethyl Benzene – Vapor Intrusion

- Concerns on ethyl benzene background and potential NJ vapor intrusion standard.
 - ASTDR and EPA have measured median levels of ethyl benzene:
 - 1 ppb Residential
 - 0.65 ppb urban / suburban outdoor air
 - 0.20 ppb rural air
 - Current proposal for vapor intrusion is 1.1 ug/m3.
 - This is equal to 0.24 ppb ethyl benzene.
- Summary:
 - Ethyl benzene would be exceeded in at least 50% of the samples taken in North American residences. (Reference: Background Indoor Air Concentrations of Volatile Organic Compounds in North American Residences (1990 – 2005): A compilation of Statistics for Assessing Vapor Intrusion.



Background and VI Concerns

- Benzene (0.65 ug/m3) and Ethyl Benzene (1.1 ug/m3) Indoor Air Samples would consistently be exceeded due to back ground levels.
- Carbon tetrachloride, Trichloroethylene, and Vinyl Chloride background levels are approaching proposed standards.



Proposed VI Standard vs 90% Concentrations in Background Indoor Air

Chemical	NJ	MA	NY	CO	MI	CAN ADA	EPA	50% Range in NJ	Standard
Benzene	10	6.8	15	-	15.3	5.21	10	<1.6-3.1	0.65
EB	9.54	5.25	7.3	-	8.9	4.76	8.6	1.0-1.7	1.1
СТ	<3.1	<3.14	0.8		0.9		0.8	<0.25 - 0.60	1.3
TCE	<2.7	<2.68	0.5	0.3	0.8	0.19	0.9	0.3 – 1.7	1.1
VC	<1.3	<1.26	<0.25				0.03	<rl< td=""><td>0.52</td></rl<>	0.52

EB = Ethyl Benzene, CT = Carbon Tetrachloride, CT = Carbon Tetrachloride, TCE = Trichloroethylene, & VC = Vinyl Chloride All measurements are in ug/m3 and numbers are taken from NJDEP VI Guidance Document Appendix G. < indicates Reporting Limit.



<u>Background Indoor Air Compilations –</u> EPA 1990 – 2005 in North America







