

Ch. 62-777/CTLs Working Group

Contaminated Media Forum Meeting

February 27, 2014

Presentation Goals

- List potentially beneficial changes identified by the working group
- Briefly describe the issue, the concerns, and possible courses of action
- Estimate a time frame within which recommendations could be reached (short, medium, long)

Apportionment

- ❑ Issue: Chapter 62-780.680 specifies that unless meeting the default CTLs on a not-to-exceed basis, CTLs must be corrected [apportioned] so that the total risk from multiple chemicals present does not exceed targets of 1E-06 excess cancer risk and HQ of 1.
- ❑ Concerns: Apportioning is technically challenging (especially for groundwater); common chemicals (e.g., arsenic, PAHs) can drive CTLs for other chemicals to vanishingly small numbers; major obstacle to use of the 95%UCL and alternative CTLs.
- ❑ Possible changes: Eliminate apportionment requirement or limit it to chemicals with established dose-additive effects (PAHs, PCBs, dioxins)
- ❑ Time frame: Medium – Any change would require rule-making

3X Not-to-Exceed Provision

- Issue: Chapter 62-780.680 contains a provision (repeated under each RMO Level) that the maximum detected concentration at a site must not exceed three times the applicable SCTL if a 95%UCL is used as the exposure concentration.
- Concerns: 3X limit is not technically based and is more conservative than some other states with similar provisions; it creates an impediment to the use of the 95%UCL as the exposure concentration; it cannot be implemented with Incremental Sampling Methodology approaches to site assessment
- Possible changes: Change to another value (management or technically based); Eliminate the 3X limit provision and address concerns for leaving hot spots by other means such as sizing of exposure units.
- Time frame: Medium – A change would require rule-making

Acute Toxicity-based SCTLs

- Issue: Chapter 62-777 has eight SCTLs (barium, cadmium, copper, cyanide, fluoride, nickel, phenol, and vanadium) for unrestricted land use based on acute contact with soil by a small child. The exposure scenario is one-time ingestion of a pica amount of soil by a toddler.
- Concerns: Acute toxicity values are not available from standard sources and had to be derived for these chemicals; toxic endpoints for many are based on transient GI effects that may not warrant protection; exposure assumptions may need to be re-evaluated; cannot evaluate with ISM
- Possible changes: Revise or eliminate some or all of the acute toxicity-based SCTLs.
- Time frame: Medium – Revision would take time to work through; any change would require rule-making

Probabilistic Risk Assessment

- Issue: CTLs are currently calculated using deterministic approaches in which a single (point) value is used for each variable in the risk equation. Should probabilistic approaches in which distributions of values are used for some or all of the variables be used in deriving default and/or site-specific CTLs?
- Concerns: Deterministic approaches can compound conservatism and may not be well suited to address 376.30701(2), F.S. requirement regarding risks under "actual circumstances of exposure."
- Possible changes: Develop guidance on deriving CTLs using probabilistic methods, including selecting distributions; fully revise Chapter 62-777 defaults using probabilistic approaches
- Time frame: Medium to long – Would require rulemaking

Sources for Toxicity Values

- Issue: Toxicity values for some chemicals are available from different sources, and the sources vary in the extent of peer review. The choice of source of the toxicity value for a chemical can influence the CTL. Chapter 62-777, Chapter 62-780.650, and the EPA Regional Screening Levels are each different with respect to preferred sources for toxicity values.
- Concerns: Different preferences for sources of toxicity values leads to inconsistencies in CTLs for some chemicals.
- Possible changes: Adopt a hierarchy of toxicity value sources that is consistent within FDEP, and perhaps consistent with EPA.
- Time frame: Medium to long – rule-making may be required.

CTL Formulas

- Issue: CTLs are calculated using formulas that account for routes of exposure and the toxic potency of the chemical. The formulas used to calculate CTLs in Chapter 62-777 are different from those used by the EPA. The existing formula for groundwater captures only ingestion, while EPA considers inhalation and dermal exposure (while showering) as well. For soil, formulas used by FDEP and EPA calculate aggregate residential exposure differently.
- Concerns: Existing formulas may not capture all of the important pathways (for groundwater) and lead to inconsistent CTLs between FDEP and EPA for the same chemicals at the same site.
- Possible changes: Modify some or all of the formulas in Chapter 62-777 to be consistent with EPA.
- Time frame: Medium to long – would require rulemaking

Toxicity Value Adjustment

- Issue: Since development of CTLs in Chapter 62-777, incorporation of an Age-Dependent Adjustment Factor (ADAF) into the CTL calculation to account for increased susceptibility to mutagenic carcinogens at early life stages has become standard with EPA. Also, EPA now uses inhalation toxicity values expressed in concentration terms rather than mg/kg/day.
- Concerns: The approaches to calculating risk from inhalation exposure and the risk of cancer to children posed by mutagenic chemicals in Chapter 62-777 are outdated.
- Possible changes: Revise the inhalation component of the SCTL formula for and incorporate the ADAF into the calculation of CTLs for mutagenic carcinogens.
- Time frame: Medium to long – would require new rulemaking and extensive recalculation of CTLs.

Updated Exposure Assumptions

- Issue: Recommendations regarding some of the exposure assumptions upon which CTLs in Chapter 62-777 have changed since 2005. Also, GCTLs do not consider exposure by children.
- Concerns: The CTLs in Chapter 62-777 in general no longer reflect the best contemporary exposure information, and the protectiveness of GCTLs for children could be questioned.
- Possible changes: A re-evaluation of the exposure assumptions used in CTL derivation could lead to a change in the values used for default CTLs. Recommendations could be provided for sources of exposure information suitable for alternative CTLs, facilitating their development.
- Time frame: Medium to long. New rule-making would be required for changes in default CTLs.

Other Issues

- Some issues discussed were considered to be low priority by the working group. These include:
 - Expanding the scenarios for which default SCTLs are available beyond the residential (unrestricted) and commercial/industrial land use.*
 - CTLs based upon vapor intrusion

* The Department currently has irrigation water guidance numbers for some chemicals, and the status of these numbers should be discussed.