

## **62-777 / Cleanup Target Levels (CTLs) Workgroup**

### ***Goals***

Workgroup goals were threefold: (a) list potential beneficial changes to existing conditions under Chapters 62-780 and 62-777, FAC; (b) describe each issue, identify potential concerns/uncertainties, and possible courses of action; and, (c) estimate a timeframe within which recommendations could be achieved.

### ***Issue 1: Apportionment***

CTLs presently must be apportioned to achieve aggregate risk of 1E-06 or Hazard Quotient of 1 if more than one chemical exceeds a default CTL. Apportionment can be challenging, especially for groundwater, and apportioning represents a major obstacle to effective use of the 95% UCL approach for alternative CTL development, because some chemicals (e.g., As, PAHs) will drive CTLs for other chemicals to very small values. Possible changes identified by the Workgroup included focusing apportionment application to chemicals with recognized dose-additive effects (e.g., PAHs, PCBs, dioxins), or eliminating an explicit apportionment requirement, while still addressing in narrative fashion a statutory requirement to address apportionment. Timeframe medium; changes would require revisions to 62-780.

### ***Issue 2: 3x Not-to-Exceed Provision***

62-780 requires that if a 95% UCL approach is used the site maximum concentration may not exceed 3x the applicable soil CTL. The 3x requirement is a management decision, is not technically based, creates an impediment to use of the 95% UCL approach, and it is not clear whether/how to address the requirement if Incremental Sampling Methodology (ISM) is used. Other states known to employ a similar requirement employ a 10x or 100x provision. Possible changes identified by the Workgroup included leaving the 3x as it is, revision of the requirement to employ a less restrictive multiplier, or eliminating the provision and addressing potential “hot spot” concerns by other means such as sizing/definition of exposure units. Timeframe medium; changes would require revisions to 62-780.

### ***Issue 3: Acute Toxicity-based SCTLs***

62-777 has seven (7) chemicals (of ~475) for which default SCTLs are based on acute toxicity considerations, assuming single event exposure by a small child to a relatively large soil quantity (10 grams). Acute toxicity-based values are not available from standard sources and *de novo* values were developed, toxicity endpoints in several cases were based on transient gastrointestinal effects which typically are not used for that purpose, the soil ingestion rate may be higher than appropriate, and it is not clear whether/how to address the requirement if ISM is used. Possible changes identified by the Workgroup included elimination of the acute toxicity-based SCTLs, or revision of those values based upon modified exposure assumptions. Timeframe medium; changes would require revisions to 62-777 and 62-780.

#### ***Issue 4: Probabilistic Risk Assessment***

CTLs now are calculated using deterministic (“point estimate”) approaches in which a single value is used for each variable in the calculation. It is possible to use probabilistic approaches in which statistical distributions of values are used for some or all of the variables in deriving default and/or site-specific CTLs, a process which is identified explicitly in 62-780. A concern with the deterministic approach is that it can compound conservatism and may not be well-suited to address 376.30701(2), F.S. requirements regarding risks under “actual circumstances of exposure”. Possible changes identified by the Workgroup included development of guidance on deriving CTLs using probabilistic methods (including selection of appropriate distributions for exposure parameters), or fully revising 62-777 defaults using probabilistic approaches and selected distributions. While preliminary efforts could investigate the degree of change attributable to probabilistic approaches, full changes to 62-777 would require rule revision in a medium to long timeframe.

#### ***Issue 5: Sources for Toxicity Values***

Toxicity values for some chemicals are available from multiple sources, and sources vary in the extent of peer review. The choice for source of a toxicity value for a chemical can influence the CTL. 62-777, 62-780.650, and the EPA Regional Screening Levels are each different with respect to articulation of preferred sources for toxicity values. Different preferences for toxicity value sources lead to inconsistencies in CTLs for some chemicals. Possible changes identified by the Workgroup included adoption of a hierarchy of toxicity value sources that is consistent within FDEP, and/or consistent with EPA. Timeframe is uncertain, since changes to existing guidance would be technically simpler, but timing could be medium to long if rule revision is required.

#### ***Issue 6: CTL Formulas***

CTLs are calculated using formulas that account for routes of exposure and the toxicity of the chemical. Formulas used to calculate 62-777 CTLs are different from those used by the EPA. The existing formula for groundwater captures only ingestion, while EPA considers inhalation and dermal exposure as well (e.g., showering). For soil, formulas used by DEP and EPA calculate aggregate residential exposure differently. Concerns were expressed that existing formulas may not capture all of the important pathways (for groundwater), leading to inconsistent CTLs between DEP and EPA for the same chemicals at a site. Possible changes identified by the Workgroup included leaving formulas as they are, or modifying some/all formulas in Chapter 62-777 to be consistent with EPA. Timeframe could be medium to long if new equations are adopted and applied to revise all 62-777 CTLs.

#### ***Issue 7: Toxicity Value Adjustment***

Since development of 62-777 CTLs, EPA has developed an Age-Dependent Adjustment Factor (ADAF) for CTL calculations to account for increased susceptibility to mutagenic carcinogens at early life stages. EPA also uses inhalation toxicity values expressed in concentration terms (risk per  $\mu\text{g}/\text{m}^3$ ) rather than  $\text{mg}/\text{kg}\cdot\text{day}$ . The former would have a significant impact on CTLs, while the latter can be addressed in existing approaches.

Possible changes identified by the Workgroup included leaving assumptions as they are, revising the inhalation component of the SCTL calculation, and revising the SCTL calculation to incorporate the ADAF for mutagenic carcinogens. Timeframe could be medium to long if ADAF was adopted and applied to revise all 62-777 CTLs.

***Issue 8: Updated Exposure Assumptions***

Some of the exposure assumptions underlying 62-777 CTLs have changed since 2005. Also, groundwater CTLs do not explicitly consider childhood exposure. It was suggested that 62-777 CTLs may no longer reflect timely exposure information. Possible changes identified by the Workgroup included leaving assumptions as they are, or reevaluation of the exposure assumptions used in CTL derivation. Timeframe could be medium to long if new assumptions are adopted and applied to revise all 62-777 CTLs.

***Other Issues***

Additional issues were discussed but considered to be low priority by the Workgroup, for example:

- Expanding the scenarios for which default SCTLs are available beyond unrestricted residential and/or commercial/industrial land use (e.g., irrigation). The Department currently has irrigation water guidance numbers for some chemicals.
- CTLs based upon vapor intrusion