

**Contaminated Media Forum Minutes:  
Chapter 62-777, FAC Contaminant Cleanup Target Levels  
Tallahassee, Florida, July 22, 2015**

Minutes of Meeting:

1. The purpose of this meeting was to review proposed updates to Chapter 62-777, FAC. These updates affect the calculation of cleanup target levels (CTLs) for soil and groundwater. Topics for discussion during the meeting included: deterministic versus probabilistic calculation of CTLs, proposed changes to CTL equations based on current EPA equations, proposed changes to default assumptions, other proposed changes including a discussion on CTLs based on acute toxicity, and proposed formatting changes to the tables presented in the Chapter. Several items of concern were then discussed in more length including the hierarchy used for updating toxicity values, route-to-route extrapolation, apportionment,  $\frac{1}{4}$  acre DU size, and 3x maximum concentration values.
2. The first item for discussion involved the use of deterministic versus probabilistic methods for calculating CTLs. It is the current practice to calculate CTLs with deterministic equations. The Florida Department of Environmental Protection (FDEP) stated that while the probabilistic method is acceptable for developing Alternative Cleanup Target levels (ACTLs), they would continue to use the deterministic method for developing CTLs. Future use of a probabilistic method was not excluded. Research into the procedures from other states found that no states currently use probabilistic methods for the purpose of developing CTLs.
3. Proposed changes to the deterministic equations used to develop CTLs for groundwater, direct contact with soil, and soil leachability were discussed next.
  - a. The University of Florida presented the equations currently used for the development of CTLs with attention directed to the variables that have changed following a basic update of chemical/physical parameters and toxicity values for chemicals found in tables 1-8 in Chapter 62-777, FAC, as well as for some exposure assumptions. Sources used for these changes can be found on EPA's hierarchy of sources for chemical/physical parameters, FDEP's hierarchy of sources for toxicity values, and EPA's 2015 recommended exposure assumptions. No updates to the equations themselves have been made at this time.
    - i. Assumptions for the drinking water consumption rate (2 L) and for body weight (70 kg) have not changed for the groundwater equations. During development of the current rule in 2005, these exposure assumptions were kept at the indicated values because it was important to be consistent with the exposure assumptions used by the EPA Office of Water. It is not clear whether this is currently the case. It was noted during discussion that this creates an inconsistency with

the body weight assumptions used to develop the SCTLs. The Department will have internal discussions to see if the need to hold these assumptions at their current values when deriving GCTLs still exists. If not, there appeared to be consensus among participants that they should be consistent for GCTL and SCTL calculation.

- ii. A concern was voiced about the use of the FDEP hierarchy for toxicity sources, questioning if the presence of a lower tiered source should supersede the absence of a toxicity value from a higher tiered source due to its availability or due to it being more recent than updates to higher tiered sources. The validity of lower tiered sources was called into question. One participant was concerned with the use of EPA's PPRTVs, a tier one source whose peer review process is not the same as EPA's IRIS. At the end of the meeting, a subgroup was formed to continue discussion of this topic (see below).
  - iii. A concern about the appropriateness of route-to-route extrapolation was voiced and was talked about in length later in the day and can be found here in section 7.b.
- b. Considerations for changes to groundwater CTL (GCTL) equations with subsequent discussions are as follows:
- i. Including inhalation and dermal pathways- This appears to be the correct direction to follow as the science of risk assessment has evolved. There was concern voiced, however, about the criteria EPA uses to determine whether a chemical is sufficiently volatile that inhalation exposure should be included. FDEP and UF were asked whether a method for classifying chemicals as volatile was being proposed. UF replied that they agreed with concerns about the EPA method, but an alternative method was not being proposed until it has been decided whether or not to include inhalation in GCTL derivation.
  - ii. Develop separate equations for mutagenic carcinogens, non-mutagenic carcinogens, and non-carcinogens to accommodate ADAFs and aggregate resident-type exposure for carcinogens- ADAF is being used by a many of the states in the U.S, where some apply the ADAF to all carcinogens and some use it more specifically for mutagenic carcinogens. There seems to be scientific support for use of ADAFs although there is concern about using them beyond mutagenic carcinogens, as well as concern about the effect their addition will have on the CTLs for some chemicals .
    - 1. One issue with adopting ADAFs is with the age-weighted averaging used for calculations by the FDEP. A decision would have to be made to keep FDEP age-weighted averaging or adopt EPA age-weighted

averaging. It was agreed that FDEP age-weighted averaging was more appropriate and it was suggested that age weighted ADAFs be created.

- iii. Exclusion of Relative Source Contribution (RSC)- Currently a RSC of 0.2 is used for all non-carcinogenic chemicals in the GCTL equation. A suggestion was made to develop chemical specific RSCs as an alternative to eliminating their use all together, although this could be very time-consuming and costly. Excluding RSCs may create an internal conflict, however and will need to be discussed with the Department of Health and internally within FDEP at a later date.
  - c. Considerations for changes to direct contact soil CTL (SCTL) equations with subsequent discussions are as follows:
    - i. Include ADAFs for mutagenic carcinogens- see previous discussion 3.b.ii
    - ii. Change age-weighted averaging of BW and soil ingestion- It was agreed upon that FDEP age-weighted averaging is preferable to EPA age-weighted averaging.
    - iii. Use RfC instead of RfD<sub>i</sub> for inhalation exposure- EPA no longer derives inhalation toxicity using RfD<sub>i</sub> but now uses concentrations by way of RfCs. RfCs appear to be acceptable as long as route-to-route extrapolation is examined more closely.
    - iv. Eliminate extrapolated RfD<sub>d</sub> and calculate dermal using dose using RAGS D equations for organics and inorganics- the RAGS D equations may be appropriate with the careful considerations of the default values before adoption.
  - d. Considerations for changes to soil leachability equations with subsequent discussions are as follows:
    - i. Add mass-based leachability equation per EPA SSL. There was a positive response to including mass consideration in some form. The specifics of how to do that would have to be determined. It was asked whether the EPA SSL approach is the only one the Department would consider, and FDEP replied they are open to any suggestions.
4. Proposed changes to default assumptions discussed are as follows:
- a. Update to values for body weight, exposure duration, skin surface area, and dermal adherence assumptions- Updates are per EPA exposure assumptions where body weight and surface area has changed for child, adult, and indoor worker, exposure duration for an aggregate resident is 26 instead of 30 years, and dermal adherence has decreased for indoor worker. Use of NHANES data to develop body weight and surface area using the FDEP age-weighted averaging approach was discussed. UF will determine the feasibility of doing age-averaging based upon the EPA exposure assumptions or whether a more detailed analysis using NHANES data as was performed for the current rule will be necessary.

- b. Changes in GCTL exposure assumptions based on child rather than adult only exposures- Over 70% of states in the U.S. consider a child in their GCTL. If adopted the development of surface area for a child ages 1-7 years will need to be established. Inclusion of children in the groundwater equation was agreed to be a policy decision.
  - c. Add an outdoor worker scenario- It is current practice to use exposure assumptions for an indoor worker only. It appeared to be a consensus that the inclusion of a separate outdoor worker scenario isn't needed. Because an outdoor worker has lower SCTLs due to a higher soil ingestion rate, use of an outdoor worker instead of an indoor worker as the default scenario was discussed. Those expressing an opinion preferred using only the indoor worker as the default for the commercial/industrial scenario.
5. Other proposed changes to CTL calculations are as follows:
- a. Eliminate estimation of cancer risk for Class C carcinogens by dividing RfD<sub>o</sub> by 10. Cancer risk would not be estimated for chemicals without a cancer slope factor- There was agreement to eliminate this practice.
  - b. Eliminate CTLs base on acute toxicity- There is concern that acute toxicity numbers do not have a real world application. There are examples of chemicals with significant acute illness including death, however, and therefore the number of chemicals with acute toxicity values may need to be redefined. FDEP would like to continue discussion on this topic.
  - c. Eliminate Csat derivation as it is rarely used- Csat is rarely used and could possibly be taken out of Chapter 62-777, FAC; however if so, it would need to be taken out of Chapter 62-780, FAC as well. There was no agreement on this topic and further discussion is needed.
6. Proposed formatting changes were discussed for tables 1-8 found in Chapter 62-777, FAC.
- a. Table 1: Separate listing for non-cancer target organs/systems or effects by RfD<sub>o</sub> and RfC, because they can be route specific. For chemicals with both a primary and secondary standard, change priority for listing secondary to primary standard- There was no objection to this suggestion.
  - b. Tables 2 and 5b: separate listing for non-cancer target organs/systems or effects by RfD<sub>o</sub> and RfC, because they can be route specific. Also, remove cancer classification from Table 5b. They are obsolete- There was no objection to this suggestion.
  - c. Table 6: Add target organs for RfCs, table currently only shows target organs for RfD<sub>o</sub>s- There was no objection to this suggestion.
  - d. Table 7: Change "health-based" column to "risk-based GCTL" and move primary standards in this column to a footnote; clarify footnotes at the table- this is for clarification and was seen as appropriate as long as information stays in the same place so it is easy to access. UF requested that if anyone has other suggestions to improve the clarity of the tables that they be brought to the group's attention.

7. Continued conversation about previous and relevant topics include: the hierarchy used for updating toxicity values, route-to-route extrapolation, apportionment,  $\frac{1}{4}$  acre DU size, and 3x maximum concentration values in regards to ISM sampling
  - a. The toxicity value hierarchy brings to light some concerns, as addressed in section 3.a.ii, and it is the belief that for certain chemicals strict adherence to the hierarchy may not be appropriate. One solution may be to truncate the tiers. Another suggestion may be to reorganize the hierarchy and add EPA's RSL tables to it. It was agreed to continue this discussion through a focus group for the chemicals for which the source suggested by the hierarchy is of particular concern. No date was agreed upon at this meeting. Interested parties are to email FDEP to coordinate a date.
  - b. Another topic of concern to be discussed further is route-to-route extrapolation of toxicity. There is not support from EPA at this time for extrapolation. Route-to-route extrapolation may only be appropriate when the effect of the chemical is systemic. One specific concern lies with the possibility of an inappropriate extrapolation from oral to inhalation due to the inclusion of inhalation exposure in the GCTL equations, as that may overestimate risk. Another concern is that if there is no extrapolation for a chemical with a systemic effect, the calculated risk may underestimate the actual risk. No decision was made at this meeting.
  - c. Next, the topic of apportionment was brought to the table with the proposal of using dose additivity as the exclusive means to address additive effects. As of now, apportionment looks at what organ/system is being affected by each chemical of concern; it may be more correct to look at mode of action and whether or not those effects are additive. One way to deal with this may be to group chemicals for which similar modes of action and dose additivity are well established (e.g., dioxin and dioxin-like compounds; carcinogenic PAHs; some pesticides). The concern with this is that there may be unknown additive effects between chemicals. FDEP is interested in looking into this topic in more depth and a work group for discussing additivity further was suggested.
  - d. The promulgated DU lot size of  $\frac{1}{4}$  acre was discussed as it has ramifications on large sites. It was asked whether DU size could be increased for larger sites. DU sizes can be larger than  $\frac{1}{4}$  acre when a restriction is placed on the property. Future use of sites isn't always known and smaller lots could be used in the future so a restriction would be necessary. It was decided that FDEP would look further into this issue for the appropriate way to handle this concern.
  - e. Lastly, it was suggested that the promulgated maximum concentration lower than 3x the CTL on a site using 95% UCL be struck from Chapter 62-780, FAC. ISM does not provide a maximum concentration, therefore the language may need to change to incorporate its use.

Striking the 3x from the rule may be acceptable as long as the DU is an appropriate size as to not underestimate risk due to dilution.

8. At the conclusion of this meeting three work groups were established to talk about the following: 1) toxicity values and the use of the hierarchy, 2) additivity, and 3) probabilistic risk assessment. No dates were scheduled for these meetings at this time. A focus group would also be established for determining whether regional or statewide background values are feasible.
9. The next Contaminated Media Forum is to take place before the next Rule Workshop and was suggested to take place the day before. The tentative location is Tampa. No dates have been scheduled at this time.