

## Methodology Focus Group Meeting Summary

September 29, 1999

Gainesville Florida

- (1) Methodology Focus Group (MFG) members agreed on the following opening statements:
  - (a) Meeting summaries are needed and the task of preparing the summaries will be shared by all members on a rotation basis.
  - (b) Meetings need to be refocused by concentrating on technical issues as opposed to legal and policy issues.
  - (c) Timeframes need to be set for pending projects.
  - (d) More meetings or teleconferences are needed.
  - (e) FDEP staff will provide support for the distribution of information.
- (2) The table of pending projects generated in the previous MFG meeting was reviewed. Bob DeMott will distribute a copy of the table, including pertinent points of discussion from this meeting, to all members. A brief description of each project will also be provided.
- (3) Chris Teaf and Ed Zillioux were charged with drafting a paragraph regarding Attributable Risk.
- (4) Chris Teaf provided an update on his work to augment the leachability column of the SCTLs table for inorganic compounds. Dissociation constants, K<sub>d</sub>, for some chemicals (*i.e.*, aluminum) are not greatly affected by pH and soil type. Leachability SCTLs for these chemicals can be generated. However, K<sub>d</sub> values for other metals (*i.e.*, lead) can vary 3 to 4 orders of magnitude depending on factors such as pH and soil type. Leachability SCTLs for these metals may have to be determined on a site-specific basis.
- (5) Chris Saranko presented the results of the Refined Exposure Assumptions study. A copy of the presentation overheads is available upon request.
  - (a) Steve Roberts stated that changes (*i.e.*, refined surface area assumptions) made in isolation of other factors (*i.e.*, bioavailability and adherence factor) may result in SCTLs that do not make sense. For example, using the refined surface area assumptions, SCTLs for many metals are driven by the dermal route even though common sense and some empirical data suggest otherwise.
  - (b) LEAF restated the concern that women are not equally protected (as a result of the default body weight) and that some of the exposure parameters are not appropriate for Florida. For example, the surface area assumption for workers assumes that the worker is wearing long sleeves (*i.e.*, arms are not exposed). MFG members explained that surface area is not necessarily the area exposed but rather the area that is covered with 0.6 mg of soil, 250 days/year for 30 years.

## Methodology Focus Group Meeting Summary

December 16, 1999  
Orlando, Florida

1. Bob DeMott distributed the Table of Issue Priorities.
2. Chris Teaf presented the *Attributable Risk Statement* that he and Ed Zillioux prepared. The group is in consensus that the statement is acceptable and is ready to be presented to the Soil Forum.
3. Chris Teaf presented the *Inorganic Soil-to-Water Partitioning Coefficients (Kds) for the SCTL Development* summary he and Bruce Nocita prepared. They concluded that the Kd range for any one metal (for those without leachability-based SCTLs) is too large to support the development of a meaningful leachability-based SCTL. If the most conservative approach is taken, that is using the lowest Kds, the resulting leachability-based SCTL may be close to or lower than background soil concentrations. In addition, there is the question of whether the literature includes the lowest Kd value. The group consensus is that no new leachability values will be proposed at this time. Ligia Mora-Applegate mentioned that Wilbur Mayorga plans to present data from golf courses and other sites in Dade County that indicate that the current arsenic leachability-based default of 29 mg/kg may be too high.
4. Chris Teaf presented the *Proposed Modifications to Identified Acute Toxicity-Based Soil Cleanup Target levels (SCTLs)*. Bob DeMott mentioned that this is one of the items the Methodology Group agreed to tackle this year, and the deadline is rapidly approaching. Changes in the acute toxicity SCTLs were proposed for barium, copper, cyanide, fluoride, nickel, and vanadium. For each chemical, the proposed change is based on revisions to the underlying toxicity value used in the calculation or on changes in the bioavailability of the chemical.

Chris Saranko raised the concern that bioavailability may be of limited relevance for local effects such as gastrointestinal irritation, an endpoint upon which several of the acute toxicity SCTLs were based. Gastrointestinal irritation is probably not dependent on an absorbed dose and may not be dose dependent. Chris Teaf commented that it is difficult to obtain good exposure information from many of the anecdotal reports documenting gastrointestinal effects. He raised the question of whether these studies were of sufficient quality for regulatory purposes.

There was extensive discussion regarding bioavailability considerations, particularly as it relates to: (1) chronic dosing versus a bolus dose such as one that might occur during the ingestion of a large amount of soil; and (2) the relevance of food bioavailability to soil bioavailability. The group seemed to agree that the assumption of 100% bioavailability is probably unrealistic in the case of a large bolus dose. Richard Lewis shared food and soil bioavailability data he obtained from Mitretek. Ligia Mora-Applegate expressed reservation on using an uniform bioavailability value across the board for any SCTL development whether acute or

chronic since at least in the literature on arsenic bioavailability that she is familiar with the bioavailability values reported fall within a very wide range. She stated that the way to go in the future is to develop site-specific bioavailability provided that economic in vitro models to do so, are validated.

Because many of these matters require further discussion and the fact that Steve Roberts' was unable to attend this meeting, the methodology focus group decided to meet the day before the next Soil Forum to discuss and hopefully resolve the acute toxicity issues. Chris Teaf will provide copies of the acute toxicity bibliography to Roger Register and will send a set to each person who indicated that they would like to receive them.

5. Chris Saranko presented information on gender and racial differences in body weight, and dermal surface area. The information presented indicated that the amount of inter-gender and inter-racial variability was lower than the amount of inter-individual variation. He also presented information on four equations used to calculate skin surface area. Three of these equations use body weight and height, while one of the equations uses only body weight. It was concluded that all of the methods yielded similar results. Chris Teaf reiterated that the term "dermal surface area available for contact with soil" is misleading. The exposed skin surface area is assumed to be completely covered by a monolayer of soil. EPA is expected to release new surface area guidance in the near future, possibly in the next 1-2 months. This guidance is expected to change many of the assumptions currently used in dermal risk assessment including parameters like soil adherence, absorption efficiency, and skin surface area.

The group agreed that using the NHANES III data with the refined annual averaging approach is the best way to determine body weight. Chris Saranko indicated that if the NHANES III data were subject to some modification by the National Center for Health Statistics. Such modification might involve weighted averaging for under-represented groups and/or regions of the country. It was the consensus of the group that the entire dermal pathway needs to be examined further before changes can be recommended. However, it was agreed that dermal surface area should be calculated using NHANES III body weight data and the univariate equation proposed by Burmaster (*Risk Analysis* 18(1): 27-32, 1998). At the present time, the assumptions regarding exposed dermal surface area will not change for Chapter 62-777, F.A.C. Finally, the group agreed to the use of daily inhalation rates calculated from caloric intakes as presented in the 1997 Exposure Factors Handbook.

The Methodology Focus Group wanted the SCTLs to be recalculated incorporating the new body weight, surface area, and inhalation rates data. After the January meeting, this group may recommend to the Contaminated Soil Forum that the SCTLs be revised to reflect more up to date information.

6. The next meeting of the Methodology Focus Group is scheduled for the afternoon of January 31, 2000, at a location to be announced. The primary goals of that meeting are to: (1) resolve the issues surrounding the acute toxicity SCTLs, (2) to reach consensus on the dermal exposure pathway and (3) to decide whether or not to recommend to the CSF that the SCTLs be revised at this time.

7. Anticipated tasks for next year include arsenic, non-soil materials (will need to include a different group of people within FDEP), anthropogenic background, remediation comparisons to “not to exceed SCTLs”, 95%UCLs, how are hotspots defined.

- (c) Bob DeMott requested providing caveats to the exposure assumptions as appropriate (*i.e.*, inhalation rate represents a daily rate).
  - (d) It was agreed by all members to utilize the most current data (NHANES III, 1997 Exposure Factors Handbook) for body weight, surface area and inhalation rate and to use the yearly averaging approach to calculate body weight.
  - (e) LEAF's issue of accounting for women's lower body weight is pending. Prior to the next meeting, UF will perform the SCTL calculation based on women's body weight and surface area.
- (6) The most recent draft of the Natural Background Guidance developed by DERM and FDEP was distributed and Wilbur Mayorga reviewed the changes from the previous draft. A copy of the guidance is available upon request.
- (7) Comments regarding 95% UCL, Hot Spots and Natural Background prepared by Ed Zillioux for FPL, available upon request, were addressed as follows:
- (a) Doug Jones responded to the comment regarding "not to exceed" values and acute toxicity (paragraph 1) by stating that the decision to regulate on acute toxicity is not a change in policy. The acute toxicity values have already gone through 2 workshops.
  - (b) In regards to the 3-times rule (paragraph 2), Doug Jones stated that this rule of thumb is still under debate. He also stated that guidance regarding Hot Spot determination would be written such that natural background levels, if higher than the 3-times level, will supercede the 3-times level.
  - (c) In regards to the issues of anthropogenic background (paragraph 3), Wilbur Mayorga stated that the reason for separating natural from anthropogenic background was explained in the previous meeting. The anthropogenic guidance will contain more legal and policy issues, whereas the natural background document is technical.
  - (d) In response to comments regarding outliers and the Ma study (paragraph 4), Wilbur Mayorga and Ligia Mora-Applegate clarified that the Miami-Dade County samples collected for the Ma study are not representative of natural background. Doug Jones stated that the variability of the data obtained from samples collected for the Ma study reinforces the need to collect site-specific data.
  - (e) Wilbur Mayorga responded to the comment regarding sample depth intervals and mechanical mixing (paragraph 5) by stating that this guidance is not intended to apply to complex cases like FPL's case. A site-specific plan is needed to deal with these types of cases.
  - (f) In regards to the last paragraph, Wilbur Mayorga stated that the guidance was developed in conjunction with FDEP and UF and that the initial draft was generated by UF.
- (8) Wilbur Mayorga provided an update on the anthropogenic background document. He stated that the guidance will address both regional and localized anthropogenic issues, will provide a number of different scenarios as examples and will be

- based, in part, on legal and policy issues. USEPA guidelines (*i.e.*, third party liability and innocent landowner) will be the basis of the guidance. A meeting with FDEP will be arranged to address the legal and policy issues. It was agreed that the MFG will review the technical aspects of the guidance and that the policy and legal issues will be referred to the Policy Group for consideration.
- (9) Items to present at the October 20, 1999 Contaminated Soils Forum include:
- (a) Proposal to use the most recent NHANES III and 1997 Exposure Factors Handbook data for body weight, inhalation rate and surface area.
  - (b) Proposal to use the annual averaging approach for body weight determination.
  - (c) Results of the SCTL calculation based on women's body weight and surface area.
- (10) Revisions must be made by January in order to allow time for notice, rule workshops, etc. Doug Jones stated that priority should be based on commitments that have been made to LEAF, to address exposure assumptions, and FCG, to address leachability and acute toxicity.
- (11) Closing statements:
- (a) A conference call will be scheduled for the week of 12/13/99. Contact Bob DeMott prior to 10/13/99 with preferred dates.
  - (b) Comments on the Natural Background Guidance are due to DERM by 10/13/99
  - (c) Draft Meeting Summary is due by 10/13/99