DRAFT

Methodology Focus Group Meeting Minutes
(August 1, 2001)

Progress Center, Alachua, Florida

Prepared by: Douglas J. Covert and Christopher M. Teaf

Bob DeMott called the meeting to order at 10:15, presented introductory remarks, goals for the meeting and the anticipated agenda.

The primary goal for this meeting is to begin forming a consensus on a recommendation regarding arsenic bioavailability.

The agenda was presented as follows:

1) Presentation by Steve Roberts on the UF arsenic bioavailability study

2) Discussion of appropriate arsenic bioavailability factors

3) Discussion of other SCTL changes

4) Discussion of limits based on PQL's vs health-based limits – laboratory perspective and problems

5) Discussion of uncertainty in risk assessment

Before getting into the agenda, Bob requested volunteers for preparation of the meeting minutes for the next meeting. Joe Sekerke will prepare the minutes for the next meeting of the Methodology Focus Group (MFG).

1) Presentation by Steve Roberts – handouts distributed

Motivation for this study is that, at present, the SCTL for arsenic is based on toxicity guidance that has as its basis arsenic in drinking water studies and an assumption of 100% bioavailability. It is generally understood that arsenic in drinking water is more bioavailable than arsenic in soil. In order to more accurately establish soil cleanup targets, we need to try to quantify the difference.

Further, the bioavailability studies that are in the literature (e.g., mining sites and smelter sites) are not necessarily applicable to soils and site types that we find in Florida.

2) Discussion of arsenic bioavailability (BA)

Chris Teaf: Within the concentration range and site types reported by UF, there is very little variation between the UF monkey study and EPA swine studies. The initial conclusion is that a correction factor in the range of 3

to 6-fold would be appropriate for adjusting the SCTL based on bioavailability.

Bob DeMott: The UF data combined with the other studies would support such a range, but, at this point, are we better off initially evaluating whether there is sufficient support for the study within the MFG?

David Ludder: Difficult and premature to draw any conclusions regarding sufficiency without having the complete study report in hand.

Group discussion ensued regarding the need for final study work product (i.e., report to FDEP) or publication in peer-reviewed journal.

David Ludder: Normally the Department would require that a study be peer-reviewed / published before they would rely on the findings.

Chris Teaf: That is preferable, and likely, but publication in journals has not been a critical step in the past when the Department used a study it commissioned in the establishment of a criterion.

Doug Jones: Agreed that the UF study is a Department-commissioned study, and, as such, the Department would accept an unpublished work product. However, they are counting on peer-reviewed publication to provide further validation of the study. The Department has relied upon non-published EPA studies and they do so based on the considerable internal EPA review that they receive. Rule development can move forward without the study being published, but the Department would be compelled to inform the ERC that the information may be subject to criticism at some point. The Department is looking to the MFG to determine the sufficiency of the UF study with particular emphasis on the use of the monkey rather than the swine as a model animal, since a swine model producing a BA value of 50% is in the literature. The MFG needs to be wary that their main interest does not appear to be relaxing regulatory control – it is generally more difficult to go back to a more stringent standard in the future.

Bob DeMott: The MFG is charged with providing recommendations based on technical merit.

Mike Petrovitch: To Department – is there a real concern with the timing of the anticipated publication and the anticipated Workshop? If the article is accepted soon and the Workshop occurs in October or November, this schedule should work for presentation to the ERC early next year.

Group discussion ensued regarding benefits of peer-reviewed published article.

Steve Roberts: Concurs with Doug Jones' point that peer-reviewed published article would be best, and that is the intent.

Tim Fitzgerald: Back to Doug Jones' other point, is the monkey BA study sufficient to characterize BA for all soils and sites in Florida?

Chris Teaf: Much time and effort on the Department's part went into developing this study, and one assumes that those discussions were held. After the cost and duration, one hopes that it satisfies the intent of the Department. The very limited variability suggests that it is sufficient (small difference between calculated mean and calculated 95% UCL value).

Doug Jones: Are we confident that we have covered all soil types and potential arsenicals? If we were to adjust the SCTL based on the UF data on BA, are we still conservative enough to protect on a default basis?

Steve Roberts: The study at present does not comment on either soil type or arsenic form.

Zoe Kulakowski: There are many different soil types at arsenic sites in Florida that were not considered in the study.

Chris Teaf: We must keep in mind that the term "arsenic site" in Florida currently is more defined by the default threshold than by the actual, reasonable threat of risk. That is, because the default SCTL is low, it is exceeded at many sites that then are defined as arsenic sites. By definition, if the default were defensibly set at a higher value, there would be fewer arsenic sites. We are not interested in relaxing the standard just for the sake of relaxing the standard. We need to focus on getting to a level that remains protective, but that is more realistic based on the science.

Ed Zillioux: Were the results of the study tested for variance? Roberts responds that 2 of the sites were significant outliers and the inter-animal variance was not significant.

Tim Fitzgerald: It is worth nothing that any "really bioavailable" soil would naturally leach the arsenic. If the arsenic were in a soil type or form that was readily available to the body, it also would be easily leached from the soil and, therefore, would not likely be detected.

Lunch Break

3) Presentation by Hugo Ochoa – SCTL updates/changes – handouts provided.

Following the SCTL presentation, discussion resumed on the issue of arsenic BA

Bob DeMott: If we assume that consensus exists on sufficiency of the study, can we reach consensus on a recommendation for adjusting the SCTL based on bioavailability? Maybe we go with the maximum reported BA to set the adjustment factor.

Brad Peebles: That may not be the best approach as it would essentially discount all the data and effort put forth in the study.

Chris Teaf: Presents information regarding the calculated UCL for all of the BA data in the study (mean BA = 16.8%; 95% UCL of the mean BA = 19.3%) and suggests that this supports the previously discussed range of 3 to 6, with 5 being a good starting point based on 19.3% BA as the 95% UCL.

Alex Padva: Soil types cannot be dismissed – particularly if the arsenic form is soluble.

A brief discussion ensued between Alex and Zoe regarding cattle dip vats and age of impact and soil type. They conclude that the one cattle dip vat soil used in the monkey BA study does not likely represent all the soil types in which dip vats may occur.

Bob DeMott: Possibly propose a range of factors to be applied on a site-specific basis depending on soil types etc.

Chris Teaf: Very tight data set suggestive of a factor of 4 or 5, based on highest BA of 24.7% (4x) and a UCL of 19.3% (5x).

Bob DeMott: Agreed, 5 is a good recommendation, 4 would be the conservative end supported by the highest BA reported.

Ed Zillioux: Should a geological review be undertaken to assess how representative the soils / sites in the study are?

Steve Roberts and Zoe Kulakowski discussed and likely "steady-state" condition of the selected sites – the pesticide sites represent possible more recent activity.

Joe Sekerke: It is difficult to assess how representative one sample is for a particular type of sites.

Bob DeMott: Does the tightness of the data suggest good sampling / study design, or does it suggest that we badly missed the target – should there have been considerably more variability?

Zoe Kulakowski: Briefly describes selection process for identifying soil sample candidates.

- Presence of arsenic in soil at greater than 100 mg / kg;
- Arsenic the only, or at least the primary, contaminant;
- Consideration of geographic location; and,
- Ability to acquire property owner's permission

Doug Jones: What would it take for the MFG to be comfortable enough as a group to make a recommendation regarding BA? Would the recommendation be unassailable? Can we go in front of the ERC and say

that this study, these five sites, are representative of all Florida sites and soils?

Ed Zillioux: It appears that most major soil types were covered with the monkey feeding study.

Bruce Nocita: There really aren't that many major soil types in Florida.

Tim Fitzgerald: Soil type may not be as important as age of contamination.

David Ludder: It isn't necessarily the data tightness, but the comfort level with the uncertainties that needs bolstering. We need qualified professionals to quantify / qualify the different uncertainties.

Bob DeMott: Can we develop a list of uncertainties specific to the present study, the Group reaches general consensus on the following list of issues requiring specific attention:

a) soil types
b) site types
c) arsenic form
d) age of sample / weathering of soil and arsenic
e) number of samples / number of monkeys
f) study did not involve chronic exposure
g) is dose administered relevant to realistic human exposures
h) is monkey data relevant to humans
i) is the monkey the best animal model for this evaluation

Bob DeMott: It would probably be appropriate to prepare an uncertainties "product" to be presented to the Soils Forum / DEP / ERC.

Chris Teaf: He and Doug Covert volunteer to coordinate the preparation of a paper regarding the uncertainty present in the UF monkey feeding study. Volunteer participants for specific sections and subject areas were determined as follows:

1)	Primary Soil Types in Florida	Bruce Nocita
2)	Primary Site Types in Florida	Zoe Kulakowski
3)	Arsenic Form	Zoe Kulakowski / Tim Fitzgerald
4)	Age of sample / impact of weathering	Zoe Kulakowski / Hugo Ochoa
5)	Number of samples	Chris Teaf / Doug Covert

6)	Study did not address chronically administered dose	Steve Roberts
7)	Study dose applicability to human exposure	Steve Roberts
8)	Number of monkeys	Chris Teaf / Doug Covert
9)	Is monkey data relevant to humans	Chris Teaf / Doug Covert
10)	Is monkey the best animal model for bioavailability	Joe Sekerke

In the written product regarding uncertainties each subsection should be short discussion with a conclusion as to the effects on BA (e.g., does it matter?). It should include an overall summary and conclusions.

Bob DeMott: We should have a White Paper available to the MFG before the next WorkShop meeting for 62-777, some time in late September / October. In summation, the UF study, combined with other studies suggests a range of 3 to 6, with the Florida-specific study centering on an adjustment factor of 4 or 5.

Doug Jones: In maintaining a conservative position regarding BA, internal Department discussions have been leaning toward the 50% value in the EPA Region 8 swine study. We need an unassailable recommendation from the MFG as an alternative.

Steve Roberts: Not really a monkey versus swine issue as much as a question of what value do the Region 8 swine studies at smelters and mines have in evaluating Florida sites and soils?

4) Presentation by Kim Bodoh – PQL vs MDL from laboratory perspective – handouts provided. This remains an issue under discussion. There are numerous problems from a data quality and reproducibility perspective when going below the PQL. This will be further discussed at the next MFG meeting.

5) Presentation by Bob DeMott – Uncertainty in Risk Assessment – handouts provided.

6) Bob DeMott allows that time permits a brief agenda addition – David Ludder has a few discussion points to be considered. A handout is discussed and will be made available through the website or by contacting Roger Register.

David Ludder: Above and beyond the bioavailability issue, he has a few concerns with the SCTL updating process and the SCTLs in general. These include:

- updating of toxicity guideline values. Are toxicity guideline values from IRIS the most appropriate values? More recent data is not always evaluated. In the last 3 years, EPA, through IRIS, has updated 14 chemicals. It will take 75 years at that rate to update the entire 62-777 list. Toxicity values based on peer-reviewed literature should be considered;

- the SCTLs do not appear to take into consideration exposure to background sources;

- Relevant to 62-777, but maybe not the Soil Forum, David also has a concern with the 6.5 grams per day fish ingestion rate.

Chris Teaf: the SCTLs assume a non-zero baseline

Ligia Mora Applegate / Doug Jones: the Department has the ability to invoke alternative cleanup levels based on site-specific information regarding unusual circumstances of exposure.

Bob DeMott: Possibly the Technical Document for 62-777 could have an expanded uncertainties section to make these issues more transparent.

Discussion of next meeting date and location – preliminary decision was to hold the next MFG meeting in Tampa on Tuesday, October 9th, 2001.

Meeting adjourned shortly after 4 pm.