

MTCA Science Advisory Board Meeting Summary

March 19, 2007
9:00 AM – 4:00 PM

Center for Urban Horticulture
Douglas Room
Seattle, Washington

Agenda:

Review 12/11/06 meeting summary
Conflict of Interest
Relative Bioavailability Estimates for Dioxins/Furans in Soils
Potential Issues for Five-Year Review of the MTCA Cleanup Regulation
Policy and Technical Issues Updating MTCA's Fish Consumption Rate

Attendees:

SAB Members Present: Dr. Bruce Duncan, Dr. Elaine Faustman, Dr. Michael Riley

Agency Staff and Presenters: Dawn Hooper, Pete Kmet, Craig McCormack (Ecology)

Audience: Bill Beckley (Rodolfi, Inc.), Larry Dunn (Lower Elwha Tribe), Tina Gary (Floyd/Snider), Greg Glass (consultant), Linn Gould (ERDA ENV), Warren Hansen (Windward Environmental), David Heineck (Summit Law Group), Dana Houkal (Malcolm Pirnie), John McCorkle (Environmental Resolutions, Inc.), Jim White (Department of Health), Julie Wilson (EnviroIssues)

I. Agenda Review; Review of 10/23/06 Meeting Summary

Ecology reviewed the agenda and goals for the meeting. Ecology asked Board members for revisions to the December 11, 2006, meeting summary. The Board approved the December 11, 2006, meeting summary with changes as provided during the meeting.

II. Conflict of Interest

Peter Kmet gave a power point presentation to the SAB summarizing Ecology's *Conflict of Interest Policy* memorandum from Peter Kmet to the SAB, dated March 19, 2007. Board members generally approved of the draft that Ecology presented, providing several comments for Ecology to consider in a future draft, summarized below.

- This document needs to be transparent and available to the public;
- Board members had various view points about whether the Board should police itself, but all thought that Ecology should have the final say in determining whether a real or perceived conflict existed and what steps would be appropriate;
- The policy should also consider conflicts resulting from an immediate family member's direct financial interest in an issue;
- Expressed concern that the 2nd bullet in the proposed Policy could eliminate Board members that are consultants;

- The policy should address current conflicts of interest, not previous work
- Set specific times that Board members should publicly declare any previously undeclared conflict of interest on issues before the Board including as part of their initial appointment and near the start of each SAB meeting,
- Some practical examples of potential real or perceived conflict of interest in the final policy would be helpful;
- Ecology should develop a form for Board members to complete upon appointment to the board, to be updated annually. The National Academy of Sciences form was suggested as an example.

Next Steps:

- ▣ Create a draft disclosure form for SAB members;
- ▣ Update Ecology's *Conflict of Interest Policy* memorandum to address SAB comments; and
- ▣ Provide the SAB with another opportunity to review the *Conflict of Interest Policy* memorandum and the draft disclosure form.

III. Relative Bioavailability Estimates for Dioxins/Furans in Soils

Craig McCormick presented Ecology's proposal and led this discussion, noting that Ecology actively engaged Marcia Bailey (U.S. Environmental Protection Agency, Region 10) and Jim W. White (Washington's Department of Health) in the technical reviews and deliberations on absorption and bioavailability of dioxins/furans. This including a meeting with Board member Elaine Faustman to discuss the quality of the database on bioavailability/ absorption and obtain her perceptions on this issue. The PowerPoint presentation on bioavailability is attached to this meeting summary. In summary, Ecology is proposing to assign a GI absorption fraction of 0.7 for the tetra and penta-chlorine substituted dioxin and furan congeners and a GI absorption fraction of 0.4 for the hexa, hepta and octa-chlorine substituted dioxin and furan congeners. The resulting GI absorption fraction would vary from 0.4 to 0.6 for sites, depending on the mixture of congeners at the site. The result is a 2,3,7,8 TCDD TEQ Method B cleanup level of 11 to 17 ppt (most likely 14 ppt) and a Method C cleanup level of 1500 to 2200 ppt (most likely of 1750 ppt).

Craig McCormack stated that Ecology believes that the bioavailability approach being recommended to the Board reasonably reflects the available information, is with in a range of scientific defensibility given the nature of the database available on absorption and bioavailability, and reflects the policies in the MTCA Statute and rule. Some of the guiding scientific principles, conventional wisdom, considered in the development of this recommendation:

- Previous Board discussion that bioavailability needs to account for the abiotic matrix effect of soil.
- Characteristics of the soil may influence bioavailability.
- Residence time and weathering characteristics may influence bioavailability.
- Different congeners may reflect different patterns of absorption and bioavailability.

Ecology reminded the Board that there is not a mathematically precise database on dioxin bioavailability. To the contrary, the database is highly uncertain and extremely variable. In spite

of these concerns, Ecology believes it is important to resolve this issue to continue to move cleanups forward.

The Board then invited public comment on this issue. Jim White, State Department of Health, provided the Board with some additional insights into the database on absorption / bioavailability.

Jim White summarized his observations in a technical memorandum to the Department of Ecology, *Bioavailability of dioxins/furans from soil – Discussion topics*, dated March 15, 2007, which is attached to this meeting summary. He noted that a recent paper by Wittsiepe et. al, 2007 does not support Ecology's premise that lower chlorinated congeners have higher bioavailability.

Following Mr. White's discussion of his memorandum, Craig McCormack provided SAB members with copies and abstracts of the following articles not available at the previous meeting:

Van den Berg, et al., 1994. Van den Berg, Martin; Jongh, Joost De.; Poiger, Hermann; and Olson, James R.; 1994. The Toxokinetics and Metabolism of Polychlorinated Dibenzop-Dioxins (PCDDs) and Dibenzofurans (PCDFs) and their Relevance for Toxicity. *Critical Reviews in Toxicology*, 24 (1): 1-74.

Wendling, et al., 1989. Wendling, Jay; Hileman, Fred; Orth, Robert; Umbreit, Thomas; Hesse, Elizabeth; Gallo, Michael. 1989. An Analytical Assessment of the Bioavailability of Dioxin Contaminated Soils to Animals. *Chemosphere*, Vol. 18, Nos 1-6, pages 925-932.

Wittsiepe, et al., 2007. Jurgen Wittsiepe, Bibiane Erlenkamper, Peter Welge, Alfons Hack, Michael Wilhelm. Bioavailability of PCDD/F from Contaminated Soil in Young Goettingen Minipigs. *Chemosphere*. 2007. [in press] Also published under same article title in the book *Organohalogen Compounds*, Volume 66, 2004, pages 2945-2951.

The remaining SAB discussion on bioavailability focused on the above articles, Jim White's memorandum and observations, and the uncertainty and variability of the database associated with the absorption and bioavailability of dioxins/furans.

SAB member discussion points are as follows:

Dr. Faustman noted the large uncertainty and variability of the database on absorption/bioavailability. References were made to tables in the issue paper on bioavailability:

- Appendix D, Table 4, column one was considered inappropriate to use to develop the 0.7 percent point estimate because the different studies used different measures and endpoints to determine absorption/bioavailability.
- Appendix G, Summary Tables of the Technical Studies – Absorption/Bioavailability Mean Estimates were used to review different point estimates and discuss the quality and limitations of the technical information.
- Table 3 and Figures 2 and 3 were discussed from Wittsiepe, et, al., 2007 regarding congener-specific absorption/bioavailability and per cent estimates.

- Based on the available information summarized in Appendix G, and the additional references provided, Dr. Faustman asked which studies are considered the most technically robust. Craig McCormack responded, after consulting Jim White, with the following list:

Lucier et al., 1986. Lucier, G.W.; Rumbaugh, R.C.; McCoy, Z.; Hass, R.; Harvan, D.; and Albro, P. (1986) Ingestion of Soil Contaminated with 2378-Tetrachlorodibenzo-p-dioxin (TCDD) Alters Hepatic Enzyme Activities in Rats. *Fundamental and Applied Toxicology*, 6, pages 364-371.

McConnell et al., 1984. McConnell, E.E.; Lucier, G.W.; Rumbaugh, R.C.; Albro, R.W.; Harvan, D.J.; Hass, J.R.; Harris, M.W. Dioxin in Soil: Bioavailability After Ingestion by Rats and Guinea Pigs. *Science*. March 09, 1984. Volume 232. Pages 1077 – 1079.

Shu et al., 1988. [Shu, H.; Paustenback, D.; Murray, F.J.; Marple, L.; Brunck, B. (1988) Bioavailability of Soil-Bound TCDD: Oral Bioavailability in the Rat. *Fundamental and Applied Toxicology* 10, 648 – 654]

Wittsiepe, et al., 2007. Jurgen Wittsiepe, Bibiane Erlenkamper, Peter Welge, Alfons Hack, Michael Wilhelm. Bioavailability of PCDD/F from Contaminated Soil in Young Goettingen Minipigs. *Chemosphere*. 2007. [in press] Also published under same article title in the book *Organohalogen Compounds*, Volume 66, 2004, pages 2945-2951.

After a range of discussions regarding the methodologies employed in the studies, measures of absorption/bioavailability, soil types used in the investigations, and routes of administration, the Board provided Ecology with several observations:

- Agreed that soil affects the bioavailability of dioxin congeners. However, the available information is highly uncertain and results from the studies are variable.
- Liver content appears to be the best measure of bioavailability.
- Available information is limited regarding soil types studied and measures of absorption/bioavailability and may not be representative of soils in Washington State. In particular, the Wittsiepe et. al. study appears to be on soil unnaturally high in organic content, which may be a function of the sludge spreading that occurred on this soil.
- Available information suggests that there may be congener-specific differences in absorption/bioavailability but is too uncertain and variable to identify a congener-specific per cent point estimate for bioavailability.
- Given the large ranges associated with bioavailability estimates a mid range, mean estimate for all congeners may be the most scientifically defensible position.

General discussion followed regarding the development of EPA's slope factor (Cancer Potency Factor) for EPA's reassessment and the slope factor used to calculate cleanup levels. Question arose regarding distinctions between the slope factor used by Ecology and the slope factor in EPA dioxin reassessment as related to absorption/bioavailability.

- The 1985 EPA slope factor [$1.56 \times 10^5 \text{ (mg/kg/day)}^{-1}$] was based on the Kociba et al., 1978 two year rat bioassay for 2378-TCDD and is currently used by Ecology to develop cleanup levels under MTCA. In the Kociba et al., 1978 male

and female Sprague-Dawley rats (50/sex) were exposed to 0, 1, 10 and 100 ng TCDD/kg-day for two years in their feed. TCDD was shown to be a multi-site carcinogen in both sexes of rats.

- In the recent EPA reassessment, the EPA cancer slope factor was derived for dioxin based on both human and animal data, using body burden as a dose metric as opposed to the usual standard default administered dose metric of daily intake. The 1985 EPA slope factor has been reevaluated as $1.0 \times 10^6 \text{ (mg/kg/day)}^{-1}$ in the current EPA reassessment, approximately 10 times more potent.
- On average, EPA estimates that 30% of dioxin in ingested soil is absorbed. The absorption correction factor of 0.375 (~0.4, 30% / 80%) is proposed for the ingestion of dioxin and dioxin-like compounds from contaminated soils. The absorption correction factor of 0.4 is the ratio of the degree of absorption of soil-bound dioxin/dibenzofuran compound relative to the degree of absorption of dioxin/dibenzofuran compounds in the study(s) used to determine the cancer slope factor. As was noted at the previous SAB meeting, Ecology and the Dept. of Health have been unable to find scientific information supporting the use of an absorption factor of 0.4.

MTCA SAB Recommendation on Bioavailability:

In recognition of the uncertainty and variability in the database, a congener-specific point estimate cannot be determined.

- Given the large ranges for relative bioavailability a median point percent estimate is recommended as being the most scientifically defensible (50%) for the mixture of dioxins/furans.
- The Board recognizes there is a difference in absorption between the 1985 slope factor developed from the Kociba et al., 1978 study and the new slope factor developed in the dioxin reassessment which assumes an 80% absorption.
- In consideration that the new EPA slope factor may be adopted at some point in the future and that there seems to be agreement regarding the scientific defensibility of the 80% as being a reasonable estimate of the absorption of the dioxins/furans, the Board recommends 0.6 estimate for relative bioavailability for all congeners. The 0.6 estimate of relative bioavailability is derived as a ratio of the absorption of soil bound dioxin (50%) relative to the absorption of the compounds used to determine the cancer slope factor ($0.5/0.8 \sim 0.6$).
- The recommended estimate needs to be qualified that it is not an upper bound estimate and that for the most sensitive and highly exposed the per cent estimate would likely be higher.

IV. Potential Issues for Five-Year Review of the MTCA Cleanup Regulation

Pete Kmet presented and led this discussion summarizing potential issues for review. The Board suggested the following additional topics:

- Consider ways to simplify MTCA.
- Should a process to evaluate naturally contaminated crushed rock be added to the rule?
- Should the life stage of the exposed population be considered when evaluating risk?
- Ecology should identify critical studies that are needed over the long term to help resolve issues.

- Freshwater sediment cleanup levels are becoming an important issue at more sites
- Ground water impact to sediments and the interstitial water as it flows to surface water is an evolving issue
- Given the legislative attention being given to PBDE's, will MTCA address this chemical group?

Audience Comment:

Bill Beckley: Will soil bioavailability for other chemicals be considered?

Linn Gould: Consider looking at what population is exposed when developing cleanup levels.

Greg Glass: Suggested a user survey to identify what has and hasn't worked and points needing clarification. Need to be careful to not go beyond the science. Don't add complexity that isn't needed.

V. Policy & Technical Issues Updating MTCA's Fish Consumption Rate

Pete Kmet led a brief presentation on this topic, using power point slides to highlight potential issues. Board comments included:

Broader definition is needed for fish-consuming populations, considering not only subsistence and recreational, but also cultural-based and tradition-based fish consumption patterns.

Audience Comment:

Larry Dunn: High fish consumption by some tribal members is needed for dietary reasons. Also, many tribal members can't afford to buy fish from cleaner areas. Also, tribal members tend to fish at the same locations, even if they move around, and this needs to be considered when establishing a fish consumption rate.

Greg Glass: May want to consider a body burden or duplicate diet study to confirm that the right assumptions are being made.

Approved summary with changes as submitted via email. May 7, 2007