October 10, 2014
Environmental Stewardship Concepts, LLC

Site-Specific Preliminary Remediation Goals for Tittabawassee River Floodplain Soil, August 2014

Major Issues

The PRGs are not protective of human health and certainly not protective of ecological receptors. The assumptions regarding the relative bioavailability are not appropriate and at least one is illogical to the point of being arbitrary and not based on any empirical data. The data that EPA and state agencies have used in setting a 100% availability remain valid and not refuted, hence must be used in setting PRGs.

General Comments

The Risk Assessment Guidance for Superfund (RAGS) Part A (EPA 1989) allows for making adjustments to Superfund site-specific risk assessment when the medium of the exposure in an exposure assessment differs from the medium of exposure assumed by the toxicity value. The effort necessary to adequately demonstrate a site-specific set of parameters for exposure to dioxin in soil versus the default values in the risk assessment have not been met by these PRGs for the Tittabawassee River Floodplain. The greatest departure from the conservative default values is that for the relative bioavailability (RBA) of dioxin in soil, where default is a value of 1, and this report indicates a much lower RBA of 0.43.

The cited work on relative bioavailability of dioxin in soil comes from an EPA paper: "Final Report Bioavailability of Dioxins and Dioxin-Like Compounds in Soil" (2010). The final conclusions of this study, as stated in the PRG report, are based on only three studies with small sample sizes, of which Budinsky et al. (2008) was Dow funded. The final conclusions indicate that the relative bioavailability of dioxin/furan mixtures in soils can be expected to be less than 100%, but that available estimates of soil dioxin RBA values are not adequate for recommending a nationwide default RBA value to use in risk assessments as an alternative to the 100% value. Further, an animal model cannot be established for adequately predicting soil RBA in humans. Even after additional study of Dow-funded work on swine and rats, it was still not clear which animal model would better represent the RBA in humans, and so it was determined an average of the two species RBA results would be used. An average is not compatible with legitimate science and the conclusions should continue to indicate that an animal model protocol cannot be determined to adequately establish RBA in humans. Studies cannot be conducted or re-analyzed to fit a management decision, a point made by the NRC/NAS in the landmark 1983 publication "Risk Assessment in the Federal Government."

Further, these PRGs do not take into consideration the already present dioxin body-burden of the local residents.

There is no discussion of or consideration of ambient levels of dioxin that are well above any "natural" conditions, owing to the decades of dioxin releases.

In a 2013 study on a contaminated site, Nunes et al. examined dioxin concentrations in plants. The report found the highest concentrations within the plant roots with lower concentrations in the leaves and stems. However, the fact that the plants absorbed dioxin indicates an avenue for bioaccumulation for grazing wildlife or livestock. As such potential for elevated plant concentrations should be included in any oral/dietary exposure assessment. A 2011 study by Fernandez et al. examined biotransfer of dioxins and PCB's from feed to livestock including chickens, pigs, sheep, and cows. They reported an increase in dioxin concentrations with age and also noted that accumulation varied significantly across specific organs and tissues. The study also suggests that both grazing livestock and those given commercial feed can be exposed to dioxins through both ingestion of plant matter and soil. Finally, Rychen et al. (2012) examined the transfer of dioxins in ruminants from feed to milk to offspring and found as much as 40% of consumed dioxins can be transferred to milk. As such, PRG's for areas with plausible agricultural uses must assess both plant and animal assimilation, accumulation, and transfer of dioxins when determining PRG's.

Specific Comments
1.0 Introduction
- "Human direct contact exposure" includes ingestion and dermal contact only and needs to include inhalation.
- The extent of the affected area slated for treatment is the 8-year floodplain. This area is far too small an area under consideration. Other rivers consider 100 year floodplains.
- "A residual risk assessment will be completed to assess the effectiveness of the response actions and to determine whether there is a need for further actions in the Floodplain. At this time, EPA anticipates that the residual risk assessment for the Floodplain will be conducted after some upstream cleanup is done, but that it will occur before all Floodplain cleanup is complete."
  - A risk assessment conducted at a point before cleanup is complete to assess progress is beneficial, but should not take the place of pre- and post remediation assessments. An evaluation of the completed cleanup is needed and a preliminary assessment cannot be used to extrapolate to some future end as a surrogate for a final risk assessment.

- "Approximately 10,000 D/F samples were assessed from about 2,000 locations in the Floodplain."
  - A Figure including the location of these points along the river should be included in this report.
- "A subset of the samples was analyzed for dioxin-like coplanar PCBs and they were not detected in Floodplain soil. Consequently, PCBs could be disregarded as contaminants for developing PRGs based on Dioxin TEQ."
  - Please indicate the subset n value and the EPA test method(s) used.
- In the assessment of the toxicity of dioxin, the previous research data on dioxin toxicity that supports a 100% adsorption rate is designed to be conservative and must still be considered- new data have not invalidated the earlier data nor provided any justification for discarding the data.

2.0 Land Use and Exposure Scenarios
- "The 8-year floodplain boundary is not a "bright line" and the actual boundary will be refined as needed during designs, based on the actual D/F TEQ levels at a property."
  - Rather than extensive, time-consuming, and costly testing of levels at every property along 21 miles of river, consideration of a larger floodplain would more likely, and more successfully, include the higher concentration soils.
- The "Maintained Residential Areas" Floodplain land use notes that "It should be noted that it is typical for the houses and house perimeters to be out of the Floodplain and to have soil D/F levels much lower than D/F levels within the Floodplain (see Figure 3)."
  - This pattern would not be the case if a more protective 100-year floodplain was used. The values indicated for dioxin concentrations in Figure 3 are not protective of the exposure endpoints.
- There are too many subcategories for the land use category "Other Land Uses" to adequately create a protective PRG. Further, any residential land use area, whether "maintained" or "unmaintained" should be held to the same cleanup level.
- There is the potential for a forty-fold increase from one land use to the next within the residential use floodplain area: from 50 ppt (Maintained Residential, outside 8 year floodplain) to 2,000 ppt (Residential Unmaintained Land). These values are not protective of a residential scenario.
- Much more of the floodplain would need to be cleaned up if "Unmaintained Residential" and "Residential Maintained" were considered Residential and cleaned up to residential standards. As the land is privately owned, the resident should be able to change how they use their land, whether maintained or

unmaintained, and should not have to bear the burden of a higher dioxin body-burden because the entirety of their land is not cleaned up properly.

- A young child, up to 6 years old, could very likely play within the 8-year floodplain in unmaintained areas adjacent to the river. Assuming that a child will not frequent these areas is not a valid assumption, is not supported by any data znd is certainly not protective of human health.

- "A very few residential properties are almost completely inside the Floodplain; therefore soil around the house perimeter may have elevated TEQ. However, most of these residences have already been cleaned up by complete excavation and backfill with clean soil at background levels."
  - o There needs to be a discussion of background levels and how they were determined.
  - o A figure depicting the location and cleanup of these residences is needed to visually represent this information.

- The few studies on which the PRG's Relative Bioavailability (RBA) is based are inconclusive (see General Comments), have small samples sizes, and are largely funded by Dow, for which there is an obvious conflict of interest.

- The connection drawn between dioxin and black carbon versus organic matter is not relevant to the PRGs or the amount of cleanup that needs to take place.

- The non-cancer RfD is based on the oil gavage control in rats and the dough-ball control in the swine which are simply 50% and 80% of the soil fed doses given to the non-control animals. Creating these values from faulty methodology and ignoring the current non-cancer RfD is unprotective. Nor is there any justification provided for using any animal model, when all are known to be inadequate in representing human physiology.

3.0 Dioxin Toxicity

- This is obviously treated as a mandatory section with required information, with no effort to relate this information to the site itself.

4.0 Derivation of PRG Values

- The values for Maintained Residential of 250 ppt and Other Land Use Areas of 2,000 ppt are much too high to be protective. These values also do not take into account the already high dioxin body-burden of these individuals.

5.0 Uncertainties and Sensitivity Analysis

- In consideration of exposure frequency, climate change will continue to affect human activities and duration of exposure. Only 260 days of outdoor exposure is underestimating exposure and this should not have to wait on a Five Year Review process to be changed.

- Information involving an informal survey do not belong in a technical document on PRGs.
- Cancer, instead of non-cancer health effects, should be the driver behind the PRGs. Simply playing with the numbers until the Young Child exposure scenarios reach an HQ of exactly 1 is not protective of the residents of the Tittabawassee River.
- A high number of uncertainties exist within the risk assessment process at this site, and thus, the most conservative default settings should be used.

Table 1: Input parameters used for computing non-cancer PRGs for exposure of residents to dioxin in soil
- The largest departures from the default that together decrease overall protectiveness include:
    - less skin surface area exposed for the younger child and adult
    - less dermal absorption fraction: 0.03 (default) vs. 0.02 (site-specific)
    - much less relative bioavailability: 1 (default) vs. 0.43 (site-specific)

Table 2: Input parameters used for computing non-cancer PRGs for exposure to adult worker to dioxin in soil
- The largest departures from the default that together decrease overall protectiveness include:
    - increased body weight: 70 kg (default) vs. 81.8 kg (site-specific), which works to "dilute" the effects across a greater mass in the site-specific figures
    - less surface area: 3,300 cm^2 (default) vs. 3026 cm^2 (site-specific) which decreased the area factored into exposure equations
    - less dermal absorption fraction: 0.03 pg absorbed/pg on skin (default) vs. 0.02 pg absorbed/pg on skin (site-specific)
    - much less relative bioavailability: 1 (default) vs. 0.43

Figure 3. Areas where residents may be exposed to soil
- This approach is an unprofessional depiction and should instead be a scale map of the land use along the river, with insets to show an actual property and the potential land use designations found there. This would greatly increase the confidence that a real assessment of the land use along all 21 miles of the cleanup will take place.
- Again, land use by a property owner may be transient at best, therefore a 40-fold difference in cleanup level on the same property due to the land use designations in this document would not be protective of the residents along the river.

References

Budinsky RA, Rowlands JC, Casteel S, Fent G, Cushing CA, Newsted J, Giesy JP, Ruby MV, Aylward LL. (2008). A pilot study of oral bioavailability of dioxins and furans from contaminated soils: Impact of differential hepatic enzyme activity and species differences. *Chemosphere* 70(10): 1774–1786.

EPA (1989) Risk Assessment Guidance for Superfund Volume 1: Human Health Evaluation Manual - Part A. Office of Emergency and Remedial Response, Washington, D.C. EPA/540/1-89/002.

EPA. (2010). Final Report: Bioavailability of Dioxins and Dioxin-like Compounds in Soil. Office of Superfund Remediation and Technology Innovation, Environmental Response Team – West; Las Vegas, NV.
http://www.epa.gov/superfund/health/contaminants/dioxin/pdfs/Final_dioxin_RBA_Report_12_20_10.pdf

Fernandes, a R, C Foxall, a Lovett, M Rose, and a Dowding. 2011. "The Assimilation of Dioxins and PCBs in Conventionally Reared Farm Animals: Occurrence and Biotransfer Factors." *Chemosphere* 83 (6). Elsevier Ltd: 815–22. doi:10.1016/j.chemosphere.2011.02.083.

NRC/NAS. 1983. Risk Assessment in the Federal Government: Managing the Process. Committee on the Institutional Means for Assessment of Risks to Public Health. http://www.nap.edu/catalog.php?record_id=366

Nunes, Margarida, Anaïs Vernisseau, Philippe Marchand, Bruno Le Bizec, Fernando Ramos, and Miguel a Pardal. 2014. "Distribution of PCDD/Fs and Dioxin-like PCBs in Sediment and Plants from a Contaminated Salt Marsh (Tejo Estuary, Portugal)." *Environmental Science and Pollution Research International* 21 (4): 2540–49. doi:10.1007/s11356-013-2178-8.

Rychen, Guido, Stefan Jurjanz, Agnès Fournier, Hervé Toussaint, and Cyril Feidt. 2014. "Exposure of Ruminants to Persistent Organic Pollutants and Potential of Decontamination." *Environmental Science and Pollution Research International* 21 (10): 6440–47. doi:10.1007/s11356-013-1882-8.