Final Comments on Human Health Risk Assessment GE/Housatonic River Site Rest of River

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Background

For the past 13 weeks, a group of scientists has been asked to review the report Human Health Risk Assessment GE/Housatonic River Site Rest of River. The Health Risk Assessment is contained in numerous volumes and appendixes that have been supplied to the Review Panel. These volumes contain several sub-reports pertaining to various aspects of the Human Health Risk Assessment (HHRA), data collected in support of the HHRA, and various other reports including detailed calculations of various risk components, maps, and other useful data. Further, several days of presentations were made exclusively to the group in preparation for the Review. Finally, the panel met in a public form to hear a final set of presentations and to deliberate on the strengths and weaknesses of the HHRA.

To guide the Review Panel in deliberations, EPA has given a Charge and list of Charge Questions. The Charge is summarized by some passages from pages 2 and 3 of the document Charge for the Human Health Risk Assessment Peer Review for the Rest of the Housatonic River, delivered by SRA as part of the contractual arrangements presented to each member and given below:

> *The Consent Decree specified that the Peer Review Panel is to review EPA's HHRA to evaluate: "(1) consistency with EPA policy and guidance; (2) the exposure scenarios and parameters used; (3) the toxicity assessment; (4) the risk calculations; and (5) the report conclusions.*
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> *Questions to be Addressed by the Peer Review Panel*
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> *"…the objectivity, consistency, and reasonableness of the procedures and inputs used by EPA both in the application of existing EPA guidelines, guidance and policy… or in the absence of Agency guidance, guidelines, and policy…."*
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> *"It is not expected or intended that the Peer Review Panel will reach consensus on all issues."*
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> *"…the term EPA guidance… EPA policies, guidelines, methodologies, directives, or other Agency procedures…."*

My Expertise

My particular expertise is in community-based exposure assessment. My research has focused on gathering of environmental and biomarker data related to both potential and real exposures experienced by individuals in community settings. In applying my expertise to the HHRA, I have focused on the exposure likely to be experienced by individuals along the Rest of the River as they might occur under normal activities ranging from simple day-to-day activities, recreational act ivies, and

certain commercial activities that might result in elevated exposures not because of the activities themselves being inherently risky, but rather because of the contamination along the river. While I may choose to make comments regarding the other components of the HHRA- toxicity estimates, point and Monte Carlo risk estimates, etc.- I will generally defer to my more knowledgeable colleagues in these areas.

Comments

> *"….the Peer Review Panel members shall give specific consideration to the following questions:*

A. Phase 1 - Direct Contact Exposure Screening

Were the procedures used in Phase 1…appropriate under the evaluation criteria? In addressing this question consider:

- *The general procedures used;*

The general procedure used in the HHRA was to develop a two-phase plan involving initial screening, followed by more detailed risk estimation where warranted. This method is certainly consistent with EPA policy and generally accepted scientific practice. Typically, one adopts conservative estimation procedures for the initial screening- a procedure that eliminates only those locations with very little likelihood to give rise to any appreciable risk. This is usually done by assuming a "highly exposed" scenario and evaluating it given the concentrations of selected pollutants to estimate a risk. If the risk is still low under these conservative conditions, one may reasonably expect it to be very low under the conditions actually present**.** In the current HHRA, an approach involving Screening Risk Based Concentrations (SRBCs) was used. In this method, the typical risk calculation was inverted; an acceptable screening level risk was adopted for each scenario and the concentration associated with this risk was determined. Several examples of the calculation are given in the document itself. Measured concentrations were then compared with this value and an algorithm applied to determine if these concentrations exceeded the SRBC was implemented (See later discussions). Parcels exceeding the SRBC through this algorithm were retained for later, more detailed (Phase II) analysis.

- *The SRBCs used for the COPC*

The screening-based risk concentrations (SRBCs) for the contaminants of potential concern (COPCs) are those normally used in the risk assessment field, namely a range of 10^{-4} – 10^{-6} risk inferred for potentially carcinogenic compounds or those giving rise to a hazard index (HI) of 1 for non-cancer effects. These values are consistent with EPA policy as I understand it and also are consistent with those commonly used in community settings. In my preliminary assessment, I found these SRBCs reasonable, and still do. However, I have not received sufficient justification for the varying choice of SRBCs. The risk deemed acceptable that were used to calculate the SRBCs are, themselves, variable over a relatively small range

(essentially 1-10 x 10^{-6}). In my opinion, this reduces the *a priori* argument that these are risk-based, but rather suggests that the values are "concentration based concentrations" and that some other criterion was used for their selection. This was then *post hoc* justified by the SRBC appellation.

While I have some concern regarding the details of the calculations, I do not believe that small differences in the way the SRBCs were determined, or in the way they were used would affect the outcome in any substantial way. It appears that few parcels were "on the margin" and such small differences are unlikely to move a significant number of parcels off the Phase II list that were originally on it, or *vice versa*. To quote panel member Owen Hoffman- "The goal is to minimize the number of false negatives without getting an irrationally high number of false positives." One may argue that taking all of the parcels above Wood's Pond into the Phase II analysis may be appropriate in that most of the contamination is in those reaches and that few parcels were eliminated. In some sense, this would be equivalent to removing all of the Connecticut reaches from more complete analysis- a geographic stratification. It is odd that a few of the parcels are eliminated in Phase I for the upper reaches, despite being surrounded by other parcels that are included. But, I still believe that the method is solid and defensible, given the caveat about selection of risks mentioned in the previous paragraph.

- *The land use and exposure categories considered and the classification of particular parcels and areas into those categories.*

This is a difficult question to address since the number of parcels involved is very large. In general, I am in agreement with the land use and exposure categories considered and the classification of those particular parcels and areas into those categories. However, I have not evaluated each and every parcel in a rigorous manner. Further, as discussed later, I may have selected a different overall scheme that may have resulted in different, and doubtless more conservative, classification of some (very few, actually) differently. It is my assessment that, in general, the land use exposure categories considered and the classification of specific parcels and areas into those categories is adequate for the screening process involved in the Direct Contact Exposure Assessment. It may not be directly on point to discuss here, but I do have some concerns regarding the "accessibility factor" included in some parcels. The values for this factor appear arbitrary and not based on any data or observation.

Summary under Direct Contact Screening Approach

The screening approaches used attempt to fulfill Dr. Hoffman's "minimize false negatives; control false positives" criterion quite well. One may quibble about the weighting of each, e.g., fewer false positives coupled with more false negatives, but the method chosen would seem adequate and sufficiently protective of the exposed population as to pass muster. As in any risk assessment, the Devil is in the details. One may argue with a specific intake rate, risk chosen, exposure frequency, calculated concentrations, etc., but little is to be gained in such an exercise. There is another level of risk assessment to be accomplished and that will address the details even more.

B. Phase 2 - Direct Contact Exposure Assessment

1. *Were the following aspect of the direct-contact exposure assessment appropriate under the evaluation criteria*

- *The exposure scenarios which were evaluated*

The exposure assessment models did a good job in assessing those scenarios likely to produce exposure among the actual population in the greater community of individuals throughout the full extent of the Rest of the River. Through meetings with individual members of the community as well as community groups, they established likely exposure scenarios including recreational use of the Rest of the River and its environs, certain commercial use, and the use of agricultural products gathered near the River or grown on or near the floodplain. Further, the exposure assessors have attempted to ascertain high-exposure individuals, selecting certain recreational activities likely to result in very high exposure to a small number of individuals as their reasonable maximum exposure. This is a conservative procedure and one that is likely to lead to excellent screening as well as quality estimates of reasonable maximum exposure. (**NB** The use of the term "screening" in this context is not to be confused with the Phase I screening process. Here "screening" means evaluation based on a relatively detailed assessment of risk but based on a modeling approach.) I must admit that, at first, I was taken aback by inclusion of a scenario for marathon canoeists. However, once I realized that they were exploring individuals likely to experience the highest level of exposure and that these individuals would serve to simulate exposures experienced by other high-exposure individuals, I became more satisfied with the approach. There is no claim that marathon canoeist represent a large fraction of the community but rather their exposures are likely to be at the very high end of all exposures experienced by those recreating on the River.

- *The exposed populations which were selected for each scenario*

As discussed under the previous heading, I believe that the populations selected are appropriate and sufficiently conservative to act as an appropriate screening tool

- *The exposure areas identified based upon potential current and future use(s).*

The exposure areas identified are consistent with measured concentrations, i.e., the 1 mg/kg tPCB concentration profile. However, I am concerned about unusual events in the past (or future) that may cause inundation of the floodplain with sediment containing higher concentrations and the concomitant later use of these areas for recreation, agriculture, or future building sites. My concerns have yet to be assuaged either by material presented in the HHRA nor by any presentation. While this may be a particular problem with my point of view and my childhood memories of flooding in western and central Massachusetts, I would still like to have more justification. It is my assessment that the exposure areas identified based upon current and future use(s) are adequate but I would like to see assessments of flooding scenarios based on 50- or 100-year

flood plains and concomitant movement of sediment from the river bed to adjacent floodplain area.

While current land use scenarios are adequately described and presented, the future uses of the land are not done so in a transparent manner. For example, is it reasonable to assume that the entire floodplain to the Massachusetts/Connecticut border will be maintained essentials as publicly-owned park land for the foreseeable future? If not, what effect does this have on the scenario assumptions? If the area were declared "cleaned" would there be a reemergence of small dairy farms along the Housatonic River? If so, it is likely that the agricultural pathway (see below) would be affected, but what of the direct contact? There would be more farmers and agricultural workers. These scenarios become more important.

An important scenario for consideration that has not been addressed focuses on the land use if the Rest of the River were cleaned up. What would be the appropriate scenarios then? Some discussion of this option would be of use and may inform the discussion of the cleanup process.

- *The routes of exposures for each scenario*

Consider the following when addressing this question

- *Current and reasonably anticipated future land uses, physical conditions and accessibility.*

- *Locations , concentrations, and distribution of COPCs in the sediment, bank soil, and floodplain soil; and*

- *Ages of the selected exposed populations.*

The routes of exposure- dermal contact, ingestion of small amounts of soil consistent with expected intake given EPA guidance, and ingestion of game, etc., are adequate. The pathways investigated appear to be those most likely to give rise to exposures and to give the most frequent exposures and exposures with the greatest magnitude and duration.

2. *Have the most important exposure pathways been identified and evaluated?*

The pathways under this direct contact exposure have been adequately characterized. However, it would be useful to examine secondary pathways influenced by the direct contact pathway. Most notable among these is ingestion of breast milk from mothers exposed through this pathway. Since PCBs are lipophilic, storage in adipose tissues for a significant amount of time is possible. Washout of stored PCBs during pregnancy and lactation has been documented in many studies. It would be of interest to explore this pathway for relevance in the population living near the Housatonic that might give rise to this secondary pathway.

3. *Were the approaches and methods used to calculate and apply exposure point concentrations (EPCs) for the direct-contact exposure assessment appropriate under the evaluation criteria?*

The principal problems I noted with the calculation of the EPCs from the use of spatial weighing and the generation of EPCs based upon the distributional characteristics of the observed data. Some background is needed to kick off the discussion.

Throughout the various reaches of the river, PCB concentrations were determined based on a sampling protocol that, while not completely transparent, was certainly not based on developing input for modeling. After sampling was completed, various regions, called Exposure Areas or EAs, were identified and characterized according to their likely use - recreational, residential, etc. Scenarios were then implemented as described above and in the document that resulted in use patterns for the individual EAs. It was then assumed that the EA would be visited randomly requiring an estimate of the mean exposure experienced on that EA. A 95% UCL for the mean was calculated using distributional assumptions where appropriate or bootstrapping methods where no distribution could be identified.

Problems occur because of a mismatch between the sampling done and the needs of the modeling used to develop the 95% UCL for the mean. Measurements were not made randomly. Often a purported hot spot was sampled or a transect made across an EA was done, etc. Determination of the mean concentration of an EA based on measured results would likely bias the expected concentrations, especially in the case of hot spot evaluation. Spatial weighting analysis was used to overcome this mismatch. Values were interpolated onto a 3m x 3m grid in each EA. We were told that the measured points for each EA were used and an inverse distance weighing was performed in which the nearest two points were used to determine the values on each grid point. The interpolated data were then used to calculate the mean and standard deviation for the whole EA. These values were used to calculate the UCL for the mean, but the original number of measured data points was used in the standard formula where N, the number of points, was needed. The equation to produce the UCL is:

$$\overline{X}_{UCL} = \overline{X}_{interpolated} + t\frac{s_{interpolated}}{\sqrt{N_{measured}}}$$

where the subscript interpolated implies that the statistic is obtained from the interpolated data while the subscript measured denotes the measured data statistic. I have used the t statistic for the multiplier here, but in actuality the value or form would be determined by the distributional characteristics of the measured values in the EA. This is sort of an apples and oranges kind of analysis but one that, I believe gives a better assessment of the true mean and standard deviation and, perhaps, a better picture of the UCL for the mean. We were given an example in a presentation, but requested several more to compare the results.

Examination of these data revealed several problems. First, a 3m x 3m grid requires interpolation of about 450 points per acre. EAs ranged in size

from under an acre to at least 50 acres, the latter requiring in excess of 20,000 interpolated points. In many cases, the number of measured points represented only a few percent of the number of points interpolated calling the accuracy of the points into question and increasing the uncertainty in these estimates substantially. Further, in examining the data sent to us, I noted cases from which the extrapolated points exceeded the maximum value actually observed within the EA, contrary to what we were told and inconsistent with the assertion that only points contained within the EA were used in developing the grid for a given EA.

I am not certain about the effect of these observations on the EPCs calculated. I believe that the modeling is a good-faith effort to improve upon the results of the measurements in determining what the likely exposure is. Indeed, there are cases in which the EPC for the measured data is lower than that calculated through the spatial weighting procedure and cases for which it is higher. The description given in the public forum for the HHRA is, I believe, inconsistent with some of the results given to us at our request. The interpolation may have been done differently than described, e.g., all data were interpolated using the closest points (some of which may have been outside a specific EA) and then the EAs drawn around them. Alternatively, errors may have been made in the calculations of the EPCs that were presented to us. We cannot know because the details have not been included. At the very least, the presentation of this interpolation scheme - a scheme that is intrinsic to the overall risk process - must be more clearly articulated. Further, a detailed calculation for a specific EA should be given and sufficient detail in the other EAs, including means and standard deviations for both measured and interpolated data. It is difficult to accept at face value the EPCs determined for each EA given inconsistencies found in the test cases and the lack of a scripted protocol for how they were developed.

There is an additional problem associated with "aging" of PCB mixtures. I am not certain of the likely magnitude of the effect, but the more water-soluble, i.e., lower Kow, PCB congeners are likely to move more quickly than the less soluble congeners. This may result in different mixtures as one proceeds further down the Rest of the River. What starts out as Arochlor 1260 on Reach 5 may look more like Arochlor 1254 at Wood' Pond. Assumption of constant ratios of various congeners, and the concomitant TEQ associated with this may change. I would like to see a discussion of this and, if it is deemed so, dismissal if no problem exists.

4. *Were the values used to represent the exposure and absorbtion parameters used in the direct-contact exposure assessment appropriate under the evaluation criteria, specifically:*

- *Exposure duration for each scenario*
- *Exposure frequency and area use factors for each scenario and exposure area*
- *Soil ingestion rates*
- *Exposure assumptions affecting dermal contact (e.g., soil adherence rates, skin surface areas assumed to contact soil or sediment); and*

- *Oral and dermal absorption factors.*

In each of the above cases, the exposure assessors have chosen factors from the EPA Exposure Factors Handbook, commonly regarded as the best source of various factors associated with exposures through various environmental media. One may indeed quibble with individual selection, or even the choice of values selected by EPA, e.g., EPA often selects a default value based on very limited, or even no, data. One may suggest that experiments on rhesus monkeys using Housatonic River soil are most relevant here. However, as Dr. Kissel pointed out, the methods used may not have been the best. This is just one example of the sparseness of the data associated with dermal contact. A single experiment costing a large amount of money to do is all we have available for this parameter. Many other parameters have no data at all. The uncertainty introduced by using a value for such a parameter is not known. However, the estimates are the best available and are the best choices we have.

In addressing this question, please consider the same factors as listed in Question 1 (as relevant).

5. *Is the approach used to estimate a Reasonable Maximum Exposure (RME) and a Central Tendency Exposure (CTE) for the direct-contact exposure assessment appropriate under the evaluation criteria?*

I expressed concerns in my initial comments regarding the use of the UCL for the mean in expressing measures of CTE and RME. I do not believe that these questions have been adequately addressed. However, the scenarios used in selecting maximally exposed individuals do appear conservative enough for me to be more confident in the overall approach.

See the discussion of the interpolation methods above.

In many cases, we do not have the data that would allow us to respond to this question effectively. We are given the procedures that are used if, for example, the distribution of measured values was deemed lognormal or had no distributional characteristics that could be gleaned. However, we are not given the measured data locations and locations of the grid points so that it is impossible to reproduce the results given. Those that were supplied to us later in summary form call into question the procedures used to generate the "working data" and do not generate confidence in the EPCs and CTEs calculated.

6. *Were the uncertainties adequately characterized and expressed?*

The uncertainties in these approaches were addressed by examining the lowest and highest values determined in the deterministic approaches. While certainly spanning some type of range, I do not believe that it adequately represents the full uncertainty of the procedures and certainly does not address the uncertainty as defined by Ferson as variability and "incertitude" associated with a Monte Carlo assessment. Further, there is little placement of these uncertainties on any kind of likelihood scale. Much more presentation is needed on the uncertainties in these estimates. Are they a factor of two, which is certainly acceptable, or several orders of magnitude, which is not likely to

be acceptable? A much more through discussion of these important concepts is warranted.

7. *Overall, was the approach used to estimate risk from direct contact reasonable for evaluating baseline risk?*

Generally, the estimates of risk from direct contact are adequate for estimating baseline risk subject to the cautions given in the above comments. However, the implementation of the methods described and the uncertainties in such estimates are not well described. This precludes answering the question. While the methods appear well-conceived, the implementation questions give one pause. Further, we have little in the way of discussion of the precision or accuracy of such estimates. Hence, it becomes difficult to assess the "reasonableness" of the baseline risk.

C. Phase 2- Fish and Waterfowl Exposure Assessment

1. *Were the approaches and methods used to calculate EPCs for the fish and waterfowl consumption scenarios appropriate under the evaluation criteria?*

I believe that the approaches and methods used in this aspect of the risk assessment were adequate under the evaluation criteria. One may question the degree to which migratory waterfowl influence the exposure and the productivity of the fisheries in the area. Does one expect a dilution of the waterfowl effect by the presence of off-site waterfowl in the area during hunting season? If so, has this been accounted for? Could the Housatonic support a large-scale fishery? What is the overall productivity? These are important questions for future use.

2. *Were the exposure assumptions and parameters used in both the assessments of fish and waterfowl consumption appropriate under the evaluation criteria?*

Questions were raised concerning use of the Maine "all-waters" fishing survey in assessing likely exposure. While these data may not be specifically relevant, and indeed their use in this assessment was criticized by the author of the study report, I think that they are the most relevant data available. Their use is in keeping with the generally conservative approach taken in the risk assessment.

3. *Was the basis for the selection of point estimate RME and CTE exposure parameter values appropriate under the evaluation criteria, and were they clearly described and referenced?*

While EPA guidance suggests the use of the 95th UCL of the mean as the measure of central tendency, I find this selection insufficiently conservative when data are plentiful. Certainly one may argue that the greater the number of data, the better predicted the mean may be and thus the shrinking of the 95th UCL is appropriate. Nevertheless, I still would argue for a more conservative approach, perhaps looking at the 95th UCL of the 75th percentile, or some such, for a screening value. It is my assessment that the RME and CTE exposure parameter values are appropriate and follow EPA guidance. However, I offer

the caveat expressed earlier regarding potential low bias in using the UCL for the mean rather than a UCL on a higher percentage point.

4. *Were the probabilistic approaches used clearly described, and were they appropriate under the evaluation criteria?*

The standard Monte Carlo procedures used in this assessment are consistent with EPA guidance on the subject. However, the use of the "probability bounds" procedure as described in the October meeting is new and has not, to my knowledge, been subject to EPA scrutiny and guidance. Despite this concern, it would appear that this new technique is at least as applicable as the more standard Monte Carlo techniques and fits within the framework of EPA's need for probabilistic assessments. Further, it offers some new features that make it of interest to the general risk assessment community in addition to its application here. It may, for example, present a more realistic picture of the influence of "uncertain" variables on the calculated risk distribution. However, the bounds so projected may be so wide as to reduce their utility in assessment the uncertainties for risk. They do represent, in some sense, what one would get from an infinite number of 2D Monte Carlo assessments, but we may be more interested in approaches that give some idea of what the most likely uncertainty bounds are. A reasonable approach might be to perform both standard 2D methods and probability bounds estimates and present both. In this way, the reader may develop a better appreciation for the effects of these uncertainties. However, there are still uncertainties not accounted for in parameters that have few data to support them.

5. *Were the distributions used in the probabilistic assessments clearly described, and were they appropriate under the evaluation criteria?*

The description given in Attachments 4 and 5 of Volume I of the HHRA describe in detail the various procures used to develop the probabilistic assessments. While the material is both dense and voluminous, it does describe in detail the procedures used. Most interesting is the Table at the end of Attachment 5 (Page 62 of the attachment) that lays out an algorithm for selection of distribution types. Not only is this table of interest in this analysis, but should be used as a teaching tool by those of us developing classroom lectures for students.

6. *Were the uncertainties in the data and models adequately characterized and expressed?*

There are many parameters in the models with uncertainty that may not be adequately described in the presentation. Further, there is little discussion about model uncertainty and other forms of uncertainty not directly discernable from the results. I would like to see at least some passing discussion of these as well.

7. *Were variability and uncertainty in the risk estimates adequately characterized and expressed?*

The comments under this heading are similar to those above.

8. *Overall, was the approach used to assess risk for consumption of fish and waterfowl and other wild food items reasonable for evaluating the baseline risk?*

The following are concerns regarding this pathway. There are very few data on waterfowl in Massachusetts and essentially no information from Connecticut. Further, those data collected may not represent that actual population of waterfowl on the river during a hunting season due to the presence of migratory birds. The application of data relating Massachusetts sediment and waterfowl may not be applicable to Connecticut sediment and waterfowl. Hence this aspect of the risk assessment may be called into question. However, these are the best data available and thus the risk assessment has been done properly.

D. Phase II- Agricultural Exposures

1. *Were the exposure scenarios evaluate appropriate and reasonable for current and reasonably foreseeable future use of the floodplain?*

I have commented on some concerns I have for use of certain floodplain areas subjected to irregular flooding with concomitant new sediment deposition. This represents my chief concern and this concern affects the agricultural exposures as well. Overall, I believe that the developed scenarios span the range of likely exposures to be experienced.

A few questions were raised in our discussion or in the public comment session. Ones that I noted as being relevant here include the following. In considering the appropriate scenarios, what consideration was there of the long-term secular trend in agricultural use in Western Massachusetts? For instance, is dairy farming on the decline with faming land being replaced by tract housing in this area? Trends in such area may suggest the need for different scenarios in the agricultural risk assessment. Also, it is necessary to reconcile EPA's assessment that there are few family farms in the area (done by inspection) and the contention from the public comments that there are many. Clearly, the scenarios involving family farm product usage will have more bearing if many such farms exist. We need the data describing them.

2. *Were the approaches used to estimate transfer of COPCs from soil to plants appropriate under the evaluation criteria?*

A question arose regarding the soil-to-grass transfer rates and models. Why are the values for PC-126 transfer coefficient an order of magnitude higher than others? Is this reasonable based on any kind of model or was something amiss?

The risk assessment used site specific data for the uptake ratios. While site-specific data are indeed the most useful, this utility must be tempered by the small number of samples analyzed. The panel suggests expanding the dataset to include non-site-specific data as a comparison to determine whether the small number of data points accessible from the current measurements is indicative of other sites. If not, what is special about this site that affects this plant uptake ratio? If they are the same, then it adds credence to the method.

The discussion of the TEQ approach really is a discussion of uncertainty in the risk associated with a given tPCB concentration. One may reasonably argue that this discussion should be in a section on Uncertainty rather than in

the body of the report. Regardless, an assessment of uncertainty is very important in this regard.

3. *Were the approaches used to estimate the bioaccumulation of COPCs in animal tissue appropriate under the evaluation criteria?*

In general, the approaches involved attempting to measure simultaneous soil and plant/agricultural commodity levels and using the ratio to simulate uptake. This seems appropriate. However, there is need to validate this approach further. It would be a small investment to perform the experiments when compared with the likely cost of a full cleanup. It may be that the models overestimate the uptake and that reduced cleanup levels are excessively stringent. The opposite may also be the case. Until validation of the approach is available, the uncertainty may propagate into unnecessary cost or lack of protection for the community. It would also be of interest to look at congener-specific bioaccumulation. The mix in the bloodstream or in the tissues may not match that in the environment due to differential uptake. Thus the calculated risk may differ, perhaps even substantially, from that projected. Experiments could aid in this, perhaps through the use of an animal model.

4. *Were the exposure assumptions and parameter values appropriate under the evaluation criteria?*

The presentation of these agricultural exposures was detailed and well developed. The exposure values selected appear well founded in the science and data currently available. Where judgments had to be made, such judgments are consistent with good scientific practice and with EPA guidance.

5. *Was the basis for selection of values clearly described and referenced?*

The selection of the parameters was well described in the detailed appendixes and summarized well in Volume I of the HHRA. However, clarity in presentation is required. Ms. Hattemer-Frey made several good comments in her write-up and I defer to her comments in that regard.

6. *Is the approach used to estimate the RME and CTE appropriate under the evaluation criteria?*

The approach used was for estimating the RME and CTE for this exposure pathway was developed in a manner similar to the other exposure pathways. With the caveats included for previous pathways, I believe that the presentation is consistent with the evaluation criteria provided by EPA. It is my assessment that the approach used to estimate the RME and CTE are consistent with best science and are appropriate under the evaluation criteria.

7. *Were the uncertainties in the assessments adequately characterized and expressed?*

Volume V devotes an entire section (Section 6) to uncertainties in each component of the risk expression. The discussion includes analytical methods, regression model uncertainty, model characterization problems, and many other factors. The uncertainty analysis is an especially strong component of this section of the report. However, the next step has not been taken. The question remains: What is the impact of these uncertainties on the risk

assessment? Are the uncertainties so large I magnitude as to swamp the efforts? There needs to be some qualitative discussion of the impact and quantitative assessment if possible.

8. *Overall, was the approach used to assess risk form consumption of agricultural products and other wild food items reasonable for evaluating baseline risk?*

Despite all the comments made, it is my assessment that the approach used in evaluating risks for the consumption of agricultural products and other wild foods is reasonable for calculating baseline risk. The data are sparse and many parameters needed to assess risk from this pathway are lacking. Nonetheless, the risk assessment as presented represents the state-of-the-science and may actually exceed such. New ground is being broken (See below.)

E. Phase II - Integrated Risk Evaluation

1. *Were the bases for the toxicity assessment adequately described including the cancer slope factors, reference doses, and calculations of the TEQ?*

This is not my area of expertise. I defer to my colleagues with greater knowledge of toxicity assessment. I do suggest that uncertainty in the toxicity assessment become a significant part of this document. Are values for toxicity-related factors, e.g., cancer slope factors, TEQs, etc., well-quantified? If so, the details should be stated here. If not, the impact of the uncertainties in such values should be discussed.

2. *Did the risk characterization describe the methods and risk summary at an adequate and appropriate level of detail?*

During the course of presentations and discussion, it became apparent that more clarity and transparency is needed in this area. A better, more concise but more complete discussion is warranted.

3. *Were the potential risks associated with exposure to a combination of pathways and COPCs (direct contact, fish and waterfowl consumption, and agricultural product consumption) adequately characterized?*

The combination pathways were only addressed in Section 7.3 of Volume 1 and are covered in only somewhat less than one page. It would be useful to look at these combination pathways in some more detail. This should not be limited to anglers and hunters, for example, but rather include standard scenarios for direct contact risk on a daily basis coupled with hunter/angler scenarios, etc. While one runs the risk of running into absurdities such as someone who hunts every day and wades in sediment all the time, realistic combination scenarios can be imagined that can account for multiple activities. It would help address the question of additive risk to some degree.

A discussion arose under this heading regarding the inclusion of background risk in these calculations. This was one important point brought forward by public comments. It is my contention that risk assessments such as this one typically perform incremental risk assessment, that is risk assessments that focus on the added risk associated with the source. I believe that this is the appropriate way to proceed in that it is not "fair" to require a potentially responsible party to clean up an area because it is perceived that that party's

contribution to the risk has "filled up the risk cup." All others have contributed and have not been required to perform activities to reduce their component of risk. Risk from other activities is not in the picture since they affect a different part of the community. The PRP should not have to reduce the risk of contracting lung cancer from smoking, for example, because they have increased the risk of another type of cancer through contamination of the river. This being said, it is important to realize that risk from PCB exposures are almost completely due to one source, namely the manufacturing site under consideration. They should be required to reduce the contamination and thus risk to which they have contributed directly.

4. *Were the uncertainties associated with both cancer and non-cancer health effects adequately characterized and expressed?*

I may have missed it, but I do not recall an overall evaluation of uncertainties for the combined risk assessment. While the risk values for each component were well characterized, the overall risk uncertainty has not been addressed. However, the authors report that under normal circumstances and for a given individual, it is most likely that a single pathway will dominate exposure; uncertainty in risk from aggregate exposure is most likely also dominated by a single pathway. However, I have been convinced by my colleagues and through my own reading that a better characterization of the uncertainties in these estimates should be forthcoming. I think this is best handled through a separate section within the document- a section dedicated to qualitative and quantitative, if possible, uncertainty evaluation.

F. General

1. *Were the EPA toxicity approaches and values (IRIS and HEAST) used for the COPCs applied appropriately under the evaluation criteria?*

This is not my area of expertise. However, it does appear that the values were used consistently and extracted from appropriate datasets

2. *Were the important assumptions for estimation of dose (i.e., toxicity and exposure) and risk identified?*

This is a difficult question to answer. We had several days of presentations over the course of our evaluation and many documents to read. The documents outline the assumptions quite well. I do not see any that have been missed and therefore conclude that the essential ones are present.

3. *Were the calculations of carcinogenic and non-carcinogenic risk performed properly and consistent with EPA guidance?*

Generally, yes but that is the point of all of the comments that preceded this one. Overall, the HHRA provides a good assessment of the risk associated with this site. Given the assumptions and scenarios, I think they did a very good job.

4. *Were the significant uncertainties inherent in the risk evaluation properly addressed and characterized? If not, please identify those that were nor properly addressed or characterized and how they should be addressed in the HHRA.*

As has been stated a number of times, there is need for a formal qualitative and quantitative uncertainty analysis placed in a separate section that thoroughly addresses this question in a clear and concise manner. As it stands now, the treatment of uncertainty is uneven and scattered throughout many places in the document. In particular, the agricultural pathway has many uncertainties that could result in significant change. However, overall, there would appear to be little likelihood that the problems found would lead to large-scale, major problems in the risk assessment results.

5. *To the best of the Panel's knowledge, have relevant peer-reviewed studies that support, are directly relevant to, or fail to support any estimate of risk been identified and considered, and had an appropriate methodology been used to reconcile inconsistencies in the scientific data?*

Speaking only for myself, it is my assessment that the relevant studies have been presented factually and in a manner consistent with good scientific practice.

6. *To the best of the Panel's knowledge, is there other pertinent information available that was not considered in the HHRA? If so, please identify the studies or data that could have been considered, the relevance of such studies or data, and how they could have been used in the HHRA.*

Speaking only for myself, it is my assessment that the relevant studies have been presented and no additional studies done would have changed the evidence or conclusions in any substantive way. During our deliberations, others mentioned studies that might be considered relevant. However, I do not believe that incorporation of such studies would have a major effect of the risk assessment.

7. *With respect to the conclusion in the HHRA report*

- *Are the conclusions (risk characterizations) supported by the information presented in the other sections of the report?*

It is my assessment that the conclusions presented are backed by information presented in the report.

- *Do the conclusions (risk characterizations) objectively and reasonably characterizer potential current and reasonably foreseeable future risks to human health in the Rest of River area?*

It is my assessment that the risk characterizations are reasonable for most current and reasonably foreseeable future risks with the exceptions noted in the above comments.