Comments on
EPA Human Health Risk Assessment
GE/Housatonic River Site
Rest Of River

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Introduction and Summary

This report has been prepared to summarize my comments on EPA's public review draft of the *Human Health Risk Assessment, GE/Housatonic River Site, Rest of River*. Overall, EPA should be commended for its efforts in preparing the risk assessment, which addresses most of the important issues at the site and reflects careful consideration of these issues. The documentation of the risk assessment approaches, assumptions, and results is also generally very good, particularly given the complexity of the evaluation. However, I strongly believe that several areas of the risk assessment merit further attention and, in some cases, revision. Specific recommendations include the following:

- The HHRA should more clearly emphasize the hypothetical nature of the exposures and risks that have been estimated. The human health risk assessment (HHRA) states that a point estimate approach was used to evaluate Reasonable Maximum Exposure (RME) and Central Tendency Exposure (CTE), with the RME intended to represent the 90^{th} percentile or greater of actual expected exposure and the CTE intended to represent an average exposure (p. ES-9). A probability bounds analysis was also included in the HHRA for the fish and waterfowl assessments, in an effort to better understand uncertainty and variability in estimating the RME and CTE. The discussions of these mathematical approaches tend to suggest that actual exposed populations in the vicinity of the Housatonic have been carefully defined and their behavior patterns studied. However, based on the combination of exposure parameters used in the HHRA and the sources of these parameters, it appears that the populations for which the RME and CTE are calculated are hypothetical (at least as defined by the exposure parameters selected for the HHRA). For example, while recreational angling occurs along the Housatonic, it is not clear that the combination of exposure assumptions that are used in the HHRA are representative of an existing or reasonably expected future population of anglers. Relatively little is known of the actual population of individuals who consume fish from the Housatonic; thus, the RME and CTE risks estimated in the HHRA are hypothetical rather than necessarily reflecting actual conditions. Similarly, given current and expected future land use, the CTE and RME for the assumed agricultural scenarios do not represent points on an actual distribution of exposure, but instead seem more directed toward answering hypothetical "what-if" questions.

- The HHRA should include a more complete discussion and interpretation of available serum data in interpreting the results of the hypothetical exposure assessment. The Massachusetts Department of Health (MPDH) has been collecting data on PCB levels in serum from volunteers for several years. A report issued by MPDH in 1997 concluded that PCB levels in serum from individuals who are expected to be most highly exposed to PCBs associated with the Housatonic River are generally within the background range reported for non-occupationally exposed populations in the U.S. A panel of nationally recognized experts convened by MPDH later supported this conclusion. On the other hand, the MPDH report appears to suggest that there may be higher serum PCB levels in older residents of the Housatonic who are frequent or long-term fish eaters, than in younger residents or those who consume relatively little fish. While it is understood that the MPDH serum data may have limitations, they should be evaluated in the context of the results of the hypothetical exposure assessment in the HHRA.

- The congener-specific evaluation for PCBs should be included only as a sensitivity analysis in the HHRA, given the uncertainties in the derivation of both the toxicity values and environmental fate and transport characteristics for individual dioxin-like congeners. As discussed in the HHRA, there are significant uncertainties each element of the congener-specific evaluation for PCBs, including the development of TEF values for "dioxin-like" congeners in PCBs, and the estimation of concentrations of dioxin-like congeners in soil, fish, waterfowl, and produce. For example, under the agricultural scenarios, the congener-specific risk assessment is dominated by exposures to PCB-126, for which little data on environmental behavior is available. Given these uncertainties, it is strongly recommended that the congener-specific evaluation for PCBs, if retained in the HHRA, be more properly placed in a sensitivity analysis.

- The HHRA should provide a more complete assessment of the potential for non-cancer effects from exposure to dioxins and furans, and clarify the discussion of potential non-cancer effects from exposure to "dioxin-like" compounds. In the HHRA, EPA states that potential non-cancer risks from exposure to dioxins and furans along the Housatonic are not quantified because a review of potential non-cancer effects associated with these compounds is on-going. This leads to the conclusion in the HHRA that potential non-cancer health risks for some scenarios (e.g., direct contact) are underestimated (see, for example, p. 7-9, Volume IIIA, Appendix B). To address public concerns, EPA should use the available toxicity information on dioxins and furans to semi-quantitatively evaluate the potential non-cancer risks for the dioxins and furan levels along the Housatonic, relative to those for PCBs, to indicate if this potential underestimation is significant or not. In addition, EPA should clarify statements regarding the assessment of non-cancer effects for "dioxin-like" compounds. For example, EPA states "Because an RfD has not been developed for PCDDs and PCDFs, the potential for noncancer effects from exposure to dioxin-like compounds is not quantitatively evaluated in this assessment" (p. 2-35, Volume I). However, the presence of dioxin-like compounds in PCBs is included in the RfD for total PCBs, since the Aroclors used in the animal experiments

included both dioxin-like and non dioxin-like congeners. What EPA cannot quantify in the HHRA is the relative contribution of the dioxin-like PCB congeners to the RfD for total PCBs.

My detailed comments are organized in this report according to the specific questions listed in EPA's June 1, 2003 charge statement for the Peer Review Panel. According to the charge statement, Panel members are to consider the following "evaluation criteria" in considering these questions:

> "*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 or policy*" (p.3)

Each specific question in the charge statement is shown below in italics, followed by my response to that question.

A. Phase 1 – Direct Contact Exposure Screening

Were the procedures used in Phase 1 of the HHRA to screen out properties and areas from further evaluation as well as the application of those procedures appropriate under the evaluation criteria? In addressing this question, consider:

- *The general procedures used.*
- *The SRBCs used for the COPCs.*
- *The land use and exposure categories considered and the classification of particular parcels and areas into those categories.*

The general procedures used to screen out properties and areas from further evaluation of direct contact exposures appear to be appropriate. Specifically, a wide range of potential receptor populations have been evaluated, usually based on conservative combinations of exposure assumptions and inputs that would be expected to lead to an overstatement, rather than an understatement, of risks. However, the following elements of the Phase 2 Direct Contact Screening should be reconsidered:

- Certain larger areas warrant additional analysis to ensure that small subareas with higher levels of contamination are properly assessed and included in Phase 2 if appropriate. In Reaches 5 and 6, screening of PCB concentrations in floodplain soil was conducted for each tax parcel regardless of size (Volume I, p. 3-4). In Reaches 7 and 8, screening was conducted on exposure areas that encompass more that one tax parcel, while screening of Reach 9 was conducted for the entire reach and Reaches 10 – 17 were screened for the entire stretch of the Housatonic River in Connecticut (Volume I, p. 3-5). If the maximum concentration in an exposure area were to exceed an SRBC, then the 95% UCL was compared to the SRBC. In some instances, however, an exposure area as defined in Phase 1 can be quite large (e.g., J4-3-13 [35 acres in floodplain]; 29-2 [102 acres in floodplain]; 19-1 [70 acres in floodplain], based on the *EPA Response to Questions from the HHRA Document Review Meeting*)

and the 95% UCL is considerably smaller than the maximum detected concentration. This suggests that there may be subareas within a tax parcel or exposure area that are relatively large (e.g., at least several acres in size) and for which a conservative estimate of the exposure concentration may be significantly higher than the 95% UCL for the tax parcel as a whole and also higher than a relevant SRBC. This issue could be addressed in a sensitivity analysis in Phase 1, with additional subareas carried into Phase 2 as appropriate.

- The SRBCs for different potential receptor populations are based on different target cancer risk levels (e.g., $5x10^{-6}$ for residents and recreational uses; $1.6x10^{-6}$ for the utility worker and $1.1x10^{-6}$ for the commercial groundskeeper). While I do not object to the use of a range of risk targets in the screening evaluation, Volume I of the HHRA should provide a clearer explanation of the reasons for the differences. In particular, it appears that the use of a $5x10^{-6}$ for residents is based on the 2 mg/kg cleanup level previously agreed to by EPA, the State of Massachusetts, and GE for PCBs in residential properties nearer to the GE Pittsfield plant, and thus reflects a risk management decision that actions would not be taken in areas where PCB concentrations are below this level in residential or recreational parcels in the "Rest of River" site. Assuming that such a management decision has been made, I concur with the HHRA that carrying areas that present a risk lower than $5x10^{-6}$ for residents is unnecessary. However, in that case, it is not clear why a more stringent target is being used for the utility worker or commercial groundskeeper.

- The report should be clarified to emphasize that Phase 1 is intended to only to screen out properties and areas from further evaluation of exposures through direct contact, but that potential exposures through consumption of livestock and produce are evaluated for all current or reasonably foreseeable agricultural areas in Phase 2. While this is clear from Volume V, there was some confusion on the panel based on the text in Volume I.

- The breast milk pathway should be further addressed for PCBs and dioxins/furans. I recognize that this pathway is often excluded from quantitative evaluation in risk assessments due to a lack of recent EPA guidance and limitations in available data. However, given the tendency for PCBs and dioxins/furans to accumulate in fat and both public and regulatory concerns regarding effects of short-term exposure on infants, I believe that the breast milk pathway should be included in an uncertainty analysis. A method for quantifying exposures through the breast milk pathway is described by Smith (1987) [*Infant Exposure Assessment for Mother's Milk Dioxins and Furans Derived from Waste Incinerator Emissions*, Risk Analysis, Volume 7]. This comment also applies to the Phase 2 direct contact, fish and waterfowl, and agricultural exposure evaluations.

- Given the assumptions used to evaluate incidental ingestion and dermal contact exposures, and the results of air monitoring at the site, I agree with EPA that including inhalation of PCBs in either vapor or particulate-bound form is not necessary in the Phase 1 screening. However, to address public comment on this issue, it may be worthwhile to expand Volume I to discuss the basis for excluding inhalation in establishing the SRBCs. This is particularly important given the

relatively large number of articles that have been published over the past several years regarding the importance of long-range atmospheric transport of PCBs.

- The discussion of future land use in Phase 1 (Volume 1, p. 3-9) should explicitly refer to EPA's guidance on the consideration of future land use in the risk assessment process, including the 1995 OSWER Directive on Land Use Policy. It is also unclear from the HHRA why the primary focus of the Phase 1 screening evaluation was current land uses, as stated on p. 3-9. The text suggests, perhaps incorrectly, that the consideration of potential future land use was largely in Phase 2, after many properties had already been screened out based primarily on the basis of current land use. This raises concerns that a more complete evaluation of potential future land use in Phase 1 may have resulted in additional parcels being carried through to further evaluation in Phase 2.

B. Phase 2 – Direct Contact Exposure Assessment

1. Were the following aspects of the direct-contact exposure assessment appropriate under the evaluation criteria?

- *The exposure scenarios which were evaluated.*
- *The exposed populations which were selected for each scenario.*
- *The exposure areas identified based upon potential current and future use(s).*
- *The routes of exposure 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 exposure scenarios, exposed receptor populations, exposure areas, and routes of potential exposures selected for the Phased 2 Direct Contact Exposure Evaluation generally appear to be appropriate, except as follows:

- The rationale for determining future land use assumptions for the direct contact evaluation is not clearly described either in Volume I or in Volume IIIA. For example, according to p. 4-26 of Volume I, "Not all properties were assessed for future residential uses, only those that had the characteristics of properties that have been converted to residential use in Massachusetts in recent years". I was not able to locate a discussion of what these characteristics are, or how they were assessed in the HHRA. Furthermore, "industrial/commercial and agricultural exposures were

assessed only for those areas currently designated for these uses" (p. 4-26). It is not clear from the information provided in the HHRA whether or not such an assumption is reasonable. I recommend that the future land use decisions be revisited and documented using the framework described in the 1995 OSWER Directive on Land Use Policy.

- The selection of age ranges for evaluation should be supported by a discussion of what is considered to represent a chronic exposure, particularly for PCBs. EPA guidance under Superfund recommends a generic assumption that chronic exposures are those that are relatively continuous over a period of at least 7 years (USEPA Risk Assessment Guidance for Superfund, Part A, 1989). If that is considered to be appropriate for PCBs, dioxins/furans, and the other primary COPCs in the risk assessment, then the age ranges that have been selected appear to be appropriate. However, if exposures of only a few years are considered to be chronic for some of the primary COPCs, or if the subchronic toxicity is considered to be similar to the chronic toxicity, then EPA should consider breaking down the "young child" (age 1 through 6) receptor group into smaller subgroups to account for differences in body weight and behavior that may lead to higher risks for infants.

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

Overall, the most important exposure pathways have been identified and evaluated. As discussed above in the context of the Phase 1 screening for direct contact, the breast milk pathway should be further addressed for PCBs and dioxins/furans in an uncertainty analysis. In addition, the discussion of site-specific data and used to eliminate inhalation as an exposure pathway of primary concern is very limited (p. 4-6, Volume IIIA), and I recommend that it be expanded to address expressed public concerns.

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?*

EPA should be recognized for using well-recognized and applicable geostatistical spatial weighting approaches for calculating EPCs for the Phase 2 Direct Contact Exposure Evaluation. These approaches allow for effective use of the existing soil datasets. However, the following elements of the development of EPCs should be reconsidered:

- EPA should emphasize that the data used as input to the Phase 2 spatial weighting approach was not randomly collected, but instead largely based on sampling biased toward areas that are believed to exhibit the highest PCB levels in soil. It appears that the spatial weighting approach will not assign concentrations exceeding the maximum detected concentration to any grid location. This limitation could be significant and lead to a possible underestimate of exposure point concentrations if EPA believes that there are soil areas in any EA where PCB concentrations might substantially exceed the maximum concentration

detected in that EA. However, the biased sampling approach used by EPA would tend to mitigate such concerns.

- Certain larger areas may warrant consideration of additional analysis to ensure that small subareas with higher levels of contamination are properly assessed. As indicated in Volume IIIA, p. 4-13, in Phase 2 "exposure was assumed to occur randomly across an EA or subarea. However, a number of these EAs and subareas are large, and, if an individual's actual exposure occurs primarily to areas of higher contamination, risks may be underestimated". EPA should consider maximum concentrations relative to the 95% UCL concentrations to determine if conclusions regarding an EA would change if relatively small but still substantial (i.e., at least an acre in size) subareas were evaluated separately.

- The data used in the regression equation to relate PCB_{teq} concentrations in soil to PCB_{total} concentrations in soil appear to be adequate and relatively consistent. However, the HHRA should provide an explanation based on the environmental behavior of the various PCB congeners for the finding that the PCB_{teq} content in soil is relatively higher in soils with lower PCB_{total} concentrations in soil. For example, according to Table 4-16 in Volume I, a 100-fold increase in the PCB_{total} concentration in soil (1 ppm to 100 ppm) results in less than a 20-fold increase in the PCB_{teq} concentration.

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

   - *Exposure duration 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).*
   - *Oral and dermal absorption factors.*

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

   In general, the combinations of exposure factors used in the Phase 2 Direct Contact Assessment appear to be conservative (i.e., more likely to overstate than understate exposures). In fact, in some cases, the combinations appear to lead to inappropriately high estimates of exposure.

   According to EPA's Policy for Risk Characterization at the U.S. Environmental Protection Agency (March, 1995), "If only limited information on the distribution of the exposure or dose factors is available, the assessor should approach estimating the high end by identifying the most sensitive variables and using high end values for a subset of

these variables, leaving others at their central values." It is not clear that this guidance has been followed in estimating the RME for direct contact exposures. While the individual exposure parameters (e.g., soil ingestion rate, fraction of contaminated soil ingested, exposure frequency, exposure duration) do not necessarily seem unreasonable when taken individually, when combined they can produce a scenario that does seem highly unlikely, at least for many of the EAs. For example, under the RME general recreation scenario, it is assumed that an individual may contact the floodplain in a single EA over 6,300 days over the course of a lifetime, that 100% of the soil ingested on each of those days comes from that EA, and that the individual displays behavior that corresponds to "high end" incidental soil ingestion on each day. To address this issue, specific recommendation include the following:

> Since Dr. Edward Calabrese is a primary source of the data used in developing the ingestion rates selected for the HHRA, EPA should revise its RME and CTE soil ingestion rates to reflect those recommended by Dr. Calabrese in his January 23 2003 letter included as Exhibit E.1 of the GE/AMEC/BBL comments on the HHRA [i.e., for young children, 20 mg/day (CTE) and 100 mg/day (RME); for adults, 10 mg/day (CTE) and 50 mg/day (RME), unless a technical rationale for rejecting those updated estimates is identified and documented. The updated soil ingestion rates recommended by Dr. Calabrese are similar to those also recommended by the Agency for Toxic Substances and Disease Registry (ATSDR) [i.e., 50 to 100 mg/day for non-pica children, and 50 mg/day for adults] in its Public Health Assessment Guidance Manual (ATSDR 1992), to represent conservative estimates of typical behavior.
>
> Combine the high-end soil ingestion rate with more likely values of fraction ingested (FI) for incidental soil ingestion and fraction contacted (FC) for dermal contact with soil, under both RME and CT scenarios. Currently, the HHRA assumes an FI value of 1.0 for both the RME and CT residential scenarios, and FI RME and CT values of 1.0 and 0.5, respectively, for the all non-residential scenarios. In addition, the HHRA appears to explicitly assume an FC value of 1.0 for all direct contact scenarios. These FI and FC assumptions are highly conservative when combined with the soil ingestion and dermal contact assumptions, which relate to the total amount of soil ingested or contacted each day, regardless of source. Alternatively, the high-end FI and FC assumptions could be combined with soil ingestion and dermal contact rates that are more representative of central tendency estimates.
>
> Avoid combining the RME exposure frequency with the RME exposure duration. For example, for the angler, the RME exposure frequency is assumed to be 60 days per year, corresponding to 2 days a week for a 7-month period. Such a frequency may not be unreasonable for a period of several years. However, when combined with an RME exposure duration of 60 years, then the result is an estimated 3,600 days spent by an angler at the same EA, and 100% of the soil ingested on each of those days comes from that EA

Adjust the use-weighting factors and exposure frequencies to better reflect the likelihood that recreationalists would routinely contact areas. The assignment of use-weighting factors in the direct contact assessment reflects considerable judgment, and based on the discussion in the HHRA, the factors for "difficult to access" and "wadable" categories seem high relative to the "walkable" category (Volume I, p. 4-9). In addition, the HHRA assumes an RME general recreational exposure frequency of 30 days/year along with an exposure duration of 70 years (or a total of 2,100 days of exposure) even for areas that are "characterized by having inundated wetlands and dense vegetation, and are remotely located" (p. 4-35, Volume I). Based on observations during a site visit, and the material presented in the HHRA, large portions of the floodplain would be expected to be contacted very rarely, if at all. These observations are consistent with the results of a Floodplain User Survey discussed during the Peer Review Panel public meeting held in November, 2003.

On the other hand, it should be noted that the following Phase 2 assumptions may lead to underestimates of potential exposures through direct contact:

Exposure frequency for the farmer: 10 days per year seems low for both CT and RME scenarios.

Soil ingestion rates for the commercial groundskeeper. The soil ingestion rate for the commercial groundskeeper is assumed to be the same as for the adult resident. Depending on the specific activities of the groundskeeper, this may be an underestimate, particularly if the updated soil ingestion rates recommended by Dr. Calabrese are adopted for the HHRA.

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?*

See comments above.

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

Given the comments above, and the results of the HHRA for the direct contact scenarios, it is recommended that EPA provide a more complete and, to the extent feasible, quantitative analysis of uncertainties.

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

With the exception of the comments listed above, the overall approach used to evaluate baseline risk in the HHRA appears reasonable.

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?*

   The following recommendations are made regarding the calculation of EPCs for these scenarios:

   - The approaches used in the HHRA to calculate the 95% UCL should be reviewed. The use of Land's H-statistic to calculate 95% UCL values for lognormal distributions is typically reliable for substantial datasets that are truly lognormal, but can provide unreliable results if the dataset is small or deviates from lognormality. It is recommended that EPA confirm the 95% UCL values using bootstrap methods, such as Efron's BCa (bias-corrected and accelerated) nonparametric bootstrap (Efron, B. and R. J. Tibshirani. 1998. An Introduction to the Bootstrap. Chapman & Hall/CRC, Boca Raton). For an empirical distribution that is approximately normal, the bootstrap confidence interval will be essentially the same as the normal confidence interval. For an empirical distribution that is not normal, however, the bootstrap prediction interval will be more accurate than a confidence interval calculated assuming a normal (or even lognormal) distribution, according to EPA guidance, "The Lognormal Distribution in Environmental Applications" (EPA 1997).

   - The HHRA does not include an evaluation of risks posed by consumption of waterfowl in Connecticut, due to a lack of data for calculating EPCs in the tissue of waterfowl along the Housatonic in that state. Given public concern regarding the consumptions of waterfowl, and the relatively high risks estimated in the HHRA for this scenario in Massachusetts, it is recommended that EPA include at least a semi-quantitative assessment for Connecticut in a sensitivity analysis based on relative concentrations of PCBs in soils and other media to which the waterfowl may be exposed.

   - It is implicitly assumed that PCB concentrations in fish and waterfowl will remain constant over the time period considered in the HHRA (i.e., up to 60 years). The HHRA should present data from the Remedial Investigation or other site studies to provide a basis for understanding to what extent this represents a significant conservative assumption, given phenomena that may act to change PCB concentrations in water, sediment, and fish tissue.

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

   Similar to comments above regarding the direct contact scenario, it does not appear that the combination of exposure assumptions and parameters used in estimating the RME for the fish and waterfowl consumption scenarios is consistent with EPA's Policy for Risk

Characterization at the U.S. Environmental Protection Agency (March, 1995). While the individual exposure parameters do not necessarily seem unreasonable when taken individually, when combined they can produce a scenario that does seem highly unlikely. To address this issue, specific recommendation include the following:

- EPA does a good job in the HHRA of summarizing relevant fish consumption rate data from the scientific literature. However, the selection of fish consumption rates for use in the HHRA appears to be overly conservative, based on a review of the Ebert et al. (1993) study selected as the foundation for the calculations. In particular, the assumption of basing the consumption estimate on a "no-sharing anglers only" scenario should be reviewed. The 90th percentile for the "no-sharing" anglers (32 grams/day) is used as the RME consumption rate in the HHRA, despite data from Ebert et al. (1993) suggesting that a great majority of anglers in that study reported sharing recreationally-caught fish. The 90th percentile of the distribution for all anglers (including those who do not share) is approximately 15 grams/day. Thus, a more reasonable RME estimate for the HHRA would be 15 grams/day, especially since it is conservatively assumed that all of the recreationally-caught fish are taken from the Housatonic. This consumption rate of 15 grams/day is similar to the default value recommended by EPA for the development of ambient water quality criteria (EPA 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health).

- The exposure durations assumed for both fish and waterfowl consumption are not adequately supported, and may lead to significant overestimates of potential exposure when combined with the assumed consumption rates. Exposure durations of 23 years and 60 years, respectively, are used in the HHRA to estimate the CTE and RME for both fish and waterfowl consumption. These durations are based on an MDPH study, from answers to questions regarding the length of time that freshwater fish is consumed (p. 4-56; Volume 4; Appendix C). However, it is not clear that these values actually reflect the lengths of time that an individual would be expected to consume freshwater fish from the Housatonic, as opposed to other sources (such as stores and restaurants).

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?*

   The selection of RME and CTE exposure parameter values were generally described very clearly and were adequately referenced. See comments above regarding selection of the point estimate values for use in the HHRA.

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

The probabilistic approaches were adequately described, and such approaches are appropriate as a sensitivity analysis in the context of the fish and waterfowl scenarios.

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

   The distributions used in the probabilistic assessments were adequately described. However, in many instances the HHRA relies predominantly on professional judgment to define these distributions, due to a lack of relevant information available regarding the site or in the scientific literature. In addition, the probabilistic assessments do not include distributions for the toxicity data, a limitation that is consistent with current EPA guidance. Therefore, in my opinion, the probabilistic assessments in the HHRA do not provide a more accurate or complete depiction of risks at the site despite the apparent statistical rigor with which they were conducted.

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

   See comments above.

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

   See comments above.

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

   In addition to the comments above, the following recommendations are made:

   - Data on PCB levels detected in fish and waterfowl from "reference areas" should be more fully discussed in the HHRA to put the risk estimates calculated for the Housatonic into context. According to the HHRA, waterfowl were captured from both Woods Pond (and its backwaters) and a reference area (Threemile Pond) for analysis of PCB concentrations in breast and liver tissue (p. 2-7; Volume 4; Appendix C). However, the HHRA does not present the results of the waterfowl data from the reference area or provide comparisons to the data from Woods Pond. Particularly given the migratory behavior of some waterfowl, the HHRA should compare the data from the reference area and Woods Pond. In addition, the HHRA states that fish were captured from four locations downstream of the GE facility and from two reference areas for PCB analysis (p. 2-4; Volume 4; Appendix C). The HHRA should include a more complete discussion comparing the fish data from the reference areas to the locations downstream of the GE facility. Based on information provided by EPA in response to Panel questions

on this issue, and using the methodologies and assumptions presented in the HHRA, it appears that PCB concentrations in fish and waterfowl from the reference areas may pose risks that are smaller than those for the Housatonic, but that are still potentially significant relative to EPA risk management goals. Such a comparison of relative risks should be included in the HHRA to put the results for the Housatonic into better context.

- As discussed above in the context of the direct contact scenarios, the breast milk pathway should be further addressed for PCBs and dioxins/furans in an uncertainty analysis for the fish and waterfowl consumption scenarios.

D. Phase II – Agricultural Exposures

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

The overall exposure scenarios selected for evaluation were reasonable as hypothetical possibilities. However, based on the information provided in the HHRA, many of the scenarios do not appear to be likely (e.g., commercial beef cattle) or incorporate elements that do not appear likely (e.g., 100% of grazing occurs within contaminated portions of the floodplain).

In addition, as discussed above in the context of the direct contact scenarios, the breast milk pathway should be further addressed for PCBs and dioxins/furans in an uncertainty analysis for the agricultural exposure scenarios.

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

In general, much of the site-specific agricultural data do not appear to be reliable for the purposes of estimating transfer of COPCs from soil to plants in the HHRA. Examples include the following:

PCB concentrations in corn cobs and corn stalks. PCBs were not detected in any corn ears, and all stalk concentrations are qualified as "J" (estimated) values. The stalk regression equation is strongly influenced by a single value (corresponding to a PCB concentration of 5.9 ppm in soil); without that data point, there would be no apparent relationship between soil concentration and corn stalk concentration. Furthermore, the regression does not include the samples where PCBs were detected in soil but not in stalks. If those non-detect (ND) data were included, the slope of the relationship between soil concentration and stalk concentration could vary significantly, from positive (increasing stalk concentration with increasing soil concentration) to negative (decreasing stalk concentration with decreasing soil concentration), depending on whether the ND is assumed to be equal to zero, ½ the detection limit, or equal to the detection limit. In addition, if the site-specific corn data are used

in the HHRA, then the transfer factor for silage should be modified to reflect that the protected portion of the corn does not contain detectable levels of PCBs.

PCB concentrations in acorn squash. The highest PCB concentration detected in the flesh of acorn squash is reported from a floodplain area where PCBs were not detected in soil (Table 2-5; Volume V; Appendix D). The second highest PCB concentration detected in the whole squash is reported from this same location. Thus, based on the site-specific data, there is no apparent relationship between PCB concentrations in soil and squash.

PCB concentrations in fiddlehead ferns. Based on the data collected in 2000, PCBs were detected only in washed fiddlehead ferns. PCBs were not detected in any of the unwashed ferns (Table 2-6; Volume V; Appendix D). This would suggest that the PCBs detected in the 2000 sampling event may have been introduced by the washing process, and are not related to concentrations in soil. In addition, there does not appear to be a strong relationship between soil concentration and fiddlehead fern concentration in the 1995 MDEP sampling event (Table 2-7; Volume V; Appendix D). Specifically, PCBs were routinely detected in the fern samples collected from the "reference" area, in some cases at levels similar to those from floodplain areas where PCB concentrations in soil are reported to be up to 156 ppm.

PCB concentrations in grass. The regression equation for total PCBs in grass (Figure 4-4a) is strongly influenced by a single value (corresponding to a total PCB concentration of 21.3 ppm in soil); without that data point, there would be no apparent relationship between soil concentration and grass concentration. (For example, the lowest total PCB concentration in grass was detected at the location of the second highest concentration in floodplain soil). The relationship between total PCBs in soil and grass improves when the grass is normalized for lipid content, and the soil for organic carbon content (Figure 4-4b), although it is still strongly influenced by two or three samples.

Similarly, the regression for PCB-126 (which contributes most significantly to EPA's estimate of congener-specific risk) is also strongly influenced by a single data point (corresponding to a PCB-126 concentration of about 1.1 ppb in soil). Without this data point, the slope of the relationship between PCB-126 concentrations in soil and grass would likely change from positive to negative. Unlike total PCBs, the relationship between PCB-126 in soil and grass does not improve when the grass is normalized for lipid content, and the soil for organic carbon content (Figure 4-4b). The limitations in the site-specific data for PCB-126 are particularly important given its contribution to the estimated congener risks and the relatively high soil-to-grass transfer factor assigned to PCB-126 in the HHRA (i.e., 0.2). By comparison, ATSDR (2000) reports that the soil-to-grass transfer factor for PCBs is less than 0.02 for most terrestrial plant species.

Finally, as stated in the HHRA (p. 4-25; Volume V; Appendix D), the grass samples were collected from areas located immediately adjacent to the river with evidence of recent floodwater inundation. Therefore, the grass samples do not appear representative of the larger areas and other timeframes over which livestock may graze.

Overall, given the limited data available for estimating congener-specific uptake by produce, the congener-specific evaluation for the agricultural pathways should be discussed only as a sensitivity analysis.

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

The overall approaches used to estimate bioaccumulation of COPCs in animal tissue are conservative, and would be expected to overstate potential risks. However, data with which to refine these approaches are extremely limited. Thus, for total PCBs, the approaches are generally appropriate, if the conservative nature of the calculations is considered in interpreting the results of the bioaccumulation estimates. However, due to the extremely limited data available for estimating congener-specific uptake by livestock as acknowledged in the HHRA it is recommended that the congener-specific evaluation for the agricultural pathways be discussed only as a sensitivity analysis.

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

The exposure assumptions and parameter values were generally appropriate for the scenarios described, although some of these scenarios have only a very low likelihood of occurring based on information provided in the HHRA and at the November public meeting.

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

The basis for selection of values was generally well described and referenced.

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

See comments above.

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

The uncertainties in the assessment were not adequately characterized or expressed in many cases. In particular, the portion of Section 6 (Uncertainty Analysis) in Volume V, Appendix

D that addresses prediction of COPC concentrations in animal feed and human food products is largely a simple recitation of uncertainties, without any quantitative or even semi-quantitative evaluation of the effect of the uncertainties on the results of the assessment (see, for example, the discussion of PCB-126 on p. 6-5 in Section 6.3.2.1.1).

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

   See comments above.

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 TEQ?*

   The bases for selection were adequately described.

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

   See comments above.

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?*

   Yes.

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

   See comments above.

F. General

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

   Yes, with the exception of the approach for evaluating "dioxin-like" PCB congeners. Based on the information and references cited in the HHRA, it appears that this approach is not contained within existing EPA guidance although it is currently under review. If the

evaluation of "dioxin-like" PCBs is retained in the HHRA, it should be included as a sensitivity analysis only.

Furthermore, a flawed approach appears to be used in the HHRA to "adjust" the results of the TEQ risk associated with dioxin-like PCB congeners to account for the presence of these congeners in the Aroclor test materials used in the animal studies that form the basis of the PCB cancer slope factor (see Section 2.2.2.3 in Volume I). Specifically, according to p. 2-11, the TEQ content assumed to be present in total PCBs (7.1 mg dioxin-like TEQ per kg PCBs) is based on the content in Aroclor 1260, because "that is the Aroclor that most closely resembles the environmental mixture at this site…" However, it appears that the TEQ content used in the "adjustment" approach should instead be based on the highest TEQ content in the PCB mixtures used in the animal studies that form the basis of the PCB cancer slope factor. From the discussion of p. 2-11, this would be Aroclor 1254, not Aroclor 1260.

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

   See comments above.

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

   Yes, with exceptions as discussed in comments above.

4. *Were the significant uncertainties inherent in the risk evaluation properly addressed and characterized? If not, please identify those that were not properly addressed or characterized and how they should be addressed in the HHRA.*

   See comments above.

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 has an appropriate methodology been used to reconcile inconsistencies in the scientific data?*

   See comments above.

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?*

   See comments above.

7. *With respect to the conclusions in the HHRA report:*

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

     See comments above.

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

     See comments above.