PEER REVIEW COMMENTS
ON THE EPA DRAFT
"HUMAN HEALTH RISK ASSESSMENT
G/E HOUSATONIC RIVER SITE
REST OF RIVER"

Prepared by

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I. Executive Summary

The Human Health Risk Assessment GE/Housatonic River Site Rest of River documents relate what was done and the results of a very complex and substantial task. The stated purpose of the assessment was to provide:

- A characterization of the potential human health risks under baseline conditions (i.e. no actions) for current and future use.
- A basis for determining the need for remediation.
- A basis for setting media protection goals for contaminants of concern.
- A basis for comparing the effectiveness of various remedial alternatives.

There is no question but what the development of the assessment to its present stage represents an enormous task drawing on the talents of many individuals with diverse talents. I commend the participants for their efforts. They have prepared an impressive work product.

In my professional judgment, the human health risk assessment does not adequately fulfill the stated purposes given above. A major deficiency is the failure to ground the report in a well-documented "Base Case" and a projected "Future Case." The report does not provide a description of either case as a starting point. Rather, the assessment moves directly to consider a set of "hypothetical individuals" carrying out different scenarios of activity and a set of "hypothetical individuals" consuming products from a "model farm." The "hypothetical individuals" and activities (frequency and duration) are not grounded in any current reality based on the General Electric Survey of use of the area and personal inspection. The "Future Case" is largely conjectural and does not appear to be well grounded in facts and documented projections.

The assessment builds on a remarkable amount of soil sampling and analysis data and a very limited number of environmental samples. It is not at all clear as to the strategy used to guide the collection of the soil samples. As a result there are major questions as to the end use of the soil data. I see a major void between the soil data collection and its use. The fish and duck flesh samples are very important but are so limited in number that controversy arises as to the true variability of contaminant concentrations. However, the limited number of fish and waterfowl samples provides insight into the likely productivity of the river. The very limited number of grass and

corn samples and the absence of analyses of other agricultural specimens (meat, milk, eggs and vegetables) provides an inadequate base of information for analyzing this pathway.

From this very modest, and indeed limited, data base the assessment proceeds to calculate the exposure to "hypothetical individuals" using a series of assumptions and parameters. In my opinion, the selection of specific assumptions and parameters appear to have resulted from interpreting EPA guidance as "rules" requiring the use of extreme upper range and, in some cases, likely implausible, values. The layering of multiple upper-range values very likely over-estimates the exposure of individuals either at the upper end or the middle of a distribution of a resident or user population.

The exposure values are then translated into risk through the use of point estimate slope factors for cancer potency and point estimates of reference dose for non-cancer health effects. The use of linear exposure-excess cancer slope factors to calculate cancer risks down to the lowest quantity of measurable contaminant without acknowledging that the true cancer risk for low levels of PCB exposure may be zero is misleading. The portrayal of the single point estimates of Reference Dose, which incorporate uncertainty factors of 100 and 300, as measures of absolute risk is misleading. Reference Doses by definition are estimates (with an uncertainty spanning perhaps an order of magnitude) of a level of continuous intake for the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious non-cancer health effects during a lifetime. Thus, it is not a risk level but rather a level of exposure where there an absence of risk. It follows then that exposure at 2 times or 10 times the Reference Dose does not equate to twice or ten times as much non-cancer risk.

The layering of multiple assumptions and parameter values in the exposure assessment and the failure to acknowledge any uncertainty in the toxicity factors leads to estimates of risk that almost certainly markedly over-estimate the likely true risks for individuals at either the upper end or middle of a distribution of a resident or user population.

In summary, the assessment can be viewed as having been conducted in accordance with the "rules" and yielded arithmetically correct estimates of exposure and risk. However, this does not, in my professional judgment, translate into estimates of

exposure and risk that fulfill the intended purposes of the assessment. In summary, the assessment in my professional judgment does not pass the "common sense" test of a synthesis and integration of scientific information to inform important societal decisions on the need for remediation of the Housatonic River flood plain and its future use.

I strongly recommend the development of a second generation human health risk assessment for the Housatonic River "Rest of River." The development of the assessment should start with very careful consideration of the goals of the assessment matched to realistic estimates of current and projected patterns of use of the Housatonic River and its flood plain. The conduct of the assessment will undoubtedly require collection and analysis of some specific environmental samples to provide essential input data for the assessment. This will include agricultural products if there are plausible projections of agricultural use of the flood plain recalling that the Massachusetts Wetlands Protection Act limits agricultural activities within 200 feet of river banks.

II. Introduction

These peer review comments, prepared in response to a consent decree, relate to the EPA public review draft – "Human Health Risk Assessment, GE-Housatonic River Site, Rest of River." In addition to reviewing the multiple documents and supporting material, I had the opportunity to review the comments provided by the General Electric Company and the public. The review was also informed by the answers provided to various fact finding questions asked by Peer Review Panel members as the review progressed. My review was also greatly facilitated by a tour on October 22, 2003 of the Housatonic River environs downstream of Pittsfield, MA, a fact gathering briefing held on October 23, 2003 in Pittsfield, MA, participation in the public meeting held in Lenox, MA on November 18-20, 2003, and the opportunity for dialogue with my fellow Peer Review Panel members at the public meeting.

The comments provided in this report represent my own professional judgment of the quality and adequacy of the EPA assessment, how it was developed and the conclusion. My comments are divided into a section addressing some over-arching issues and a section providing response to specific questions in the consent decree. My scientific credentials are summarized in a personal biographical sketch included at the end of this report.

III. Over-Arching Issues

The Consent Decree posed a number of specific questions that were to be addressed by the Peer Review Panel. However, reviewing the questions it is apparent that there are a number of over-arching issues that relate to multiple questions. Therefore, in this section I briefly comment on the most significant of those over-arching.

A. EPA Guidance versus Rules

A recurring theme is whether the appropriate EPA Guidance was used in the preparation of the Human Health Risk Assessment (HHRA). The short answer to the question is "yes." However, in this case a "yes" answer is not reassuring nor informative. Let me explain. The EPA Guidance documents provide useful guidance for conducting risk assessments. Unfortunately, the staff preparing the Human Health Risk Assessment have tended to not always use the documents as guidance, but rather have generally interpreted them as rigid "rules" to be followed. Thus, in many instances the staff have failed to exercise professional judgment and "common sense" in developing the risk assessment. This approach has resulted in a product that documents the "rules" have been followed. However, it fails to always clearly communicate what was done and the rationale for the specific action and how it relates to other actions in the assessment process. In my professional judgment, the collective result is an assessment that systematically over-estimates the likely exposures and risks associated with the baseline (as is) case for use of the Housatonic River and environs and future uses.

B. Population versus Personal Risk

The HHRA purports to assess exposure and risks for information on individuals with Rreasonable Maximum Exposure (RME) and the Central Tendency Exposure (CTE). It does not present a population risk assessment for residents of the Housatonic River Rest of River. As a result, the estimates of the risk to the "hypothetical individuals" cannot be placed in perspective relative to the population. In my opinion, the approach taken leads to an exaggeration of risks for the modeled scenarios and an exaggerated public perception of risk to the population at large and members of the population. If the Agency persists in using the "individual risk" orientation, then it is

incumbent on the Agency to increase its communication efforts both in the revised HRRA and by other means to help the public better understand the approach taken and to place the risk estimates into perspective.

C. Cancer Risk Potency Values

The risk potency values for Cancer Slope Factor (CSF) selected for use in preparing the HRRA represent upper-range values that very likely result in over-estimation of cancer risk and non-cancer risks to individuals and populations. Indeed, there is credible evidence that PCBs at the concentrations encountered in the Housatonic River environs do not pose a risk for causing either cancer or non-cancer health effects. The topic of PCBs and human cancer has recently been reviewed by Golden *et al* (2003) noting the absence of evidence of an association between PCB exposure, in many cases at high levels, and excess risk of cancer. This includes the latest report by Kimbrough *et al* (1999) of 7000 workers exposed to high levels of PCBs and followed for a long period of time, on average over 30 years.

If the Agency persists in using the values presently cited for the CSF for PCBs, it should, at a minimum, provide an extended discussion of the uncertainties associated with the values. This should include the possibility of there being no excess cancer risk for low levels of exposure to PCBs. It is not sufficient to note the values listed in IRIS or some other sources have been used.

D. Dioxin, Dioxin-Like Compounds and Use of Toxicity Equivalence (TEQ) Approach

The present assessment makes use of the TEQ approach to estimate cancer risks for PCB congeners. Concentrations of the so-called dioxin-like PCB congeners, as well as dioxin and furan compounds are converted into TEQs of 2, 3, 7, 8-tetrachlorobenzo-p-dioxin through the use of Toxic Equivalency Factors and then assessed as to potential cancer risk using the cancer slope factor for dioxin. The approach used in the assessment, including the potential for double-counting of risks, is confusing. If this approach is used in future assessments, the approach and the details of the analytical procedures must be more clearly described.

There continues to be substantial controversy concerning both the cancer risk for dioxin and the use of the TEQ approach for assessing cancer risks. The dioxin

reassessment referenced in the Housatonic River risk assessment and the associated cancer slope factor are in limbo. The dioxin risk Assessment has been referred to the National Academy of Sciences/National Research Council for review and recommendations. It is my understanding that until this review is completed it is not appropriate to use the values cited in the EPA Dioxin Reassessment. I recommend that the TEQ method and the associated use of the cancer slope factor for dioxin not be used in the Housatonic River Human Risk Assessment until the National Academy of Sciences/National Research Council issues its report and recommendations.

E. Mis-use of Reference Doses and Hazard Index

The HHRA erroneously presents Reference Doses (RfDs) as though they are bright line values, below the RfD no risk and above the RfD excess risk. The EPA's RfD values are an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous intake for the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious non-cancer health effects during a lifetime. Rather than treating the Hazard Index (a value of 1 is equal to an individual RfD) as a bright line, it would be more appropriate to view it as a level above which it is appropriate to do a more detailed evaluation.

It is erroneous to view exposure at the RfD level as causing harm and that an exposure at 2 times or 10 times the RfD causes 2 times or 10 times as much harm as implied in the assessment. The RfD is not a quantitative measure of harm. It is a reference level for guiding subsequent evaluations of the potential for harm. This should be made clear in the assessment.

F. Selection of Various Model Inputs

Numerous assumptions must inevitably be made when prospectively estimating health risks for individuals or populations exposed to environmental agents. Many of the assumption and parameter values selected for use in the HHRA appear to be biased very substantially on the high side such that when collectively layered one on another in the models the results are exaggerated estimates of risk to "hypothetical individuals."

G. Consideration of Site-Specific Data

The assessment should include specific reference to two reports that provide insight into how Housatonic River PCB contamination may or may not have impacted on the local population. One study by the Massachusetts Department of Public Health (1997) reports the results of PCB analyses on blood samples of residents of the area. The report indicates that the PCB blood levels of non-occupationally exposed individuals were within the normal background range for the general population.

The second report is from the Agency for Toxic Substances and Disease Registry (2002). It relates that cancer rates for communities in the town near the river do not appear elevated. Although it is recognized that such cancer rate surveys are "blunt tools" the results are nonetheless reassuring.

It would also be appropriate for the assessment to include a brief section summarizing morbidity and mortality statistics for key endpoints postulated to be associated with PCB exposure. The availability of these data in the assessment will help provide perspective to the estimates of excess risk reported in the assessment.

IV. Specific Comments

A. Phase I – 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; and*
- *the land use and exposure categories considered and the classification of particular parcels and areas into those categories.*

The Phase I Direct Contact Risk Assessment is a conservative risk-based screening of flood plain and river bank soils and sediment on the basis of potential human exposure from direct contact to PCBs only. It is intended to serve as a screen providing a basis for a more focused and in-depth Phase II assessment. A key question is whether the degree of conservatism to be used in the screening assessment was appropriate. In my opinion, the screening process was excessively conservative, i.e., the approach used retained a higher portion of the parcels for evaluation in Phase II than was necessary.

The excessive conservatism came about through the selection of assumption and parameter values used in the calculation of screening risk-based concentrations. This includes (a) assumed exposure frequency, (b) assumed soil ingestion rates, and (c) assumed PCB dermal absorption factor. The exposure frequency used, especially for recreational use, appears to have been arbitrarily selected. The exposure frequencies are not consistent with the survey data developed by G.E. While it may have been appropriate to assume extended daily use for screening purposes, this is not appropriate for use in Phase II.

The dermal absorption factor used was 0.14 based on Wester et al (1993). A more appropriate value would have been 0.04 based on the work of Mayes et al (2002) using Housatonic River flood plain soil.

An additional consideration relates to the handling of parcels that include both property in and outside of the flood plain. The assessment does not provide an adequate rationale for handling such properties in Phase I.

I would prefer to have seen a target risk level of $1x10^{-5}$ used in calculating the screening risk-based concentrations for all receptors rather than the $5x10^{-6}$ value used. The use of a value of $1x10^{-5}$ would have been adequately conservative being a factor of 10 greater estimated risk than the $1x10^{-4}$ level typically used to trigger remediation.

Changes in any one or some of these parameters would have provided a more realistic basis for eliminating properties from further consideration for direct contact based upon current land use or, conversely, retaining the properties for Phase II evaluation.

B. <u>Phase 2 – Direct Contact Exposure Assessment</u>

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.*

It is difficult to evaluate the adequacy of the direct contact exposure assessment scenarios because the report does not provide adequate background information on the demographics of the Pittsfield, MA area including the Rest-of-River.

The report would be substantially improved if population-based data were provided including historical and current information as well as projections for the future. Some overall trends regarding land use would also have be useful.

In the absence of more data, it would appear that most of the exposure scenarios evaluated were appropriate. This included for soil, (a) residential exposure scenarios throughout life, (b) six recreational exposure scenarios including one that included children and five that considered individuals aged 7 through 18 years, and (c) two commercial/industrial scenarios. In addition, a generic assessment was done for sediments. A strong rationale has not been provided for the separate sediment assessment.

It is noteworthy that the assessment also evaluated the water pathway. A screening exercise found that all chemical concentrations, including PCBs, in surface water were less than conservative screening concentrations, i.e., concentrations that were health protective. I concur with the decision that it was not necessary to conduct a quantitative evaluation for the water pathway.

The assessment also eliminated consideration of the air and inhalation exposure as a pathway. Based on recent PCB air measurements made in the Pittsfield, MA area, I concur that it was not necessary to quantitatively evaluate the air pathway.

For soil and sediment, PCBs were retained as the primary Contaminants of Potential Concern (COPC). I concur with this decision. I disagree with one of my fellow panelists whose initial comments argued for inclusion of aluminum, manganese, chromium and thallium as COPC in either soil and/or sediment.

During panel discussions the question of a separate evaluation for a construction worker was raised. I think it is appropriate to assume that permanent construction will not take place in the flood plain and, thus, it is not appropriate to have a separate scenario for a long-term construction worker.

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

The most important exposure pathways were evaluated in the assessment.

As noted earlier the water pathway was evaluated by comparing measured concentrations with health protective concentrations and a decision reached that this

pathway did not require a quantitative evaluation. I concur with this decision. I also concur with the decision to not do a quantitative evaluation of the air 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?*

There are two major difficulties with the approach taken to calculating and applying exposure point concentrations (EPCs). One difficulty relates to the use of the Land H-statistic to calculate the 95% UCL for soil concentrations in specific parcels. This approach may be appropriate when using a large data set and there is confidence that the data points are log-normally distributed. A number of Exposure Areas (EAs) evaluated had relatively few data points and the Land H-statistic was still used. Recognizing that the data were very likely not log-normally distributed it is very likely that the upper bound was over-estimated.

One approach to remedying this problem would be to use Hall's Bootstrap procedure. This procedure uses a transformation to correct for bias and skewness of the data points. Another alternative would be to treat several smaller parcels, with limited number of data points, as a composite EA. This would require a judgment to be made that the tax parcels were similar in geography and use potential.

A second difficulty in calculating EPCs relates to the focus on use within the 1 ppm isopleth and a failure to consider related use that would occur in the portion of the parcel outside of the 1 ppm isopleth. It is very likely that most use of the River area will involve being on property both within and outside of the 1 ppm isopleth.

Both of the difficulties discussed above likely result in risks being over-stated to some degree.

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 for each scenario;*
- *Exposure frequency and area use factors for each scenario and exposure area;*
- *Soil ingestion rates;*

The assessment appears to have systematically over-estimated exposure duration and exposure frequency for many activities. The values used in many cases are totally at odds with the survey data developed by G.E. for exposure frequency.

The values of 30 days/year or 90 days/year used for the General Recreation scenario are certainly too high. Values that are lower by a factor of 3 would appear to be adequately conservative.

For the dirt biker/all terrain vehicle operator the use of an exposure frequency of 90 days per year and a duration of 12 years appears unwarranted. These exceptionally high values are especially inappropriate when it is assumed that all of the exposure occurs within the 1 ppm isopleth. An exposure frequency of 30 days per year would be adequately conservative.

For anglers the assessment assumed an exposure frequency of 60 days per year and an exposure duration of 60 years. The exposure frequency is inconsistent with the most relevant survey data for anglers fishing on rivers. A value of 30 days per year would appear to be conservative for the most popular fishing exposure areas. Even this value would appear to be much too high for most of the exposure areas along the river. The exposure duration value of 60 years appears to be a flawed interpretation of survey data on fish consumption. Duration of consumption of fresh water fish from multiple sources does not equate to years of angling on a single river.

The upper-end values for both exposure frequency and exposure duration would translate into a total level of angling activity that would appear incompatible with the likely productivity of the Housatonic River. It is important from a "common sense" viewpoint to not view the upper-end values in isolation, they are part of a distribution. How many fish and pounds of fish can this stretch of the River product?

The exposure frequency, 48 days/year, and exposure duration, 58 years, for the waterfowl hunter do not appear to be justified even as high-end estimates. These values could be reduced to one-half or one-third of the stated values. Even such reduced values would strain plausibility, especially as regards frequency. The use of the high-end values used in the assessment would translate into a total kill rate for waterfowl that does not match the total likely productivity of non-migratory birds on the river. How many ducks and pounds of duck can this stretch of the River product? Indeed, it is difficult to

envision the projected kill rate even if it included both non-migratory and migratory birds. Of course, it must be recognized that the residence time of migrating birds on the river makes it unlikely that they accumulate significant burdens of PCBs.

The upper-bound soil ingestion rates of 200 mg/day for young children and 100 mg/day for older children and adults are excessive. It is reasonable to project that recreational use per day will vary from perhaps an hour up to all day. The recent work of Stanek and Calabreze (2000) and Stanek *et al* (1997) appear to support values of 100 mg/day for young children and 50 mg/day for older children and adults. Moreover, even the latter values would appear to be over-estimates when it is recognized that the individuals are likely to be in the Exposure Areas for only some modest portion of each day. For many exposure areas there will also be a high likelihood that individuals will spend substantial time in adjacent areas devoid of contamination. Indeed, EPA's (1989) own guidance has provision for taking accounting of time spent in contaminated versus non-contaminated areas.

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

The dermal contact values appear to be high and may not be appropriate relative to the amount of time most individuals will spend in the flood plain.

The use of a dermal absorption factor of 0.14 does not appear warranted when a value derived from a study with Housatonic River soil is available. Mayes *et al* (2002) conducted such a study and reported a dermal absorption factor of 0.04. When site-specific data are available such data should be used rather than defaulting to other generic data.

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?*

The approach taken to estimating the risks to the Reasonable Maximum Exposure (RME) individuals are ultra-conservative. In my opinion, they represent Extreme Maximum Exposure individuals unlikely to be representative of any individuals in the future. It is a misnomer to designate them as Reasonable Maximum Exposure. The extreme estimates of exposure result from the layering of conservative to ultra-conservative assumptions and parameters one after another to yield calculated extreme value estimates. These assumptions and parameters have been discussed elsewhere but in the interest of completeness, I will recapitulate them here:

(a) Individuals are assumed to spend all their time within the 1 ppm isopleth even when a substantial portion of the activity may be outside of the 1 ppm isopleth.

(b) Exposure is assumed to occur at the 95% UCL PCB concentration or the maximum value measured.

(c) Recreation occurs in the same area for 84 days per year for essentially a lifetime.

(d) Individuals ingest soil exclusively at a high rate from only the contaminated area.

(e) The skin of individuals become contaminated by soil exclusively from within the 1 ppm isopleth and absorption occurs at a high rate estimated from the study of soil samples not representative of the Housatonic River floor plain.

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

The substantial uncertainties that are embedded in the Direct Contact Baseline Assessment are not adequately acknowledged or described. While the text in some place acknowledges the existence of uncertainties, the text does not acknowledge that the uncertainties are far more likely to over-state the true risk

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

The overall approach taken is not reasonable in that it very likely substantially over-estimates the Direct Contact Baseline Risk. The layering of multiple conservative or ultra-conservative values for multiple assumptions and parameters yields a distorted view of the likely true risk for Direct Contact for even the upper end of the distribution of individuals.

While the selection of the individual parameters may be justified by a "rule book" reading of specific EPA Guidance, the composite effect is not consistent with the EPA overall guidelines for conducting exposure assessments (EPA, 1992). Indeed, the outcome does not satisfy the test of making "common sense."

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 approach taken to calculate Exposure Point Concentrations is likely to substantially over-estimate exposure and risk. A major difficulty occurs because the assessment fails to provide a clear picture of the Rest-of-River's potential for producing fish and wild life. Only a glimpse is gained when it is recognized that availability of water fowl and fish imposed a serious limitation on the availability of samples of waterfowl and fish for measuring contaminant levels. I understand the waterfowl sampling had to be truncated to avoid decimating the local population. Beyond simply "crunching numbers," it is important to step back and ask whether the assessment makes "common sense." In this case, could the River produce the waterfowl and fish matched to the quantities estimated to be caught or shot and ingested in the assessment? I think the answer is NO!

The small size of the data sets on waterfowl and fish tissue poses a major statistical problem with how to characterize the distribution of PCB concentrations. The Land H-statistic used for fish and duck samples probably over-estimate the 95% UCL.

A major issue of concern for the waterfowl exposure relates to the killing and eating of local or native birds versus migratory birds. In my opinion, as noted above

the productivity of the river very likely does not provide sufficient ducks for harvesting to match to the input parameters in the modeling. In order to satisfy even realistic estimates of ducks harvested (numbers that are likely much smaller than used in the assessment), it is necessary to assume that a substantial portion of the ducks harvested are migratory fowl. These migratory fowl will have a very low content of PCBs from the Housatonic River flood plain because of their short residence time. Most assuredly, the migratory fowl will not have PCB levels equivalent to those found in the resident birds.

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

The baseline assessment appropriately attempted to project risk in the absence of advisories on consumption of Housatonic River fish and birds. However, as already noted the assessment provides no estimates of the River's productivity for producing either fish or waterfowl. Although the assessment is not intended to explore options for future use of the river and flood plain, it would still be useful for the assessment to state the obvious – if fish are not caught, waterfowl are not shot and the flesh consumed, there is no risk. This obvious statement will impact on decisions as to remediation and future land/river use, i.e., catch and release fishing, a wild life preserve, etc.

Several assumptions embedded in the assessment are open to question:

(a) The assumption that the angler consumes all of his/her catch and does not share with others is not realistic.

(b) The assumption that the angler is only fishing and consuming fish from the Housatonic River is not realistic.

(c) The assumption that all of the duck hunters consumption represents Housatonic River native birds is not realistic.

(d) The failure to consider cooking loss of PCBs in the analysis of the Reasonable Maximum Exposure individual is not realistic.

(e) The use of 60 years as an exposure duration in making Reasonable Maximum Exposure estimates does not appear reasonable.

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?*

For the reasons stated above, I am of the opinion that the parameters used to develop the point estimate Reasonable Maximum Exposures and Central Tendency Estimates values are very likely to over-estimate the likely true risk for individuals either at the upper end or the middle of the distribution of a population of fisher persons or hunters. Indeed, one can ask if one Reasonable Maximum Exposure Hunter leaves any ducks for a single Central Tendency Exposure Hunter?.

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

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

In my opinion, the probabilistic approaches used were not clearly and succinctly described. The explanatory input provided at the October meeting was helpful but also raised significant questions. The Probability Bounds Analysis used in the assessment is not a tool routinely used by EPA or others to estimate uncertainty for environmental exposures. Thus, its use as a special "tool" in this assessment is open to question.

The Monte Carlo probabilistic analyses do not appear to be complete or adequate. For some input parameters single upper-bound estimates were used rather than a full distribution of values. This was the case with duck and fish tissue. In some cases, the data were extended yielding implausible values, such as for fish consumption. The analyses were not extended to consider the likely productivity of the river. The number of fish and ducks is finite.

Most significantly the Monte Carlo analyses were truncated and used only to describe uncertainty in the exposure estimates. They did not include uncertainty in the toxicity (exposure-response) parameters. Inclusion of the toxicity parameters in the Monte Carlo analyses would have explicitly recognized the high degree of uncertainty in both toxicity parameters; (a) the cancer slope factor (since PBCs are not known carcinogens, it would be necessary to recognize the potential for zero cancer risk) and, (b)

for the RfDs the substantial uncertainty factors (100 to 300) used to extrapolate from No Observed Adverse Effect Levels or Lowest Observed Adverse Effect Levels to Reference Doses.

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

The uncertainties associated with the fish and waterfowl exposure assessment have not been adequately described. Narrative comments are provided in the text on the extent to which various parameters influence the estimates. However, these uncertainties are not clearly presented in an integrated manner. Rarely is there an indication of whether the uncertainty is likely to increase or decrease the estimates of exposure and risk. The key issues have been discussed above, however, I will briefly review them again here.

(a) Assigning 95% UCL values for fish and duck concentrations to all fish and waterfowl consumed.

(b) Assuming that the duck meat consumed is all from ducks resident full-time on the Housatonic River.

(c) Assigning upper-bound values for fish consumption, thereby assuming all fish consumed are from the Housatonic River.

(d) Assuming that the angler consumes all fish caught without any sharing.

(e) Assuming no loss of PCBs in cooking.

(f) Assuming a high level of consumption of fish caught in the Housatonic River over 60 years.

Taken collectively, the use of these extreme values and assumptions results in estimates that very likely markedly over-estimate exposures from consumption of fish and waterfowl. Nowhere in the assessment are the uncertainties in the estimates clearly conveyed. Indeed, to the contrary the reader is left with the impression that the estimates are realistic and well founded.

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

The variability and uncertainty in the estimates has not been adequately characterized and expressed. Indeed, the manner in which the analyses are conducted and results expressed fails to distinguish between variability (inherent quantifiable differences in parameter values) and uncertainty (differences related to what is known and not known, but knowable about a parameter or some as yet unidentified parameter). The report, Science and Judgement in Risk Assessment (1994) from the National Academy of Science/National Research Council emphasized the importance of distinguishing between variability and uncertainty. That has not been done in the Assessment.

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?

As I have related above, it is my opinion that the baseline risk from consumption of fish and waterfowl has not been reasonably evaluated. The major short-coming relates to the systematic use of extreme values (in some cases of questionable plausibility) to develop estimates that are not only upper range, but very likely unrealistic for describing the real exposure of any individual fishing or hunting on the Housatonic River now. Most importantly, these same serious limitations apply to estimating risks of future use of the river.

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 agricultural exposure scenarios evaluated do not appear appropriate nor reasonable as related to current and reasonably foreseeable future use of the flood plain. The assessment does not adequately describe current agricultural practices in the flood plain and adjacent areas. Likewise, it does not provide an adequate picture of likely future use. It appears that currently only a small portion of the flood plain within the 1 ppm isopleth is used for agricultural purposes. Moreover, commercial agricultural

enterprises that use some flood plain land also appear to utilize substantial land outside of the flood plain. I recognize that this poses a challenge for developing a baseline case.

One option would be to develop assessments for some specific agricultural enterprises that have substantial holdings within the flood plain. Unlike the need to create a "hypothetical recreationalist or angler" the assessment would be for a real farm. The present assessment did not take this approach but rather created a "hypothetical model farm" with assumed PCB concentrations. Unfortunately, the "model farm" is not grounded in reality as to any Base Case and is of dubious relevance to any future situation.

Looking to the future it is most likely that if trends throughout the United States continue and occur in this specific area most, or perhaps all of the flood plain, will ultimately be preserved for recreational use. This could well be the case irrespective of consideration of PCB contamination. If this stretch of the Housatonic River should be developed exclusively for recreational use, then the recreational scenarios developed within the assessment will provide guidance for assessing risks related to use of property that might have been used for agriculture in the past. It is understood that the Massachusetts Wetlands Protection Act places a statutory limitation on farming within 200 feet of river banks. It is not clear how much of the property that might previously been considered for agricultural use in the "Rest of River" would be excluded by this Act.

The present "model farm" scenario is seriously flawed in several ways. A major flaw is the assumption that all of the agricultural activity is conducted within the 1 ppm isopleth with contamination at either 0.5 or 2.0 ppm tPCB. It is my understanding that this situation does not describe any actual existing agricultural enterprise. Thus, it would be inappropriate to use the assessments scenario in the assessment as a basis for extrapolating risks for individuals in the area consuming local agricultural products. Beyond the issue of blended use of flood plain within the 1 ppm isopleth and non-flood plains land, the assessment does not make clear how it deals with the likely substantial use of grain, and perhaps forage, imported from outside the immediate area. This imported feed, very low in PCBs, will be a substantial contribution to the caloric intake needs of any livestock and poultry that may have access to the flood plain. The values used in the assessment do not seem to be linked to any local practices but rather appear to

have been plugged into the equations. They may not be realistic either for commercial or backyard farms in this area.

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

There are serious shortcomings in the approach used to estimate the transfer of Contaminants of Potential Concern from soil to plants. The approach built on an extremely small data set of soil samples for which tPCB concentrations used in the analysis (0.5 and 2 ppm) were converted to concentrations of dioxin-like PCB congeners and PCDDs/PCDFs using regression models. In my opinion, the data sets were too limited for the task. Moreover, their use involved extrapolation downward by a factor of 6 to 24 to the levels of concern in the modeling exercise.

The soil-to-grass transfer factors are based on only 10 samples. Moreover, the samples (a) were collected in warm months of the year rather than throughout the growing season, (b) during a period with limited rain that would potentially wash off particulate surface contamination and (c) in an area adjacent to the river with potential for flooding. It is important to recall that the Massachusetts Wetlands Protection Act places a limitation on agriculture within 200 feet of the river bank. This clearly makes the soil-to-grass data developed from samples collected near the river irrelevant. All of these factors introduce uncertainties and probably result in over-estimates of the transfer factors. Indeed, lower transfer factors have been reported by Chaney *et al* (1996). In the absence of a more robust data set based on Housatonic River flood plain soil, it would be appropriate to use the values from Chaney *et al* (1996).

The soil-to-corn transfer factor was developed on an even more limited data set. Recognizing that it was desirable to establish the relationship between soil and corn silage, it is not apparent why data were collected on corn stalks and corn ears separately when corn silage was of interest. This suggests a real gap between the sampling activities and the assessment activities which needs to be remedied in future work. In any event the low levels detected make the data highly uncertain. Moreover, since data were not obtained on PCB congeners in corn it was necessary to take a convoluted approach to develop the soil-to-corn transfer factors using soil-to-grass transfer factors. It is important to recall that these factors are not highly reliable. It is

important to recall the earlier discussion of the Massachusetts Wetlands Protection Act and the limitation on agriculture within 200 feet of the river bank. Extensive research on the transfer of contaminants from sludge amended soils suggests that PCBs are not translocated from soil to corn. (Gan and Berthouex, 1994; Webber *et al*, 1994; O'Connor *et al*, 1990). Thus, the analysis in the assessment would appear to be at odds with the scientific literature.

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

The approach to estimating the transfer of Contaminants of Potential Concern for soil via feed to dairy cattle, beef cattle and chicken is open to question. The difficulties start with the uncertain input data on grass and corn silage discussed above. The next issue relates to the assumption of 100% bioavailability for the Contaminants of Potential Concern in the feed. I question whether this is realistic. The reliability of the estimates is further clouded by use of maximum or upper-bound values for bioconcentration factors. The result of this compounding of conservatism is bottom line estimates that are extreme values unlikely to be representative of what would be found even for animals maintained continuously on 2 ppm soil.

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

The values generally appear appropriate although I have serious reservations about the likelihood of some of the scenarios occurring. As I have stated repeatedly, I am concerned about the layering of conservative assumptions.

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

The basis for the parameter values appear to have been taken largely, if not exclusively, from the relevant EPA guidance which has been appropriately referenced.

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

As for other scenarios, I am concerned that the approach taken to developing Reasonable Maximum Exposure and Central Tendency Estimates overstates the risk to individuals at the upper end or in the middle of a distribution of a population.

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

I have a high degree of concern as to the validity of the estimates developed for agricultural products. The use of the "model farm" approach is flawed by the limited data available for use as crucial input parameters. I have great reservations about using the "model farm" estimates to draw conclusions as to the potential risks associated with any specific parcel that has potential for agricultural use (land more than 200 feet from the river bank) and likely consisting of property both within the 1 ppm isopleth and outside the 1 ppm isopleth. It is certainly possible to more adequately describe the uncertainties in the present assessment for agricultural products. However, a better description of a flawed approach may not be the answer.

The best approach would be to collect actual site-specific data on the critical agricultural products; milk, beef, chickens, eggs, and typical garden products. While it would be useful to also obtain data on forage, and perhaps silage from the site, this data is of secondary importance to developing empirical data on the relationship between soil and the products consumed by people. If data were obtained on forage and silage it would be important to take an "animal feed bucket" approach which would represent a blending of feed produced from within the 1 ppm isopleth and outside the 1 ppm isopleth and feed purchased from other areas. One cannot over-estimate the value of a "common sense," empirical approach as contrasted to a more theoretical modeling approach even though the latter may be more scientifically satisfying.

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?

As noted above, the modeling approach used is not satisfactory in large part because of the limited input data. Also, as noted above, if this pathway is truly

important for the Housatonic River "Rest of River" and its residents then it may be appropriate to proceed to the empirical approach suggested above. If it proves impractical to obtain site-specific agricultural data because of the difficulty in locating relevant farms, then the answer is at hand – the agricultural pathway is not likely to be important for the Housatonic River "Rest of River."

I will raise an additional point here that relates to evaluating the human mother's milk pathway for infants. If this pathway is evaluated I think it is important to avoid the temptation to use the flawed agricultural products assessment presented as a starting point for assessing the human milk to infant pathway.

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 sources of the cancer slope factors, reference doses and the TEQ methodology are adequately documented, the authors interpreted appropriate EPA guidance as providing "rules" to follow. What is seriously lacking is a clear presentation as to the origin of these values and a discussion of the substantial uncertainty associated with the cancer slope factors, the reference doses and the use of the TEQ methodology. As noted in my "over-arching issues" comments there are major issues associated with these values. The uncertainties in these toxicity values is probably equivalent to the uncertainties associated with estimating exposures.

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

No. The risk characterization is not a succinct and clear presentation of what was done and the results. The total assessment seems to be anchored at two extremes. Most of the documentation is turgid with details. The relevant information can usually be found if one spends days searching. At the other extreme are some summaries that are so minimalist as to not be informative. I suspect very few well-educated "lay persons" would be able to grasp what was done and what was found. The authors seem to have bent over backwards to avoid offering any interpretations.

The figures were useful in identifying the bottom line results. They would have been much more useful if a modest amount of interpretative text were added to guide the reader through the contents of the summary figures and tables.

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 assessment does not do an adequate job of addressing the implications of exposure via multiple scenarios and pathways. By failing to adequately address the complex issue the reader is left to their own devices. In some cases, this may mean that some readers will envision a simple adding of all the different scenarios and pathways. I will leave it to the readers of this report to develop their own mental picture of the individual(s) having these multiple exposures.

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

The very substantial uncertainties in the estimates of both cancer and non-cancer risks are not adequately described in the assessment. In my opinion, both kinds of risks are substantially over-estimated through the use of an assessment approach that systematically incorporates extremely conservative parameters and assumptions, i.e., more likely to over-estimate than under-estimate risk.

F. <u>General</u>

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

As noted throughout my comments the toxicity approaches and values used throughout the assessment are used in "rule book" fashion with minimal consideration of alternative scientific literature or the exercising of professional judgment. When professional judgment is used the assessors usually opted to select a conservative value.

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

The important assumptions in the assessment are not always clearly identified and articulated. Moreover, the assumptions associated with a given calculation are usually presented individually and rarely enumerated in a manner that leads the reader to look at them collectively to see if in the aggregate they pass the "common sense" test. If the document were re-written it would be appropriate, at least in the summary section, to carefully identify each assumption and data based parameters and their origin in a manner that allows the reader to quickly grasp how they relate to each other and are used in the aggregate.

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

The handling of cancer risk calculations is flawed in that the possibility of there being no excess cancer risk at the levels of exposure calculated is not acknowledged. Treatment of the cancer slope factor as one or two point estimates is not appropriate for a class of compounds for which human carcinogenicity has not been established.

The calculations for non-cancer risks are flawed by the inappropriate use and handling of the reference dose. A reference dose is an estimate (with an uncertainty spanning perhaps an order of magnitude) of a continuous intake for human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious non-cancer health effects during a lifetime. Stated another way, exposure at a level equal to the Reference Dose does not equate to a level of specific excess risk. It follows that exposure at a level of 10 or 100 times the Reference Dose does not equate to 10 or 100 times more risk. Such exposures would warrant further evaluation but it is inappropriate to relate the exposures as producing 10 or 100 times more risk. I will elaborate with two relevant examples.

Early in the assessment (starting on pg 2-12) there is a brief description of how the Reference Dose is calculated for Aroclor 1254 and Aroclor 1016. For Aroclor 1254, the starting point is a study of the compound in monkeys ingesting 0.005 to 0.08

mg/kg-day doses. Subtle immunological changes, as well as other changes, were observed at 0.005 mg/kg-day. Hence, this level was designated as the Lowest Observed Adverse Effect Level (LOAEL). To obtain the Reference Dose the LOAEL was reduced by a total uncertainty factor of 300. This included uncertainty factors of (1) 3 for extrapolation for monkeys to humans, (b) 3 because the study was less than lifetime, (c) 10 to account for inter-individual variability, and (d) 3 for extrapolation from a LOAEL for effects not considered of marked severity.

The slope of the exposure-response function below 0.005 mg/kg-day is unknown. Thus, it is not possible to precisely estimate what the effects might be at any level down to 0.00002 mg/kg-day, the Reference Dose. It is quite conceivable that some levels 10 times lower (0.0002) or even 100 times lower (0.002) might be without effect in humans. Thus, it is inappropriate to leave the impression that a hazard index of 10 or100 has some specific level of effects.

A similar situation exists for Aroclor 1016. In this case monkeys were studied at levels of 0.007 and 0.028 mg/kg-day for 22 months. Based on reduced birth weights at the 0.028 mg/kg-day level, it was identified as the LOAEL and the 0.007 mg/kg-day level was identified as the No Observed Adverse Effect Level (NOAEL). The NOAEL was reduced by an uncertainty factor of 100 to arrive at a Reference Dose of .00007 mg/kg-day. The 100-fold uncertainty factor consisted of (a) a factor of 3 for extrapolating from monkeys to humans, (b) a factor of 3 to account for less than lifetime exposure, (c) a factor of 3 to account for inter-individual variability, and (d) a factor of 3 to account for limitations in the data base, i.e., no male reproductive data.

As with Aroclor 1254, the exposure-response function is unknown. Indeed, it is possible that if the experiment had been performed with different exposure levels a NOAEL might have been observed at a higher level, perhaps 0.0010 or 0.020 mg/kg-day and hence have led to a higher Reference Dose. Clearly, because of uncertainty in the data, it is not known whether human exposure at some level between 0.007 and 0.0007 would have produced effects. Thus, it is inappropriate to suggest that these levels produce excess adverse health effects simply because they are 10 or 100 times larger than the Reference Dose.

It is important to recognize that the Reference Doses are based on a threshold exposure-response model unlike the assumed linear exposure-response model assumed for cancer. While for cancer it can be assumed that each increment of exposure above zero leads to a calculable excess of cancer, i.e., twice the exposure – twice the amount of excess cancer risk with the slope factor determining the amount of excess cancer. For the Reference Dose there is no slope factor. It is appropriate to note that while exposure at twice the Reference Dose may have doubled, this does not necessarily translate to the risk doubling. The actual level of estimated risk at twice the Reference Dose is unknown and is uncertain below the NOAEL.

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.

As repeatedly noted, the assessment does not adequately describe the significant uncertainties that are inherent in the risk assessment processes such as carried out here for the Housatonic River. Some of the factors that lead to uncertainty and variability are identified and described. Rarely is a judgment offered as to whether the parameter selected will lead to an over-estimation, under-estimation or be neutral as an impact on risk. In my opinion, the assessment tends through its following the "rules" and the exercise of limited professional judgment to use parameters and conduct analyses that over-estimate the true risk, if it were known, of the vast majority of individuals including those at the conceivable high end of a distribution.

In considering the issue of uncertainty it is important to recognize that the assessment is largely deterministic in character. A deterministic approach cannot adequately address the inter-related statistical concepts of uncertainty and variability. This assessment, as are most risk assessments, are loaded with both uncertainty and variability. In several instances only limited data were available on which to proceed, for example, exposure duration and exposure frequency. In other cases specific data were identified but the number of samples available precluded the development of reliable estimates of variability. In some cases, such as the Agricultural Product scenario,

extensive use was made of models building on very limited data and dubious extrapolations.

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?*

By and large, most of the relevant peer-reviewed literature has been considered. However, in most cases it is apparent that the assessors used EPA guidance documents and review articles rather than the primary literature. Several key publications which should be considered have been noted elsewhere in this report.

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.*

I have cited in this report several papers that should be considered.

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

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

This is a very large and complex assessment with substantial documentation. The reviewer faces two major challenges. First, it is not easy for the reader to gain a big picture in view of what was done and what was found. The Executive Summary is very terse and the author appears to have bent over backwards to simply state the facts without communicating very well what was actually done and the results. Second, the rest of the material is turgid with details. Although it is apparent the authors have strived to provide linkages between inter-related material, it is still difficult to dig out specific information and place it in context. I hesitate to request yet more tables and figures. However, I think a few additional selected figures and tables would be very helpful, especially in the Executive Summary and Volume 1. This would definitely include listings of all the key parameter values and underlying assumptions used in evaluating each scenario.

- *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?*

In my opinion, the assessment conclusions do not objectively and reasonably characterize ~~potential~~ current and reasonably foreseeable future risks to human health for the Rest of River area. I have purposefully drawn a line through the word – potential – because I think it biases the question. In short, there are many potential options. I think it is more appropriate to focus on what is plausible.

A major shortcoming of the assessment is that it assesses risks to "hypothetical individuals" using extreme worst cases assumptions with regard to exposure frequency, exposure duration, fish caught and consumed, birds shot and eaten, where cows graze, the consumption of cows and goats milk, beef, mutton, goat meat, etc. Many of the assumed values for usage of the Housatonic River and its flood plain are at extreme odds with a use survey conducted by General Electric. The results of that survey appear to have been totally ignored. Rather, values in some cases seem to have been pulled out of the air and would appear not to pass a "common sense" test.

The assessment would be substantially strengthened if it were built on current demographic and land use data. The General Electric Use Survey has already been mentioned. Specific data on the potential productivity of the river for fish and waterfowl would help provide a "common sense" evaluation of the Reasonable Maximum Exposure and Central Tendency Estimates for anglers and waterfowl hunters. Are the estimates of fish and bird intake consistent with what the river can likely produce? To state the obvious, a fish can only be caught and eaten once and a bird can only be shot and eaten once. What is the use of the river by canoeists and hikers? Are the values used in the assessment consistent with the Survey conducted by General Electric? What is the actual use of areas more than 200 feet from the Housatonic River for agricultural purposes? Are the backyard cows, beef animals, goats, sheep and chickens referred to in the assessment plausibly real or clearly hypothetical? If real, is it one, ten or hundred of each? These questions were asked and not answered. In some cases, the answer was we are following the "rules" and assessing risks to individuals, not

populations. That answer may be bureaucratically satisfying but it does not pass the "common sense" test.

With regard to the question of conclusions relative to the "reasonably foreseeable future" the assessment provides very limited insight. The documentation is devoid of any clear presentation on the likely foreseeable use of the Housatonic River and adjacent flood plain. It has been implied that such consideration would involve crossing the line into the risk management areas. I strongly disagree. A serious deficiency of the assessment is the failure to realistically address future use. Serious consideration of future use should have been used to guide the selection of potential exposure scenarios. For example, attention should have been given to how much acreage and of what kind was more than 200 feet from the river bank (which could actually be more than 200 feet if the outer bounds of a meandering river are considered in assigning the location of the river bank) and the 1 ppm isopleth. The result would guide the development, or a decision to not develop, an Agricultural Products scenario. Likewise, the projection of use of the Housatonic River, the related flood plain and environs as a Wildlife Preserve with no hunting, catch and release fishing and access for recreation would have yielded a very different assessment.

The bottom line is that a huge amount of effort has been expended conducting the assessment by following the "rules" and focusing on "hypothetical" extreme use cases. In my opinion, it does not pass muster as a "common sense" approach to integrating and synthesizing scientific information along with other information to inform important societal decisions on the remediation of the Housatonic River and flood plain and its ultimate use.

I strongly recommend the development of a second generation human health risk assessment for the Housatonic River "Rest of River." The development of the assessment should include very careful consideration of the goals of the assessment matched to realistic estimates of current and projected patterns of use of the Housatonic River and its flood plain. The conduct of such an assessment will undoubtedly require collection and analysis of some specific environmental samples to provide essential input data for the assessment.

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VI. BIOGRAPHICAL SKETCH FOR

ROGER O. McCLELLAN

ROGER O. McCLELLAN, DVM, MMS, DABT, DABVT, FATS is currently an advisor to public and private organizations on issues concerned with human health risk analysis, inhalation toxicology, and strategic business analysis for science-based organizations.

Dr. McClellan received his Doctor of Veterinary Medicine degree from Washington State University in 1960 and a Master of Management Science degree from the University of New Mexico in 1980. He has more than 4 decades of experience in toxicology and human health risk analysis. He is the author or co-author of over 350 papers and edited 10 books in these fields including the 2 leading texts on inhalation toxicology/respiratory toxicology.

He is President Emeritus of the Chemical Industry Institute of Toxicology, Research Triangle Park, NC, having served as Chief Executive Officer and President of the Institute from September 1988 through July 1999. The Institute has a mission of creating an improved knowledge base for understanding and assessing the adverse effects of exposure to chemicals. During his tenure, the organization achieved international recognition for the development of science undergirding important environmental and occupational health regulations.

Prior to his appointment as President of CIIT, Dr. McClellan was Director of the Inhalation Toxicology Research Institute, and President and Chief Executive Officer of the Lovelace Biomedical and Environmental Research Institute, Albuquerque, New Mexico. He began his career with Lovelace in 1966. During his 22 years with the Lovelace organization, he provided leadership for development of one of the world's leading research programs concerned with the toxic effects of airborne materials. The Institute continues operation today as a core element of the Lovelace Respiratory Research Institute.

Dr. McClellan has served in an advisory role to numerous public and private organizations. He is past Chairman of the Clean Air Scientific Advisory Committee, Environmental Health Committee, Research Strategies Advisory Committee, and Member of the Executive Committee, Science Advisory Board, U. S. Environmental Protection Agency; Member, National Council on Radiation Protection and Measurements; Past Member, Advisory Council for Center for Risk Management, Resources for the Future; a former Member, Health Research Committee, Health Effects Institute; and service on National Academy of Sciences/National Research Council

Committees on Toxicology (Past Chairman), Risk Assessment for Hazardous Air Pollutants, Health Risks of Exposure to Radon, Research Priorities for Airborne Particulate Matter, as well as the Committee on Environmental Justice of the Institute of Medicine. He currently serves on Advisory committees to the CDC Center for Environmental Health and DOE's Biological and Environmental Research Program and as Chair of the Board of Trustees, Toxicology Excellence in Risk Assessment.

Dr. McClellan serves or has served as Adjunct Professor at Duke University, University of North Carolina at Chapel Hill, North Carolina State University, University of New Mexico, University of California-Los Angeles, University of Arkansas, Colorado State University, and Washington State University. In addition, he frequently speaks on risk assessment and air pollution issues at other institutions and meetings in the United States and abroad. He is active in the affairs of a number of professional organizations, including past service as President of the Society of Toxicology and the American Association for Aerosol Research. He serves in an editorial role for a number of journals, including service as Editor of Critical Reviews in Toxicology. He is a Diplomate, by examination, of the American Board of Toxicology and the American Board of Veterinary Toxicology and a Fellow of the Academy of Toxicological Sciences.

Dr. McClellan's contributions have been recognized by receipt of a number of honors, including election to membership in the Institute of Medicine of the National Academy of Sciences. He is a Fellow of the Society for Risk Analysis, the Health Physics Society, and the American Association for the Advancement of Science. He has a long-standing interest in environmental and occupational health issues, especially those involving risk assessment and air pollution, and in the management of multidisciplinary research organizations. He is a strong advocate of risk-based decision-making and the need to integrate data from epidemiological, controlled clinical, laboratory animal and cell studies to assess human health risks of exposure to toxic materials.