ATTACHMENT A

SPECIFIC COMMENTS

The specific comments are based solely on EPA's review of Section 2.0 of the IMPG Proposal (which was based on the EPA HHRA and ERA), and reflect evaluation of the IMPG Proposal for the following four types of issues:

1. Instances where GE did not correctly incorporate factual elements of the EPA risk assessments (HHRA, February 2005 and ERA, June 2005) in the derivation of RMCs, and typographical errors.

2. Instances where GE ignored or otherwise excluded pertinent findings from the EPA risk assessments in calculating the RMCs.

3. The rationales used in the IMPG Proposal to combine lines of evidence from the EPA risk assessments, including the degree of protectiveness and the scientific validity of assumptions made during development of the RMCs.

4. EPA's directives regarding the narrative IMPGs.

1. General Issues

- GE shall remove Appendix A.

- GE states that the use of risk ranges is "consistent with the fact that there is a wide range of scientific opinion on most of the inputs and interpretations in the HHRA and the ERA, as evidenced by the substantial divergence of opinions among the peer reviewers on such issues ... The use of ranges reflects this broad spectrum of views, as well as the underlying uncertainties that they represent." EPA disagrees that the RMC ranges proposed by GE reflect the full spectrum of scientific views. Rather, in some cases the RMCs represent GE's positions on these issues, but do not reflect the full range of opinions expressed by EPA, the States, Trustees, the Peer Review Panel or the public.

  GE shall revise the introductory material for the human health RMCs to remove the language identified in the comment above.

2. Human Health Exposure Pathways

2.1 General Issues

- For all exposure pathways, GE did not address the issues of breast milk exposure or cumulative exposure. GE shall incorporate a qualitative discussion of the risks associated with breast milk exposure and of cumulative risk in the preamble to the human health RMCs.

2.2 Direct Contact Exposure Pathways

- The CTE exposure duration for the adult waterfowl hunter was incorrectly listed as 38 years in Table 8a. The correct value of 25 years was listed in Table 8b. GE used the correct value (25 years) in the derivation of the RMC for the CTE adult waterfowl hunter scenario.

  GE shall correct Table 8a.

- GE shall revise the narrative goal as follows:

  To reduce PCB exposure point concentrations in floodplain soil and sediment in the Rest of River so that they do not present significant risks of harm to the health of individuals who contact such soil or sediment directly, taking into account the accessibility of the soil and sediment and the actual and reasonably anticipated future uses of the exposure areas. The exposure point concentrations that shall be used are the 95th UCL of the mean derived using inverse distance weighting (IDW) for floodplain soil and the 95th UCL of the mean for sediment without the use of spatial weighting. Definitions of the significance of risks, accessibility, and actual and future uses shall be those used in the HHRA. The desired outcome is that, for PCBs in sediment, the Rest of River portion of the Housatonic River will attain the designated uses defined in the Massachusetts and Connecticut Water Quality Standards.

2.3 Fish & Waterfowl Consumption Pathways

Point estimates

- The equation for calculating the RMC based on potential for non-cancer effects in Section 2.2.1 of GE's IMPG proposal (p. 27) is incorrect in that it incorporates exposure during childhood and adulthood. However, GE performed the calculations correctly, developing non-cancer RMCs for PCBs separately for adults and children.

  GE shall correct the equation on page 27.

- The unit conversion factor (1E-03 kg/g) is missing from the denominator of the RMC_{cancer} and RMC_{nc} equations on page 1 of Attachments 14, 15, and 16. It is also missing from the RMC_{cancer} equations on page 1 of Attachments 17, 18, and 19 (see comment below). Also, this unit conversion factor variable (CF) is not listed and defined below the RMC equations.

  GE shall correct these items in the IMPG Proposal.

- The Cancer Slope Factor (CSF) variable is defined twice under the RMC equation in Attachments 14 - 19.

GE shall remove the repetitive definition in the Attachments.

- In the following tables, the units of body weight should be kg, not kg/mg: This mislabeling occurs on Tables 14a, 14b, 15a, 15b, 16a, 16b, 17a, 17b, 18a, 18b, 19a, and 19b.

  GE shall correct the labeling on the tables.

- In Attachments 15, 16, 17, 18 and 19 (on page 1), the units of the exposure frequency (EF) should be days/year, not days, for the point estimate RMCs. EF and ingestion rate (IR) units for the 1-D MCA waterfowl RMCs differ from the point estimate RMCs (i.e. EF has units of meals/year, and IR has units of grams/meal) but are not specified in the equation. The units are shown correctly for the waterfowl RMC calculations in Tables 16b and 19b.

  GE shall correct the units for EF.

- Using the RMC_{cancer} equation in Attachment 17, the units of the RMC_{cancer} for TEQ would be ng/g (or µg/kg), not ng/kg as shown in Table 2-2, the summary of results in Attachment 17 (page 2), Table 17c, and Table 17d. Furthermore, the units of the conversion factor in Table 17a and 17b (kg/g), do not match the units of the conversion factor defined in the RMC_{cancer} equation on page 1 of Attachment 17 (ng/mg). To obtain an RMC in units of ng/kg, the equation should incorporate the kg/g unit conversion factor in the denominator of the equation and the ng/mg conversion factor in the numerator of the equation. Table 17c lists both of these unit conversion factors.

  GE shall correct the units as identified above.

- EPA did not include an oral absorption factor in its fish and waterfowl risk equations (Table 4-8 & 4-10 in HHRA, Volume IV), but GE included this factor in its RMC calculations at an assumed value of 1. Therefore, this approach differs from EPA's approach but makes no difference to results.

  GE shall remove the oral absorption factor from the calculations.

<u>Probabilistic Estimates</u>

- GE calculated probabilistic RMCs using 1-D MCA that are similar to those calculated using EPA's risk model presented in the HHRA (See Table 1 for this comparison).

Table 1. Comparison of Fish & Waterfowl 1-D MCA RMCs Presented by GE and Calculated Using EPA Inputs (in mg/kg for PCBs and ng/kg for TEQ)

	Bass Fillet RMCs				Trout Fillet RMCs				Duck Breast RMCs			
	5th percentile		50th percentile		5th percentile		50th percentile		5th percentile		50th percentile	
	EPA	GE	EPA	GE	EPA	GE	EPA	GE	EPA	GE	EPA	GE
PCB Cancer Risk=10^{-4}	0.60	0.26	5.5	3.1	1.2	0.70	12	6.7	0.71	0.75	7.5	7.2
PCB Child HI=1	0.056	0.040	0.65	0.49	0.11	0.11	1.4	1.0	0.065	0.12	0.64	1.2
PCB Adult HI=1	0.11	0.047	1.4	0.53	0.25	0.14	3.0	1.1	0.14	0.12	1.4	0.87
TEQ Cancer Risk=10^{-4}	8.0	3.4	73	42	17	9.4	157	90	9.5	10	101	96

Notes:
Risk-based media concentrations (RMCs) in the EPA column were calculated using input values and model equations used in the HHRA.

RMCs in the GE column are those presented in General Electric's *Interim Medial Protection Goals Proposal for the Housatonic River, Rest of River Site.*

As indicated on Table 1, fish RMCs based on PCB and TEQ cancer risk using EPA's approach are slightly higher than GE fish RMCs. Fish RMCs based on PCB noncancer hazard using EPA's approach are similar to or slightly higher than GE fish RMCs. Waterfowl RMCs based on PCB and TEQ cancer risk using EPA's approach are nearly identical to GE waterfowl RMCs. Waterfowl RMCs based on PCB noncancer hazard to adults and children using EPA's approach are slightly higher and slightly lower, respectively, than GE waterfowl RMCs.

GE appears to have used the correct inputs from the HHRA with one exception: GE used a fraction ingested (FI) point estimate of 1 to calculate the bass and trout RMCs instead of the FI distribution used by EPA. The relatively small discrepancies between RMCs calculated using EPA's approach and RMCs calculated by GE might be explained by one or more of the following factors:

– For the fish RMCs, GE used a point estimate of 1 to represent FI instead of the distribution used by EPA. GE shall use the distribution from the HHRA for FI.

– For all fish and waterfowl RMCs based on non-cancer hazard, GE indicates that it used the exposure duration distribution, but EPA did not use this distribution because ED cancels from the noncancer dose equation. Therefore, the EPA RMCs in Table 1 that are based on noncancer hazard do not incorporate a distribution for ED. GE shall remove the distribution for ED.

– Without access to GE's calculations, it is not possible to check whether any distribution truncation explains any of the difference between EPA and GE RMCs. GE shall review their calculations to ensure that distributions were truncated correctly.

– Without access to GE's calculations, it could not be confirmed whether specification of the stochastic mixture of cooking loss distributions within Crystal Ball differs from EPA's specification of this mixture. However, GE's documentation does not suggest that there is any difference; GE appears to have mixed the distributions in a manner similar to EPA.

To produce a stochastic mixture of distributions for the fish cooking loss variable, EPA entered the distributions for baking, broiling, pan frying and deep fat frying from Table 6-2 of the Fish and Waterfowl report into Crystal Ball. EPA truncated all of these distributions at a min of 0 and a max of 1. To "mix" the four distributions, a weight was assigned to each distribution based on information about cooking preferences. The following equation was used to sample from the four distributions in proportion their assigned weight:

=IF(A5<0.2,A1,IF(A5<0.2+0.2,A2,IF(A5<0.2+0.2+0.2,A3,A4)))

Where:
A1 = baking cooking loss distribution;
A2 = broiling cooking loss distribution;
A3 = deep fat frying cooking loss distribution;
A4 = pan frying cooking loss distribution; and,
A5 =independent variable with a uniform distribution from 0 to 1 (used to determine the probability of sampling each cooking loss distribution).

Unless GE is aware of a difference from the approach used in the HHRA, no action is required.

- GE used input values from the HHRA, and there are small discrepancies between two inputs listed in HHRA tables and values actually used by EPA in the Crystal Ball spreadsheet. The EPA RMCs presented in Table 1 are based on input values used in the Crystal Ball spreadsheet so that they correspond to risks estimated in the HHRA. The differences between the values used in the spreadsheet and listed in the HHRA report appear to be small typographical errors that make little difference to RMCs.

  No action is required by GE.

- EPA identified the following errors in the documentation of the probabilistic RMC:

  – The Distribution Type for the fraction ingested shall be changed from "empirical distribution function" to "point estimate" in Table 17b. This matches the distribution type listed for this parameter in Tables 14b, 15b, 16b, 18b, and 19b.

  – There is a minor discrepancy between Table 15b and Table 18b in the minimum ingestion rate for the young child (0.14 vs. 0.135), but this difference is likely due to rounding. Therefore, no action is required by GE.

- GE back-calculated RMCs by re-arranging risk and HI equations to solve for exposure media concentrations. This approach is not consistent with EPA's recommendation to calculate preliminary remediation goals using iterative forward calculations to obtain a concentration that corresponds to a risk distribution (See page 7-7 in *Risk Assessment Guidance for Superfund (RAGS), Volume III - Part A: Process for Conducting*

Probabilistic Risk Assessment. Review of calculations performed in verification of the cancer risk and noncancer hazard associated with each EPA RMC (5^{th} percentile) for fish and waterfowl found that they correspond to the target values when rounded to one significant figure.

Therefore, this failure to comply with EPA guidance is inconsequential in this case and GE does not have to revise the calculations but shall incorporate the discussion provided above in the revised IMPG Proposal.

- GE calculated RMCs for edible fish tissue without reference to the uncertainty analysis conducted for traditional fish preparation practices of the Schaghticoke Reservation (Section 7.2.2 in HHRA Volume IV) or other anglers who might eat fillets with skin-off, fillets with skin-on, or whole fish. This issue is important for interpretation of RMCs for these receptors.

  GE shall include a discussion of the quantitative impact of these alternative consumption practices on the RMCs.

- GE calculated RMCs for bass and trout but does not discuss the applicability of these RMCs to other fish species. On pages 4-49 and 4-50 of HHRA, Volume IV, EPA explains that "all waters" consumption rate data are applicable to largemouth bass, brown bullhead, sunfish, and perch, and "rivers and streams" consumption rate data are applicable to trout. These consumption rate assumptions are incorporated into RMCs for bass and trout, respectively. Therefore, bass RMCs are applicable to largemouth bass, brown bullhead, sunfish, and perch. Trout RMCs are applicable to trout.

  GE shall add this discussion to the text for these RMCs.

- GE shall revise the narrative goal as follows:

  To reduce PCB and TEQ exposure point concentrations in the edible portion of fish and waterfowl in the Rest of River so that they do not present significant risks of harm to the health of individuals who consume such fish and waterfowl, taking into account the actual and reasonably foreseeable frequency of their consumption of such fish and waterfowl from the Rest of River. The exposure point concentrations shall be the 95^{th} UCL of the mean. Definitions of the significance of risks, edible portions of fish, and frequency of fish and waterfowl consumption shall be those used in the HHRA. The desired outcome is that, for PCBs, the Rest of River portion of the Housatonic River will attain the designated uses defined in the Massachusetts and Connecticut Water Quality Standards.

2.4 Agricultural Products Pathways

- The RME and CTE adult consumption rates used to derive an RMC for cow milk at a backyard dairy farm were reversed in the calculations performed by GE. That is, 20.9 g/kg-d was used as the RME consumption rate and 18.1 g/kg-d was used as the CTE consumption rate. The RME consumption rate is actually less than the CTE consumption rate because the consumption rates are age-weighted and are based on intake per unit body weight (g/kg-d). Thus, since intake per unit body weight is larger at younger ages and the CTE exposure duration is 9 years (7 to16 years of age), the age-weighted CTE consumption rate is higher than the RME consumption rate (based on a 39 year exposure from ages 7 to 46).

  GE shall revise the calculations using the correct consumption rates.

- Table 2-3 does not indicate whether RMCs were calculated on a wet weight or dry weight basis. Verification of the calculations indicates that they were calculated on a wet weight basis.

  GE shall amend the labeling accordingly.

- GE did not incorporate losses due to preparation or cooking as was done in the HHRA. This exclusion results in lower RMCs than GE would have calculated by incorporating cooking loss terms.

  GE shall revise the calculations to account for cooking loss as was done in the HHRA.

- GE shall revise the narrative goal as follows:

  To reduce PCB exposure point concentrations in the edible tissue of cows (milk and meat), chickens (meat and eggs), and fruits and vegetables on farms and other properties where such animals and plants are maintained for food production in the Rest of River floodplain so that they do not present significant risks of harm to the health of individuals who consume such agricultural products, taking into account the actual and reasonably foreseeable frequency of their consumption of such products from the Rest of River. The exposure point concentrations that will be used in the CMS shall be a conversion to soil concentrations equivalent to the RMC calculated using the 95th UCL of the mean derived using IDW for floodplain soil. Definitions of the significance of risks and frequency of agricultural product consumption shall be those used in the HHRA.

3. Ecological Assessment Endpoints

3.1. General Issues

- Section 1.6 of the IMPG proposal states that "Section 2 presents ranges of numerical RMCs that have been calculated based directly on the assumptions and interpretations used in EPA's risk assessments." This statement is incorrect. Section 2 includes

numerous "assumptions and interpretations" that are not included in the EPA risk assessment and which EPA does not agree with. These assumptions and interpretations have a significant bearing on the degree to which the RMCs satisfy (or do not satisfy) the ERA Assessment Endpoints and/or are protective of the environment.

GE shall revise Section 2 to eliminate discussion or references to assumptions and interpretations which are not included in the ERA.

- GE correctly states that multiple effects thresholds are presented in the ERA (e.g., EC_{20} and EC_{50} values for benthic community endpoints). However, GE then goes on to incorrectly assume that any effects threshold presented in the ERA can be considered as a cleanup goal. The presentation of multiple types and sizes of effects was included in the ERA as a means of illustrating the nature of the concentration-response relationship (i.e., distinguishing indications of "high risk" from "low" or "intermediate" risk) and for thoroughness. Presentation of multiple effects in the ERA does not mean that all effects presented are acceptable.

  GE shall revise the RMCs as specified below in the discussion of individual Assessment Endpoints to only consider those RMCs that are protective of the Assessment Endpoint and of the environment.

- Section 2.4 (Page 40) states that the ERA ecological receptors were "benthic invertebrates, frogs, shrews, fish, mink and otter, ospreys, bald eagles, and wood ducks."

  The above list is limited to the some of the representative taxa that are surrogates for broader groups of organisms (e.g., piscivorous mammals, amphibians, threatened and endangered species) that were selected for the Assessment Endpoints. It is common practice when performing an ERA to select representative species for formal quantitative assessment, and to subsequently extrapolate the findings for representative species to the receptors of concern (as was performed in the risk characterization sections of the ERA). GE has not addressed the latter step in the IMPG proposal.

  GE shall address the relationship between the RMCs for representative species and the other species included in the Assessment Endpoint in the preamble to the Ecological RMCs and to each Assessment Endpoint. In addition, GE shall revise the RMCs as specified below for each Assessment Endpoint such that the discussion and assumptions used can be considered protective of all species of concern for the Assessment Endpoint, not just the representative species.

- GE's IMPG Proposal states that numerical risk-based values were derived for "those ecological receptors for which: (a) the ERA found significant risks due to TEQs; (b) those TEQ risks were found to be greater or more certain than the risks due to PCBs; and (c) the ERA developed Maximum Acceptable Tissue Concentrations (MATCs) for TEQs". Despite this statement, GE omitted some TEQ-based risks, including risks

for species that exhibited similar qualitative risk statements (e.g., "high risk"), but for which HQs indicated that risks were higher for TEQs than for tPCBs. For example, the TEQ HQs shown in Section 12 for bald eagle and mink are greater than the corresponding PCB HQs, but TEQs were not considered by GE for eagles.

GE shall include an RMC for TEQ, in addition to the tPCB RMC, when the HQ for TEQ for a representative species at risk is greater than that for tPCBs. The inclusion of the RMC for TEQ is not further specified in the comments for each Assessment Endpoint, but shall be included in the IMPG Proposal when applicable.

- Section 2 of the GE IMPG proposal summarizes the numerical thresholds used by EPA in the development of MATC values in the ERA. However, GE fails to acknowledge in Section 2 that the MATC values were developed considering multiple lines of evidence, including considerations such as protection of species other than the representative species, and uncertainties in the data as appropriate. When available, results of field surveys, modeled exposure and effects, and site-specific toxicity studies were all considered in the process of deriving an appropriate MATC in the ERA.

  While GE does not acknowledge all of the supporting lines of evidence considered by EPA in MATC derivation, GE sometimes references supporting lines of evidence in Section 2. For example, results of field population surveys are discussed in Section 2.4.4 (RMCs for Fish) but are not discussed in Section 2.4.2 (RMCs for Amphibians). There is an obvious bias in the IMPG proposal toward discussion of supporting lines of evidence that do not indicate evidence of harm.

  GE shall eliminate such discussion of specific supporting lines of evidence in the IMPG Proposal; the discussion of the various lines of evidence is presented in a complete and balanced manner in the ERA and does not need to be repeated in the IMPG Proposal.

- The discussion of "Ecological Goals" in the IMPG Proposal states that there is "no comparable EPA regulation or guidance on numerical levels of risk reduction", and suggests that quantitative guidance on risk levels and/or risk ranges for ERAs is lacking. While the EPA Superfund program has not established numerical levels for risk reduction, other guidance exists for the establishment of effects thresholds (e.g., Suter et al. (1995). For appropriate measurement endpoints, an approximate 20% effect level has often been applied as the threshold for ecological significance in aquatic studies (Plafkin et al., 1989; Suter et al., 1995), and the "20% level is also consistent with practice in assessments of terrestrial effects" (Suter et al., 1995). As stated in the ERA (Appendix D) the use of the EC_{20} approach is also consistent with regulatory guidance from other jurisdictions (e.g., BC MELP 1997).

  GE correctly cites EPA (1999) guidance stating that the overall goal "is to reduce ecological risks to levels that will result in the recovery and maintenance of healthy local populations and communities of biota." Later, GE states that specific goals for protection of ecological receptors should consider "the overall goal of protecting

ecological receptors at the local population or community level." There are two problems with the above GE narrative: (1) the important qualifier "healthy" has been removed from the overall goal; and (2) GE has misinterpreted the term "population or community level" as it applies to measurement and assessment endpoints in ERAs. These issues are discussed below.

The removal of the word "healthy" from what is implied to be the GE definition of the generic ERA protection goal (IMPG Proposal; Appendix A, Page 5) is significant because it reflects a bias toward discounting significant ecological effects, provided that some level of sustaining reproduction occurs. Existence of a self-sustaining local subpopulation alone does not provide proof that a community/population is unimpaired in terms of productivity, quality, or susceptibility to other stressors. In the Peer Review of the Ecological Risk Assessment, several Panelists emphasized that the health of resident organisms, not simply their presence or absence, is of significant interest in the ERA. The term "health" applies not only to the health status of individuals in the population or community (i.e., deformities, disease), but also to the characteristics of the local subpopulation/community that could be affected by contaminant stress, including:

- Species diversity and composition (by either deletion or addition);
- Densities of organisms;
- Trends of population growth; and
- Resilience in the face of other perturbations.

Ecological resilience has been defined as the amount of disturbance that an ecosystem can withstand without changing its self-organizing processes and variables that control its structures, or shifting to an alternative stable state (Holling, 1973; Ludwig et al., 1997). Resilience can be manifested or mediated as changes in the risks of population decline ("quasi-extinction"), density-dependence regulating population growth, and trophic or competitive interactions among species.

GE shall add the statement of the generic ecological goal as written above including the term "healthy" in the preamble to the ecological RMCs. In addition, GE shall add to the generic ecological goal the following language:

The desired outcome of the ecological goal is that, for PCBs, the Rest of River portion of the Housatonic River will attain the designated uses defined in the Massachusetts and Connecticut Water Quality Standards.

- Appropriate measurement endpoints for ecological systems depend on the level of organization of each receptor type. GE states that specific goals for protection of ecological receptors should consider "the overall goal of protecting ecological receptors at the local population or community level." EPA agrees with this generic statement of level of ecological organization of concern, except in the case of

threatened and endangered species, which require protection at the individual organism level. However, EPA does not agree that all measurement endpoints for assessing local subpopulation and/or community level impacts must be at the highest level of organization, or that local subpopulation/community studies should receive increased weighting by default over other studies such as toxicity tests as GE suggests. EPA (1997) notes that "although population- and community-level studies can be valuable, several factors can confound the interpretation of the results." Therefore, interpretation and weighting of measurement endpoints requires consideration of all endpoint attributes that affect their relevance to the assessment endpoint. In emphasizing the results of field studies, GE has confused the appropriate level of organization for an *assessment endpoint* with the appropriate level of organization for a *measurement endpoint*.

Ecologically relevant measurement endpoints may be identified at any level of organization (EPA, 1998). For example, Suter et al. (1995) defines the following measurement endpoints that correspond to the generic definitions of assessment endpoints commonly applied in ERAs:

- **Organism level** — Any effect on survivorship, growth or fecundity in a toxicity test of surrogate species for a threatened or endangered species. Any observed death or morbidity of individuals of a threatened or endangered species, or any detectable reduction in the abundance or production of an exposed population of a threatened or endangered species relative to reference populations.

- **Population level** — A 20% effect on survivorship, growth or fecundity in a toxicity test of surrogate species for an endpoint species. A 20% reduction in the abundance or production of an exposed endpoint population relative to reference populations.

- **Community level** — A 20% effect on survivorship, growth or fecundity in a toxicity test of surrogate species for an endpoint community. A 20% reduction in the species richness or abundance of an exposed endpoint community relative to reference communities.

- **Ecosystem level** — A 20% effect on survivorship, growth or fecundity in a toxicity test of surrogate species for an endpoint ecosystem or a 20% or greater reduction in functions of a surrogate ecosystem in a microcosm toxicity test. A 20% reduction in an ecosystem function or a change in 20% of the area of an endpoint ecosystem that is indicative of loss of function. Any net loss of wetlands.

From the above generic measurement endpoint definitions, it is clear that effects observed to individuals (e.g., in toxicity tests) are appropriate endpoints for extrapolation to local subpopulation and community level responses. The above endpoints also indicate that local subpopulation and community level endpoints should be evaluated relative to uncontaminated reference conditions; mere presence of

organisms or presence of reproduction does not indicate a lack of ecologically significant population or community responses.

GE shall revise the narrative to remove any bias toward a particular ecological level of organization and to include a clear statement of the ecological level of organization used to derive the RMC and its applicability to the Assessment Endpoint.

- The argument is made in the IMPG proposal that a range of RMCs could be considered protective, depending on the assumptions made. While this is correct, the appropriateness of a given RMC is dependent on the validity of assumptions made, and where uncertainty exists, it is inappropriate to extend the range of RMCs only toward higher (i.e., less-protective) values as GE has done. In Appendix A (page 6), GE states that, based on the assumptions used, all of the RMCs in the proposed ranges are protective "for the particular scenarios, receptors, and risk or effect levels to which they apply." However, the discussion and RMCs included in the IMPG proposal only reflect the possibility that the MATCs are over-protective and not the possibility that they are under-protective, which is required for an unbiased uncertainty assessment and in consideration of other species that are to be protected for that Assessment Endpoint.

  Following the rationale provided by GE, an RMC could be manipulated to virtually any value simply by changing the level of acceptable risk, required level of certainty, or technical assumptions used in the derivation. However, if assumptions are false, or are uncertain and with a moderate-to-high probability of being false, then RMCs within a given range clearly are not protective of the Assessment Endpoint.

  EPA has identified several instances in which the IMPG proposal states assumptions that have a high probability of being false. For example, in Appendix A (page 5), GE suggests that where literature-based TRV derivation is applied, "it may be appropriate to select a value or values within the specified range (e.g., the midpoint of the range) as the cleanup goal." This approach is non-conservative because it results in a 50% chance of over-estimating the threshold, even under the assumption of a normal distribution of adverse responses. Because safety-factors were not applied in the derivation of the TRV or MATC in the ERA, such an approach has a high probability of being non-protective of the assessment endpoint. The problem is magnified when the underlying distribution is log-normal. For example, given a TRV threshold range (minimum to maximum) of 1 to 100 mg/kg, GE's "midpoint" calculation procedure would result a proposed TRV of 50.5 mg/kg (as compared to the geometric mean of 10 mg/kg) and would yield a 50% probability that an observation drawn at random from the distribution would be more than 5 times lower than the RMC proposed by GE.

- GE states that "The use of ranges of RMC values is particularly appropriate in light of the substantial uncertainties underlying the risk assessments and the range of scientific opinion on the key inputs to those risk assessments." EPA agrees that risk assessment findings have associated uncertainties, but disagrees that the uncertainties should be

addressed only by increasing the range of RMCs in the positive direction. For all receptors, more conservative MATCs could be have derived in the ERA by applying safety factors or by adopting smaller threshold effect sizes to reflect the uncertainty that the risk may be underpredicted. Because this was not done, there is no basis for increasing thresholds but not decreasing them in the development of RMC ranges.

- GE states that "the predicted risks are uncertain given the absence of any obvious adverse effects on the fish and wildlife populations and communities in the Rest of River area, which appear to be abundant, diverse, and thriving." First, the lack of "obvious adverse effects" is a highly subjective term and is not a reasonable standard by which potential effects are judged in ERAs. Second, EPA disagrees that adverse effects are not substantial for some of the high risk receptors, as was documented in the ERA.

- GE states that the use of risk ranges is "consistent with the fact that there is a wide range of scientific opinion on most of the inputs and interpretations in the HHRA and the ERA, as evidenced by the substantial divergence of opinions among the peer reviewers on such issues .... The use of ranges reflects this broad spectrum of views, as well as the underlying uncertainties that they represent." EPA disagrees that the RMC ranges proposed by GE reflect the full spectrum of scientific views. Rather, in some cases the RMCs represent GE's positions on these issues, but do not reflect the full range of opinions expressed by EPA, the States, Trustees, the Peer Review Panel or the public.

GE shall revise the introductory material for the ecological RMCs to remove the language identified in the preceeding four comments and shall modify the RMCs as directed for the specific Assessment Endpoints below.

3.2 Benthic Invertebrate Assessment Endpoint

- In the IMPG proposal (page 42) it is stated that chironomid growth endpoints suggest that "*Chironomus* growth is not impaired by PCB exposure at the EC_{20} and EC_{50} values used in the ERA" and argues that NOAEL and LOAEL values for the dry weight endpoint should be directly incorporated in the RMC derivation. This statement and procedure are both incorrect.

  Figure D.3.5 in the ERA shows the relationship between tPCB concentration and *Chironomus* growth for both dry-weight and ash-free dry-weight measures of growth; the data do not support GE's claim. Both endpoints indicate a severe reduction in dry weight (i.e., on the order of 40-fold reduction in dry weight) at the synoptic tPCB concentration of 8.7 mg/kg tPCB. Although the nature of the concentration-response between 0.3 mg/kg tPCB and 8.7 mg/kg tPCB is unknown due to the wide spacing of concentration treatments that resulted from the field-collected sediment concentrations, the 8.7 mg/kg tPCB concentration represents a very large adverse

effect size, irrespective of choice of reference station or choice of growth endpoint (dry weight or ash-free dry weight).

GE argues that the statistical endpoint (NOAEL) of <72 mg/kg tPCB[1] is a more meaningful threshold than the point estimation procedure, even though the latter shows a 98% reduction in growth (relative to reference) within a factor of two of the calculated EC_{50}. This is an example of how arguments put forward in the IMPG proposal assign undue weight to the results of particular statistical significance tests even when the data are clearly unsuited to their application.

- In Table 2-5, GE incorrectly assigns an EC_{50} finding of "no effect" to three endpoints for fine-grained sediments. These endpoints should have been assigned a finding of either "outside the range of measured PCBs" or ">14.1 mg/kg," because the lack of 50% responses is partially attributable to the limited exposure range over which fine-grained sediments were evaluated. As shown in Table D.2-2, the mean and median tPCB concentrations in fine-grained sediment treatments are below 5 mg/kg tPCB, with the exception of Station 8 (mean of 14.1 mg/kg tPCB). In coarse-grained sediments, 50% effects were observed at PCB concentrations close to these ranges.

GE shall revise the document to correct the errors identified above.

- In proposing a range of sediment RMCs based only on the values presented in Tables 2-4 and 2-5, GE ignores the results of all in-situ toxicity tests presented in the ERA. In contrast, EPA considered the in-situ results by demonstrating the concordance in the distribution of effects thresholds between in-situ and laboratory endpoints (ERA Appendix D; Figures D.3-13 and D.3-14). GE does not provide a rationale for the exclusion of in-situ toxicity endpoints.

- GE ignores the distribution of the various threshold values in setting an RMC range. In including the maximum values within the proposed RMC range, the upper end of the range is driven by endpoints that are highly insensitive to PCB exposure. The toxicity data show that multiple species, endpoints, and testing regimes yielded EC_{20} and EC_{50} values near the lower end of the RMC range proposed by GE, with few values near the upper end of the range. Therefore, the upper end of the RMC range is protective of a very few species and/or endpoints, specifically those that are insensitive to PCB exposure. For example, the higher exposure concentration associated with the lack of adverse growth response to chironomids is considered in the RMC range even though *mortality* to chironomids is observed at much lower PCB concentrations.

In establishing a range of RMCs, GE ignores the weight-of-evidence from all ERA findings other than toxicity testing and field community assessment. For example, all comparisons of measured concentrations to literature-based thresholds are ignored.

[1] The NOAEL of <72 mg/kg tPCB is a statistical artifact that results from the high mortality observed in most contaminated sediment replicates. In several treatments, there was complete mortality, or only a single replicate with surviving animals. In these cases, pairwise statistical comparisons to reference are not possible, because variation cannot be quantified. The high NOAEL concentration results from lack of surviving animals, not lack of response.

Although EPA agrees that the latter should be assigned lower weight than site-specific studies, they should not be dismissed altogether.

- GE implies that the "intermediate risk" and "high risk" thresholds were derived solely on the basis of the most sensitive effect thresholds shown in Table 2-4. This is misleading for several reasons:

  – The values of 2.0 and 4.7 mg/kg tPCB may not represent the most sensitive of the chronic toxicity endpoints listed. The *Chironomus* survival and emergence endpoints were unbounded at a concentration of <8.7 mg/kg. The next lowest concentration was the reference station (A3) concentration of 0.28 mg/kg tPCB; therefore, the actual effects threshold could lie anywhere between 0.28 and 8.7 mg/kg tPCB. Furthermore, the magnitude of the response at (and above) 8.7 mg/kg tPCB (i.e., greater than 90% mortality) suggests that the actual effects threshold may be substantially lower than 8.7 mg/kg tPCB.

  – The selection of the "intermediate risk" and "high risk" thresholds considered the multiple lines of evidence available. Specifically, the thresholds derivation (ERA Page D-62 [text box]) specifically mentions other toxicity endpoints that are in agreement with the MATC. In some cases, other toxicity endpoints yield thresholds that are lower than the selected MATCs (e.g., 48-h LC_{20} for *Daphnia* of 1.3 mg/kg tPCB relative to Station A1).

  Although several in situ toxicity endpoints yielded numerical values above the "intermediate risk" and "high risk" thresholds, these differences are explained by test duration and endpoint sensitivity. The in situ tests evaluated mortality (i.e., sublethal endpoints were not evaluated) and considered a maximum test duration of 10 days.

- GE states that "results from the benthic community study are more directly relevant" to the assessment endpoint. However, GE does not present a rationale for this assumption, which is contrary to the results of the formal weight-of-evidence assessment conducted by EPA (summarized in ERA Table D.4-1). Using the formal weighting procedure following the approach of Menzie et al. (1996), EPA found that the toxicity test endpoints merited higher weighting relative to the benthic community endpoints, once all endpoint attributes were taken into consideration.

  Therefore, GE shall revise the RMCs for protection of the benthic community Assessment Endpoint to include the chronic MATC from the ERA, and shall eliminate reference to all other endpoints.

- GE shall revise the narrative goal as follows:

  To reduce the PCB concentrations in sediment to prevent significant impairment of benthic communities relative to reference (i.e., similar habitats that are not influenced by elevated PCB concentrations). Significance is defined as a 20% or greater response relative to reference. Impairment is defined as a reduction in survival,

growth, abundance, diversity, or other biological metric that has relevance to the benthic community health and function.

3.3 Amphibian Assessment Endpoint

- In Section 2.4.2, GE incorrectly implies that the biological endpoints shown in Table 2-6 of the ERA are the only endpoints that exhibited significant effects. For example, significant larval malformation was also observed in Phase II; these malformations correlated with both the sediment tPCB concentrations and the Phase III study findings. The subset of endpoints chosen for derivation of the MATC considered the mechanism of action of PCB toxicity in developing amphibians. For example, Phase III malformations were emphasized over Phase II malformations in MATC development because the latter reflect site-specific PCB exposure in sediment over a longer period and through an ecologically relevant and sensitive life stage (i.e., metamorphosis).

  GE shall correct the discussion of the endpoints demonstrating significant effects.

- There are major errors in the evaluation of the Phase III wood frog metamorph malformation endpoint presented in the IMPG Proposal. These errors affect the statistical significance of the concentration-response between tPCB and biological endpoints, and therefore are relevant to the discussion of proposed RMC ranges discussed in Section 2.4.2 of the ERA. Specifically, GE claims that a statistical analysis of tissue PCB concentrations and the malformation rate (BBL et al., 2003) "showed no statistically significant relationship, and this finding makes any conclusions regarding the relationship between sediment PCB concentrations and malformation rates unclear." The GE data analysis and corresponding conclusion are incorrect, for several reasons:

  The PCB concentration data reported by BBL et al. (2003) in the analysis of Phase III malformation incidence versus larval tissue tPCB concentrations are incorrect. As summarized in Table 2 (below), the tissue data presented in BBL et al. (2003; Table 57, Section 7.2.1) have been assigned to the incorrect vernal pools. Erroneous rearrangement of the tissue tPCB data also occurred for the analysis of the sex ratio endpoint. Statistical analyses conducted using these erroneous tissue data (i.e., correlations against sex ratio and malformation endpoints) are therefore incorrect.

  – The statistical analyses conducted by GE excluded one location (8-VP-1), due to small sample size (n=3 metamorphs). The elimination of station 8-VP-1 from analysis of Phase III malformation data is inappropriate, because the effects data are in agreement with the concentration-response relationship indicated by the

Table 2. Summary of Errors in GE Analysis of Wood Frog Phase III Metamorph Endpoints

Station ID			Tissue sample ID – Phase III metamorph composite	Sediment PCB (Average Vernal Pool, mg/kg dw)	Correct Tissue PCB (as reported in ERA and FEL wood frog study) (mg/kg tPCB)	Incorrect Tissue tPCB as reported in BBL et al. 2003 Review Document (mg/kg tPCB)	
Weston ID	Stover / FEL ID	Woodlot Vernal Pool ID				Used in analysis of tissue PCB vs. malformation	Used in analysis of tissue PCB vs. sex ratio
TA02RS20	20	8-VP-1	H2- TA02RS20-0-C001	14.5	**15**	Deleted	Deleted
TA04RS27	27	18-VP-2	H3-TA04RS27-0-C001	6.05	**2.9**	0.13	2.93
TA05RS28	28	23b-VP-1	H3-TA05RS28-0-C001	0.19	**0.3**	1.22	1.61
TA05RS29	29	23b-VP-2	H3-TA05RS29-0-C001	0.11	**1.22**	2.93	5.37
TA08RS30	30	38-VP-1	H3-TA08RS30-0-C001	28	**1.61**	4.37	0.3
TA08RS21	21	38-VP-2	H3-TA08RS21-0-C001	62	**5.37**	No value reported	1.22
TA08RS31	31	39-VP-1	No tissue sample	52	**NA**	NA	NA
TA08RS32	32	46-VP-1	H3-TA08RS32-0-C001	0.5	**0.13**	1.61	0.13
TA10RS22	22	46-VP-5	H3-TA10RS22-0-C001[a]	2.2	**0.57**	5.37	0.57
TAWLRS41	41	WML-1	H9-TAWLRS41-0-C001	0.07 (ND)[b]	**4.36**[c]	15	4.36
TAWLRS42	42	WML-2	No tissue sample.	0.13 (ND)	**NA**	NA	NA
TAWLRS43	43	WML-3	H9-TAWLRS43-0-C001	0.11 (ND)	**0.16**[b]	0.3	No value reported

[a] A tissue sample duplicate exists for this station: H3-TA10RS22-1-C001. The tPCB concentration was 0.55 mg/kg ww.

[b] Detection limit substituted for non-detected concentration.

[c] Anomalous tissue concentration, as discussed in ERA Section E.2.7.4.2 and E.4.12.1.

remaining stations. Station 8-VP-1 exhibited the highest tissue tPCB concentration and exhibited a malformation rate of 67%, and station 38-VP-2 exhibited the second highest tissue tPCB concentration and exhibited a malformation rate of 52%. Therefore, 8-VP-1 is not a statistical outlier. Although the precision of the 8-VP-1 sample is lower than other locations, the sample is representative and unbiased.

– When statistics are applied using the correct data, there is a statistically significant relationship between Phase III metamorph tissue concentrations and the observed incidence of malformation. EPA conducted Spearman's rank correlation tests both with and without station 8-VP-1. In each case, when the correct tissue/malformation data pairings were applied, the relationship was statistically significant ($p < 0.05$).

The correct tissue concentrations are reported in the EPA/WESTON tissue database (including a March 2002 version of the database transmitted to GE, and spreadsheets delivered by Fort Environmental Laboratories in 2002 along with their final report). Therefore, the errors resulted during data processing following delivery of the data to GE.

GE shall correct the calculations and associated text to reflect the errors identified above if the discussion is maintained in the revised IMPG Proposal.

- GE ignored other amphibian species' sensitivities to PCBs in the development of RMCs for the Amphibian Assessment Endpoint. Based on range, habitat requirements, and habitat availability, 19 amphibian species could potentially occur in the study area. Although the wood frog measurement endpoints are important for use in the establishment of IMPGs, it is also important to balance the wood frog results against knowledge of other amphibian responses, both from site-specific studies and the literature. As discussed in the ERA, information on other amphibian species indicates that their sensitivity may be greater than wood frogs. EPA considered this information in the selection of the MATC, whereas GE only considers wood frog effects endpoints when assessing PCB risks to amphibians.

  GE's proposed narrative for the protection of amphibians includes "supporting a sustainable reproducing <u>population</u> of amphibians" (emphasis added). EPA does not consider that protection of a single population of an amphibian species (i.e., wood frogs) is sufficient to protect amphibians. The purpose of the amphibian MATC, as described in the ERA, is to be protective of all species of amphibians inhabiting Rest of River. The wood frog effects endpoints from which the sediment MATC was derived are meant to serve as surrogate endpoints for the many amphibian species within the Housatonic River floodplain, and require an assessment of uncertainty due to interspecies extrapolation. The selection of the amphibian effects threshold, therefore, must consider the other lines of evidence available, even where such lines of evidence are semi-quantitative or qualitative.

  Evidence of the potential presence of more sensitive species comes from:

  – Literature information on the relative sensitivity of amphibians – Birge et al. (2000) presents information on the sensitivity of numerous amphibian species to contaminants. Based on that information, the species selected as representative species for the ERA are not the most sensitive. Leopard frogs are shown to be "sensitive" to metals but "moderately tolerant" to organic

contaminants (based on comparisons with approximately 20 other amphibian species). Tree frogs (*Hylidae*) are considered to be more sensitive; this group includes the gray tree frog (*Hyla versicolor*) that is expected to occur in shallow emergent marshes in the PSA (ERA Appendix A, Ecological Characterization Report). Like anurans, salamanders (Urodela) are known to be sensitive to organic contaminants and other environmental toxicants (Rehage et al. 2002; Gendron et al. 1997; Johnson et al. 1999; Berrill et al. 1993).

- Site-specific toxicity testing using leopard frogs – EPA observed increased sensitivity to the effects of PCBs in leopard frogs relative to wood frogs. Leopard frog larval mortality was high across all target site treatments, and of the larvae that survived, few organisms successfully completed metamorphosis. Sediment tPCB concentrations were significantly correlated with abnormal sperm cells in the male leopard frogs, and adult female leopard exhibited a low proportion of mature eggs in egg masses. Although there are uncertainties associated with some of the measurement endpoints, the magnitude of response in the site-specific leopard frog studies requires consideration in the selection of IMPGs.

- Life-history characteristics of other PSA amphibian species – Although wood frogs spend approximately 2 weeks a year of their adult life in the temporary vernal pools, leopard frogs can spend their entire adult life in and around the permanent vernal pools and associated backwater habitats. Five salamanders of regulatory concern potentially occur within or next to the study area: Jefferson, blue-spotted, spring, four-toed, and marbled salamanders. Some of these species have life-history traits (e.g., longer lifespan, long larval periods, carnivorous feeding, extended contact with contaminated vernal pools, neotony[2]) that make them more susceptible to PCB-related effects relative to wood frogs (Duellman and Trueb, 1986; Whitford and Vinegar 1966; Stebbins 1951). Salamanders appeared in lower numbers in vernal pools with high sediment tPCB concentrations (Woodlot Alternatives, Inc. 2003).

- EPA conducted community surveys in 1999-2000 (Woodlot Alternatives, Inc., 2003); data were collected for wood frogs (e.g., numbers of frogs entering and leaving pools, numbers of metamorphs captured leaving the pools). In addition, species abundance, richness, and malformation rates were assessed for multiple species in selected vernal pools. GE's IMPG proposal briefly mentions wood frog sex ratio data collected for this study, but fails to consider the remaining endpoints and their concordance with the wood frog toxicity study results. Specifically, several observations indicate adverse population and/or community responses:

[2] Neotony refers to the phenomenon whereby salamanders reproduce while still in the larval stage. Therefore, they can spend an indefinite period of time in a permanently flooded vernal pool or backwater environment, never completing metamorphosis and migrating to terrestrial habitats (Duellman and Trueb 1986).

- Species richness was lower in the vernal pools with higher average sediment tPCB concentrations.

- Organism density and biomass (per m^2) were lower in the more contaminated vernal pools.

- Salamanders (including Species of Special Concern) appeared to be sensitive to tPCBs, appearing in lower numbers in vernal pools with high sediment tPCB concentrations.

- Malformation rates in larval wood frogs were high in all pools, and highest in pools with the highest tPCB concentrations. The high rates of malformations in amphibians observed in the field are in agreement with the individual organism responses observed in the wood frog laboratory study (FEL, 2002).

In summary, the EPA field surveys provide multiple indications of potential harm to resident amphibian populations and communities, and are consistent with results of site-specific toxicity testing. Cumulatively, these findings support the derivation of the MATC by EPA and demonstrate that the upper end of GE's proposed range of RMCs is not protective of the Assessment Endpoint.

- In Section 2.4.2, GE states that, in the wood frog study, "most of the endpoints evaluated showed no effects of PCB exposure." This statement is misleading because it fails to consider the relationship between the sensitivity of amphibian toxicity endpoints and the route, duration, and timing of PCB exposure during development. The increased sensitivity of the late-juvenile life stages is attributable to the biochemical processes that occur during development and metamorphosis (Gutleb et al. 2000). The biological processes that occur in amphibians during development provide a mechanistic basis to explain the pattern of responses observed in the wood frog developmental study. The biochemical processes occurring in late development are a fundamental premise in EPA's conclusions of risks to wood frogs and amphibians in general; observations of reduced response in early life stages is not evidence of lack of harm, but rather an artifact of the timing of measurement. GE has not considered the importance of the route and timing of exposure, and therefore inappropriately interprets the findings of both the wood frog studies.

  GE did not correctly interpret the results of the Phase I malformation endpoint, which was used in the establishment of the upper RMC of 62 mg/kg tPCB. Use of the Phase I malformation endpoint effect concentrations for RMC derivation is inappropriate because those malformation data only include the external metamorph malformations. In contrast, the Phase III data include both the external and internal malformation incidence, which is the more biologically relevant measure of total PCB effects on the wood frog juveniles. Table 3 demonstrates the differences between the Phase I and Phase III malformation data. The pattern of correlation between sediment tPCB concentrations and malformations is similar.

Table 3. Phase I and Phase III wood frog metamorph malformations, with associated sediment tPCB concentrations.

Station ID	Average Sediment tPCB (mg/kg)	Spatially Weighted Sediment tPCB (mg/kg)	Phase I Percent Malformed (External Only)	Phase III Percent Malformed (Internal + External)
WML-1	0.07	-	0.4	0.0
23bVP2	0.11	0.3	4.5	5.9
WML-3	0.11	-	0.5	2.9
WML-2	0.13	-	2.4	-
23bVP1	0.19	0.21	0.6	4.9
46VP1	0.50	0.8	2.8	8.6
46VP5	2.18	0.7	3.0	9.2
18VP2	6.05	4.9	16.6	26.9
8VP1	14.5	24.6	13.0	66.7
38VP1	28	28.5	16.4	41.0
39VP1	52	43.0	-	-
38VP2	62	32.3	17.0	51.5

- GE proposes the following RMCs:
  - 3.27 mg/kg tPCB to 38.6 mg/kg tPCB (based on spatially weighted sediment data)[3]
  - 3.61 mg/kg tPCB to 62 mg/kg tPCB (based on average vernal pool sediment data)[4]

  EPA disagrees with GE's assertion that the upper ends of the RMC ranges (38.6 mg/kg and 62 mg/kg tPCB) are justified, for the following reasons:
  - Use of a 50% response size for the Phase III malformation endpoint (38.6 mg/kg tPCB) is too large an effect size for RMC derivation, particularly given

[3] The sediment tPCB concentration of 38.6 mg/kg is the EC50 for the Phase III malformation endpoint.
[4] The sediment tPCB concentration of >62 mg/kg represents the unbounded EC20 and EC50 for the Phase I malformation endpoint.

that many of the observed internal malformations were malformations of female gonadal tissue. These types of malformations can lead to sterility in females (i.e., link between malformation and reproduction). To put this effect size into perspective, Ouellet et al (1997) notes that a malformation incidence of greater than 5% is considered "abnormally high" for most amphibian populations.

- Although there were no significant PCB-related effects on survival, growth, or metamorphosis in wood frogs in the toxicity tests, weighting these endpoints equally with the sensitive endpoints (e.g., sex ratio and metamorph malformation) is not justified. The malformations observed were sufficiently severe to have population-level implications, irrespective of the results of the other endpoints, as demonstrated in the amphibian population modeling conducted as part of the ERA. Dilution of sensitive and relevant endpoints with results of insensitive study endpoints is not scientifically justifiable.

- As described in Section 4.3.2, the lack of internal malformation measurements in the Phase I study (used by GE to establish the upper bound RMC of 62 mg/kg tPCB) resulted in an underestimation of the total number of malformations in those organisms.

- GE claims that there is an absence of effect of the juvenile malformations on the net output of abnormality-free metamorphs. EPA does not agree with the use of the net metamorph output (NMO) metric. GE first introduced this metric in their comments on EPA's wood frog developmental study (BBL et al., 2003), in which GE questioned the effect of the [Phase 1] metamorph malformations on the wood frog population.

  GE's NMO metric is essentially the inverse of the incidence of Phase I metamorph malformations, except that the NMO is not calculated as a proportion, but rather as a count (e.g., number of normal metamorphs). Specific concerns related to the NMO metric include:

  - The NMO metric does not provide proof of a healthy population; the metric extrapolates far beyond the capabilities of the data. GE has failed to provide appropriate evidence (e.g. literature citations) of the use of a metric like the NMO to validate population health.

  - The NMO should not be included in the regression with sediment or tissue tPCB; this NMO metric incorporates mortality in addition to normal/abnormal metamorphs, and therefore does not allow isolation of the malformation parameter. The indirect inclusion of mortality removes any possibility of normalizing the incidence of malformations across treatment groups.

  - The NMO metric incorporates the inverse relationship observed between larval wood frog mortality and sediment tPCB concentration (ERA Appendix E, Attachment EE.4, Figure 3). However, there is no known toxicological mechanism by which increased PCB concentrations could result in increased

wood frog abundance; therefore this relationship is likely spurious and masks the malformation effect. Moreover, EPA included this inverse survival relationship in the stochastic population model, yet increased risk was still predicted.

The regression does not support the argument that the number of normal metamorphs is sufficient for the long-term success of the population. Even if it were useful, the appropriate variable for the NMO would be a proportion (i.e., percent normal or abnormal), rather than a discrete count (number of normal metamorphs). As presented, the regression model is not an appropriate tool for indicating the adequacy of juvenile recruitment.

Therefore, GE shall revise the RMC to be the MATC derived for amphibians from the ERA and shall eliminate reference to all other endpoints.

- GE shall revise the narrative goal as follows:

To reduce the PCB concentrations in soil and sediment to prevent impairment of the local subpopulations of amphibian species. Significance is defined as a 20% or greater response relative to reference. Impairment is defined as a reduction in amphibian abundance or other biological metric, or community composition, that has relevance to a change in community quality and/or function.

3.4 Fish Assessment Endpoint

- GE does not acknowledge that the literature reviews of PCBs effects to freshwater fish are in agreement with the MATC values derived by EPA. Although not numerically incorporated in the MATC derivation, the literature data provided important corroborating evidence for the reasonableness of the EPA MATCs.

GE correctly identifies that the rainbow trout species used in Phase II of the fish reproductive study are non-native organisms. However, GE does not acknowledge that the Fish Lake strain of rainbow trout used in the Phase II study (Tillitt et al., 2003) is less sensitive than other rainbow trout strains identified in the literature. This difference increases the probability that the use of Fish Lake strain as a surrogate for Housatonic River coldwater fish species will underestimate adverse effects.

- The main difference between the EPA MATC derivations and the GE RMCs is that GE separated the Phase II ED_{50}s into three groups of ED_{50} values based on species (medaka, largemouth bass, rainbow trout). Presumably this separation was based on a hypothesis that the three test species have different sensitivity to PCB (and TEQ) toxicity. Because the ED_{50} values were similar among species, the range of RMCs identified by GE for tPCBs (43 to 92 mg/kg ww) is close to the EPA point estimate based on all species combined (55 mg/kg ww). Similarly, the range of RMCs identified by GE for TEQ (31 to 59 ng/kg ww) is close to the EPA point estimate

based on all species combined (44 mg/kg ww). However, there are two problems with GE's proposed RMCs:

– If GE's hypothesis regarding interspecies sensitivity differences is correct, then the upper end of RMC range will protect only the most tolerant of the three species tested. Therefore, non-tested warmwater fish species in the PSA (e.g., yellow perch) have a high probability of not being protected by the upper end of this RMC range. GE does not provide an explanation for the intended use of the upper end of the RMC range.

– The use of 43 mg/kg ww in the RMC range for coldwater species does not take into consideration the lower sensitivity of the Fish Lake fish strain used in the Phase II study. The principal investigator (Tillitt, 2003) estimated that the Fish Lake strain is approximately 3 times less sensitive than other trout strains used in toxicity testing. In the absence of site-specific information on the coldwater species sensitivity downstream of the PSA (rainbow trout and brown trout), it is inappropriate to directly apply a threshold based on a species with relatively low sensitivity to dioxin-like effects. If the factor of 3 is applied to the 43 mg/kg ww tPCB value (identified by GE based on consideration of the ED_{50} values for rainbow trout), the resulting value (14 mg/kg tPCB) is identical to the MATC already identified by EPA for protection of coldwater species (ERA Appendix F; Section F.4.6.2).

Therefore, GE shall revise the RMCs to be the MATCs for warmwater and coldwater fish species, respectively, from the ERA and shall eliminate reference to all other endpoints.

- GE shall revise the narrative goal as follows:

To reduce the PCB and TEQ concentrations in fish tissue to prevent significant impairment of local subpopulations of coldwater and warmwater fish species in the Rest of River. Significance is defined as a 20% or greater response relative to reference, except for combined juvenile deformity endpoints (i.e., ED_{50}), for which a 50% response is used in recognition of compensatory responses in fish recruitment. Impairment is defined as a reduction in abundance, reproductive output, fish health (i.e., fish condition and lack of deformities and disease) or other biological metric relevant to community health.

3.5 Piscivorous Birds Assessment Endpoint

- The inclusion of a RMC using a scaling factor of 0.008 to account for foraging time (FT) of transient individuals is unacceptable. Use of this scaling factor could be valid if PCBs in osprey diet (or the diet of other piscivorous birds) were only found in a small portion of the Rest of River Area. However, the presence of PCB exposures in other portions of the osprey foraging ranges in the Housatonic River invalidates the application of this linear scaling factor. In addition, the assumption of transients and

not resident birds is inappropriate for an IMPG. GE describes the assumption of a 3-day stopover each year as "quite conservative", while simultaneously disregarding all species that are residents. Foreseeable future use includes expansion of and/or management for osprey (or other piscivorous bird) nesting and reproduction.

GE shall revise the calculations to represent the foraging time of 100% assumed in the ERA.

- In Section 2.4.6, GE adopts three tPCB TRVs for avian species, including the 0.12 mg/kg-bw/day and 7.0 mg/kg-bw/day values selected by EPA for developing a threshold range. The third TRV was based on an arithmetic mean of these two values. GE neither provides an explanation for the intended use of this "midpoint" TRV (3.6 mg/kg-bw/day), nor provides a justification for the use of an arithmetic mean over any other method (e.g., geometric mean). Because GE presents an RMC corresponding to this "midpoint" value, it appears that an inherent assumption is being made that the "midpoint" RMC represents the "most likely" RMC.

  This assumption is flawed if the avian toxicity thresholds come from a log-normal (or otherwise skewed) sampling distribution. The use of the arithmetic mean suggests that a PCB dose within a factor of two of the threshold for the most tolerant species is assumed to be protective, even though this dose is 30-fold greater than the dose that caused growth reduction (Lillie et al., 1974) and 12-fold greater than the dose that caused significant reproductive harm (Platonow and Reinhart, 1973) in the most sensitive species.

  Therefore, GE shall revise the RMCs to be based upon the TRV associated with the most sensitive species identified in the ERA and a dietary exceedance probability of 20% as assumed in the ERA and shall eliminate reference to all other endpoints.

- GE shall revise the narrative goal as follows:

  To reduce the PCB and TEQ concentrations in Housatonic River fish tissue to prevent significant impairment of local subpopulations of piscivorous bird species in the Rest of River area. Populations of interest include both resident (i.e., nesting) species and migratory birds. Significance is defined as a 20% or greater response relative to relative to reference. Impairment is defined as a reduction in abundance, reproductive output, or other biological metric relevant to population health.

3.6 Insectivorous Birds

- GE proposes RMCs for tissue concentrations in aquatic invertebrates based on consumption by wood ducks, but does not present RMCs for tissue concentrations in terrestrial invertebrates based on consumption by wood ducks. Because wood ducks have exposures to both aquatic and terrestrial organisms, any assessment considering aquatic biota only is incomplete.

GE shall revise the calculations to include exposure to floodplain invertebrates using the dietary composition assumed in the ERA.

- GE adopts three tPCB TRVs for avian species, including the 0.12 mg/kg-bw/day and 7.0 mg/kg-bw/day values selected by EPA for developing a threshold range. The third TRV was based on an arithmetic mean of these two values. GE neither provides an explanation for the intended use of this "midpoint" TRV (3.6 mg/kg-bw/day), nor provides a justification for the use of an arithmetic mean over any other method (e.g., geometric mean). Because GE presents an RMC corresponding to this "midpoint" value, it appears that an inherent assumption is being made that the "midpoint" RMC represents the "most likely" RMC. This assumption is flawed if the avian toxicity thresholds come from a log-normal (or otherwise skewed) sampling distribution. The use of the arithmetic mean means that PCB doses within a factor of two of the threshold for the most tolerant species is assumed to be safe, even though this dose is 30-fold greater than the dose that caused growth reduction (Lillie et al., 1974) and 12-fold greater than the dose that caused significant reproductive harm (Platonow and Reinhart, 1973) in the most sensitive species.

- While GE correctly points out that the RMCs for wood ducks are uncertain, they incorrectly claim that RMC derivations are conservative. The statement that "conservative assumptions were applied to compensate for the uncertainties" is misleading. Some of the assumptions were conservative, but others were clearly not conservative. Therefore, GE's uncertainty assessment is biased toward characterization of uncertainties as conservative. In particular, it is unclear how the use of the most tolerant avian species (American kestrel) in the RMC derivation can be construed as a "conservative" assumption. Here and elsewhere in the document, GE has inappropriately equated "uncertainty" with "conservatism".

  Therefore, GE shall revise the RMCs to include only the calculations using the TRV associated with the most sensitive species, exposure to a mixed diet of both aquatic and terrestrial invertebrates, and a 20% probability of exceedance in the diet as assumed in the ERA and shall eliminate reference to all other endpoints.

- GE shall revise the narrative goal as follows:

  To reduce PCB and TEQ concentrations in Housatonic River aquatic and terrestrial invertebrates to prevent significant impairment of local subpopulations of wood ducks, and other insectivorous bird species, including those that breed, nest and rear young in the Rest of River, as well as well as migratory birds. Significance is defined as a 20% or greater response relative to reference. Impairment is defined as a reduction in abundance, reproductive output, or other biological metric relevant to population health.

3.7 Piscivorous Mammals

- GE proposes RMCs for prey items consumed by mink and otter, but does not evaluate the relative contribution of terrestrial and aquatic prey items to the total dietary intake of PCBs for mink. Because mink have exposures to both aquatic and terrestrial organisms, consideration of remedial options requires the use of assumptions regarding bioaccumulation from the dietary contribution from each of these habitats, and also the respective contribution of these habitats to total food intake.

- EPA disagrees with the proposed use of the 3.7 mg/kg PCB threshold concentration (from the Michigan State University (MSU) mink feeding study) for inclusion in the RMC range. The MSU study indicated that feeding adult mink with a diet containing 3.7 mg/kg PCB (using fish collected from the Housatonic River) resulted in a 46% reduction in kit survival to 6 weeks of age (relative to negative control). The large magnitude of this response and severe effect endpoint (reproductive success) indicate that use of this concentration is not sufficiently protective of the assessment endpoint. The juvenile mortality occurred in treatments for which sublethal effects (increased incidence of jaw lesions, and enzyme induction) were also observed; these sublethal effects were also observed at lower concentrations in the diet.

  Therefore, GE shall revise the RMC to be the MATC for the Assessment Endpoint identified in the ERA, and in addition shall modify the exposure for mink to incorporate the floodplain components of dietary uptake as assumed in the ERA, and shall eliminate reference to all other endpoints.

- GE shall revise the narrative goal as follows:

  To reduce PCB and TEQ concentrations in diet from the Housatonic River watershed to prevent significant impairment of local subpopulations of piscivorous mammals in the Rest of River area. Significance is defined as a 20% or greater response relative to reference. Impairment is defined as a reduction in abundance, reproductive output, or other biological metric relevant to population health.

3.8 Omnivorous and Carnivorous Mammals

- GE states that their study documented the highest short-tailed shrew densities ever recorded. However, George *et al*. (1986) reported densities of up to 121 animals/hectare (almost twice that of the GE study).

- GE summarizes the results of the EPA supplemental analysis of the site-specific population demography study (Boonstra and Bowman, 2003). The summary is biased because it emphasizes uncertainty in the EPA analysis of the data without also acknowledging the uncertainties in the original Boonstra and Bowman (2003) analysis. Many of the "qualifications" mentioned by GE apply equally to both analyses (e.g., low number of sample sizes and treatments, confounding effects of flooding and habitat differences). Moreover, GE does not provide a rationale for why

presence of uncertainty should be used as an argument to increase the soil RMC, but not to decrease it.

GE also stresses the lack of statistically significant responses for endpoints other than survival. A mortality response is sufficiently severe that sublethal responses are not necessary for a determination of overall adverse response. Furthermore, body mass was used as a surrogate for reproductive fitness; as described in the ERA (Appendix J; page J-53), the use of body weight to imply reproductive fitness may not be appropriate because it is insensitive to potential reproductive impairment.

Recruitment, possibly the most important demographic measure that could affect the assessment of a contaminant known to disrupt reproduction in other mammals, was not determined in the GE study. The authors acknowledge that fecundity and juvenile survival could not be assessed and that seasonal flooding can confound data interpretation. The GE study failed to account for immigration from adjacent unaffected areas, possibly masking effects on shrew populations.

Overall, EPA disagrees that the shrew study supports the use of an unbounded (> 43.5 mg/kg) soil PCB concentration in the RMC range or that this would be protective of the Assessment Endpoint.

- GE cites the results of EPA's small mammal surveys, which indicated that short-tailed shrews were the most abundant shrews caught in the PSA. The field observations of short-tailed shrews, and the increased abundance of short-tailed shrews relative to other shrew species, do not provide compelling evidence of lack of effects to small mammals. The argument being made by GE appears to be that mere presence of organisms is an indicator of lack of ecological harm. These observations do not indicate whether the abundance or other attributes of any shrew population are adversely affected by PCBs. Also, the high abundance of northern short-tailed shrews relative to other shrew species only indicates variation in density among species, which is expected either with or without contaminant stress. Smoky shrews (which are common in New England) were only rarely found during PSA trapping studies; using GE's logic, this could be interpreted as evidence of harm to smoky shrews because of their absence.

  Therefore, GE shall revise the RMC to reflect the MATC calculated in the ERA and shall eliminate reference to all other endpoints.

- GE shall revise the narrative goal to read as follows:

  To reduce PCB and TEQ concentrations in Housatonic River floodplain soil to prevent significant impairment of local subpopulations of omnivorous and carnivorous mammals in the Rest of River area. Exposure concentrations shall be the 95th UCL of the mean derived using IDW for floodplain soil. Significance is defined as a 20% or greater response relative to reference. Impairment is defined as a

reduction in abundance, reproductive output, or other biological metric relevant to population health.

3.9 Threatened and Endangered Species

- The inclusion of a RMC using a scaling factor of 0.008 to account for foraging time (FT) of transient individuals is not acceptable. Use of this scaling factor could be valid if PCBs in the eagle diet (or the diet of other endangered species) were only found in a small portion of the Rest of River Area. However, the exposure to PCBs in other portions of the eagle foraging ranges in the Housatonic River and watershed invalidate the application of this linear scaling factor. In addition, the assumption of transients and not residents birds is inappropriate for an IMPG, particularly for an endangered species. Foreseeable future use includes expansion and/or management for eagle nesting and reproduction, or for that of other endangered species.

  GE shall revise the calculations to represent the foraging time of 100% assumed in the ERA.

- The discussion of the RMC for bald eagles fails to recognize that bald eagles are a threatened/endangered species and therefore warrant increased protection relative to non-threatened species, including assessment at the organism level. Under the federal Endangered Species Act of 1973 (as amended), the term "take" means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Endangered species are afforded a much higher level of protection because they are faced with the threat of extirpation.

  GE shall revise the narrative discussion for the Threatened and Endangered Species Assessment Endpoint to incorporate the points discussed above.

- GE states that the RMCs are “quite uncertain because the ERA evaluated bald eagles based solely on modeled exposures and effects”. The MATC developed by EPA considered species-specific and ecologically relevant endpoints. It is unreasonable to expect site-specific studies to be conducted on bald eagles given their endangered status in Massachusetts. Furthermore, the uncertainty that exists in the RMC is present in both directions, such that the RMC may either understate or overstate actual sensitivity. In addition, the modeled risk estimates based on extrapolation of tolerable daily dose of PCBs in kestrels (Fernie et al., 2001a; 2001b) indicate greater risks than those based on the toxicity threshold for bald eagle eggs. Finally, GE’s statement ignores the high risk due to TEQ, which is suggested by a study that is independent from the Fernie et al. studies and therefore provides confirmation of PCB risks at low exposure levels.

  Therefore, GE shall revise the RMC to include only the MATC for resident bald eagles identified in the ERA and shall eliminate reference to all other endpoints for eagles.

- GE shall revise the narrative goal as follows:

  To reduce PCB and TEQ concentrations in diet from the Housatonic River watershed to prevent any effect on survivorship, growth or fecundity of threatened of endangered species, including bald eagles, American bittern, and small-footed myotis and other T&E species. Any observed death or morbidity of individuals of a threatened or endangered species, or any detectable reduction in the abundance or production of an exposed population of a threatened or endangered species (relative to reference) from exposure to PCBs or TEQ is unacceptable.

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