

1                                   **Ecological Risk Assessment of the Housatonic River, Rest of River**  
2                                   **Final Comments of Ralph G. Stahl, Jr., Ph.D., D.A.B.T.**  
3                                   **February 16, 2004**  
4

5 I have read the entire ERA (Vols 1&2), all of the Appendices, all of the public comments on the ERA, and  
6 skimmed the pre-ERA materials and the RFI information. However, there simply was not time sufficient to review  
7 all of the documents in detail, nor would that be necessary to render a scientific opinion opposite the charge to the  
8 panelists. I participated, by conference phone, in the December 2003 and January 2004 public meetings. I  
9 appreciate the opportunity to provide comments and suggestions on the ERA and hope that these will be useful to  
10 GE, EPA and the authors of the ERA in subsequent revisions of the final product.  
11

12 Before I begin my comments, I would like to suggest changes to this particular peer review process. First, the  
13 peer review would be much more effective if the panelists were able to communicate among ourselves during and  
14 outside of the formal meetings, etc., and in a deliberative fashion. The ability to learn from the strengths each of  
15 us brings to the review would be very beneficial to our abilities to formulate more effective suggestions for  
16 improving the ERA. Second, the format of the meeting with GE, EPA and their contractors on December 18, 2003  
17 did not lend itself to the type of scientific dialog that most peer reviews are noted for. I have served on various  
18 national panels over the years but have yet to encounter a format such as was used on December 18. Having to  
19 formulate questions in lieu of a didactic discussion seemed to constrain the dialog. A similar format was used for  
20 the public meetings in January, and once again I felt that our dialog was constrained.  
21

22 One additional suggestion. If there are similar reviews specified by the consent agreement, I believe it would be  
23 much more effective to have provided the documents first and then schedule a series of conference calls for the  
24 panelists to discuss their observations with GE and EPA, before holding any public meetings. Even better, having  
25 the documents for at least 3 months before any public meetings would lead to a more thorough reading especially  
26 if the materials are similar in volume to the current ERA, Appendices, etc. On the other hand, I am cognizant of  
27 the need to get the review done in a set period of time, and recognize that much of the peer review for the site  
28 activities has been completed.  
29

30 **Charge to Panelists**  
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32 ***In considering these questions, the Panel members shall evaluate the following (hereinafter the***  
33 ***“evaluation criteria”): the objectivity, consistency, and reasonableness of both the procedures and inputs***  
34 ***used by EPA in the application of existing EPA guidelines, guidance, and policy; and those used by EPA***  
35 ***in the absence of Agency guidelines, guidance, or policy (see Attachment A for the list of relevant EPA***  
36 ***guidelines, guidance, and policy documents).***  
37

38 ***If significant errors are observed in the application of the appropriate methodologies, the Panel members***  
39 ***shall provide specific comments, describing the error(s) and suggested improvements. The suggested***  
40 ***improvements must be specific, clear, and consistent with existing EPA methodologies and guidelines.***  
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42 **Assessment Endpoints**  
43

44 ***Community reproduction, and development***

- 45       ***1. Benthic invertebrates***
- 46       ***2. Amphibians***

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48 ***Survival, growth and reproductive success***

- 49       ***3. Fish***
  - 50       ***4. Insectivorous birds***
  - 51       ***5. Piscivorous birds***
  - 52       ***6. Piscivorous mammals***
  - 53       ***7. Omnivorous and carnivorous mammals***
  - 54       ***8. Endangered species***
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57 **Overall, Summary Comments**  
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59 Overall, the ecological risk assessment (ERA) for the Housatonic River, rest of river, is a substantial amount of  
60 work and it is evident that GE, EPA and the authors of the document have invested a significant amount of time  
61 and effort to complete this draft. Such a large volume of information was a challenge to review effectively in the  
62 time provided.

63  
64 In general the text was well written and sufficiently detailed although the frequent reference to appendices for  
65 more detailed discussion of specific topics was troubling given that the ERA (Vols 1 & 2) was already over 900  
66 pages in length. When faced with such a large document already, the reader is not particularly enthusiastic about  
67 being tasked with reading yet more text in an appendix in yet another document. This was a bit tedious but did  
68 not detract substantially from the ERA. Given the volume of information generated for the ERA, I do not have a  
69 suggestion on how to alleviate this problem.

70  
71 The initial screening of COCs for this ERA is one area where additional discussion among the ERA authors would  
72 be useful. After reading parts of the pre-ERA and the ERA itself, it is not fully obvious that tPCBs and TEQ  
73 caused all of the toxicity or developmental abnormalities observed in the benthic community, fish and the frogs.  
74 Inorganic mercury for example is also capable of causing skeletal and other malformations in finfish, yet mercury  
75 was given little discussion within the ERA. There is some evidence that methylmercury may also cause endocrine  
76 modulation in some fish (Drevnick & Sandheinrich 2003) In addition, the statement that PAHs were not  
77 considered for their potential effects on fish because they are readily metabolized seems to be a major  
78 overstatement. I have not read the source paper cited for this statement, but it is difficult to agree fully that  
79 benzo(g,h,i)perylene and other high molecular weight PAHs are readily metabolized by fish.

80  
81 In my opinion, it would be much better to have indicated that given the situation on the Housatonic River, tPCBs  
82 and TEQ would be the COCs simply on the basis of practicality. The screening process for determining which  
83 COCs would be carried into the ERA was effective for the most part, although there are some concerns with the  
84 reasoning expressed in the text. I agree that pesticides were not an issue at this site given the analytical  
85 chemistry results, and the apparent absence of a pesticide manufacturing activity in the area. I am less convinced  
86 however, that mercury and perhaps PAHs were not involved in some or part of the observed toxicity and  
87 developmental abnormalities, yet these were not given much credence in the document. Whether or not they  
88 originated from site activities is not evident from the ERA or supportive materials. Nevertheless, although it is not  
89 mentioned in the ERA (nor should it be) it is obvious that a final remedy that addresses the tPCBs and the TEQ is  
90 likely to also address potential risks posed by PAHs and other contaminants in the system.

91  
92 There were some figures and some tables which were difficult to read and / or understand. This is particularly the  
93 case where the axes and scales, and labels for the specific plots, were not clearly legible. I have noted these in  
94 my more detailed comments. Other panel members have also indicated the need for more detailed maps which  
95 illustrate the synoptic sampling of sediments, floodplain soils, surface water and biological tissues. I support this  
96 comment and suggest that EPA consider developing maps which more clearly illustrate the combined chemical,  
97 toxicological and biological results.

98  
99 Some relatively new approaches to data analysis were provided in this ERA and the individual scientists who  
100 conducted these analysis on behalf of EPA are recognized for their expertise in this area. For those schooled in a  
101 less robust form of data analysis, it was pleasing and challenging to read through the discussion of using  
102 propagation tools and bounding analyses to more fully describe the data as well as the uncertainties within those  
103 data sets. Despite the assumptions that underlay the analyses, I think this is a strength of the current ERA. This  
104 work is, without question, breaking new ground in ERA and in so doing will no doubt push the science forward.  
105 Even so, there were some sections in the ERA where the discussion was much too detailed and the various  
106 manipulations of data so complicated that it was not easy to follow the logic. I have noted these in my detailed  
107 comments.

108  
109 The use of the Massachusetts Weight-of-Evidence process so broadly in this ERA is not something I have  
110 observed previously in an ERA context. When Dr. Menzie worked with the group to develop the process, I'm not  
111 sure any of the participants appreciated that it could be used in this manner. I found that it was difficult to  
112 understand just how much professional judgement went into the final assignments in the matrix, and how much

113 “weight” was given to professional judgement compared to the other endpoints in the matrix. After attempting to  
114 discern how many empty, partial or full circles it took to achieve a certain final assignment, only then did it  
115 become clear that professional judgement, more or less, was the final arbiter of the assignment. Fundamentally  
116 it appeared that toxicological data tended to override field data, but not in all cases. The chemical data did not  
117 appear to be given a great deal of weight except in the case of benthic invertebrates, where the chemical data  
118 were a line of evidence that showed “impacts” throughout the PSA. In most cases the toxicological and biological  
119 field data were given greater weight even when there were problems in study design, execution or results  
120 (depredation of nests for example). As GE, EPA and the authors of this ERA fully appreciate, it is seldom the  
121 case in environmental studies that all lines of evidence are fully concordant. This leads to the use of professional  
122 judgement, and its use was in evidence throughout this ERA.

123  
124 I strongly recommend that the authors of the ERA be more forthcoming and descriptive with their use of  
125 professional judgement in the WOE discussion so that the reader is not confused about how the final assignments  
126 of risk were determined. In this regard, I found the evaluations at the end of each of the assessment endpoints to  
127 be inconsistent with one another, and not wholly objective. Others on the peer review panel have noted this in  
128 their verbal and written comments. If anything, a high degree of subjectivity is apparent in the final assignment of  
129 risk. Whether this can be remedied by clarifying more fully the use of professional judgement remains to be seen.

130  
131 As one of several peer reviewers of the EPA’s Ecological Risk Assessment Guidelines in 1998, and the ERA  
132 guidelines for Superfund in 1997, I do not recall any codification of the Massachusetts WOE approach. A general  
133 discussion of the “weight-of-evidence” is part of the guidelines, but there is no specific recommendation for a  
134 particular methodology. Thus its (WOE) widespread application within this ERA would appear to be counter to, or  
135 at least outside of existing EPA guidelines. Otherwise, the ERA in general appeared to follow the intent, if not the  
136 specifics, of the two EPA guidelines noted above. I would caution however that simply following guidelines does  
137 not guarantee a high quality ERA. While it might be useful to have followed guidelines so others understand the  
138 basis for how the ERA was conducted, it should not be used as prima facie evidence of providing a high quality  
139 end product. The quality and scientific merit come of themselves, not as a result of following guidelines.

140  
141 Another area where additional discussion might be beneficial centers on the “causative” agents believed to be  
142 responsible for the observed toxicity and developmental abnormalities. In that regard, I believe that the authors of  
143 the ERA did not consider accurately those substances which might have also elicited some of the same  
144 developmental or morphological malformations. I believe the authors would benefit from a review of the EPA’s  
145 stressor identification guidelines (USEPA 2000). This could be useful in the Problem Formulation discussion to  
146 provide support to the statements made later in the ERA concerning tPCBs and TEQ being the primary causative  
147 agents for the observed malformations in frogs and fish, and toxicity in some samples. I believe the initial  
148 manuscript, by Glen Fox of the Canadian Wildlife Service, for the term “ecoepidemiology” may or may not have  
149 been cited. If not, it would be helpful to review this document as well (Fox 1991) and reiterate in the ERA the  
150 criteria applicable to assigning causality. See also (Diamond & Serveiss 2001)

151  
152 I also reiterate my earlier comment that the ERA is not the document whereby the finding of an unacceptable risk  
153 is made. This is a risk management decision, arrived at after reviewing all the pertinent information in addition to  
154 the ERA ((Stahl *et al.* 2001;Pittinger *et al.* 2001)).

155  
156 **Summary of Recommendations**

- 157  
158 1. EPA should consider additional characterization of the sediments located behind dams in Connecticut that are  
159 in closest proximity to the PSA.  
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161 2. In support of the comment made repeatedly during the January 2004 public meetings, it is strongly  
162 recommended that the authors of the ERA provide detailed maps that clearly illustrate the synoptic sediment,  
163 water column and biological tissue sampling and results.  
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165 3. The authors of the ERA should more fully explain the reasoning for not including such receptors as the  
166 dragonfly and waterfowl.  
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4. The authors of the ERA should temper their statements with respect to causation, tPCBs, TEQ and the observed impacts on aquatic receptors. Other COCs noted in the sediments are known to elicit some of the same developmental malformations attributed to PCBs and TEQ.
  5. The authors of the ERA should refer to the EPA Stressor Identification Guidance (USEPA 2000) and incorporate the tenets of that guidance into the Problem Formulation section of the ERA.
  6. The authors of the ERA should re-word the assessment endpoints to reflect more specifically those attributes of the assessment endpoint (or receptor) that are most valued and worthy of protection. The current assessment endpoints are overly broad and thereby lead to difficulty in interpretation of and linkage to the measurement endpoint results.
  7. The authors of the ERA should be more forthcoming and descriptive with their use of professional judgement in the WOE discussion so that the reader is not confused about how the final assignments were determined. It is clear that a large component of the final assignment of risk is directly related to professional judgement. The final assignment of risk was not fully consistent nor objective among the 8 assessment endpoints.
  8. The term "ecologically significant" is used in various places throughout the ERA; however, this term is not defined adequately within the document. The authors of the ERA should develop and clearly articulate the definition for "ecologically significant".
  9. The use of the HQ approach and the definition of what constitutes "low", "moderate", and "high" risk, either quantitatively or qualitatively should be formally and fully articulated in the ERA. In some cases an HQ of less than 1 is considered indicative of no risk, but this designation is not applied consistently in the ERA.
  10. The exposure estimates of benthic invertebrates to tPCBs and TEQ in the laboratory-based sediment toxicity studies should be revised and based on the most synoptic sediment chemistry data. The current exposure estimate and the subsequent MATC of 3 mg/kg currently is not reflective of the most synoptic sediment chemistry data, and thereby, is inappropriate.
  11. Because the results of the wood frog studies by FEL and GE are the most comprehensive and potentially the primary basis for estimating potential risks to amphibians inhabiting the Housatonic River watershed, I recommend that EPA re-evaluate the Resetarits study, and where feasible, incorporate those data into the modeling projections conducted by Dr. Ferson.
  12. Based on the January 2004 public meetings, there appears to be a substantial information base on DELTs in local finfish populations. If accurate, I recommend that this information be more fully displayed and discussed in the main text of the ERA. It is potentially a key element of the field work that does not appear to have been highlighted in the ERA.
  13. Because it has potential implications for the estimate of exposure (and risk) for piscivorous birds and mammals, I recommend that the tissue analyses conducted for any finfish in the Housatonic River be fully displayed and discussed in the main text of the ERA. These data appear to exist but are not readily found in the ERA or the appendices. The existing datasets should not be truncated so that only tPCBs and TEQ are provided.
  14. The estimate of risk to piscivorous birds is uncertain and may warrant further evaluation by EPA. The lack of a strong field study, coupled with the results of the modeled exposure and effects suggests this assessment endpoint may not have been adequately evaluated in the ERA. This does not negate the findings of the tree swallow study. However, given the differences in feeding between insectivorous and piscivorous birds, one cannot conclude that the results in tree swallows is or could be applicable to belted kingfishers, osprey or other piscivorous birds. Therefore, I recommend that EPA collect and evaluate biological survey data on populations of osprey that inhabit the Housatonic River watershed to help reduce the uncertainty associated with potential risk to this species. If there are no biological survey data, or, as GE has contended, osprey do not inhabit the Housatonic River watershed, then EPA should consider another piscivorous bird species for

223 the conduct of the ERA. Where biological survey data are available for heron in the Housatonic River  
224 watershed, then it is reasonable to pursue this receptor in the ERA in lieu of the osprey.  
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- 226 15. There is uncertainty associated with the cause of death of kits in the mink feeding study. It appears that kits  
227 which died unexpectedly in the study were not necropsied nor the cause of death determined. If however,  
228 these animals were necropsied and the cause of death determined, I recommend that information be provided  
229 in the ERA and clearly discussed. Otherwise, there doubts will remain as to whether the drop in kit survival at  
230 6 mos of age is due to maternal exposure to tPCBs or due to other causes.  
231
- 232 16. There was significant debate during the January 2004 public meetings as to the statistical analysis for the  
233 Boonstra study on small mammals, and this was reflected within the ERA. Because the conclusions drawn  
234 for small mammals are important for determining the need for potential remediation of soils in the PSA, it is  
235 imperative that one and only one mutually acceptable approach is presented in the ERA. I recommend that  
236 EPA and GE select a single statistical approach and provide that one approach and the results thereof in the  
237 ERA.  
238
- 239 17. In my opinion, the use of rodent data to support a modeled estimate of effects in red fox is not scientifically  
240 supportable. The uncertainty is so large that there is little to be gained from this evaluation. I recommend  
241 that EPA delete the red fox assessment endpoint from this ERA. There are sufficient data from the other  
242 assessment endpoints on which to base a final risk management decision.  
243
- 244 18. The Land H-statistic discussion in the main text of the ERA and in some of the Appendices is complex and  
245 not easily followed. I recommend that the authors consider a re-writing of the description to simplify the  
246 strengths and weaknesses of the approach.  
247
- 248 19. I recommend that the biological surveys conducted for the T&E species be included in the weight-of-evidence  
249 evaluation. Given the magnitude of the risk question at hand it is important that all relevant information be  
250 brought to bear in the evaluation of potential risk. To exclude this information on the basis that it is not  
251 quantitative is not appropriate, objective or reasonable.  
252

### 253 **Specific Charge Questions and Responses**

254

- 255 1. *Was the ecosystem of the Housatonic River watershed properly characterized, and was this information*  
256 *appropriately applied in the Problem Formulation and subsequently in the ERA?*  
257

258 I believe the ecosystem of the Housatonic River was properly characterized within the boundaries of  
259 Massachusetts, but it is not clear that the same rigor was applied to sections of the watershed in Connecticut.  
260 I found the comments of Dr. de Fur at the January public meeting to be persuasive with regards to the need  
261 for additional sediment characterization in the Housatonic River watershed in Connecticut. In this regard, the  
262 characterization of the ecosystem of the Housatonic River watershed was not consistent. I recommend that  
263 EPA consider additional characterization of the sediments located behind dams in Connecticut that are in  
264 closest proximity to the PSA. It is likely that, over time, sediments and their PCBs have been transported  
265 downstream and have settled behind one or more of these structures. Thus while the concentrations of PCBs  
266 decline downstream of the PSA, as would be expected in the absence of a continued source of the PCBs, this  
267 decline would not be observed in sediments deposited behind downstream dams. Uncertainty remains high  
268 as to whether or not PCBs, at potentially problematic concentrations, are present in these depositional areas  
269 and simply have not been characterized. Characterization of sediments is not needed for all dams on the  
270 Housatonic River in Connecticut, but should be sufficient to reassure the public and decision makers that this  
271 issue has not been overlooked.  
272

273 I do not believe that additional characterization is needed for soils in the floodplain within Connecticut;  
274 however, additional floodplain sampling may be beneficial in areas immediately downstream of the PSA in  
275 Massachusetts. These additional data may be helpful in refining some of the exposure estimates for  
276 terrestrial receptors such as birds, mammals and amphibians. As stated previously, it would be very  
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279 beneficial to develop detailed maps which illustrate the synoptic sampling of floodplain soils, sediments, water  
280 column, and biological tissues. Where possible, results from this sampling should be displayed for each of  
281 the reaches of the river and the associated reference locations.

282  
283 2. *Was the screening of contaminants of potential concern (COPCs), selection of assessment and measurement*  
284 *endpoints, and the study designs for these endpoints appropriate under the evaluation criteria?*

285  
286 I believe the process of screening the COPCs was appropriate; however, I am not convinced that PAHs and  
287 perhaps mercury or other contaminants were not partially responsible for some of the observed effects in  
288 aquatic receptors. I do not believe that the screening approach in the ERA requires substantial revision, but I  
289 recommend that the authors temper their statements with respect to tPCBs and TEQ being the causative  
290 agents of malformations observed in fish and amphibians. In this regard the screening of COPCs is not  
291 consistent and potentially not objective. It is reasonable however given the magnitude of risk question at  
292 hand where all the possible COPCs simply cannot be evaluated effectively.

293  
294 I believe Dr. Oris has pointed this out in his semi-quantitative analysis of the HQs resulting from stressors  
295 other than tPCBs and TEQ. In some cases COPCs produced HQs greater than 1, yet these were not  
296 discussed in any systematic manner in the ERA, nor was the potential for these other COPCs to produce the  
297 morphological abnormalities noted in some of the receptors.

298  
299 I believe the assessment and measurement endpoints were, in general, selected properly. As others on the  
300 panel have noted, there is some concern on the wording of the assessment endpoints. For example, an  
301 assessment endpoint should not be so overly broad that one is incapable of linking the measurement  
302 endpoint results to potential risks. Most, if not all, of the 8 assessment endpoints are written very broadly and  
303 this becomes problematic in the final assignment of risk in the WOE process. I recommend that the authors  
304 reconsider the wording of the assessment endpoints to reflect more specifically those attributes of the  
305 assessment endpoint (or receptor) that are most valued and worthy of protection. In this way the final  
306 assignment of risk in the WOE process will be more evident given the measurement endpoint results  
307 presented in the ERA.

308  
309 Based on some of the EPA presentations, it appears that some information was collected on receptors (or  
310 assessment endpoints) yet these did not warrant further evaluation in the ERA. Two examples are the  
311 dragonfly and waterfowl. It is not clear from the ERA why these two receptors, or assessment endpoints  
312 were not included even though preliminary data were presented on them. Even more puzzling is the fact that  
313 a waterfowl consumption advisory is listed for some portions of the Housatonic River due to the potential for  
314 tPCB contamination in edible tissue, yet waterfowl are not given any substantive discussion or evaluation in  
315 the ERA. If this point has been covered in the human health risk assessment for the Housatonic River, it  
316 should be so noted in the Housatonic River ERA. If not, I recommend that the authors of the ERA more fully  
317 explain the reasoning for not including such receptors as the dragonfly and waterfowl. In this regard, the  
318 selection of receptors does not appear to be consistent.

319  
320 Some of the measurement endpoints resulted in data sets that were limited. For example, there were limited  
321 numbers of fledgling piscivorous birds (belted kingfisher) observed in the field study conducted by GE, yet this  
322 was the only field investigation available for use in the ERA. The bulk of the ERA relative to the piscivorous  
323 birds was based entirely on modeling, and therefore carries a substantial level of uncertainty. In another  
324 example, few mink and otter were observed in the field despite significant effort both by EPA and GE,  
325 resulting, again, in sparse data sets. The lack of high quality field data became the underlying reason for the  
326 uncertainties and conflicts noted in the conclusions on potential risks.

327  
328 With this in mind, it is important given the circumstances and the significant efforts undertaken by EPA and  
329 GE, that all data collected in the PSA and elsewhere be utilized to the maximum extent possible. Some data  
330 sets will be sparse owing simply to the difficulty in obtaining the organisms that are the subject of the study.  
331 These should, nevertheless, be utilized as is appropriate in helping to understand the potential for risks to  
332 ecological receptors in the Housatonic River and its watershed. Simply dismissing the studies out of hand, or  
333 on the basis of the absence of prior review of the design is not prudent given the magnitude of the risk

334 question at hand. Therefore it is reasonable to include as much of the data as is possible, and identify those  
335 strengths and weaknesses of those data in the ERA.  
336

- 337 3. For each of the 8 assessment endpoints evaluated in the ERA (listed in Attachment B, and for which a  
338 specific Section and Appendix was prepared), address the following questions (discuss and label responses  
339 as 3.(assessment endpoint number).(question letter) for consistency):  
340

### 341 3.1 Benthic Invertebrates 342

343 3.1.a Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies,  
344 comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted scientific  
345 practices?  
346

347 The EPA field studies were appropriate under the evaluation criteria and based on accepted scientific practices.  
348 The field studies, while limited, were sufficient to estimate potential impacts on benthic invertebrate abundance  
349 and diversity. The field studies suggest a limited depression, if any, of abundance and diversity, and there  
350 appears to be no significant concentration-response between tPCBs and abundance.  
351

352 The site specific toxicity studies in and of themselves were appropriate under the evaluation criteria. However, on  
353 further review, the most synoptic exposure values for tPCBs in the sediment toxicity studies appears to not have  
354 been used and therefore fail to meet the criteria of appropriate and objective. In my recommendations I have  
355 noted the need to revise the evaluation so that the most synoptic data are utilized.  
356

357 Comparison of effects in the site-specific toxicity studies appears to stray from accepted scientific practices. In  
358 some cases a comparison was made between the laboratory control and the treatments whereas it is standard  
359 practice to make this comparison between the reference area (reference control) and the treatment. Where the  
360 authors choose to make comparisons using both the reference area and the laboratory control, or other "control"  
361 this should be described clearly in the ERA. Where only one approach was used, then this too should be clearly  
362 stated in the ERA so there is no ambiguity in or mis-interpretation of the analysis.  
363

364 3.1.b Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g.,  
365 field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated  
366 appropriately in the ERA?  
367

368 There were no GE studies conducted for benthic invertebrates that were listed in the ERA.  
369

370 3.1.c Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of  
371 analyses for the contaminants of concern (COCs) for each assessment appropriate?  
372

373 As noted above, it appears that the most synoptic sediment exposure values for tPCBs were not used in the ERA.  
374 Therefore, the exposure estimates for benthic invertebrates does not meet the evaluation criteria of consistent  
375 and objective.  
376

377 3.1.d Were the effects metrics that were identified and used appropriate under the evaluation criteria?  
378

379 The effects metrics were appropriate under the evaluation criteria. As noted above however, the comparisons  
380 made between the treated and laboratory controls in the site-specific toxicity studies generally is not standard  
381 practice and should be articulated in the ERA.  
382

383 3.1.e Were the statistical techniques used clearly described, appropriate, and properly applied for the  
384 objectives of the analysis?  
385

386 The statistical techniques were not clearly described and their application to the toxicological assessments should  
387 be reviewed by the authors. The calculation of the MATC for tPCBs in sediment does not meet the evaluation  
388 criteria because it is not based on the most synoptic data collected for the toxicity assessment.  
389

390 3.1.f *Was the characterization of risk supported by the available information, and was the characterization*  
391 *appropriate under the evaluation criteria?*  
392

393 The characterization of risk is not fully supported by the available information. However, the process of  
394 characterizing the risk was appropriate under the evaluation criteria.  
395

396 The uncertainty with the characterization of risk to benthic invertebrates is high. Benthic abundance throughout  
397 the PSA was variable and based on one sampling event. Site-specific toxicity tests indicate impacts at two  
398 stations in the PSA (7&8), yet there are not similarly significant depressions in benthic abundance at these same  
399 locations. The risk of harm to benthic invertebrates is not consistent across the PSA, and appears to be localized  
400 to these two stations. There is no clear dose-response from the site-specific toxicity tests which also tends to  
401 cloud the evaluation. The results of the TIE, while interesting, are not conclusive with respect to tPCBs causing  
402 the observed toxicity.  
403

404 3.1.g *Were the significant uncertainties in the analysis of the assessment endpoints identified and adequately*  
405 *addressed? If not, summarize what improvements could be made.*  
406

407 There appears to be limited reflection given to the potential influence of grain size and potential seasonal changes  
408 in abundance and diversity in dynamic river systems such as the Housatonic River. On the basis of results in the  
409 coarse-grained sediments, one might conclude there were significant effects on benthic invertebrates. In  
410 contrast, where the fine-grained sediments were tested, there appears to be little or no effects on benthic  
411 invertebrates despite the fact it was these areas where some of the high levels of tPCBs were found. These  
412 points should be more fully discussed in the ERA.  
413

414 3.1.h *Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be*  
415 *improved?*  
416

417 The weight-of-evidence (WOE) analysis was appropriate, in part, under the evaluation criteria. It is reasonable  
418 but was not objective nor consistent (throughout the ERA). However, the use of professional judgement in the  
419 final assignment of risk was not clearly or fully articulated within the ERA. Numerous panel members have  
420 commented on this point previously.  
421

422 3.1.i *Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific*  
423 *studies were not conducted?*  
424

425 The risk estimates for reaches of the river where site-specific studies were not conducted were objective. They  
426 may not be appropriate however. Because the MATC of 3 mg/kg tPCB is likely overly conservative, and to the  
427 extent that extrapolations of risk downstream are based on this MATC, the estimates may also be overly  
428 conservative.  
429

430 3.1.j *In the Panel members' opinion, based upon the information provided in the ERA, does the evaluation*  
431 *support the conclusions regarding risk to local populations of ecological receptors?*  
432

433 The evaluation supports the conclusions regarding high risk to local populations of benthic invertebrates;  
434 however, this risk is localized to specific stations within the PSA. The estimates of exposure, based on the data  
435 selected for this purpose, and the method used to derive the MATC, are overly conservative. This will drive the  
436 HQs higher and may indicate a higher level of risk than is present.  
437

438 In my opinion, there is clear evidence of a risk of toxicity to benthic invertebrates residing at stations 7 and 8 in the  
439 PSA, yet this is not fully reflected in the abundance and diversity observations from the field. The conflict  
440 between toxicological results, abundance of benthic invertebrates, and sediment chemistry results is not unique to  
441 the Housatonic River. It is also evident that, in the final evaluation of risk, sediment chemistry (tPCB content in  
442 bulk sediment) was given significant weight compared to the benthic diversity and abundance results.  
443

## 444 **3.2 Amphibians**

445



446 3.2.a *Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies,*  
447 *comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted scientific*  
448 *practices?*  
449

450 Field studies conducted by EPA were appropriate under the evaluation criteria. The inability to find adult leopard  
451 frogs in the reference area for use in the FEL-conducted studies is puzzling. There is no clear explanation for the  
452 absence of adult leopard frogs in the reference area during the collection period. The collection may have been  
453 conducted inappropriately but there is no evidence that this was problematic during previous field work.  
454 Unfortunately the inability to find adult frogs casts substantial doubt on the usefulness of the FEL leopard frog  
455 toxicity studies, as noted below.  
456

457 To compensate for the absence of adult leopard frogs in the reference area, FEL purchased adult frogs from a  
458 commercial supplier. As a result, these adult frogs were used in lieu of true "reference area" frogs. One  
459 conclusion drawn from the FEL toxicity studies was that the high predominance of immature oocytes in female  
460 leopard frogs resulted from their exposure to tPCBs and TEQ in the PSA. However, information supplied by GE  
461 during the January 2004 public meetings suggest that EPA's finding of a predominance of immature oocytes in  
462 leopard frog females from the PSA may be due to low temperatures at the time of collection rather than as a  
463 result of exposure to tPCBs. In effect the female frogs in the PSA appear to have been collected at less than  
464 optimal temperatures. This suggests that the leopard frog field collection may have been conducted at a time  
465 when oocytes had not yet developed more fully.  
466

467 Therefore, site-specific leopard frog toxicity studies conducted by FEL were not based on accepted scientific  
468 practices. For example, adult frogs were not obtained from the reference area. Instead, adult frogs were  
469 purchased from a commercial supplier and utilized in the laboratory testing. Although this deviation from standard  
470 practice was detailed in the ERA, the results of this specific study are, in my estimation, only qualitative in nature.  
471 Direct comparisons between frogs obtained from the PSA and the reference area cannot be made since the  
472 commercially purchased frogs (in lieu of reference area frogs) were not exposed to the site-specific environmental  
473 conditions that would have been present in the reference area.  
474

475 The separation of the PSA into areas based on low, medium and high tPCB content in the sediments, appears to  
476 be appropriate. There appears to be a correlation, albeit weak, between the tPCB content in sediments and the  
477 whole body burden of tPCBs in frog tissues. In contrast, the FEL study showed a poor dose-response between  
478 tPCBs in sediments and the percentage of abnormal sperm in adult male leopard frogs. This lack of a dose-  
479 response is also evident from the FEL toxicity study where the percentage of stage VI oocytes in adult females at  
480 all sampling locations is significantly less than the reference. As noted previously, the adult female leopard frogs  
481 used in this toxicity test were purchased commercially and thus makes highly uncertain any comparisons and  
482 conclusions that might be drawn from this particular study.  
483

484 3.2.b *Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g.,*  
485 *field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated*  
486 *appropriately in the ERA?*  
487

488 The GE studies conducted on the leopard frog were appropriate under the evaluation criteria and were  
489 incorporated appropriately in the ERA. The leopard frog egg mass field survey conducted by GE failed to  
490 quantitatively evaluate the number of fertilized eggs within the egg masses; however, this oversight was  
491 discussed in the ERA and the conclusions that could be drawn from this qualitative evaluation were appropriate.  
492

493 The wood frog study conducted on behalf of GE by Dr. Resetarits was appropriate under the evaluation criteria  
494 and was incorporated appropriately in the ERA. The conclusions drawn from this study suggest that wood frog  
495 populations are density dependent which does not seem to be accounted for properly in the modeling projections.  
496 Because the results of the wood frog studies by FEL and GE are the most comprehensive and potentially the  
497 primary basis for estimating potential risks to amphibians, I recommend that EPA re-evaluate the Resetarits study  
498 as well as the modeling projections conducted for EPA.  
499

500 3.2.c *Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of*  
501 *analyses for the contaminants of concern (COCs) for each assessment appropriate?*

502  
503 The estimates of exposure were appropriate under the evaluation criteria, as was the refinement of analyses for  
504 the COCs.

505  
506 *3.2.d Were the effects metrics that were identified and used appropriate under the evaluation criteria?*  
507

508 The effects metrics were appropriate under the evaluation criteria. The large number (up to 11) of effects  
509 measurements provides substantial coverage of potentially problematic physiological and morphological impacts.  
510 Impacts that impair reproductive success are potentially more indicative of potential population level effects than  
511 those which may be construed as individual-level impacts (morphological abnormalities not associated with  
512 reproductive ability).

513  
514 *3.2.e Were the statistical techniques used clearly described, appropriate, and properly applied for the*  
515 *objectives of the analysis?*  
516

517 The statistical techniques were appropriate and properly applied for the objectives of the analysis.

518  
519 *3.2.f Was the characterization of risk supported by the available information, and was the characterization*  
520 *appropriate under the evaluation criteria?*  
521

522 The characterization of risk is not fully supported by the available information. The results of the leopard frog  
523 toxicity studies are suspect given the problems noted earlier. Field studies by EPA and GE suggest populations  
524 of leopard frogs are present in a number of pools within the PSA; however, whether those populations are  
525 numerically sub-optimal as a result of exposure to tPCBs and TEQ is not clear. In some instances it appears that  
526 habitat may be limiting factor for the presence of leopard frogs.

527  
528 The results of the FEL wood frog toxicity studies suggest potential impacts to metamorphs, but the case for these  
529 impacts to be ecologically significant is not well made. Further, it is not clear that these impacts are effective at  
530 the population level either.

531  
532 The wood frog field work conducted by EPA indicates low levels of DELTs (deformities, erosion, lesions, tumors)  
533 in wood frogs within the PSA and reference area. This supports the FEL wood frog toxicity results where  
534 morphological impacts to metamorphs were observed. However, there is no field evidence to support a conclusion  
535 that there is a significant impact to the wood frog population.

536  
537 *3.2.g Were the significant uncertainties in the analysis of the assessment endpoints identified and adequately*  
538 *addressed? If not, summarize what improvements could be made.*  
539

540 The uncertainties in the analysis of the amphibian assessment endpoint were identified clearly and adequately.

541  
542 *3.2.h Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be*  
543 *improved?*  
544

545 The WOE analysis was not fully objective, but was reasonable. As stated previously, there is a high degree of  
546 professional judgement in the WOE analysis which tends to increase the subjectivity. And, it is not altogether  
547 consistent either as applied across all 8 of the assessment endpoints.

548  
549 *3.2.i Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific*  
550 *studies were not conducted?*  
551

552 The risk estimates were derived objectively and appropriately for reaches of the river where site-specific studies  
553 were not conducted. However, as noted previously, the MATC for sediments in the PSA was not based on the  
554 most synoptic data and is therefore overly conservative. As the basis for estimating risks to other reaches of the  
555 river where studies were not conducted, then it may also be providing an overly conservative estimate.  
556

557 3.2.j *In the Panel members' opinion, based upon the information provided in the ERA, does the evaluation*  
558 *support the conclusions regarding risk to local populations of ecological receptors?*  
559

560 The conclusion of high risk to leopard frog populations is not fully supported by the information provided in the  
561 ERA. There are significant questions regarding the conduct of the FEL toxicity studies on the leopard frog, and  
562 the timing and conduct of observations in the field with respect to leopard frog egg masses.  
563

564 The conclusion of high risk to wood frog populations is partially supported by the information provided in the ERA.  
565 The FEL toxicity studies on the wood frog indicate potential morphological effects on young life stages from  
566 exposure to tPCBs and TEQ, yet these effects are not evident in any widespread nature from the field  
567 observations in the PSA (low levels of DELTs). In my opinion, the more defensible conclusion of risk to wood frog  
568 populations is that it is moderate, given the lack of concordance between the field and laboratory studies.  
569

### 570 3.3 Fish

571 3.3.a *Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies,*  
572 *comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted scientific*  
573 *practices?*  
574

575 The EPA field studies were appropriate under the evaluation criteria and were based on accepted scientific  
576 practices.  
577

578 The site-specific toxicity studies and comparison of exposure and effects were appropriate under the evaluation  
579 criteria and based on accepted scientific practices. However, there were problems noted in the egg injection  
580 studies where there was a high percentage of the eggs that became impaired due to the injection of the solvent  
581 control substance. This suggests that there were egg handling problems associated with this study, which  
582 increases the uncertainty associated with any conclusions drawn from this portion of the toxicological effort.  
583

584 3.3.b *Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g.,*  
585 *field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated*  
586 *appropriately in the ERA?*  
587

588 The GE field studies for largemouth bass were appropriate under the evaluation criteria, based on accepted  
589 scientific practices, and were incorporated appropriately in the ERA. The study design was specific to  
590 understanding potential habitat related influences on the population of largemouth bass residing in the PSA.  
591

592 3.3.c *Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of*  
593 *analyses for the contaminants of concern (COCs) for each assessment appropriate?*  
594

595 With one exception, the estimates of exposure were appropriate under the evaluation criteria, as was the  
596 refinement of analyses for COCs. The MATC for coldwater species, extrapolated from that of warmwater species,  
597 is not fully supported by the discussion in the ERA nor in subsequent responses from EPA and its contractors  
598 during the January 2004 public meeting. For example, there is little evidence to help determine whether or not  
599 the division of the warmwater MATC (49 mg/kg) by 4 is over or under protective. Thus the extrapolation of  
600 exposure and the derivation of an HQ based on a MATC divided by 4 is not objective nor consistent. It may be  
601 reasonable however.  
602

603 3.3.d *Were the effects metrics that were identified and used appropriate under the evaluation criteria?*  
604

605 The effects metrics used were appropriate under the evaluation criteria.  
606

607 3.3.e *Were the statistical techniques used clearly described, appropriate, and properly applied for the*  
608 *objectives of the analysis?*  
609

610 The statistical techniques were clearly described and appropriate.  
611  
612

613 3.3.f *Was the characterization of risk supported by the available information, and was the characterization*  
614 *appropriate under the evaluation criteria?*  
615

616 The characterization of risk is supported by the available information, and was appropriate. During the January  
617 2004 public meetings it was noted that substantial work on the presence of DELTs in local finfish populations had  
618 been conducted. This information was not readily evident in the ERA or the appendices and should be discussed  
619 more fully in the main text of the ERA.

620  
621 3.3.g *Were the significant uncertainties in the analysis of the assessment endpoints identified and adequately*  
622 *addressed? If not, summarize what improvements could be made.*  
623

624 The significant uncertainties in the analysis of the assessment endpoints were identified and, for the most part,  
625 adequately addressed. Improvement could be made by further discussion of the possibility that COCs other than  
626 tPCBs and TEQ could have caused some of the morphological abnormalities observed in the fish. For example,  
627 inorganic mercury is known to cause skeletal malformations in finfish yet this is not fully discussed in this section.

628  
629 3.3.h *Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be*  
630 *improved?*  
631

632 The weight of evidence analysis was appropriate under the evaluation criteria. It could be improved by giving  
633 more weight to the field investigations whether conducted by EPA or GE.

634  
635 3.3.i *Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific*  
636 *studies were not conducted?*  
637

638 In general the risk estimates were objectively and appropriately derived for reaches of the river where site-specific  
639 studies were not conducted. However, as mentioned earlier, there is uncertainty and some about the division of  
640 the warmwater MATC (49 mg/kg) by 4 for use in assessing potential risks to coldwater species downstream of the  
641 PSA.

642  
643 3.3.j *In the Panel members' opinion, based upon the information provided in the ERA, does the evaluation*  
644 *support the conclusions regarding risk to local populations of ecological receptors?*  
645

646 In my opinion, the evaluation supports the conclusions regarding low risk to local populations of finfish. The non-  
647 lethal, developmental abnormalities are noteworthy and potentially indicative of chronic, subtle effects that may or  
648 may not have ecological significance. These same developmental abnormalities do not appear to be reflected in  
649 the field observations, nor does the percentage of fish with DELTs appear to be increased above other areas that  
650 are not contaminated with tPCBs. Risk may be intermediate or higher for the fish, but the evidence from the field  
651 and laboratory studies is simply not concordant. See also (Barnhouse *et al.* 2003)  
652

### 653 3.4 Insectivorous Birds

654  
655 3.4.a *Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies,*  
656 *comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted scientific*  
657 *practices?*  
658

659 The EPA field study in the tree swallow was appropriate under the evaluation criteria, and based on accepted  
660 scientific practices. The modeling of exposure and effects was based on accepted scientific practices except that  
661 the exposure estimates for the American robin did not appear to follow methods described in EPA's Wildlife  
662 Exposure Factors Handbook.  
663

664  
665 The modeling of effects was reasonable given the lack of specific toxicological data on tree swallows or American  
666 robins exposed to tPCBs or TEQ.  
667

668 3.4.b *Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g.,*  
669 *field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated*  
670 *appropriately in the ERA?*

671  
672 The American robin study conducted by GE was appropriate under the evaluation criteria. This study was  
673 conducted for a single year and the number of nests available for inclusion through the period dropped  
674 significantly in the PSA and reference areas due to depredation, abandonment, or other factors not readily  
675 identifiable. This resulted in a study with low numbers of nests on which to base conclusions. Nevertheless, the  
676 results provided by the limited study were incorporated appropriately into the ERA.

677  
678 3.4.c *Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of*  
679 *analyses for the contaminants of concern (COCs) for each assessment appropriate?*

680  
681 The estimates of exposure may not be appropriate under the evaluation criteria due to the extensive use of  
682 modeling, and thereby the insertion of subjectivity into the assessment. In itself, the modeling work for exposure  
683 was reasonable. Site-specific information was available for the dietary intake of prey items by tree swallows, and  
684 EPA's Exposure Factors Handbook should be consulted to estimate exposure for American robins.

685  
686 3.4.d *Were the effects metrics that were identified and used appropriate under the evaluation criteria?*

687  
688 The effects metrics were identified and appropriate under the evaluation criteria. Both the EPA and GE studies  
689 evaluated effects on reproductive success of the tree swallow and the American robin. These metrics are difficult  
690 to evaluate but were done so in a reasonable and objective manner.

691  
692 3.4.e *Were the statistical techniques used clearly described, appropriate, and properly applied for the*  
693 *objectives of the analysis?*

694  
695 The statistical techniques were clearly described and appropriate.

696  
697 3.4.f *Was the characterization of risk supported by the available information, and was the characterization*  
698 *appropriate under the evaluation criteria?*

699  
700 The characterization of risk was supported by the available information and was appropriate under the evaluation  
701 criteria.

702  
703 3.4.g *Were the significant uncertainties in the analysis of the assessment endpoints identified and adequately*  
704 *addressed? If not, summarize what improvements could be made.*

705  
706 The significant uncertainties in the analysis of the assessment endpoints were identified and adequately  
707 addressed.

708  
709 3.4.h *Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be*  
710 *improved?*

711  
712 The weight of evidence analysis was not appropriate under the evaluation criteria. The modeled exposure and  
713 effects was given a weight of "moderate" which does not appear to be objective nor reasonable. Given that there  
714 were two field studies, one for tree swallows and one for American robins, the modeled exposure and effects  
715 should be given a "low" weighting in the analysis.

716  
717 3.4.i *Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific*  
718 *studies were not conducted?*

719  
720 The risk estimates were appropriately derived for reaches of the river where site-specific studies were not  
721 conducted.

722

723 3.4.j *In the Panel members' opinion, based upon the information provided in the ERA, does the evaluation*  
724 *support the conclusions regarding risk to local populations of ecological receptors?*  
725

726 The information provided in the ERA supports the conclusion of low risk to local populations of insectivorous  
727 birds. Despite the statement that the conclusion is uncertain due to the lack of concordance between the lines of  
728 evidence, the 3-yr tree swallow study appears to be significantly robust and clearly supportive of the conclusion.  
729 The modeled exposure and effects results are interesting, but should be given a lower weight than was done in  
730 the weight-of-evidence analysis. If there is any uncertainty with this overall conclusion, it appears to be quite low.

### 731 **3.5 Piscivorous Birds**

732  
733  
734 3.5.a *Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies,*  
735 *comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted scientific*  
736 *practices?*  
737

738 There were no field studies, or site-specific toxicity studies conducted by EPA for this assessment endpoint. The  
739 exposure and effects were all based on modeling. The fact that all the EPA-sponsored work was based on  
740 modeling has injected high uncertainty into the analysis.

741  
742 3.5.b *Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g.,*  
743 *field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated*  
744 *appropriately in the ERA?*  
745

746 The belted kingfisher study conducted by GE was appropriate under the evaluation criteria and represents the  
747 only field study conducted on this assessment endpoint. Unfortunately this study was conducted for only 1 year,  
748 the number of nests examined small, and no nests remaining in the examination were located in a reference area.  
749 Despite the small number of burrows (nests) that were evaluated for this study, the study was incorporated  
750 appropriately into the ERA. The belted kingfisher study was based on accepted scientific practices but could  
751 have been improved significantly by extending the duration and spatial scale. The loss of nests to depredation  
752 and other factors is unfortunate but does not warrant the exclusion of this study from the ERA.

753  
754 3.5.c *Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of*  
755 *analyses for the contaminants of concern (COCs) for each assessment appropriate?*  
756

757 The estimates of exposure were based solely on a modeling evaluation. These estimates are therefore highly  
758 uncertain and potentially problematic with respect to conclusions on risk. In this case however, the estimates are  
759 reasonable but not fully objective.

760  
761 3.5.d *Were the effects metrics that were identified and used appropriate under the evaluation criteria?*  
762

763 The effects metrics identified were appropriate under the evaluation criteria.

764  
765 3.5.e *Were the statistical techniques used clearly described, appropriate, and properly applied for the*  
766 *objectives of the analysis?*  
767

768 The statistical techniques were clearly described and appropriate for the objectives of the analysis.

769  
770 3.5.f *Was the characterization of risk supported by the available information, and was the characterization*  
771 *appropriate under the evaluation criteria?*  
772

773 The characterization of risk is dependent on the single, limited duration, limited scope field study in the belted  
774 kingfisher. The remainder of the information used to characterize risk stems directly from modeling efforts.  
775 Although there is great uncertainty in the conclusions drawn on risk, the characterization of risk is supported by  
776 the available information and was appropriate under the evaluation criteria.  
777

778 The modeled exposure and effects, given the weaknesses found in the belted kingfisher study, were given an  
779 appropriate weight in the characterization of risk.

780  
781 *3.5.g Were the significant uncertainties in the analysis of the assessment endpoints identified and adequately*  
782 *addressed? If not, summarize what improvements could be made.*

783  
784 There are significant uncertainties in the analysis of the assessment endpoints, particularly that of the osprey.  
785 The information supplied by GE during the January 2004 public meetings suggest that osprey are not found in the  
786 Housatonic River watershed, and, therefore, should not be used as a potential receptor in the ERA. This point  
787 does not seem to be covered adequately in the ERA and should be examined in view of the potential significance  
788 of a piscivorous bird receptor to the final risk management decision.

789  
790 *3.5.h Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be*  
791 *improved?*

792  
793 The weight of evidence analysis was appropriate under the evaluation criteria. As noted earlier, the field study  
794 provided a limited dataset and was weighted appropriately in this analysis. Thus the modeled exposure and  
795 effects assessment needed to receive a weighting of "moderate".

796  
797 *3.5.i Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific*  
798 *studies were not conducted?*

799  
800 The risk estimates were objectively and appropriately derived for reaches of the river where site-specific studies  
801 were not conducted.

802  
803 *3.5.j In the Panel members' opinion, based upon the information provided in the ERA, does the evaluation*  
804 *support the conclusions regarding risk to local populations of ecological receptors?*

805  
806 Based upon the information provided in the ERA, the evaluation supports the conclusion of low risk to local  
807 populations of belted kingfishers, and possibly other piscivorous birds. The conclusion of potentially high or  
808 moderate risk to osprey is supported by the modeling work, but is highly uncertain given the lack of field studies or  
809 biological survey data from the PSA on this species. In general the conclusions on risk drawn from the  
810 information in the ERA carry a high degree of uncertainty.

### 811 812 **3.6 Piscivorous Mammals**

813  
814 *3.6.a Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies,*  
815 *comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted scientific*  
816 *practices?*

817  
818 The EPA field studies for mink were appropriate under the evaluation criteria and based on accepted scientific  
819 practices.

820  
821 There is one area of potential concern regarding the mink feeding study and its acceptability under the evaluation  
822 criteria. It was mentioned at the January 2004 public meetings that kits which had died unexpectedly in the  
823 feeding study were not necropsied nor the cause of death determined. It is standard practice in long term studies,  
824 particularly where animals might die from natural causes and / or disease during long periods of confinement, to  
825 necropsy those animals which die unexpectedly and to the extent feasible, determine the cause of death. Without  
826 this approach significant uncertainty results in any conclusions regarding exposure to a toxicant and the  
827 survivability of the adults or offspring. Therefore, if EPA's contractor did not necropsy the animals which died  
828 unexpectedly, nor attempt to determine the cause of death, then the mink feeding study does not meet the  
829 evaluation criteria and is not based on accepted scientific practices.

830  
831 *3.6.b Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g.,*  
832 *field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated*  
833 *appropriately in the ERA?*

834  
835 The GE field study in mink was appropriate under the evaluation criteria, based on accepted scientific practices,  
836 and was incorporated appropriately into the ERA. There is one area of concern regarding this statement. Under  
837 questioning during the January 2004 public meetings it was revealed that standard practices for implementing  
838 scent posts for mink or other mammals may not have been followed consistently. For example, the ERA  
839 speculated that the lack of sightings at GE-implemented scent posts may have resulted from the posts being  
840 compromised by human contact (scent). To offset the potential for compromising the posts, field crews are  
841 generally instructed to wear rubber gloves and rubber boots. It appears that those who conducted the scent post  
842 studies for GE did not wear rubber gloves consistently during the studies. Whether this or another factor resulted  
843 in the “low” numbers of individual mink visiting the posts is unknown. If it is determined that there were numerous  
844 infractions with regards to the implementation of the scent posts by GE’s contractors, then the mink field study  
845 would not meet the evaluation criteria.

846  
847 *3.6.c Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of*  
848 *analyses for the contaminants of concern (COCs) for each assessment appropriate?*

849  
850 The estimates of exposure were appropriate under the evaluation criteria. As noted previously, it is important to  
851 provide and discuss all chemicals detected in fish tissues particularly since these substances become the basis  
852 for exposure evaluations in the mink feeding studies, and ultimately in the risk designation. The datasets for the  
853 fish used in the feeding studies appear to have been truncated and / or summarized so that only tPCBs and TEQ  
854 were reported. This is not appropriate under the evaluation criteria and should be rectified by including the  
855 specific information on fish tissues in the main text of the ERA.

856  
857 *3.6.d Were the effects metrics that were identified and used appropriate under the evaluation criteria?*

858  
859 The effects metrics were reasonable and consistent, but were not objective. For one, there is no evidence to  
860 conclude that the numbers of mink or otter found in the PSA are depressed or linked quantitatively to the levels of  
861 tPCBs or TEQ in soils, sediments, surface water or biological tissues (fish or prey items). Thus to suggest there  
862 is a cause and effect is not objective. Second, the feeding study in mink appears to have overstated the  
863 significance of the jaw lesions found in kits. While EPA argues that the lesion is potentially indicative of a pre-  
864 neoplastic process, there is no evidence presented to support this finding in kits allowed to reach adulthood. In  
865 fact, none of the kits appear to have been kept to an age sufficient to determine conclusively whether the jaw  
866 lesions lead to a malignant, potentially metastatic tumor or not. Relatedly, there is substantial speculation  
867 provided in the ERA indicating that those kits suffering from the jaw lesion may, over time, starve to death, and  
868 this too was suggested as a reason why the numbers of adult mink in the PSA appeared to be “low”. Again,  
869 there are no data presented to support this finding in feral mink, since it does not appear that any adult feral mink  
870 were trapped or examined in the PSA. In the absence of such site-specific, confirmatory information, any  
871 conclusion regarding the jaw lesion leading to starvation and causing depression of the resident mink population  
872 in the Housatonic River watershed is purely speculative.

873  
874 There is some debate as to the significance of the measurements conducted during the mink feeding study. On  
875 the one hand, the reproductive successes of the adult females do not appear to have been compromised from  
876 exposure to HR fish containing tPCBs and TEQ. Yet, kits born to the females did show a slight, but evident  
877 depression of body weight at 3 wks of age, and more significant depression in survival rate at 6 mos of age.  
878 While there are less than convincing data regarding impacts to reproductive health in the adult females, these  
879 results in the kits are of concern and were identified clearly in the ERA. I have identified another concern with  
880 the survival data discussed more fully in my later comments. This comment on the kit survival at 6 mos is  
881 germane to assessing whether the mink feeding study was conducted under the best of scientific practices.

882  
883 *3.6.e Were the statistical techniques used clearly described, appropriate, and properly applied for the*  
884 *objectives of the analysis?*

885  
886 The statistical techniques were clearly described and appropriate.

887  
888 *3.6.f Was the characterization of risk supported by the available information, and was the characterization*  
889 *appropriate under the evaluation criteria?*



890  
891 The characterization of risk was not fully supported by the available information. In my opinion, the ERA is highly  
892 speculative with respect to the field observations and the reason for there being apparently “low” numbers of adult  
893 mink in the PSA. Finding and quantitatively documenting adult mink in the PSA and the watershed is a very  
894 difficult undertaking and the ability to conduct such a study is as dependent on proper implementation of field  
895 protocols as it is on a myriad of other confounding influences (weather, flood stage, food sources, human  
896 interferences, season, etc.) Second, I have concerns about the discussion rendered for the jaw lesions, their  
897 etiology, and their potential for impacts on populations of mink exposed to tPCBs in the Housatonic River  
898 watershed.

899  
900 The feeding studies provide the largest set of evidence of potential harm to kits and it is those data which appear  
901 to be the most appropriate under the evaluation criteria. Similar to results from the other assessment endpoints,  
902 there is a lack of strong concordance between the field and laboratory studies. Comments were provided by GE  
903 suggesting that the mortality of kits at 6 mos of age could be a result of causes other than exposure to tPCBs and  
904 TEQ. It appears that kits which died unexpectedly in the study were not necropsied to determine the cause of  
905 death. This is a legitimate point and should be given serious consideration in the revision to the ERA. It is  
906 standard practice in long term studies to determine the cause of death in any animal that dies unexpectedly  
907 during the treatment. Without this standard practice the many 2-yr carcinogenicity bioassays in rats would be of  
908 little value to assessing the carcinogenic potential of a substance. This is also true for the mink feeding studies  
909 and appears to be a serious oversight of the EPA contractors. If, on the other hand, the kits were necropsied and  
910 the cause of death ascertained, then that information is crucial to resolving the point raised by GE.

911  
912 *3.6.g Were the significant uncertainties in the analysis of the assessment endpoints identified and adequately*  
913 *addressed? If not, summarize what improvements could be made.*

914  
915 The significant uncertainties in the analysis of the assessment endpoints were identified and adequately  
916 addressed.

917  
918 *3.6.h Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be*  
919 *improved?*

920  
921 The weight of evidence analysis was appropriate under the evaluation criteria. As noted earlier, the speculation in  
922 the ERA on jaw lesions / starvation being the cause of “low” numbers of adult mink in the PSA should be excised.

923  
924 *3.6.i Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific*  
925 *studies were not conducted?*

926  
927 The risk estimates were objectively and appropriately derived for reaches of the river where site-specific studies  
928 were not conducted.

929  
930 *3.6.j In the Panel members’ opinion, based upon the information provided in the ERA, does the evaluation*  
931 *support the conclusions regarding risk to local populations of ecological receptors?*

932  
933 In my opinion, the information provided in the ERA and the evaluation thereof generally support the conclusions  
934 regarding intermediate risk to local populations of mink. The feeding studies are not without problems, but are the  
935 most robust of the data evaluated that suggest the potential for high risk to kits. I temper this statement with my  
936 concerns on whether the kits that died unexpectedly were necropsied and the cause of death determined. On this  
937 point, the EPA should give serious consideration to re-examining any archived whole bodies or organs from the  
938 kits that died unexpectedly. Further, as noted in the ERA, there was no definitive dose-response between kit  
939 survival and tPCB content of the fish, which further clouds the conclusion that might be drawn from the study.  
940 Even so, results from other mink feeding studies in the Great Lakes have clearly demonstrated potentially harmful  
941 effects in mink which cannot be overlooked in the context of mink consuming tPCB-contaminated fish within the  
942 Housatonic River watershed. However, the magnitude of the risk to mink posed by exposure to contaminated  
943 fish in the watershed appears to be less than that reported from studies in the Great Lakes and elsewhere. This  
944 also supports the categorization of risk to mink as intermediate.

945

946 **3.7 Omnivorous and Carnivorous Mammals**

947  
948 3.7.a *Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies,*  
949 *comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted*  
950 *scientific practices?*

951 The EPA field studies were performed appropriately under the evaluation criteria and based on accepted scientific  
952 practices. There were no site-specific toxicity studies conducted for this assessment endpoint.

953  
954 I do not believe the estimate of effects for red fox was appropriate under the evaluation criteria. The toxicity  
955 reference value used for the comparison of exposure and effects was based on rodent data. Rodents are  
956 physiologically, substantially dissimilar from red fox. This makes any comparison highly uncertain and, in my  
957 opinion, not useful in the context of this ERA.

958  
959 3.7.b *Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g.,*  
960 *field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated*  
961 *appropriately in the ERA?*

962  
963 The Boonstra study conducted in small mammals was appropriate under the evaluation criteria, but was not  
964 without design problems. The study duration was limited and there does not appear to be any reference areas  
965 evaluated in this study design. Thus it may not have been based on accepted scientific practices. Nevertheless,  
966 the study was incorporated appropriately into the ERA.

967  
968 3.7.c *Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of*  
969 *analyses for the contaminants of concern (COCs) for each assessment appropriate?*

970  
971 The estimates of exposure were appropriate under the evaluation criteria.

972  
973 3.7.d *Were the effects metrics that were identified and used appropriate under the evaluation criteria?*

974  
975 The effects metrics were appropriate under the evaluation criteria. However, the use of rodent data to estimate  
976 potential effects in the red fox is not, in my opinion, scientifically defensible.

977  
978 3.7.e *Were the statistical techniques used clearly described, appropriate, and properly applied for the*  
979 *objectives of the analysis?*

980  
981 The statistical techniques were not clearly described, nor based on the January 2004 public meetings, applied  
982 properly for the objectives of the analysis. The debate between EPA and GE concerning the proper statistical  
983 evaluation of the Boonstra study leaves the reader and this panel member confused and frustrated. I have  
984 recommended that EPA and GE settle on one mutually agreeable approach and use it in the ERA.

985  
986 3.7.f *Was the characterization of risk supported by the available information, and was the characterization*  
987 *appropriate under the evaluation criteria?*

988  
989 The characterization of risk to small mammals is supported by the available information and appropriate under the  
990 evaluation criteria. However, the assignment of risk may change if the statistical analysis can be conducted to the  
991 mutual agreement of EPA and GE. Until that time, there will continue to be some concern as to whether the  
992 characterization of risk to small mammals is overly conservative or not.

993  
994 The characterization of risk to red fox is not supported by the available information nor appropriate under the  
995 evaluation criteria. The modeled effects are based entirely on a comparison to rodent data which is not  
996 scientifically defensible in my opinion. I therefore recommend that the red fox assessment endpoint be deleted  
997 from the ERA evaluation. It provides little useful information, and will likely have no influence on the risk  
998 management decision.

999  
1000

1001 3.7.g *Were the significant uncertainties in the analysis of the assessment endpoints identified and adequately*  
1002 *addressed? If not, summarize what improvements could be made.*

1003  
1004 The significant uncertainties in the analysis of the small mammal assessment endpoint were identified and  
1005 adequately addressed. I do not believe the significant uncertainty in the assessment of the red fox was clearly  
1006 identified nor adequately addressed in the ERA. The assessment for the red fox could be improved by reviewing  
1007 data on dogs or other canines exposed to tPCBs or TEQ. This was not done nor the possibility of needing to do  
1008 so discussed in the ERA.

1009  
1010 3.7.h *Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be*  
1011 *improved?*

1012  
1013 The weight of evidence analysis for small mammals was appropriate under the evaluation criteria. Because of the  
1014 problems associated with the exposure and effects assessment for the red fox, the weight of evidence analysis for  
1015 the red fox should be separated from that of the shrew, and, even better, deleted from the ERA.

1016  
1017 3.7.i *Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific*  
1018 *studies were not conducted?*

1019  
1020 The risk estimates were appropriately derived for reaches of the river where site-specific studies were not  
1021 conducted.

1022  
1023 3.7.j *In the Panel members' opinion, based upon the information provided in the ERA, does the evaluation*  
1024 *support the conclusions regarding risk to local populations of ecological receptors?*

1025  
1026 The evaluation supports the conclusions regarding intermediate risk to small mammals, although pending the  
1027 outcome of a singular, mutually agreeable statistical approach, there could be some modification to this  
1028 designation.

1029  
1030 The evaluation does not support the conclusions regarding intermediate risk to red fox. The evaluation of effects  
1031 was not appropriate under the evaluation criteria and, in my opinion, was not scientifically defensible. The  
1032 conclusions are insupportable currently and I recommend that the red fox assessment endpoint be deleted from  
1033 the ERA.

### 1034 1035 **3.8 Endangered Species**

1036  
1037 3.8.a *Were the EPA studies and analyses performed (e.g., field studies, site-specific toxicity studies,*  
1038 *comparison of exposure and effects) appropriate under the evaluation criteria, and based on accepted scientific*  
1039 *practices?*

1040  
1041 There were no site-specific toxicity studies and very limited field studies conducted by EPA. The limited field  
1042 studies (playback calls, anabat study, eagle surveys) were appropriate under the evaluation criteria and based on  
1043 accepted scientific practices. As noted in the ERA however, these field evaluations were not designed to be  
1044 quantitative and therefore were not included in the weight-of-evidence evaluation of risk.

1045  
1046 The comparison of exposure and effects was based entirely on modeled information which inserts a high degree  
1047 of uncertainty in the analysis.

1048  
1049 The use of stomach contents from the tree swallow study to estimate tPCB exposure to the small footed myotis  
1050 presents a high degree of uncertainty in this portion of the analysis. Estimates of exposure for the bald eagle are  
1051 based on prey (fish, waterfowl, small mammals) data collected from the PSA. Estimates of exposure for the  
1052 American bittern are based on prey (amphibians, insects, crawfish) data collected from the PSA. In this regard,  
1053 the estimates of exposure for the bald eagle and the American bittern are appropriate under the evaluation  
1054 criteria.

1055

1056 3.8.b *Were the GE studies and analyses performed outside of the framework of the ERA and EPA review (e.g.,*  
1057 *field studies) appropriate under the evaluation criteria, based on accepted scientific practices, and incorporated*  
1058 *appropriately in the ERA?*

1059  
1060 There were no GE studies conducted for this assessment endpoint.

1061  
1062 3.8.c *Were the estimates of exposure appropriate under the evaluation criteria, and was the refinement of*  
1063 *analyses for the contaminants of concern (COCs) for each assessment appropriate?*

1064  
1065 Estimates of exposure were heavily based on modeling although site-specific prey item data were utilized in the  
1066 assessment.

1067  
1068 The use of stomach contents from the tree swallow to represent potential exposure to tPCBs from prey insects  
1069 consumed by the small footed myotis inserts a high degree of uncertainty into the exposure estimates. The tPCB  
1070 analysis of the insects represents the only site-specific exposure information available to make this estimate, yet it  
1071 is uncertain whether small footed myotis consume the same insects as found in tree swallows. The exposure  
1072 assessment for the small footed myotis was appropriate under the evaluation criteria.

1073  
1074 The use of site-specific fish, waterfowl and small mammal tissue tPCB and TEQ content was appropriate for the  
1075 estimate of exposure, via diet, to the bald eagle. The statistical treatment of these exposure data is complex and  
1076 not all together well understood. After re-reading both the main text of the ERA and Appendix K there is still a  
1077 high degree of confusion as to the strengths and weaknesses of the statistical treatment (Land H-statistic). I  
1078 recommend that the authors of the ERA revisit the statistical discussion to determine if there are ways that the  
1079 description can be simplified. The exposure assessment for the bald eagle was appropriate under the evaluation  
1080 criteria.

1081  
1082 The use of site-specific tPCB, TEQ from amphibians, benthic insects and crawfish was appropriate for estimating  
1083 exposure in prey items for the American bittern. The exposure assessment for the American bittern was  
1084 appropriate under the evaluation criteria.

1085  
1086 3.8.d *Were the effects metrics that were identified and used appropriate under the evaluation criteria?*

1087  
1088 The effects metrics generally were appropriate under the evaluation criteria. However, the primary basis for  
1089 determining effects to bald eagle and American bitterns was based on literature-based studies in domestic  
1090 species (chickens, pheasants), kestrels, herons or similar species. The relative sensitivity of bald eagles and  
1091 American bittern compared to the species tested in toxicological evaluations is not known, but is likely to be lower  
1092 than those evaluated in these laboratory studies. The effects metrics for the bald eagle and the American bittern  
1093 were appropriate under the evaluation criteria.

1094  
1095 In the case of the small footed myotis, toxicological evaluations were available for the big brown bat and little  
1096 brown bat. These species are likely to be relatively close in physiology, metabolism and perhaps sensitivity to  
1097 organochlorine chemicals as the small footed myotis. The effects metrics for the small footed myotis were  
1098 appropriate under the evaluation criteria.

1099  
1100 3.8.e *Were the statistical techniques used clearly described, appropriate, and properly applied for the*  
1101 *objectives of the analysis?*

1102  
1103 The statistical techniques were clearly described, appropriate and properly applied for the objectives of the  
1104 analysis.

1105  
1106 3.8.f *Was the characterization of risk supported by the available information, and was the characterization*  
1107 *appropriate under the evaluation criteria?*

1108  
1109 The characterization of risk was not fully supported by the available information, and carries a high degree of  
1110 uncertainty due to the characterization relying entirely on modeling. American bittern are known to inhabit the  
1111 PSA according to the ERA, and bald eagles are known to nest in the Housatonic River watershed downstream of

1112 the PSA in Connecticut. It is also known that the bald eagle has attempted to nest in the PSA; however, whether  
1113 this was successful or failed is not clearly articulated in the ERA. Further, if the nesting attempts failed, there is  
1114 no discussion as to whether this resulted from exposure to tPCBs or TEQ in the watershed.

1115  
1116 There is evidence that 2 of the 3 T&E species under consideration are found in the watershed and appear to be  
1117 either utilizing the area and / or nesting there. In contrast to the modeled exposure and effects evaluations, the  
1118 limited survey data appear to indicate that these two species are not significantly impacted by the tPCBs or TEQ.

1119  
1120 *3.8.g Were the significant uncertainties in the analysis of the assessment endpoints identified and adequately*  
1121 *addressed? If not, summarize what improvements could be made.*

1122  
1123 The uncertainties in the analysis of the assessment endpoints were clearly identified and adequately addressed.  
1124 As noted earlier the fact that the entire exposure and effects assessment were based on modeling inserts a high  
1125 degree of uncertainty into the analysis.

1126  
1127 *3.8.h Was the weight of evidence analysis appropriate under the evaluation criteria? If not, how could it be*  
1128 *improved?*

1129  
1130 The weight of evidence analysis was not fully appropriate under the evaluation criteria. One concern is the fact  
1131 that the site-specific biological surveys were excluded from this analysis. This does not appear to be objective,  
1132 reasonable or consistent with evaluations for other receptors.

1133  
1134 The reason given in Appendix K for not including this survey information is that the studies were not quantitative  
1135 in nature; however, given the significance of the risk question at hand it is important that all available information  
1136 be considered to the maximum extent possible. These are the only site-specific data which can be useful in  
1137 evaluating the potential for risk. The presence of the T&E species in the PSA and the Housatonic River watershed  
1138 is crucial to understanding whether the tPCBs and TEQ exposure may be problematic. If the T&E species are  
1139 found to inhabit the PSA, or use it for feeding, resting, etc. then there is some evidence that the exposures to  
1140 tPCBs and TEQ are not sufficiently problematic as to impair the utilization of the area by these important species.

1141  
1142 *3.8.i Were the risk estimates objectively and appropriately derived for reaches of the river where site-specific*  
1143 *studies were not conducted?*

1144  
1145 The risk estimates were appropriate for reaches of the river where site-specific studies were not conducted.

1146  
1147 *3.8.j In the Panel members' opinion, based upon the information provided in the ERA, does the evaluation*  
1148 *support the conclusions regarding risk to local populations of ecological receptors?*

1149  
1150 The information provided in the ERA generally supports the conclusions regarding moderate, but not high risk to  
1151 T&E species.

1152  
1153 *4 Are the summary discussions and conclusions in the ERA supported by the information provided in the report,*  
1154 *and did the conclusions describe the risks in an objective, reasonable, and appropriate manner?*

1155  
1156 The summary discussions and conclusions in the ERA are supported by the information in the report. Other than  
1157 those specific areas identified in my previous comments, the conclusions described the risks in an appropriate  
1158 manner. There were instances, identified above, where the risks were, in my opinion, not described in an  
1159 objective nor reasonable manner.

1160  
1161 *5 To the best of the Panel's knowledge, is there other pertinent information available that was not considered in*  
1162 *the ERA? If so, identify the studies or data that could have been considered, the relevance of such studies or*  
1163 *data, and how they could have been used in the ERA.*

1164  
1165 In my recommendations and comments above I have identified pertinent information that was not discussed nor  
1166 presented in detail. It is important that these data be discussed or included in the main text of the ERA or in the  
1167 Appendices.

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### Detailed Comments on the ERA

P 3-72: Please consider providing a fuller explanation for the following statements found in the paragraph from page 3-72, Vol 1 of the ERA.

*A discussion of attributes considered in the WOE is provided in Section 2, and the rationales for weighting of measurement endpoints are provided in Appendix D. A summary of the derived weightings for each attribute is provided in Table 3.4-1. The chemistry endpoints yielded the lowest overall values because of lower site-specificity and some uncertainties in the biological association between the measurement endpoints and the assessment endpoint(s). The toxicity testing endpoints yielded the highest overall values, because of the high degree of biological relevance of the tests. The benthic community structure endpoints had intermediate values. Although these endpoints were site-specific, collected at a time when effects would be expected, and were measures of the community structure component of the assessment endpoint, the potential for the confounding effects of other factors in the direct attribution of the response to the stressor reduced the utility of these endpoints to some degree.*

P3-75, Table 3-4.2: Despite the widespread use of the WOE process, it would be useful to more fully explain how the finding of a chemical in a medium can be evidence of harm or impact when there have been no measures of biological response. This may be more an issue of semantics than of substance.

C1 – concentration in the water column

C2- concentration in the sediment

P 3-78. How does an LC50 or EC50 indicate an ecologically significant response ? These values are generally relevant to acute toxic responses but those are not equivalent to ecologically significant responses. Unless these apply to ecologically relevant endpoints such as reproduction, then it is inaccurate to suggest they have an ecological relevance.

*Above a concentration of 3 mg/kg tPCB, numerous endpoints indicated ecologically significant responses, with many LC50/EC50 values falling in this range.*

P 3-79. As noted in an earlier comment, the designation of a risk being “unacceptable” is not a question answered by an ERA. It is a risk management decision as to whether the finding of a risk is unacceptable. At best the ERA is charged with evaluating the risks, quantifying them if possible, and indicating the sources of those risks.

*Unacceptable risks are predicted for the majority of sediment sampled within Reach 5A.*

Section 4: Amphibians. As a general comment on this section, I suggest the authors of the ERA consult the recently published book “*Amphibian Decline: An intergrated analysis of multiple stressor effects*”. Linder, G., Krest, S.K. and Sparling, D.W. (eds) 2003, SETAC Press, Pensacola, FL. I believe it will help in the interpretation of both the leopard and wood frog data sets.

P 4-34. Please explain how conclusions can be drawn that implicate the presence of PCBs in soils / sediments as related to presence or absence of leopard frogs in the contaminated areas when no leopard frogs were found in the reference locations.

#### **4.4.1.2.1 Leopard Frog Study**

**Reproductive Fitness:** *Adult male and female leopard frogs (and some juveniles of both sexes) were collected from the nine contaminated sampling areas in the PSA and transported to Fort Environmental Laboratories, Inc. (FEL). No leopard frogs were collected at the three reference areas; therefore, control animals purchased from a commercial supplier (Carolina Biological Supply, CBS) were used. These frogs were collected in Vermont directly upon order, shipped to CBS, and then forwarded to FEL (formerly part of The Stover Group).*

1224 P 4-36, Figures 4.4-1, 4.4-2. These figures would, without benefit of the initial text on the leopard frog  
1225 study, lead the reader to believe that adult frogs were obtained from the “reference areas”. These figures  
1226 are misleading in that respect and a notation should be added to them to remind the reader that no adult  
1227 frogs were collected from the reference areas.  
1228

1229 P 4-36, Figure 4.4-2. The percentage of mature Stage IV oocytes in adult female frogs from the so-called  
1230 “reference area” seems to indicate a particularly striking impact on oocyte maturation at very low PCB  
1231 concentrations as indicated by the vertical axis. Even in areas with extremely low but measurable levels  
1232 of PCBs in the sediments, there are few if any mature stage IV oocytes. What is the basis for the last  
1233 sentence in the paragraph below when there is no correlation between sediment PCB concentration and  
1234 depression of mature Stage IV oocytes ?  
1235

1236 *Few of the PSA sites produced female specimens that possessed any biologically*  
1237 *significant quantity of Stage VI oocytes (mature eggs capable of fertilization), with*  
1238 *the exception of Station W-7a (Figure 4.4-2). Immature oocytes (< Stage III) were*  
1239 *observed in mature female specimens collected from all PSA sampling areas,*  
1240 *however developing oocytes were found in specimens from Sites W-7a, W-4, EW-3,*  
1241 *and W-1 (18.0, 0.5, 30.0, and 0.2 mg/kg sediment tPCBs, respectively). Therefore,*  
1242 *the lack of success in artificially fertilizing oocytes from contaminated site specimens*  
1243 *was not surprising, and appeared to be the primary limiting factor in the reproductive*  
1244 *dysfunction observed in the contaminated site specimens evaluated from the PSA.*  
1245

1246 P 4-37. Similar to comments noted above for P 4-36, please clarify, what adult male frogs are being  
1247 referenced in Table 4.4-1 with regards to sperm head abnormalities. Based on the description in the text  
1248 of this table, the “reference area” frogs were in fact purchased from Carolina Biological Supply and did not  
1249 originate from the Housatonic River watershed.  
1250

1251 P 4-44. Please clarify the statements below concerning conclusions of the leopard frog study. At the  
1252 station (E-1) with the highest level of tPCBs in the sediment (E-1, 160 mg/kg), the mean percent  
1253 abnormal sperm head was 14.3. Even with the data manipulations (spatial weighting for sediments), and  
1254 the presence of tPCBs in the water column, there would appear to be a very high uncertainty associated  
1255 with the conclusions detailed in the text box. There appears to be an absence of a concentration  
1256 response for both the male and female data, further complicated by the inability to judge the findings  
1257 against reference areas since no adult male or female frogs were found in them.  
1258

1259 *male and female adult frogs showed signs of reproductive stress, with the females showing more severe*  
1260 *effects. Males exhibited a high incidence of malformed sperm in the higher-sediment tPCB sites (up to*  
1261 *50%). Females had virtually no mature eggs (Stage VI, which the eggs must reach in order for fertilization*  
1262 *to occur). Incidences of immature oocytes (Stage III or smaller) were high in the sites with high*  
1263 *concentrations of sediment tPCB (up to 99% Stage III).*  
1264

1265 P 4-46. Table 4-45. It is difficult to determine the basis for the “n” in this table. Please clarify what it  
1266 represents. For example, does each “n” represent an individual frog assessed for the various endpoints  
1267 over time, or different frogs collected over time for the specific endpoint measured, or something else all  
1268 together. This is not clear.  
1269

1270 P 4-67. Table 4-5-1. It is difficult to recall the literature based toxicity thresholds (1 and 10 mg/kg) while  
1271 reviewing this table. It would be helpful for the reader if the toxicity threshold were noted either in the title  
1272 of the table, on the table, or in a footnote to the table. More specifically, it would be important to clearly  
1273 identify which of the thresholds was used in the comparison.  
1274

1275 P 4-78. Please add units to the PCB concentrations cited in the paragraph below.  
1276

1277 *The Phase III wood frog metamorph results for the Housatonic sampling exhibited a range of sex ratios.*  
1278 *Sediment in the two most contaminated vernal pools (38-VP-1 and 38-VP-2) contained PCB*  
1279 *concentrations of 28.5 and 32.3 PCBs based on spatial weighting of sediment data.*

1280  
1281 P 4-78. The term “feminization” is used incorrectly in the paragraph below. Typically it refers to the  
1282 alteration in males whereby morphologically or in their behavior they are essentially female. It does not  
1283 mean a change in the sex ratio of a feral population of organisms. If there are morphological or behavioral  
1284 changes in the frogs studied, it is not made clear in the text.

1285  
1286 *The Housatonic River vernal pool sex ratio data for wood frog metamorphs and breeding adults exhibit*  
1287 *strong differences from Berven’s data at a non-contaminated site. The general trend for the wood frogs*  
1288 *examined near the Housatonic River PSA is a marked decrease in the male to female ratio in both*  
1289 *metamorphs and breeding adults. This feminization of the wood frogs in this study may be adversely*  
1290 *impacting the local population.*

1291  
1292 P 4-82. Given that no adult leopard frogs were found in the “reference areas”, and the range of PCB  
1293 concentrations in sediments was not strongly correlated with some of the endpoints measured, how is the  
1294 statement below fully supported by these highly variable results ? There may be validity to the statement  
1295 with respect to the wood frog, but this would not appear to be fully supported by the leopard frog results.

1296  
1297 *ERA findings suggest that amphibian populations are impacted throughout much of the PSA, with leopard*  
1298 *frogs impacted at a wide range of sediment concentrations (likely due to the life history of contact with*  
1299 *sediment PCB concentrations, which were not measured in the study), and with stronger responses from*  
1300 *wood frogs expected in the more highly contaminated vernal pools. The indications of community*  
1301 *responses from the population studies (i.e., localized depressions of richness and abundance near high*  
1302 *tPCB vernal pools, and high incidence of malformations observed) substantiate these findings.*

1303  
1304 P 5-17. Please explain the scientific reasoning for the statements below. Although I have not read the  
1305 cited paper, it is difficult to understand how benzo(g,h,i)perylene could be as metabolically active in fish  
1306 as pyrene for example. Thus the statement that PAHs appear to be rapidly metabolized and therefore  
1307 fish tissues were not analyzed for these constituents would seem to be a substantial oversimplification of  
1308 the issue.

1309  
1310 **5.2.3 Sediment Chemistry Assessment (Exposure to PAHs)**  
1311 *There were no data on fish tissue concentrations in the PSA for the eight individual PAHs retained as*  
1312 *COCs for fish, or for total PAHs because PAHs are readily metabolized by most aquatic biota, including*  
1313 *fish (Johnson 2000). Exposure for these contaminants was therefore assessed based on sediment*  
1314 *concentrations only.*

1315  
1316 P 5-19. Please explain what percentage of the samples collected for Table 5-24 were actually a  
1317 calculated concentration stemming from the use of the detection limit (DL) rather than an actual analytical  
1318 tissue concentration.

1319  
1320 P 5-20. For Table 5-25 please explain the basis for the differences in the number of sediment samples  
1321 collected for PAH analysis among the various reaches. It is not clear from the text or the table why there  
1322 is such a large difference.

1323  
1324 P 5-32. What “extracts” are referred to in the statements below ? Water, sediment, other ? The  
1325 reference to “extracts” occurs several times in this section and in the following pages, yet there is no  
1326 specification as to what extract was tested. Please clarify.

1327  
1328 *survival was also observed in medaka exposed to Housatonic River extracts. Between 3 and 15 days*  
1329 *post swim-up, medaka exposed to extracts from Reach 5BC and Reach 6 exhibited statistically significant*  
1330 *reductions in survival relative to control fry. Survival was not affected in largemouth bass and rainbow*  
1331 *trout exposed to Housatonic River extracts.*

1332  
1333 P 5-33. Please discuss how the influence of handling the eggs and the potential synergistic effects of  
1334 damaging the physical integrity of the egg (via injection) is not also one of the potential confounding  
1335 influences on the outcome of these studies ? It is generally the case, in my experience, that rainbow trout



1336 and medaka eggs, while appearing to be hardy during laboratory manipulation, are in fact quite sensitive  
1337 to physical trauma as well as that associated with exposure to toxic substances (and to direct light in  
1338 some cases). Often this sensitivity is not evidenced until several days or weeks after fertilization and  
1339 handling. Dr. Tillett, in his personal communication with the authors of the ERA, is no doubt aware of this  
1340 and may have shed light on it, but this is not noted in this particular section. This is, in my opinion, shown  
1341 clearly in Figure 5.3-3 where the incidence of deformities in uninjected eggs and those injected with  
1342 triolein. Please explain.  
1343

1344 *Overall, medaka at 15 days post swim-up exhibited the lowest LD50s, relative to other species, for all*  
1345 *extracts and standards, with the exception of TCDD. The overall results (i.e., order of magnitude*  
1346 *difference in TEQ-based LD50s between site extracts and standards) appears to indicate that the*  
1347 *Housatonic River extracts are more toxic than would be predicted on the basis of an additive model of*  
1348 *dioxin-like toxicity alone. The increased toxicity observed with the Housatonic River extracts could be*  
1349 *attributed to synergistic effects of PCB mixtures and effects of other PCBs in the mixture that are not*  
1350 *considered using the TEQ approach (Tillitt, personal communication 2003).*

1351  
1352 P 5-34. One could argue that these were not exposures “in ovo” per se, but most specifically exposure  
1353 via injection. In ovo would connote exposure of the entire egg to the substance of concern in an  
1354 aqueous exposure scenario, without penetration of the egg membrane. Based on the description in the  
1355 text, the latter was not done. I understand the purpose of these experiments but I take issue with the use  
1356 of the terminology “in ovo”.  
1357

1358 *Fish exposed in ovo to high doses of Housatonic River extracts exhibited similar types of gross*  
1359 *pathologies as the dioxin-like standards, including craniofacial deformities, fin deformities, spinal*  
1360 *deformities, swim bladder deformities, hemorrhage, pericardial edema, peritoneal edema, .....*  
1361

1362 P 5-34. One could argue that another interpretation of the lack of a dose response, and that similar  
1363 deformities were observed in fish when eggs were injected with the “extracts” from the PSA and reference  
1364 areas, as well as the control, is that the experimental design was inappropriate. Please explain.  
1365

1366 *Some of the deformities observed in fish were only weakly related to tPCB or TEQ*  
1367 *concentrations for one species/life stage/treatment combination. The lack of a dose-response in fish*  
1368 *injected with Housatonic River extracts and/or PCB and TCDD standards and the occurrence of these*  
1369 *deformities in fish injected with control and reference site extracts indicates that these abnormalities are*  
1370 *not the most reliable markers of PCB exposure.*  
1371

1372 P 5-38. The discussion of the cytochrome P450 studies appears to be overly simplified and not  
1373 particularly informative. I am at a loss to understand what exactly is meant by “tissues”(liver ?) since the  
1374 text tends to mix references to the egg injection work, and P450 induction in tissue. Please clarify.  
1375

#### 1376 **Cytochrome P450**

1377 *Cytochrome P450 induction was evaluated qualitatively in largemouth bass, medaka, and rainbow trout*  
1378 *tissues using immunochemical histological techniques. Cytochrome P450 induction was observed in fish*  
1379 *exposed to both standards and Housatonic River extracts. Rainbow trout was the most sensitive test*  
1380 *species, exhibiting apparent dose-related increases in cytochrome P450 induction. The strongest*  
1381 *response (i.e., highest induction) was observed in trout exposed to Reach 5BC extracts. Low and*  
1382 *moderate level cytochrome P450 induction was observed in bass exposed to 6 µg TCDD/kg egg and*  
1383 *medaka exposed to 2 to 6 µg TCDD/kg egg. Medaka also exhibited moderate dose-related cytochrome*  
1384 *P450 induction following exposure to reference site extracts containing 0.15 mg tPCBs/kg egg.*  
1385 *Largemouth bass did not appear to exhibit a dose-related induction of cytochrome P450 following*  
1386 *exposure to Housatonic River extracts.*  
1387

1388 P 5-38. Ibid, earlier comments concerning confounding influences on the egg injection study.  
1389

1390 *The increased toxicity associated with the Housatonic River extracts could be attributed to synergistic*  
1391 *toxicity of the PCB mixtures, as well as the effects of PCBs that are not incorporated into the TEQ model*  
1392 *(Tillitt, personal communication 2003).*

1393  
1394 P 5-39, 5-40. I believe the ED concept is not used or defined appropriately by the authors as there has  
1395 been a mixing of sublethal and lethal effects. In classical toxicology the ED is that dose which elicits a  
1396 non-lethal response whereas the LD is that dose which elicits a lethal response. It is inappropriate,  
1397 unless it is made clear that this definition is specific to this study alone, to use the term in this manner.  
1398 Further, as I stated in previous comments and questions, I do not believe it is the purpose of the ERA to  
1399 make judgments as to the acceptability or unacceptability of a particular level of harm or risk.

#### 1400 1401 **5.3.3.2.1 ED50 Estimates**

1402 *ED50s derived from the Phase II study data were used to develop thresholds for Housatonic River*  
1403 *extracts and PCB-126 and TCDD standards. An ED50 value represents the concentration at which*  
1404 *sublethal or lethal effects (i.e., either mortality or one or more abnormalities) was observed in 50% of the*  
1405 *population, relative to the negative controls. This combined toxicity endpoint provides an indication of the*  
1406 *concentration threshold for sublethal and lethal effects in early life stages of fish. The ED50 endpoint*  
1407 *represents a large effect size and indicates an unacceptable level of biological harm.*

1408  
1409 P 5-42. Figure 5.3-8. All labels for the x-axis in this figure are illegible. All labels have been blacked out  
1410 in the current figure.

1411  
1412 P 5-44. It is not clear that the exclusion of the reference station is justified based on the short discussion  
1413 in the paragraph below. Does the exclusion of data illustrating the lack of response at lower  
1414 concentrations force the MATC downwards? Why not incorporate all the relevant information into the  
1415 MATC estimation?

1416  
1417 **Exclusion of Reference Station**—*Threemile pond extracts were excluded from the MATC derivation; the*  
1418 *maximum PCB concentrations tested for these reference fish (0.15 mg/kg tPCB and 6 pg/g TEQ) were*  
1419 *insufficient to yield large toxic responses or provide meaningful information on the magnitude of the ED50*  
1420 *value. The concentrations in these extracts were well below the levels causing effects in the*  
1421 *contaminated site extracts.*

1422  
1423 P 5-55. What is the definition of “ecologically significant” in the context of the discussion shown below?  
1424 It is not clear that all of the endpoints or results used in the evaluation were those which might be  
1425 considered as ecologically relevant.

1426  
1427 *Figure 5.4-1 depicts hazard quotients for PSA fish tissue concentrations compared to the average of the*  
1428 *site-specific (Phase I and Phase II) fish effects thresholds derived for the PSA (i.e., 49.4 mg/kg tPCB). All*  
1429 *mean HQs are below 3 and median HQs are below 2, indicative of an ecologically significant but low*  
1430 *magnitude of risk.*

1431  
1432 P 5-63. Table 5.4-2. Please explain the designation “DL” in the table. It would be helpful to note its  
1433 meaning on the table itself.

1434  
1435 P 5-64. Please explain the scientific basis, other than the application of professional judgement, for the  
1436 statement that an HQ of greater than 1 but less than 3 is indicative of “ecologically significant”, but low  
1437 magnitude risk.

1438  
1439 *Figure 5.4-7 depicts hazard quotients for PSA fish tissue concentrations compared to the average site-*  
1440 *specific effects threshold (i.e., 42 ng/kg TEQ). All 75th percentile-based HQs exceed 1, but mean and*  
1441 *median HQs for adult fish are below 3 for all species. These HQs are indicative of ecologically significant*  
1442 *but low magnitude risk.*

1445 P 5-74. The sentence below is confusing and requires editing. I'm not sure in what context rainbow trout  
1446 would be more "toxic".  
1447

1448 *Although the ED50 values for trout were within a factor of 2 of warmwater species*  
1449 *in the Phase II trials, other indications of toxicity (Tillitt et al. 2003b) suggest that rainbow trout were slightly more*  
1450 *toxic than the warmwater species.*

1451  
1452 P 5-74. Please explain the scientific basis for the use of a factor of "4" to adjust the MATC.  
1453

1454 *Furthermore, the rainbow trout strain applied in the Phase II testing (Tillitt, personal communication 2003)*  
1455 *is less sensitive than other test strains, and the sensitivity of other downstream trout species (e.g., brown*  
1456 *trout) has not been assessed. Therefore, the PSA effects threshold of 49 mg/kg tPCB was divided by a*  
1457 *factor of 4 to account for potential increased sensitivity of downstream coldwater species (i.e., coldwater*  
1458 *MATC of 12 mg/kg tPCB whole body, wet weight).*

1459  
1460 P 9-44. Were these studies conducted under the applicable Good Laboratory Practice (GLPs)  
1461 regulations ?  
1462

1463 *All procedures were executed according to CERC Standard Operating Procedures (SOPs) and QA/QC*  
1464 *procedures.*

1465  
1466 P 10-32. Were there no data from studies in dogs such that those data could be used as a surrogate for  
1467 the red fox ? Using the rat as a surrogate for red fox would not appear to be scientifically supportable  
1468 given the substantial differences in metabolism, etc.  
1469

1470 *As a result, laboratory studies involving surrogate species were used to estimate effects to the representative*  
1471 *species. For short-tailed shrew and red fox, the rat was used as a surrogate species for effects due to exposure to*  
1472 *tPCBs. In the case of exposure to TEQ, the mouse was used as a surrogate species for short-tailed shrew, while*  
1473 *the rat was used for red fox.*

#### 1474 References

1475  
1476  
1477 Barnthouse L. W., Glaser D., & Young J. (2003) Effects of historic PCB exposures on the reproductive  
1478 success of the Hudson River striped bass population. *Environmental Science and Technology* 37: 223-  
1479 228.

1480 Diamond J. M. & Serveiss V. B. (2001) Identifying sources of stress to native aquatic fauna using a  
1481 watershed ecological risk assessment framework. *Environmental Science and Technology* 35: 4711-  
1482 4718.

1483 Drevnick P. E. & Sandheinrich M. B. (2003) Effects of dietary methylmercury on reproductive  
1484 endocrinology of fathead minnows. *Environmental Science and Technology* 37: 4390-4396.

1485 Fox G. A. (1991) Practical causal inference for ecoepidemiologists. *Journal of Toxicology and*  
1486 *Environmental Health*. 33: 359-373.

1487 Pittinger C. A., Turnley J. G., & Mehrle P. M. (2001) A multistakeholder ecological risk management  
1488 framework. In: *Risk Management: Ecological risk-based decision making*. (eds R. G. Stahl, R. Bachman,  
1489 A. L. Barton, J. R. Clark, P. L. deFur, S. J. Ells, C. A. Pittinger, M. W. Slimak, and R. S. Wentsel) pp. 21-  
1490 32. SETAC Press, Pensacola, Florida.

1491 Stahl R. G., Bachman R., Barton A. L., Clark J. R., deFur P. L., Ells S. J., Pittinger C. A., Slimak M. W., &  
1492 Wentsel R. S. (2001) *Risk Management: Ecological Risk-Based Decision Making*. SETAC Press,  
1493 Pensacola.

1494 USEPA (2000) Stressor Identification Guidance Document. USEPA, Washington, DC.

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